

CHAPTER 15

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Adult Conservative Management

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Adult Conservative Management

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A. INTRODUCTION

Conservative treatment is any therapy that does not involve pharmacological or surgical intervention. It includes principally, lifestyle interventions, physical therapies, scheduled voiding regimens, complementary therapies (eg not considered part of the traditional biomedical model), anti-incontinence devices, supportive rings/pessaries for pelvic organ prolapse and pads/catheters. In some countries the first three are encompassed by the term “behavioural therapy” (defined as an approach that seeks to alter the individuals actions or their environment in order to improve bladder control). On the whole these treatments are simple, low cost remedies and differ from other forms of incontinence and prolapse management, in that they have a low risk of adverse effects and do not prejudice other subsequent treatments. Consequently conservative measures should be included in the counselling of patients who suffer from either incontinence or prolapse regarding their management options. As the prevalence of incontinence and pelvic organ prolapse is high, and with the current constraints on most healthcare economies, conservative treatment constitutes the principal form of management at primary care level. It is also indicated for those patients for whom other treatments, in particular surgery, are inappropriate, for example, those who are unwilling to undergo or who are not medically fit for surgery, and women who plan future pregnancies (as these may adversely affect surgery). Other indications include patients awaiting surgery or who wish to delay surgery and those whose symptoms are not serious enough for surgical intervention.

To date, however, only a relatively small number of objective clinical comparative studies with adequate

patient numbers have been carried out to assess the effectiveness of conservative management of urinary incontinence and pelvic organ prolapse. This chapter reviews the main types of conservative management (excluding anti-incontinence devices and pads/catheters see chapter 4, volume 1) with regard to their ability to prevent and treat urinary incontinence and prolapse effectively. Comment is also made on the effect of conservative management on other lower urinary tract symptoms (in addition to incontinence) and also factors affecting outcome, in particular age. This information will assist in the counselling of neurologically “normal” adults regarding these treatment options (readers are directed to the chapters on children, the frail elderly and neuropathic patients for discussion on the effect of conservative management in these specific groups). A systematic review of the literature has been carried out, comment made on the quality of all relevant studies identified, and recommendations on effectiveness made on the best available level of evidence reviewed. (volume 2, pages 804-805)

B. URINARY INCONTINENCE IN WOMEN

INTRODUCTION

Female urinary incontinence is a distressing condition with significant social implications. It is common – the median level of prevalence estimates gives a picture of increasing prevalence during young adult life (prevalence 20-30%), a broad peak around middle age (prevalence 30-40%), and then a steady increase in the elderly (prevalence 30-50%).

Although the proportions of different types of urinary incontinence are difficult to estimate, approximately half of all incontinent women are classified as stress incontinent, a smaller proportion as mixed incontinent and urge incontinence is the smallest category. The various types most likely reflect different pathologies and aetiologies.

Stress urinary incontinence is thought to occur due to a lack of bladder neck support and/or poor urethral closure. As a result the urethral lumen is not closed effectively during exertion with consequently involuntary leakage during effort, exertion, sneezing or coughing. (If during cystometry there is involuntary urine loss synchronous with a rise in intraabdominal pressure in the absence of an involuntary detrusor contraction this is described as urodynamic stress incontinence).

Urge incontinence can be due to an uninhibited rise in intravesical pressure due to involuntary detrusor contraction and the condition is called detrusor overactivity. This is further subclassified as idiopathic (cause unknown) or neurogenic (where there is a known neurological cause for detrusor muscle overactivity. Some women experience urgency without leakage, with or without urinary frequency or nocturia. This collection of symptoms is called the overactive bladder syndrome. Other causes of urinary incontinence in women are due to overflow incontinence and fistula (in particular in the developing world).

B1. LIFESTYLE INTERVENTIONS

Various lifestyle factors may play a role in either the pathogenesis or, later, the resolution of incontinence. While published literature about lifestyle factors and incontinence is sparse, alterations in lifestyle are frequently recommended by health care professionals and lay people alike. However, to date, most studies about lifestyle report associations only and do not assess the actual effect of applying or deleting the behaviour in question on incontinence. Currently, only a relatively small number of randomized trials have been carried out to assess the effect of a specific lifestyle on incontinence.

This section will examine the evidence for the association and use of lifestyle interventions in the management of female urinary incontinence. A summary of the search strategy and inclusion/exclusion criteria is given in Appendix.

I. PREVENTION

a) Quality of data

No randomised trials assessing the effect of lifestyle interventions on urinary incontinence prevention were identified.

b) Results

No trials identified.

c) Summary

Given the low annual incidence of urinary incontinence, it is unlikely that large scale prevention trials related to the impact of lifestyle factors are feasible. However, there is now consistent epidemiological evidence (see below) that obesity is related both to the prevalence and incidence of urinary incontinence. Epidemiological evidence is nearly consistent that smoking is related to a higher prevalence of severe urinary incontinence. In addition, caffeine and carbonated beverages are associated with the incidence of overactive bladder symptoms. Therefore, it is reasonable to recommend that women avoid becoming obese or smokers, and avoid caffeine and regular carbonated drinks, to maintain improved bladder health.

d) Recommendations

Prevention trials regarding the effect of lifestyle interventions on urinary incontinence onset will be difficult to execute because of the low annual incidence rate of urinary incontinence. Further research is needed on the impact of lifestyle interventions on the treatment of urinary incontinence. With that data in hand, preventive strategies can be assessed in high-risk groups.

II. TREATMENT

1. WEIGHT LOSS

a) Quality of data

Two randomized studies were found [1, 2]. Two prospective cohort studies [3, 4] evaluated the effect of weight loss. Other study designs were cross-sectional [5-9], retrospective cohort [10], or case-control studies [11].

Sample sizes for the interventional trials were 12, [3], 138 [4], 10 [1], and 47 [2]. Sample sizes for studies, which assessed the association between obesity and incontinence, but in which no intervention was

done, ranged from 193 [10] to 27,936 [8]. The case control study had a sample size of 108 cases and 108 controls [11].

The outcome measure in all studies with the exception of Bump[12] and Subak [13] was subjective, as determined by a self-administered questionnaire. Bump also utilized objective measures including urodynamics, bladder diary and standardized fluid loss quantification test. Subak also utilized a 7-day urinary diary.

Follow-up periods for the interventional studies were one year after gastroplasty surgery [3](Bump), 6 months after completion of weight reduction, either by means of low calorie liquid or reduced calorie solid diet [1], 3 months after completion of a very low calorie liquid diet and exercise [2] and not stated [4].

b) Results

Many researchers [5-8, 10, 11, 14-17] have reported an association between increased weight, or increased body mass index, and urinary incontinence. This association held after controlling for age and parity. In one multivariate analysis, Brown [5] reported that the prevalence of daily incontinence increased by an odds ratio of 1.6 per 5 BMI (body mass index, kg/m²) units. In a multivariate analysis of a different population, Brown [6] found that the prevalence of at least weekly stress incontinence increased by 10% (OR 1.1) per 5 units BMI. Similarly, Foldspang [18] reported an odds ratio of 1.07 for incontinence prevalence per BMI unit, after controlling for other factors. Hannestad [8] described a dose-response type relationship between BMI and severe urinary incontinence. Compared to women with a BMI < 25, OR's for the following BMI groups were: 25-29, OR 2.0 (1.7-2.3), 30-34, OR 3.1 (2.6-3.7), 35-39, OR 4.2 (3.3-5.3), 40+, 5.0 (3.4-7.3).

Two groups[5],[4] reported resolution of incontinence in the majority of cases after massive weight loss in morbidly obese women undergoing surgical weight reduction procedures. While obesity is commonly considered a risk for stress incontinence, in Bump's study, women with urge incontinence were as likely to experience post-operative continence as women with stress incontinence. In Subak's pilot study [2] of 10 women, all 6 of the women achieving a weight loss of at least 5% had at least a 50% reduction in incontinent episodes compared to one out of the four women with <5% weight loss. In the larger randomized trial [1], mean baseline weight (93 +/- 13 kg) and number of incontinent episodes (24 +/- 15

per week) were similar between the groups. Women in the weight loss group lost 15 +/- 7 kg, compared to 0 (+/- 4 kg in the control group) and experienced a 51% reduction in weekly incontinent episodes compared to 5% in the control group. Randomization was blocked by urge incontinence and stress incontinence; while the numbers are small, no difference in the effect of weight loss on incontinence was seen by incontinence type.

In a cross-sectional study of 1800 Swedish women [9], 15% of incontinent women reported at least a 5 kg weight loss in the preceding 5 years, compared to 11% of continent women (p=.05). This may be secondary to intentional weight loss as a treatment for urinary incontinence, rather than some effect of weight loss itself.

c) Summary

Obesity is an independent risk factor for the prevalence of urinary incontinence. Massive weight loss significantly decreases incontinence in morbidly obese women. Preliminary evidence suggests that moderate weight loss may also result in decreased incontinence. (Level of Evidence: 2/3).

d) Recommendation

Weight loss is an acceptable treatment option for morbidly and moderately obese women. Based on the current evidence, maintaining normal weight through adulthood may be an important factor in the prevention of the development of incontinence. Given the high prevalence of both incontinence and obesity in women, the dual issues of weight loss and prevention of weight gain should receive high research priority.

Grade of recommendation: B/C

Obesity is an independent risk factor for urinary incontinence. There is level 2 evidence that weight loss in morbidly obese women decreases incontinence, and scant level 1 evidence that moderately obese women who lose weight have less incontinence than those who do not.

2. PHYSICAL FORCES (EXERCISE, WORK)

a) Quality of data

No randomized trials exist in which incontinence prevalence is compared between subjects assigned to heavy work or high impact activity versus sedentary activities. One case-control study compared the incidence of surgery for incontinence and/or prolapse

[19], while a second compared nulliparous women with and without stress incontinence symptoms [20]. Bø [21] and Nygaard [22] evaluated the difference in incontinence prevalence between women engaged in high versus low impact activities. Davis [23] described a series of women who became incontinent after parachute jumping. In a retrospective cohort study, Nygaard [24] compared incontinence prevalence in high-impact versus low-impact former Olympic athletes. Bø [25] compared incontinence prevalence between Norwegian Olympians and controls. The Norwegian EPINCONT study compared both any and severe incontinence in women according to three levels of high impact physical activity [8]. Benjamin and Hearon studied the association between high gravitational forces in women aviators [26]. Sample sizes range from 144 [22] to 305 [21] for the cohort studies. One case series had nine subjects [23] while another had 25 [26]. The population-based case control study compared 28,619 cases with 1,652,533 controls. The recent study by Bø [25] compared 572 athletes, ages 15-39 years, with 574 controls. The EPINCONT cross-sectional study had 27,936 participants.

b) Results

Minimal stress incontinence is common in young exercising women [20, 21, 27]. College athletes participating in high impact activities are more likely to report the symptom of stress incontinence during exercise than those participating in low impact exercise [22]. Bø [25] found no difference in incontinence prevalence between elite athletes and controls. However, the prevalence of stress and urge incontinence symptoms was higher in athletes who had a diagnosed eating disorder than those without such a diagnosis. There is little available information on whether strenuous exercise or activity causes the condition of incontinence later in life. In a study which questioned women who were Olympians approximately 25 years ago, those who competed in gymnastics or track and field were not more likely to currently report daily or weekly incontinence than Olympians who competed in swimming [24].

Certain provocations may cause stress incontinence: one report described nine nulliparous infantry trainees who developed stress incontinence and pelvic floor defects for the first time during airborne training, which included parachute jumping [23]. The precise number of total trainees is unknown but is estimated to be approximately 500. In a small series of women aviators, self-report of urinary incontinence was not found to increase at high gravitational forces [26].

Surprisingly little information is available on the relationship between stresses in the workplace and urinary incontinence. Danish nursing assistants, who are exposed to frequent heavy lifting, were 1.6 fold more likely to undergo surgery for genital prolapse and/or incontinence than women in the general population; the study did not control for parity [19].

The EPICONT study found no difference in either all or severe incontinence in women that reported high impact physical activity 1-2 hours per week or 3 or more hours per week compared to those that reported exercising less than one hour per week (after adjusting for age, BMI, parity, coughing and wheezing).

c) Summary

Strenuous exercise is likely to unmask the symptom of stress incontinence during the provocation. There is no evidence that strenuous exercise causes the condition of incontinence. In a small number of women without other known risk factors, extreme provocations such as parachute jumping may cause incontinence. There is scant uncontrolled data that suggests that women engaged in occupations with heavy lifting may be predisposed to genital prolapse and/or incontinence. The data is insufficient to draw any firm conclusions. (Level of Evidence: 2/3).

In spite of the fact that healthcare professionals commonly advise restricting exercise and heavy lifting following incontinence or prolapse surgery, there is no published evidence that this improves surgical outcome.

d) Recommendations

Given the large proportion of women who are employed in various occupations that require heavy lifting and the paucity of scientific data about the association of such exertions and incontinence, this association should be investigated further. Specifically, research must establish whether heavy exertion is an etiologic factor in the pathogenesis of incontinence, and whether changing exertions can alleviate established incontinence.

Grade of recommendation: B

There is scant level 2 and 3 evidence that suggests that active women may be more likely to report incontinence than sedentary women, and that heavy occupational work may be associated with pelvic organ prolapse and urinary incontinence. However, there are no trials that assess the role that reducing strenuous activity plays in treating urinary incontinence.

3. SMOKING

a) *Quality of data*

One case-control study compared incontinent smokers with incontinent non-smokers [28], while a second compared smoking behaviour between continent and incontinent women [29]. Five large cross sectional studies evaluated multiple risk factors for incontinence, including smoking [5, 8, 30, 31] [32]. In vitro studies assessed the effects of nicotine on bladder muscle contraction. Sample sizes were 189 [28], 160 [29], 7949 [5], 7338 [30], 1761 [32], 3302 [31] and 27,936 [8].

b) *Results*

Smokers were more likely to report incontinence than non-smokers in some studies [8, 29-31], but not in others [5] [32]. After adjusting for age, parity, type of delivery, and pre-pregnancy BMI, smokers had a 1.3 fold higher risk (95% CI 1.0-1.8) of reporting incontinence at 16 weeks gestation than non-smokers [30]. The adjusted odds ratio for moderate or severe incontinence among women reporting incontinence was 1.38 (95% CI 1.04-1.82) in current smokers, after adjusting for perimenopausal status, BMI, diabetes and ethnicity [31]. In the large population based study by Hannestad et al [8], smoking increased the risk of severe incontinence (OR 1.4, 95% CI 1.2-1.6) but not of any (that is, mild) incontinence. Incontinent smokers were found to have stronger urethral sphincters and lower overall risk profiles than incontinent non-smokers [28]; therefore, it was proposed that more violent coughing promotes anatomic defects which allow incontinence. In potential support of nicotine as a risk factor for incontinence, Hisayama [33] and Koley [34] found that nicotine produces phasic contraction of isolated bladder muscle probes in vitro. However, Milsom [35] reported an apparent paradoxical local estrogenic effect of nicotine on the vagina, resulting in a decrease in vaginal pH and an increase in lactobacilli.

c) *Summary*

Current data suggests that smoking increases the risk of more severe urinary incontinence. Smokers may have a different mechanism causing their incontinence than non-smokers (Level of Evidence 2/3/4). No data has been reported examining whether smoking cessation resolves incontinence.

d) *Recommendations*

Further prospective studies are needed to determine whether smoking cessation prevents the onset, or promotes the resolution, of incontinence.

Grade of recommendation: B/ C

No data has been reported examining whether smoking cessation resolves incontinence.

4. DIETARY FACTORS

a) *Quality of data*

One randomized trial [36] assessed the effects of a caffeine reduction intervention upon frequency, urgency and urge incontinence. Subjects were those with urinary symptoms who consumed more than 100 mg caffeine daily. Those randomised to the experimental group received bladder training and a caffeine-fading method to decrease caffeine intake to less than 100 mg per day, while the control group also received bladder training but no caffeine reduction information. No randomized trial was identified that addressed dietary changes. One study compared women with detrusor instability with continent women who received caffeine tablets [37] (Creighton), while another compared caffeine intake between women with detrusor overactivity and those without [38]. The effect of decreasing caffeine intake in a small cohort of incontinent women was examined in a prospective fashion [39]. One large epidemiologic trial analysed the effect of coffee drinking in a multivariate fashion [5]. Another cross-sectional study (Norwegian EPINCONT) analysed the association between tea, coffee, and alcohol intake and incontinence [8]. In a prospective questionnaire study, dietary risk factors for the one-year incidence of stress incontinence and overactive bladder symptoms were reported [40]. Participants completed a 130-item validated food frequency questionnaire. Sample sizes were 95 with results provided on 74 women that completed the study [36], 30 [37], 126 [41], 7949 [5], 6037 [42], 159 [38], 34 [39], 27,936 [8], and 6,424 [40].

b) *Results*

Caffeine: Following caffeine intake, women with detrusor overactivity had increased detrusor pressure on bladder filling, while continent women had no such abnormality [37]. In a population of 259 consecutive women presenting for urodynamics [38], 131 women with detrusor instability had a significantly higher mean caffeine intake (484 +/- 123 mg/day) than women without this diagnosis (194 +/- 123 mg/day). This association persisted after controlling for age and smoking. In 34 women with symptoms of urinary incontinence (mostly mixed) who decreased caffeine intake (from 900 mg/day to 480 mg/day), episodes of daily urine loss also decreased

(from 2.33 to 1.0 per day) [39]. In the caffeine reduction study [36], subjects in the intervention group decreased daily caffeine consumption to a mean of 96.5 mg, compared to 238.7 mg in the control group. This group of bladder training and caffeine reduction had a statistically significant reduction in urgency episodes (61% vs 12%) and number of voids/24 hours (35% vs 23%) compared to the control, bladder training, alone group. The intervention also had a greater reduction in the number of incontinence episodes (55% compared to 26% in the controls) but this was not statistically significant ($p=.219$). In a multivariate analysis, Brown [5] found no association between coffee drinking or alcohol drinking and daily incontinence. In the Norwegian EPINCONT study [8], tea drinkers had a slightly higher risk for all types of incontinence (OR 1.2 (1.1-1.2) for 1-2 cups per day compared to none and OR 1.3 (1.2-1.5) for 3 or more cups per day compared to none), while no association was found between either coffee (at any dosage) or alcoholic beverages (3 or more drinks per two weeks compared to 0-2 drinks per 2 weeks) and incontinence.

Decrease fluid intake: In incontinent women over age 55 years, there was a modest positive relationship between fluid intake and severity of incontinence in women with stress incontinence; fluid intake accounted for 14% of the explained variability in number of incontinent episodes [41]. No such correlation was found in women with detrusor overactivity. In a randomized trial [43], 32 women were assigned to one of three groups: increase fluid intake by 500 cc over baseline, decrease by same amount, or maintain baseline level. While non-adherence to the protocol made results difficult to interpret, the authors reported that 20 women who had fewer incontinent episodes at the end of the trial attributed this to drinking more fluids.

Alcohol: After adjusting for age and gender, no association was found between urinary incontinence and consumption of alcohol [42]. After adjusting for age and fluid intake, consumption of wine, beer or spirits did not increase the incidence of either stress incontinence or overactive bladder (there was a trend towards less stress incontinence in beer drinkers; OR 0.75 (0.56-1.01) for weekly drinkers versus those that drank beer less than monthly) [40].

Diet: After adjusting for age, physical functioning, stress incontinence at baseline, obesity, smoking and certain dietary factors, the incidence of overactive bladder was increased with the consumption of car-

bonated drinks, and decreased with high consumption of vegetables, bread and chicken [40]. After similar adjustment, the incidence of stress incontinence was increased with carbonated drinks and decreased with bread consumption. Anecdotal evidence suggests that eliminating dietary factors such as artificial sweeteners and certain foods may play a role in continence; however, no treatment trials have tested this hypothesis.

c) Summary

Fluid intake plays a minor, if any, role in the pathogenesis of incontinence. The data on caffeine intake and incontinence are conflicting. While large cross-sectional surveys indicate no association, small clinical trials do suggest that decreasing caffeine intake improves continence. Consuming carbonated drinks appears to increase the risk of overactive bladder. (Level of Evidence: 2/3).

d) Recommendations

Given the fact that decreasing fluids may lead to urinary tract infections, constipation, or dehydration, this intervention should be reserved for patients with abnormally high fluid intakes.

Caffeine consumption is pervasive in many societies and may play a role in exacerbating urinary incontinence. Larger randomized trials to assess the effect of caffeine and other dietary factors are feasible and important.

Grade of recommendation: B

Level 2 and 3 evidence is conflicting on whether caffeine intake is associated with urinary incontinence. There is scant level 1 evidence that decreasing caffeine improves continence.

5. CONSTIPATION

a) Quality of data

No published trials were found which assess the effect of regulating bowel function on incontinence. An observational study compared the self-report of straining as a child with urogynaecologic symptoms as an adult. Population-based studies assessed multiple risk factors for incontinence [44, 45].

Sample sizes range from 73 for the observational study [46] to 213 in a study correlating the surrogate measures of perineal descent and pudendal neuropathy [47] to 1154 and 1051 in the population-based studies [44, 45].

b) Results

In a small observational study, 30% of women with stress incontinence and 61% of women with uterovaginal prolapse reported straining at stool as a young adult, compared to 4% of women without urogynecologic symptoms [46]. In a large population-based study of 1154 women over age 60 years, those with urinary incontinence were slightly more likely to report constipation than those who were continent of urine (31.6% vs 24.7%) [44]. After adjusting for demographic and obstetric confounders, women who reported straining at stool were 1.9 times (95% CI 1.3, 2.6) and 1.7 times (95% CI 1.2, 2.4) more likely to report stress incontinence and urgency, respectively [45]. There appears to be an association between straining and pudendal nerve function. The mean pudendal nerve terminal motor latency (PNTML) increased after straining, correlated with the amount of descent, and returned to resting by four minutes after a strain [48]. Others found evidence of pudendal neuropathy in only 25% of women with abnormal perineal descent; in this large group of patients with defecating dysfunction no relationship was seen between neuropathy and pelvic descent, leading to the conclusion that pelvic descent and neuropathy may be two independent findings [47].

c) Summary

There is fair data to suggest that chronic straining may be a risk factor for the development of incontinence. (Level of Evidence:2/3) There are no intervention trials that address the effect of resolving constipation on urinary incontinence.

d) Recommendations

Further research is needed to delineate the role of straining in the pathogenesis of incontinence. If the association holds, public education, particularly of parents and paediatricians, is needed to make an impact on the common problem of straining due to constipation in children.

Grade of recommendation: B/ C

Chronic straining due to constipation may be a risk factor for pelvic organ prolapse and urinary incontinence (level 2 and 3 evidence). No intervention trials have examined the impact of resolving constipation on urinary incontinence.

6. OTHER

a) Quality of data

One study rigorously assessed urine loss during

various postural changes (crossing legs and bending forward) [49]. No study has evaluated whether postural changes are a satisfactory form of treatment outside of the laboratory setting. Bladder training, timed voiding and relaxation techniques, particularly for urge incontinence, are discussed in IV 2. There are many other lifestyle interventions suggested either by health care professionals or the lay press for the treatment of urinary incontinence, including reducing emotional stress, wearing non-restrictive clothing, utilising a bedside commode, decreasing lower extremity edema, treating allergies and coughs, wearing cotton underwear, and increasing sexual activity. These interventions are, however, all anecdotal in nature.

b) Results

Postural changes: Urine loss during provocations can be significantly decreased by crossing the legs or by crossing the legs and bending forward [49].

c) Summary

There is no scientific evidence about whether other lifestyle changes except for some postural changes, affects either the treatment of, or the prevention of, urinary incontinence. (Level of Evidence 2B, 4, 5)

d) Recommendations

As various lifestyle interventions are recommended by physicians, studies evaluating the effect of implementing these factors on incontinence are warranted. While some lifestyle changes may prove beneficial for individual patients, it is unlikely that manipulating these factors will have a major effect on the overall incontinence problem.

Grade of recommendation: B, C, D

There is level 2 evidence that postural changes may decrease urinary incontinence. There is no evidence whether other such lifestyle changes decrease urinary incontinence.

III. OTHER LUTS

Most published data on the effect of lifestyle interventions (in particular, dietary factors) on other lower urinary tract symptoms pertain to males only, and thus, are not included in this review. In one study of a geriatric population (sample size 128), there was a strong relationship between evening fluid intake, nocturia, and nocturnal voided volume; this relation-

ship was weaker for diurnal intake and voiding [50]. Future work should separately evaluate the impact of lifestyle interventions on nocturia, diurnal frequency, urgency and urge incontinence to delineate whether certain interventions preferentially affect different areas of overactive bladder.

IV. FACTORS AFFECTING OUTCOME

1. AGE

Randomised intervention trials are sparse in this area, and none specifically describe the impact of age on outcome.

2. OTHER

The paucity of literature in this area precludes drawing conclusions about the impact of specific variables on outcome.

B2. PHYSICAL THERAPIES – PELVIC FLOOR MUSCLE TRAINING (PFMT)

Graded muscle training, with or without adjunctive biofeedback or intravaginal resistance, is used to improve the function of pelvic floor muscle (PFM). The therapeutic uses of pelvic floor muscle training (PFMT) include the prevention and treatment of urinary incontinence.

There are three grades of prevention: primary, secondary and tertiary [51]. Primary prevention aims to remove the causes of a disease, and secondary prevention aims to detect asymptomatic dysfunction and treat it to stop progression. Tertiary prevention is intervention for existing symptoms to prevent disease progression (i.e. treatment). Because PFM appears to have a role in the continence mechanism, a variety of hypotheses are suggested to support the use of PFMT to prevent urinary incontinence. For example, trained muscle might be less prone to injury, and/or previously trained muscle might be easier to retrain after injury because the appropriate motor patterns are already learned. It may be that previously trained muscle has a greater reserve of 'strength' and functional use, so that injury to the muscle or its nerve supply does not cause sufficient loss of function to reach the threshold where symptoms occur. For childbearing women, PFMT during pregnancy might help counteract the increased intra-abdominal pres-

sure caused by the growing fetus, the hormonally mediated reduction in urethral pressure, and the increased laxity of fascia and ligaments in the pelvic area.

The use of PFMT as a treatment for stress urinary incontinence (SUI) appeared to become more widespread after Arnold Kegel reported on the successful treatment of 64 cases of female stress urinary incontinence using pelvic floor muscle exercises, with a perineometer for resistance and biofeedback [52]. The biological rationale for PFMT in the management of SUI is that a strong and fast PFM contraction will clamp the urethra, increasing the urethral pressure, to prevent leakage during an abrupt increase in intra-abdominal pressure [53]. DeLancey has also suggested that an effective PFM contraction may press the urethra against the pubic symphysis, creating a mechanical pressure rise [54]. Timing might also be important; Bø has suggested that a well-timed, fast and strong, PFM contraction may prevent urethral descent during intra-abdominal pressure rise [55]. Miller et al. (1998) demonstrated that a voluntary pelvic floor muscle contraction (VPFMC) before or during cough can reduce leakage after a week of training [56]. However, in healthy continent women, activation of the PFM before or during physical exertion seems to be an automatic response and does not require conscious effort [57-59]. There is some evidence that the PFM 'reflex' contraction is a feed-forward loop, as it may precede bladder pressure rise by 200-240 milliseconds [60, 61].

Therefore, for SUI, the objective of PFMT is usually to improve strength and/or timing of the PFM contraction. Muscle bulk (cross-sectional area) is one determinant of strength. When muscles do repetitive intensive work that exceeds the demands of normal everyday activity this stimulates an increase in muscle fibre size (hypertrophy), which increases muscle bulk [62]. Hypertrophy is not an immediate training response, but strength increases are noticed long before visible hypertrophy. Early improvements in strength result from neural adaptation including a greater number of activated motor units, an increased rate of motor unit excitation, more synchronised motor unit firing, and more persistent activation of type II motor units [63-65]. Hypertrophy begins only after regular and intense strength training for more than eight weeks [66]; with increased resistance, hypertrophy may continue for some years.

PFMT may also be used in the management of urge urinary incontinence (UUI). The biological rationale is that a detrusor muscle contraction can be reflexly

or voluntarily inhibited by PFM contraction [67-69]. Therefore, single or repeated VPFMC may be used to control urgency and prevent urge leakage.

In this section PFMT is defined as any program of repeated VPFMC taught by a health care professional. This definition allows for variations in the purpose of PFMT (e.g. PFMT for strengthening or urge suppression), the teaching of PFMT (e.g. individual or group teaching), and the parameters of training (e.g. length of hold, number of contractions). PFMT is used in preference to other previously used terms such as Kegel's exercises, pelvic floor exercises and pelvic floor muscle exercises. 'Kegel's exercises' no longer seems appropriate because current practice is very different to the program originally described by him. Descriptors that fail to include muscle also seem inappropriate, as it is the muscular component of the pelvic floor that is the focus of training. Ideally, it should also be clear that it is the pelvic floor muscles, not pelvic muscles in general, which are the target of intervention. Further, it is suggested that training is a more appropriate word than exercise; exercise is commonly interpreted as one episode of training or a single muscle action, whereas training means repeated exercise over time. The use of the term pelvic floor muscle training (PFMT) is proposed and used throughout.

In some trials PFMT was the primary intervention, although other advice was given. This was usually the addition of urge and/or frequency strategies. Trials that combined PFMT with urge/frequency strategies were included as PFMT trials unless the trial report called the additional intervention bladder (re)training, or stated that a timed or scheduled voiding program was used. Trials were excluded if the primary intervention was clearly a combination treatment (e.g. PFMT with bladder training, PFMT with oestrogen). The exceptions were biofeedback and intravaginal resistance. These adjuncts are not stand-alone interventions; they are used to enhance the effect of PFMT.

This section will examine the evidence for the use of PFMT for the prevention and treatment of urinary incontinence in women of all ages. Questions addressed are:

- Can PFMT prevent urinary incontinence?
- Is PFMT better than no treatment, placebo or control treatments for urinary incontinence?
- Is one approach to PFMT better than another?
- Is PFMT better than other treatments?

- Does the addition of PFMT to other treatments add any benefit?
- What factors might affect the outcome of PFMT?
- What is the effect of PFMT on other LUTS?

To address these questions, the literature was searched (see appendix x) for reports of relevant systematic reviews and reports of randomised controlled trials (RCTs) and quasi-randomised controlled trials (qRCTs) e.g. alternate assignment to groups. Therefore, only Level 1 evidence is considered in this section. Recommendations are based on the findings of existing systematic reviews if up to date, or new systematic reviews of RCTs undertaken by the author of this section (JHS).

There was little consistency in the outcome measures used and reported by trialists. In prevention trials the commonly reported outcomes were incontinence and some measure of PFM activity.

The four most common measures in treatment trials were self-reported cure, self-reported cure/improvement, number of or change in leakage episodes, and some measure of PFM activity. Some trials used pad tests, but the type of test varied. There is sufficient doubt about the comparability of data between different pad tests, and the interpretation of pad test data, that these data are not presented [70].

Nor are PFM activity data discussed; these data are a surrogate for the primary outcomes of interest. In this section, the pre-specified primary outcomes of interest were urinary incontinence (for prevention studies), self reported cure and/or improvement in incontinence symptoms (for treatment studies), leakage episodes (treatment studies) and quality of life (prevention and treatment studies).

With regard to quality of data there are many quality checklists available, but no gold standard [71]. Attempting to weight primary studies in meta-analysis by quality score is problematic; the choice of scale can dramatically influence the effect estimate [72]. However, there is empirical evidence that two elements of trial quality, allocation concealment and double blinding, are important in the precision of estimating treatment effect; trials with inadequate or unclear concealment of allocation appear to overestimate treatment effect by about 30%, and trials that are not double blind overestimate effect by about 15% [73].

Therefore, trials that reported adequate allocation concealment are noted. It is often difficult, or not possible, to blind treatment providers and patients to

conservative treatments, but trials that reported blinding of outcome assessment are also noted. Readers may wish to consider these factors in their interpretation of the data.

I. PREVENTION

This subsection addresses the question, 'Is PFMT effective for the primary and/or secondary prevention of urinary incontinence in women of all ages?' Clinically it may be difficult to screen trial participants to see if a disease process is absent altogether (for primary prevention studies), or present although asymptomatic (for secondary prevention), and in many cases there is no reliable and valid clinical test available. Trials investigating prevention of incontinence usually enrol people purely on the basis of symptom absence. Thus, the trials are probably a combination of primary/secondary prevention effects. No attempt is made to distinguish between primary and secondary prevention effects in this subsection.

The literature search revealed two previous systematic reviews addressing prevention of urinary incontinence [74, 75]. Harvey included trials in childbearing women only. Hay-Smith and colleagues included trials of PFMT and other physical therapies (e.g. vaginal cones). Further searching did not find any new RCTs published since these reviews. There were three main groups of trials included in the reviews. The first group were trials investigating the effect of PFMT on PFM activity in women, but did not measure continence related outcomes. These trials are not considered here. The second group recruited only childbearing women. For the purposes of this chapter, childbearing women were defined as women who were pregnant or within the first six months postpartum. Women of childbearing age, but not pregnant or within six months of delivery, are defined as non-childbearing. Because childbearing women seem to be a distinct group, with regards the physiology of pregnancy and postpartum, these trials were considered together under the next heading, which addresses prevention of incontinence in childbearing women. The third group were trials for prevention of post prostatectomy urinary incontinence; these trials are considered in the section on men.

No trials investigating the primary/secondary prevention effects of PFMT for urinary incontinence in non-childbearing women were found.

1. PREVENTION OF URINARY INCONTINENCE IN CHILDBEARING WOMEN

While there are two previous systematic reviews of PFMT for prevention of urinary incontinence in childbearing women [75, 76], there are problems with both reviews. Hay-Smith and colleagues did not separate data from childbearing and other women. Although Harvey included only trials in childbearing women, she did not differentiate primary/secondary prevention from tertiary prevention. Critical evaluation of the trials included in both reviews reveals that women were often recruited to trials without regard to previous continence status.

The methods of most trials investigating PFMT for prevention of urinary incontinence in childbearing women have allowed inclusion of women with prior incontinence symptoms. Therefore, it is usually not possible to differentiate primary/secondary prevention effects from treatment effects. Greater rigour is needed in any further trials addressing this question.

Based on these reviews, it seemed that there were four main groups of trials. The first group included trials investigating the effect of PFMT on PFM activity in childbearing women, but did not measure continence related outcomes. These trials are not considered here. The second group comprised trials of PFMT for primary/secondary prevention of urinary incontinence in childbearing women. Thirdly, there were trials where it was not possible to differentiate primary/secondary prevention from treatment effects. Fourthly, there were treatment trials. Three separate systematic reviews were performed to address the following questions:

- Does PFMT prevent urinary incontinence in childbearing women?
- What is the effect of PFMT in a wider population of childbearing women, i.e. where some women have prior urinary incontinence symptoms and some do not?
- Is PFMT an effective treatment for urinary incontinence in childbearing women?

2. PRIMARY/SECONDARY PREVENTION OF URINARY INCONTINENCE IN CHILDBEARING WOMEN

Only trials addressing primary/secondary prevention of urinary incontinence in childbearing women are

considered here. Three RCT's were included [77-79]: Reilly et al. recruited primigravid women without a pre-pregnancy or current history of urinary incontinence, but with bladder neck hypermobility at 18 to 20 weeks gestation; Sampsellet al. and Mørkved et al. also recruited primigravidae, at 18 and 20 weeks gestation respectively. In both studies some women had leakage symptoms pre-pregnancy or at recruitment, but published or unpublished data were available for the subgroup without any prior incontinence symptoms. Three RCTs were excluded [80-82]. All three included childbearing women with urine leakage symptoms at the time of recruitment, as well as continent women, and did not report the data separately for the two groups. These mixed prevention/treatment studies are considered subsequently.

In all three trials the controls received usual antenatal care, which may have included advice on PFMT from a variety of maternity carers. There was some variation in the PFMT parameters:

- Eight to 12 near maximal VPFMC held for six to eight seconds with six seconds rest, with three to four fast contractions at the end of each contraction, twice per day from 20 weeks gestation. Also a weekly exercise class from weeks 20 to 36 [77]. Three sets of eight to 12 VPFMC with six second hold and two second rests, twice per day, from 18 weeks gestation [78] Up to 30 near maximal VPFMC per day [79]. Mørkved et al [77] and Sampsellet al [79] stated a correct VPFMC was checked prior to training.

a) Quality of data

Allocation concealment appeared adequate, and outcome assessors were blinded in all three trials. Mørkved et al [77] randomised 301 women, Reilly et al [78] 268 women, and Sampsellet al [79] 72. Dropout rates ranged from four percent [77], to 36% [79] and 38% [78]. Mørkved et al. and Reilly et al. measured outcomes at three months postpartum, and 36 and 34 weeks gestation respectively. Sampsellet al. assessed women at 35 weeks, and then postpartum at six weeks, six and 12 months; the primary endpoint was 12 months. Reilly and colleagues were the only trial with long-term follow up, at four years .

b) Results

Pooled data from two trials [77, 78] showed women in the antenatal PFMT group were less likely to report urinary incontinence at three months postpartum (relative risk (RR) 0.62, 95% confidence interval (CI) 0.42 to 0.92), although individually Reilly et

al reported a statistically significant difference in favour of the PFMT group (RR 0.59, 95% CI 0.37 to 0.97) while Mørkved et al. did not (RR 0.73, 95% CI 0.33 to 1.63). At four years Reilly and colleagues found that women from the training group were still less likely to report urinary incontinence (RR 0.37, 95% CI 0.18 to 0.77), although only 100 of the original sample of 268 women responded [83].

Sampsellet al [79] reported postnatal urinary incontinence severity (average score based on amount of self-reported leakage with gentle cough, hard cough, sneeze and laugh). Analysis of unpublished data found statistically significantly less incontinence severity in the PFMT group at six weeks postpartum (mean difference (MD) -0.38, 95% CI -0.72 to -0.04). There were no statistically significant differences between the groups at 35 weeks, six or 12 months.

Reilly et al. [78] found little impact of postnatal SUI on incontinence specific quality of life, and no statistically significant differences between the groups on the eight domains of the King's Health Questionnaire. Women in the PFMT group reported statistically significantly higher general health scores (one of eight scales) on the SF36. Only Mørkved and colleagues mentioned adverse events in their paper; women reported none.

c) Summary

Pooled data from two good quality trials of antenatal PFMT suggest that women who train are at less risk of postnatal incontinence in the short term (three months). This effect might last long term (up to four years).

d) Recommendations

Primiparous women should be offered a sufficiently intensive and supervised antenatal PFMT program to prevent postnatal incontinence. Those caring for childbearing women should consider whether their current PFMT policies are sufficiently 'intensive' in light of the available evidence. Further large good quality RCTs, with appropriate inclusion criteria and longer follow up, are needed to investigate the effect of antenatal PFMT on preventing postnatal urinary incontinence in other groups of women (e.g. multiparae).

Primiparous women should be offered a sufficiently intensive and supervised antenatal PFMT program to prevent postnatal urinary incontinence (Grade B).

3. PREVENTION AND/OR TREATMENT OF URINARY INCONTINENCE IN CHILDBEARING WOMEN

Trials that recruited continent and incontinent childbearing women were considered. Five RCT's were included [77, 79-82]. The trial by Hughes et al [81] was published only as a conference abstract. One qRCT was excluded [84], because the pelvic floor rehabilitation comprised PFMT and electrical stimulation. Three included trials recruited antenatal women [77, 79, 81], and two included postnatal women [80, 82].

Antenatal women: The interventions of two trials in antenatal women [77, 79] are described previously. Hughes et al. [81] recruited nulliparous women at 20 weeks gestation. Women randomised to PFMT attended one individual appointment then a group session (maximum 6 women) on PFMT with a physiotherapist between 22 and 25 weeks gestation. No details of the training parameters were reported. Women with no palpable VPFMC or a flicker of contraction were randomised. Controls received usual community antenatal care.

Postnatal women: Chiarelli and Cockburn [80] and Sleep and Grant [82] recruited women following vaginal delivery, from postnatal wards. Chiarelli and Cockburn (2002) restricted inclusion to women who had forceps or ventouse deliveries, or delivered a baby of 4000 grams or more in weight. The control groups received usual postnatal care, which included invitation to postnatal classes taught by physiotherapists. In PFMT groups, women were visited by a midwife or physiotherapist on the postnatal ward, and were recommended to train as follows:

VPFMC as often as remembered, integration of VPFMC with activities of daily living, and mid stream urine stop. No check of correct VPFMC [82]

VPFMC with three to six second holds, three times a day. Not clear if correct VPFMC checked. A variety of adherence strategies used (e.g. red stick up dots, home or hospital visit after eight weeks) [80]

a) Quality of data

Antenatal women: Two of the three trials had adequate random allocation concealment and blinded outcome assessors [77, 79]. Hughes et al. randomised 1169 women, Mørkved et al. 301 women, and Sampsel et al. 72. Drop out rates were four percent [77], 36% [79], and 68% answered the six month questionnaire in Hughes et al. All three trials collected antepartum data (35 or 36 weeks), and postpar-

tum data at three months [77], six months [81], and six weeks, six and 12 months [79]. In the latter trial, the primary endpoint was 12 months.

Postnatal women: Random allocation concealment was adequate, and outcome assessors were blind, in Chiarelli and Cockburn [80]. Sleep and Grant randomised 1800 women, and Chiarelli and Cockburn randomised 720. Both trials measured outcome at three months, with the loss of 191 (11%) and 44 women (6%) respectively.

b) Results

Antenatal women: Pooled data from two antenatal training trials [81] [77] showed no statistically significant difference between the PFMT and control groups for urinary incontinence at three months postpartum (RR 0.86, 95% CI 0.73 to 1.02), although Mørkved et al. found a significant difference in favour of the training group (RR 0.61, 95% CI 0.41 to 0.91) while Hughes et al. did not (RR 0.94, 95% CI 0.79 to 1.13).

Sampsel et al. [79] reported postnatal incontinence severity. Analysis of unpublished data found no statistically significant differences for incontinence severity at six weeks, six or 12 months. Only Mørkved and colleagues mentioned adverse events in their paper; women reported none.

Postnatal women: Pooled data from the two trials, showed no statistically significant difference between the PFMT and control groups for urinary incontinence at three months postpartum (RR 0.92, 95% CI 0.80 to 1.06), although Chiarelli and Cockburn [80] found bare statistical significance (RR 0.81, 95% CI 0.66 to 1.00), Sleep and Grant [82] did not (RR 1.00, 95% CI 0.83 to 1.20). Sleep and Grant found the PFMT group were less likely to report depression at three months postpartum, although there were no statistically significant differences in self-reported wellness between the groups. Neither trial report mentioned adverse events.

c) Summary

Regular supervised antenatal strength training for women who have a correct VPFMC confirmed and/or a postnatal PFMT program that incorporates adherence strategies targeted at women following instrumental delivery and/or birth of a large baby might reduce the prevalence of postpartum urinary incontinence at three months. Reinforced, but less intensive PFMT (sub-optimal training parameters, less supervision, lack of compliance strategies), might not be effective in the wider population of childbearing women.

It is not clear if antenatal or postnatal training has a greater effect. The long-term effects of training (e.g. at one year) are not established.

d) Recommendations

To reduce the prevalence of postnatal incontinence those caring for childbearing women should offer intensive supervised PFMT to antenatal women and/or individual postnatal PFMT instruction with adherence strategies to women after instrumental delivery and/or delivery of a large baby. Maternity caregivers should consider whether their current PFMT policies are sufficiently 'intensive' in light of the available evidence.

Because it may be easier to offer supervised intensive PFMT to all childbearing women (regardless of continence status), than target specific groups (e.g. antenatal women, women after forceps or ventouse delivery), more large good quality RCTs are needed in the general population of childbearing women. Further research might consider a comparison of antenatal training, postnatal training and usual care on long-term urinary continence in childbearing women. Researchers need to consider the intensity of PFMT programs.

To reduce the prevalence of postnatal incontinence primiparous women with a correct VPFMC should be offered a supervised intensive antenatal PFMT program, and women following instrumental delivery, or delivery of a large baby, should be offered a postnatal PFMT program that incorporates adherence strategies (Grade B)

II. TREATMENT

The purpose of this subsection is to address the following questions:

- Is PFMT better than no treatment, placebo or control treatments for urinary incontinence?
- Is one approach to PFMT better than another?
- Is PFMT better than other treatments?
- Does the addition of PFMT to other treatments add any benefit?
- What factors might affect the outcome of PFMT?
- What is the effect of PFMT on other LUTS?

The literature search revealed eight systematic reviews addressing the treatment of urinary inconti-

nence [75, 85-91]. Harvey considered only childbearing women and none of the others were up to date. The previous systematic reviews were used as the basis of this section, with the addition of data from subsequently published RCTs.

1. PFMT FOR URINARY INCONTINENCE IN CHILDBEARING WOMEN

Only trials addressing the treatment of existing urinary incontinence in childbearing women were considered. Two RCTs were included [92, 93]. Both trials recruited women with symptoms of urinary incontinence three months following delivery.

The control groups in both trials received standard care, which included antenatal and postnatal advice on PFMT. Wilson and Herbison[93] randomised women in the intervention group to PFMT, PFMT with vaginal cones, or vaginal cones. Only the PFMT group is described here. PFMT comprised:

- 80-100 VPFMC (mix of fast and slow) per day, with three home visits by nurse, health visitor or continence advisor[92].

As above, with instruction from physiotherapist on four occasions[93].

a) Quality of data

Random allocation concealment was adequate in both trials, and outcome assessors were blinded in Glazener et al[92]. Wilson and Herbison[93] randomised 230 women (117 controls, 39 PFMT, 38 PFMT and vaginal cones, 36 cones), and Glazener et al. 747. There were 85 losses to follow up in the trial by Wilson and Herbison, with high attrition rates in all intervention groups (20/39 PFMT, 24/38 PFMT and vaginal cones, 15/36 cones). Glazener et al. reported 223 (30%) losses to follow up. Both trials measured outcome 12 months after delivery, and longer term follow up 24 to 44 months post delivery [93], and six years after the index delivery [94].

b) Results

Pooled data showed PFMT women were less likely to experience urinary incontinence 12 months postpartum (RR 0.84, 95% CI 0.74 to 0.95). Women in the PFMT group were less also likely to have more severe incontinence (leakage once or more per week) (RR 0.62, 95% CI 0.46 to 0.84)[92]. The effect of PFMT on urinary incontinence, and incontinence severity, was not sustained in the sample of 516 women that Glazener and colleagues followed up six years from the index delivery (RR 0.96 for urinary incontinence, 95% CI 0.88 to 1.05; RR for inconti-

nence once or more per week 0.97, 95% CI 0.78 to 1.21). At six years women had an average of 1.5 deliveries since the index delivery. Long-term follow up data from Wilson and Herbison[93] did not differentiate between the three intervention groups.

With regard to quality of life, Wilson and Herbison collected data on sexual satisfaction at 24 to 44 months postpartum, but data were not differentiated for the three intervention groups. Glazener and colleagues measured anxiety and depression (Hospital Anxiety and Depression Scale) at 12 months and six months (data not reported), and general wellbeing at 12 months. Women in the PFMT group were less likely to be anxious at 12 months (RR -0.74, 95% CI -1.43 to -0.05), but there were no statistically significant differences between the groups for depression or general wellbeing. Neither trial report mentioned adverse events.

c) Summary

PFMT for women who have symptoms of urinary incontinence at three months postpartum is a more effective treatment than standard postnatal care. It is not clear if the effect is sustained in the long-term.

d) Recommendations

Women with symptoms of urinary incontinence three months postpartum should be offered a supervised and suitably intensive PFMT program. Further high quality trials, with long term follow up, are needed to investigate long-term effects of training and effects of training on quality of life.

Supervised PFMT is more effective than standard postnatal care for the treatment of urinary incontinence at three months postpartum (Grade B)

2. PFMT VERSUS NO TREATMENT, PLACEBO OR CONTROL TREATMENTS IN ALL OTHER WOMEN

Nine RCTs comparing PFMT with no treatment for women with urinary incontinence were found [95-103], and two were excluded. O'Brien et al.[103] added bladder training to PFMT for women with symptoms of urge urinary incontinence; data were not reported separately by symptoms. The report of the trial by Bidmead and colleagues[96] was a conference abstract. There were no useable data (mean without measure of variance).

Five RCTs [104-108] and two qRCTs [109, 110]

compared PFMT with a sham, placebo or control treatment. Lagro-Janssen et al. added bladder training to PFMT for women with symptoms of urge urinary incontinence; data were reported separately by diagnosis [111], so this qRCT was included. Yoon et al [110] was a conference abstract; no data were reported and there was no detail of the PFMT intervention or control conditions. This trial was excluded.

No treatment comparison: Of the seven RCT's four stated a correct VPFMC was checked prior to training[95, 97, 98, 102]. Henalla et al.[101] gave no details of the training program; the PFMT parameters in the other trials were:

- 10 VPFMC with five second holds and 10 second rests, three times a day, daily for eight weeks. Treatment was progressed to 10 second holds and 20 second rests[95]
- Eight to 12 high intensity VPFMC with six to eight second holds and six seconds rest, three times a day, daily at home, and a weekly PFMT exercise class for six months[98]
- 20 VPFMC, 10 fast (three second holds) and 10 sustained (10 second holds), four times a day, daily for eight weeks. Progressed by 10 VPFMC per set, to a maximum of 200 contractions per day[100]
- Five VPFMC with five second holds, five times an hour, daily for 12 weeks[102]
- VPFMC prior to cough and held until abdominal wall relaxed, for one week[97]
- 30 VPFMC (strength and endurance) daily for eight weeks[99]

The controls in all seven trials did not receive any treatment.

Placebo, sham or control comparison: Supervised PFMT was compared with placebo drug[104], placebo PFMT [108], sham electrical stimulation [107], self-help booklet including advice on PFMT[105, 106], and advice on protective pads [109]. Three of the six trials stated a correct VPFMC was taught prior to PFMT; all used anorectal biofeedback for teaching [104-106]. Because biofeedback was not used repeatedly over the training period, these three trials were not classified as biofeedback trials. Hofbauer et al. [107] gave no details of training parameters. In the other trials, the PFMT parameters were:

- 15 VPFMC, 10 second hold, three times a day,

daily for eight weeks. Also VPFMC with activities likely to cause leakage, and urge strategies[104]

- As above[105]
- 15 VPFMC, two to four second hold, equal period of rest, three times a day for eight weeks. Treatment progressed to 10 second hold and 10 second rest. Also VPFMC with activities likely to cause leakage, and urge strategies[106]
- 10 VPFMC with six second hold, five to 10 times per day for 12 weeks[111]
- Four maximal VPFMC with four second hold and 10 second rest every waking hour, daily for three months[108]

a) Quality of data

No treatment comparison: Of the seven RCT's only one reported adequate random allocation concealment [98]. Four trials stated the outcome assessor was blind to group allocation [97-100]. The number of women allocated to training/control groups was 25 or less per group in five trials [95] [97, 99, 101, 102], and between 26 and 50 per group in the other two[98, 100]. There were no dropouts in three trials [95, 97, 102], less than 10% in one [100], 12% in two [98, 99], and one trial did not make this clear[101]. All women were assessed post treatment (see treatment intervals above); further follow up at six and nine months was conducted by Burns et al. and Henalla et al. respectively.

Placebo, sham or control treatment comparison: None of the six trials reported adequate allocation concealment. Ramsay and Thou[108] and Burgio et al[104] blinded participants to group allocation by providing a placebo PFMT and placebo drug respectively. Two trials stated the outcome assessor was blind to group allocation[104, 109]. The number of women allocated to training/control groups was 25 or less per group in two trials [107, 108], and more than 50 per group in the remainder. There were no dropouts in two trials [107, 108], less than 10% in one [109], 12% [105], 14%[104] and 23% [106] in the others. All women were evaluated post treatment (intervals detailed above). Further follow up was conducted by Hofbauer and colleagues (six months), and Lagro-Janssen and coworkers (six and 12 months).

b) Results

No treatment comparison: Although Henalla and co-workers[101, 102] and Burns et al.[100] reported cure/improvement these data were from pad test and urinary diary respectively, and were excluded from

the analysis of self-reported cure/improvement. For women with USI, leakage was more likely to be “unproblematic” (defined as cure by Bø et al) after treatment in the PFMT group than the controls (RR 16.80, 95% CI 2.37 to 119.04). The effect was greater for self-reported cure/improvement (RR 27.60, 95% CI 4.00 to 190.24). Pooled data on leakage episodes showed statistically significantly less leakage episodes in 24 hours in the PFMT group compared to the no treatment group in women with USI [98] and women with USI with or without DO[100] (weighted mean difference (WMD) -1.00 , 95% CI -1.62 to -0.39). Regarding quality of life, two trials used the Social Activity Index[95, 98]; both found higher scores after treatment in the PFMT than the no training group for women with USI. Only Bø and colleagues mention adverse events in their paper; PFMT women reported none. In longer term follow up Henalla et al. reported three of 17 PFMT women had recurrent symptoms at nine months.

Placebo, sham or control treatment comparison: Unfortunately it was not clear if the cure/improvement data reported by Hofbauer and colleagues were based on self report or voiding diary. Cure data reported by Burgio et al appear to be derived from a voiding diary. These data were excluded from the analysis of self-reported cure/improvement. Pooled data from five trials [104-106, 112] found PFMT women were more likely to report cure/improvement than women in control groups (RR 1.42, 95% CI 1.28 to 1.58). Only Ramsay and Thou did not find a statistically significant effect in favour of PFMT. In this trial, placebo PFMT consisted of hip abductor exercise with feet crossed at the ankles. Strong isometric hip abductor activity may indirectly train the PFM, because muscles of the abdomen, hip, gluteal region and pelvic are known to work synergistically [57]. This might have confounded the comparison. In addition, Ramsay and Thou reported training adherence was very poor, so women in the PFMT group might not have been training at sufficient levels for treatment to be effective. Removing the data from Ramsay and Thou from the comparison makes little difference (RR 1.47, 95% CI 1.32 to 1.63). Pooled data from four trials [104-106, 109, 112] demonstrated PFMT women had fewer incontinence episodes per day than controls (WMD -0.70 , 95% CI -0.96 to -0.45). The effect of training was seen in samples of women with stress urinary incontinence only [111], women with USI with or without DO [106], and DO with or without USI[104, 105].

In the two meta-analyses, the effect was greatest in the trial of Lagro-Janssen and colleagues. This was a

qRCT, rather than a RCT. In all trials, except that of Lagro-Janssen and colleagues, there were statistically significant improvements (before and after) in many outcomes for the placebo, sham or control groups as well as the PFMT group.

With regard to quality of life, three trials collected data using the Hopkins symptoms checklist for psychological distress [104-106], and two also used the Incontinence Impact Questionnaire (IIQ) and SF36 [105, 106]. No data were reported in any of these three trials. The trial reports state that psychological distress and IIQ score decreased in all groups, but there are no statistically significant differences between the groups post-treatment. SF36 scores did not demonstrate statistically significant changes. Goode and colleagues, and Burgio and co-workers, mentioned adverse events; Goode et al reported that no one withdrew due to adverse events, and Burgio et al collected data on drug side effects.

c) Summary

Considering there were nine RCT's comparing PFMT with no treatment for women with urinary incontinence, it is disappointing that so few data were available for analysis. Most trials did not collect any data on the outcomes of interest; occasionally data of interest were collected but were not reported or were reported poorly (e.g. mean without measure of variation). Only one trial measured all four outcomes of interest and two others measured one apiece. Based on data from one good quality trial it seems self-reported cure, and cure/improvement are much more likely after PFMT than no treatment in women with USI. Based on data from two trials it appears that women with USI who train experience one less leakage episode per 24 hours than controls. The ability to participate in social activities is greater in women who train.

More data on the outcomes of interest were available from the six trials comparing PFMT with placebo, sham or control treatments. Based on pooled data from five trials it seems women who train are more likely to report cure/improvement; this effect was seen in women with USI, DO and mixed urinary incontinence. Women who trained also reported approximately two less incontinence episodes per three days than controls.

There did not seem to be important differences in quality of life between the training and control groups. Placebo and control treatment groups usually demonstrated statistically significant improvements after intervention.

d) Recommendations

Based on the evidence of efficacy and the apparent lack of adverse events, PFMT should be offered, as first line therapy, to all women with USI, predominant USI (with or without DO), and predominant DO (with or without USI). Clinicians may feel, based on other summaries of evidence in this chapter, it is worth combining PFMT with urge strategies, bladder training or other physical therapy adjuncts.

In any future research, it is suggested that researchers design trials that collect data on outcomes that are likely to matter to patients, (e.g. self-reported cure/improvement, number of leakage episodes, and quality of life), and then report these data accurately.

PFMT should be offered, as first line therapy, to all women with stress, urge or mixed urinary incontinence (Grade A).

3. ONE APPROACH TO PFMT VERSUS ANOTHER

Trials were considered for inclusion in this section if they compared two or more approaches to PFMT. Differences in approach included the addition of an adjunctive, but not stand alone therapy (e.g. biofeedback), differences in supervisory intensity, or addition of adherence strategies. Trials adding stand alone therapies (e.g. cones, electrical stimulation) to PFMT were excluded. With regard to adjunctive biofeedback (BF), or intravaginal resistance (IVR), included trials needed to use repeated home or clinic based BF or IVR. A single use of BF, to assist with teaching a correct VPFMC, was not sufficient for inclusion [105, 106]. BF could be visual and/or auditory, and generated from vaginal squeeze pressure, anorectal, vaginal or perineal surface electromyography (EMG). (Figures 1 & 2)

Twenty-five RCTs and four qRCTs comparing two or more approaches to PFMT were found. Eleven of these were excluded. Three trials used a combination intervention (PFMT with bladder training) and data were not presented separately for those who received PFMT only [113-115]. Seven trials were excluded because they did not report any data on continence outcomes, collected such data but did not report it, or presented the data inadequately (e.g. by diagnosis and not by group allocation) [116-122]. One trial was not published in English, and an English language translation was not available in time for inclusion in the review [123].

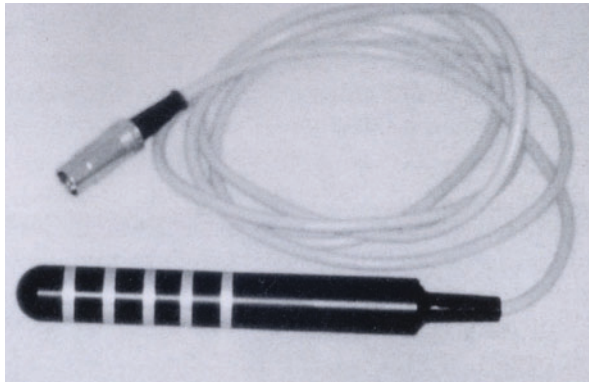


Figure 1. Surface EMG electrodes on vaginal probe

The 18 included trials addressed the effect of the following:

- Differences in supervisory intensity [124-126]
- Provision of a cue to PFMT [127]
- Differences in PFMT parameters [76, 128]
- Biofeedback assisted training [95, 100, 129-136]
- Training with intravaginal pressure device for resistance [137, 138]

Among the trials with differences in supervisory intensity, the trials addressed the effect of:

- An extra weekly PFMT class for six months. Both groups had home training and six individual clinic visits over six months [124]
- Nine two hour group sessions versus eleven 30 minute individual clinic visits. Both groups had home training for 12 weeks [126]
- Twelve individual clinic visits versus one clinic visit. Both groups had home training for six weeks [125]

In the one trial addressing cues to exercise, the trial investigated the effect of:

- An electronic device with chime to cue PFMT. Both groups had home training for eight weeks [127]

In the two trials that compared different PFMT programs, the trials addressed the effect of:

- Near maximal (90% of maximal for 10 minutes) versus sub-maximal VPFMC (60% of maximal for 15 minutes). Both groups were asked to train at home three times a day, using vaginal electromyography device, for six weeks [128].

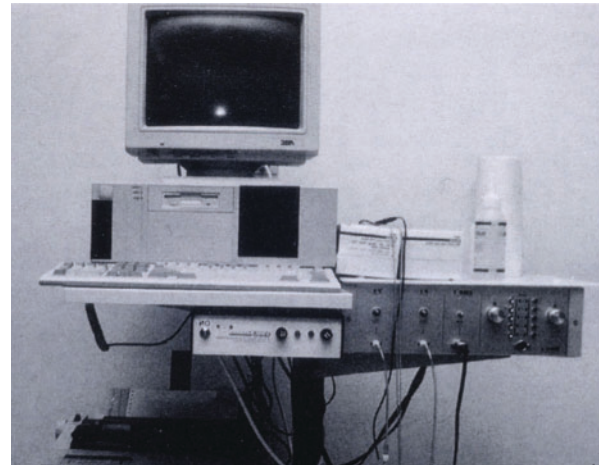


Figure 2. Vaginal biofeedback (pelvic floor muscle contractility reflected on a lighted scale on the screen)

- A strengthening PFMT program (10-12 near maximal VPFMC, six to eight second hold with equivalent rest, three times a day, at least three days a week). Both groups were asked to train using a motor relearning PFMT program (VPFMC in different body positions, and preceding and sustained during different provocative activities). Both groups trained for 18-20 weeks [139].

BF trials used either home or clinic based BF. Potentially, home based BF offers women more opportunity to make use of this adjunct. It might be expected that any BF effects would be greater in this group of trials. Clinic and home-based BF trials were therefore considered separately. Clinic based BF comprised:

- Vaginal EMG with visual and auditory BF three times a week for four weeks [130]
- Vaginal EMG with visual BF, weekly for eight weeks [100]
- Vaginal EMG with visual BF, weekly for four weeks [131]
- Vaginal squeeze pressure with visual and auditory BF five times a week for four weeks [134]
- Vaginal EMG with visual BF, twice a week for 12 weeks [136]

In two trials there were other differences between the groups. In the trial by Pages and colleagues the BF group did four sets of 10 VPFMC five times a week, but the non-BF group were asked to do 100 VPFMC per day integrated with activities of daily living and 10 minutes of VPFMC twice a day in a lying position. Glavind and co-workers had a greater amount of supervisory contact with the BF group than the group doing PFMT alone.

Home based BF comprised:

- Vaginal squeeze pressure, three times a week for eight weeks[95]
- Vaginal EMG with auditory BF, daily for 12 weeks[129]
- Vaginal squeeze pressure with visual BF, daily for 12 weeks [132]
- Vaginal squeeze pressure, daily for six months [133]
- Vaginal squeeze pressure with visual BF, daily for six weeks [135]

It was not clear if the groups were treated identically, apart from BF, in the trial by Aukee and colleagues. In the trial by Aksac and co-workers it appears BF group were instructed to exercise for 20 minutes three times a week at home (it is not absolutely clear whether this was with BF), but the non-BF group were recommended to repeat three sets of 10 VPFMC per day.

In both trials of IVR, it seemed the comparison groups were treated identically, except for the use of air/gas filled vaginal balloon catheters in the IVR group. Women in the trial by Ferguson [137]and colleagues trained daily for six weeks, and Klingler [138] and co-workers measured outcome after nine weeks of training.

a) Quality of data

Supervisory intensity: Two trials reported adequate allocation concealment [124], [126], and in one outcome assessors were blinded (Janssen et al. 2001). The number of women allocated to intervention groups was less than 25 in one trial [125], between 25 and 50 in one [124], and more than 100 in the other [126]. Wilson and colleagues had no dropouts, and no more than 12% of participants withdrew from either of the other two trials. Women were assessed post treatment at six weeks [125], three [126] and six months [124]. Further follow up was conducted at six months [125], 12 months [126], and five years (intensive supervision group only)[124].

Cue to exercise: Sugaya et al reported inadequate allocation concealment. It was not stated if outcome assessors were blind to treatment allocation. Less than 25 women were randomised to each comparison group; the dropout rate was 11%. Women were followed up at eight weeks.

PFMT parameters: Hay-Smith [139] reported adequate random allocation concealment, and blinded outcome assessors. Hay-Smith et al [76] randomised

more than 50 women per group; Johnson [128] randomised less than 25 women per group. Four percent of women withdrew from the trial by Hay-Smith and colleagues and 14% dropped out from Johnson's trial. Post-treatment evaluation was at seven weeks [128], and 18 to 20 weeks [76]. Neither trial reported further follow up.

Clinic BF: Of the five trials, two had adequate random allocation concealment [130, 136]. Two trials used blinded outcome assessors [100, 130]. Two trials randomised between 25 and 50 women to each comparison group [100, 136], with 25 or less per group in the remaining trials. There were no withdrawals or losses to follow up in one trial [130], less than 10% in one [100], less than 15% in two [131, 136], and 22% in the other [134]. In the latter trial all the dropouts were from the BF group. All women were assessed post treatment (see treatment intervals above); further follow up was conducted by Burns and co-workers at three and six months, and by Glavind and colleagues at three months and two to three years.

Home BF: Of the five trials random allocation concealment was adequate in just one [133]. Outcome assessors were blind to allocation for some or all of the outcomes in three trials [129, 133, 135]. The number of women allocated to the comparison groups was 20 or less in three trials [95, 129, 135]. Laycock and colleagues randomised women in a ratio of 2:2:1, so there were about 40 women in the BF group and 20 in the PFMT only group. Mørkved and co-workers randomised 50 women or more to each group. Three trials had complete data sets on trial completion [95, 129, 135], Mørkved and colleagues reported nine percent withdrawal, and 33% dropped out of the trial by Laycock and co-workers. All women were assessed post treatment (see treatment intervals above), and none followed women up beyond this.

Intravaginal resistance: It was not clear if allocation concealment was adequate or outcome assessors were blind in either trial. There were less than 25 women in each intervention group in both trials, and it seemed neither had any dropouts from treatment. Both trials assessed women post treatment (see treatment intervals above); Ferguson and colleagues also followed women up at 12 to 24 months[137].

b) Results

Supervisory intensity: The contrast in supervisory intensity varied. Two trials [124, 125] made high contrast comparisons (i.e. considerable difference in supervisory intensity) in women with USI. Bø et al

found no statistically significant difference in the proportion of women reporting cure (RR 6.25, 95% CI 0.31 to 124.10). Pooled data from both trials found women in the high intensity group were more likely to report cure/improvement (RR 4.14, 95% CI 2.01 to 8.56). Neither trial reported data on leakage episodes. Although Bø et al [124] used the Social Activity Index to collect quality of life data these were only reported for the intensive supervision group. Neither paper mentioned adverse events.

Janssen and colleagues compared individual with group training in women with symptoms of urinary incontinence, but there was not much difference in amount of contact time with the health care professional between the groups. It appeared that more time in a group was thought to compensate for the loss of individual attention. This trial included advice in addition to PFMT where appropriate, e.g. urge strategies. There was no statistically significant difference in the proportion of women who reported they were “dry” post treatment between groups receiving individual and group supervision (RR 1.51, 95% CI 0.93 to 2.46). Nor was there a statistically significant difference in the number of leakage episodes per day after treatment (WMD 0.18, 95% CI -0.61 to 0.41). No quality of life measure was reported. Adverse events were not mentioned in the trial report.

Cue to exercise: Sugaya [127] found that SUI women who used an electronic device to cue PFMT were more likely to be satisfied with treatment outcome (RR 3.17, 95% CI 1.02 to 9.88), but there was no difference between device and no device groups for the number of leakage episodes per day post treatment (WMD -0.50, 95% CI -1.55 to 0.55). Although Sugaya and colleagues report using a quality of life index, this is in fact self-reported satisfaction with treatment outcome. Adverse events were not mentioned.

PFMT parameters: Johnson[128] compared near maximal VPFMC (strengthening program) with sub-maximal VPFMC (endurance program) for women with USI. After six to seven weeks of training there was no statistically significant difference between the groups in the number of leakage episodes per day (WMD -0.36, 95% CI -1.85 to 1.13). Data were not collected on self-reported response to treatment, or quality of life. Hay-Smith et al. (2002) compared combination strength and motor relearning PFMT with motor relearning PFMT alone for SUI women. There were no statistically significant differences between the groups for self-reported cure (RR 0.25,

95% CI 0.03 to 2.21), cure/improvement (RR 0.88, 95% CI 0.59 to 1.31), or the number of leakage episodes in 24 hours (WMD -0.2, 95% CI -0.55 to 0.15). Nor were there consistent differences in the nine domains of the Kings Health Questionnaire. Participants reported no adverse events.

Clinic BF: Pooled data from Pages et al[134] and Wang et al [136] did not find any statistically significant difference in the proportion of women reporting cure after treatment with or without BF (RR 1.06, 95% CI 0.70 to 1.61) in women with SUI or OAB respectively. Similarly, there was no statistically significant difference for cure/improvement. At one to two years after treatment Glavind and co-workers found five of 19 BF women and none of 14 PFMT women with USI reported cure (RR 8.25, 95% CI 0.47 to 137.94). Pooled data from three trials [100, 130, 136] did not find any statistically significant difference in the number of leakage episodes per day between the BF and PFMT only groups (WMD -0.11, 95% CI -0.32 to 0.10). No trial individually demonstrated a statistically significant difference between the groups. The trials recruited women with USI, USI or MUI, and OAB respectively. With regard to quality of life, Berghmans and colleagues reported a symptom score, which included items on social limitations and emotional impact. These data were not reported separately from items about leakage (amount and frequency). Wang and co-workers measured quality of life using the Kings Health Questionnaire. There were no statistically significant differences between the groups for post treatment scores on any of the nine subscales. With regard to adverse events, Berghmans and colleagues stated that women reported none. Pages and co-workers similarly stated there were no adverse events, but they excluded 22% of BF participants after randomisation because the women were unable to use a vaginal probe (e.g. prolapse). Wang et al reported two women had allergic reaction to the BF lubricant.

Home BF: One trial did not report any outcome of interest [129]. It was difficult to combine the remaining data in a meaningful way. Aksac and colleagues[95] used a quality of life related measure (the Social Activity Index), but data were unusually reported as median with standard deviation. Therefore it was impossible to combine these data with Social Activity Index data reported by Mørkved et al [77]. Laycock and co-workers measured leakage episodes, but presented means without a measure of variance in their trial report. The only other trial to measure leakage episodes unfortunately reported the

data as mean with range [135]. Pooled data from Shepherd et al and Mørkved et al found no statistically significant differences between the groups for self-reported cure (RR 1.54, 95% CI 0.95 to 2.50) or self-reported cure/improvement (RR 1.17, 95% CI 0.93 to 1.47). Both trials recruited women with USI. Mørkved and colleagues did not find any statistically significant differences between the groups on the Social Activity Index post treatment. Mørkved and colleagues stated that no women reported an adverse event, while Aukee and co-workers found small number of women who could not use a vaginal probe due to discomfort or reported discomfort with PFMT without a probe.

Intravaginal resistance: Of the two trials, one did not collect any data for the prespecified outcomes of interest [137] and the other reported data for just one. Klingler et al [138] found no statistically significant difference between the groups for self-reported cure/improvement in women with USI (RR 0.95, 95% CI 0.86 to 1.05). Neither trial report mentioned adverse events

c) Summary

Considering the number of trials, it is disappointing there were so few data for analysis. Many trials collected no data for the pre-specified outcomes of interest, collected data for only one of these outcomes, and/or did not report the collected data appropriately (e.g. presented mean without measure of variance).

Self-reported cure and/or improvement in SUI women were more likely after more intensively than less intensively supervised PFMT. It seemed that there were no important differences in self-reported cure or cure/improvement or leakage episodes for women with symptoms of urinary incontinence, where the amounts of individual or group supervision were roughly equivalent.

Although SUI women might be more satisfied with the outcome of PFMT if accompanied by an exercise cue, this may not be reflected in differences in number of leakage episodes.

For women with USI, there may be no difference in the number of leakage episodes per day after six weeks of strength versus endurance PFMT. It is possible the training period was insufficient to be sure about the lack of difference. For SUI women, combination strength/motor relearning PFMT versus motor relearning PFMT alone seemed equally effective.

With regard to clinic based BF it seemed that there was no statistically significant difference between BF assisted and non-BF groups for self-reported

cure, cure/improvement, or leakage episodes per day or quality of life. This pattern appeared to be consistent across trials that recruited SUI women only, women with USI or mixed incontinence, or OAB. There were a similar number of trials addressing the effect of home BF, but fewer data. There were no statistically significant differences between home BF and non-BF groups for self-reported cure, cure/improvement, or quality of life for women with USI.

Only one small trial, presented in a conference abstract, reported any data of interest for the comparison of PFMT with IVR versus PFMT alone. There was no statistically significant difference in self-reported cure between the groups for women with USI.

d) Recommendations

Clinicians should provide the most intensive PFMT supervision that is possible within service constraints. Supervision could be provided in individual or group settings. Cues to exercise might be useful. It is not clear what the most effective PFMT parameters are; clinicians and researchers should refer to exercise physiology literature to provide a biological rationale for their choice of training parameters, which should be selected based on the aim of treatment, e.g. strength, endurance, co-ordination and function. More research is needed to investigate which PFMT parameters, and supervisory styles, are most effective. Future trials should include outcomes that are likely to matter to patients, and researchers should give some thought to the length to training programs.

There does not appear to be any benefit of home or clinic BF assisted PFMT over PFMT alone. However, although there have been a number of trials addressing this comparison, the quality of trials and/or quality of reporting could be improved. Further large good quality trials are probably warranted.

There may be no added benefit of IVR assisted PFMT versus PFMT alone. There are so few trials making this comparison, that further trials are warranted if clinicians/researchers feel that the comparison is of interest. Given that much PFMT is based on the aim of strengthening PFM, there seems to be some biological rationale for IVR devices.

Clinicians should provide the most intensively supervised PFMT program possible within service constraints (Grade B).

There does not appear to be any post treatment benefit of biofeedback (home or clinic) assisted PFMT, over PFMT alone (Grade B).

4. PFMT VERSUS OTHER TREATMENTS

Trials were considered for inclusion in this section if they compared PFMT with another stand-alone intervention, e.g. vaginal cones, bladder training, drug therapy. Twenty-three RCTs comparing PFMT with another stand-alone treatment were found. Four trials were excluded. Two were reported as conference abstracts and contained no useable data [140, 141], one was reported in two conference abstracts with inconsistent data [142], and the fourth compared combined PFMT/vaginal cones with electrical stimulation [143].

The 19 included trials addressed the following comparisons:

- PFMT versus vaginal cones or balls [98, 132, 144-146]
- PFMT versus electrical stimulation [98, 102, 107, 136, 147-150]
- PFMT versus bladder training [99, 151]
- PFMT versus drug [101, 102, 104, 152, 153]
- PFMT versus surgery [154]

PFMT versus vaginal cones/balls: No two trials had the same PFMT or cones protocol. PFMT comprised:

- 20 maximal VPFMC with five second hold and five second rest twice per day, 15 sub-maximal VPFMC with three second hold and three second rest once per day, and one two minute sub-maximal VPFMC per day, for four months[144]
- eight to 12 near maximal VPFMC with six second hold and six to eight second rest, with three to four fast contractions at the end of every contraction, three times a day for six months. Additional weekly exercise class[98]
- 10 forceful VPFMC and 10 sustained VPFMC with 10 second hold, repeated as able, for 12 weeks [145]
- 10 minutes per day of long maximal VPFMC with four seconds rest between and short one second maximal VPFMC, for 12 weeks[132]
- 50 VPFMC per day [146]

Training with vaginal cones included:

- 20 second maximal VPFMC and 20 second rest with 65g ball twice per day, and 15 minutes of sub-maximal VPFMC with performing activities of daily living once per day, for two months. Then

same protocol with 100g and 80g ball respectively for second two months [144]

- 20 minutes per day, progressing from 20g to 40g and 70g cone as able, for six months[98]
- 5 minutes twice a day (except during menstruation) with heaviest cone possible, for 12 weeks[145]
- 10 minutes per day, with heaviest cone able to retain while walking for two minutes and with 10 coughs/jumps, for 12 weeks [132]
- 15 minutes twice a day, with heaviest cone that can be retained for one minute [146]

Supervisory intensity (i.e. number of clinic visits/therapist contacts) was the same in PFMT and cones groups in the trials by Arvonen et al and Laycock et al, greater in the cones group in the trials by Peattie and Plevnik ,and Cammu and Van Nylen, and greater in the PFMT group in the trial by Bø et al.

PFMT versus electrical stimulation: There were different PFMT and electrical stimulation (ES) protocols in each study. Hofbauer et al [107], Laycock et al [148], Spruijt et al[149] and Wang et al. [136] gave no details of the PFMT parameters, but in the other trials PFMT comprised:

- eight to 12 near maximal VPFMC with six second hold and six to eight second rest, with three to four fast contractions at the end of every contraction, three times a day for six months. Additional weekly exercise class[98]
- five to 10 maximal VPFMC with five second hold and five seconds rest, and one sub-maximal contraction with 30 to 40 second hold, six to eight times per day, for six months[147]
- five VPFMC with five second holds, five times an hour, daily for 12 weeks [102]
- 60 slow and quick VPFMC per day for four months [150]

The ES parameters were:

- vaginal electrode, biphasic intermittent current at 50Hz, pulse duration 0.2 milliseconds, with individualised duty cycle depending on ability to hold VPFMC, at maximal tolerated intensity up to 120mA, 30 minutes per day, for six months[98]
- vaginal electrode, intermittent current at 12, 20 or 50Hz, for six to eight hours per night, for six months [147]
- Interferential current, at 0-100Hz, at maximal

tolerated intensity, 20 minutes once a week for 10 weeks [102]

- extra-vaginal and lumbar electrodes, intensity increased until noticeable PFM contraction and patient added VPFMC, 10 minutes three times a week for six weeks[107]
- Interferential current, 10-50Hz, 30 minutes two to three times a week for four to six weeks[148]
- vaginal electrode, asymmetric balance biphasic intermittent current at 12.5 and 50Hz, pulse duration 300 microseconds, five second contraction time (two second ramp up and one second ramp down), duty cycle one to two, intensity to 80mA, up to 60 minutes twice a day for four months[150]
- vaginal electrode, biphasic intermittent current at 50Hz, pulse duration one millisecond, two second contraction, duty cycle one to two, at maximal tolerated intensity up to 100mA, for 30 minutes three times a week for eight weeks for predominant SUI. For women with predominant UUI, as above, but 20Hz[149]
- vaginal electrode, biphasic symmetric intermittent current at 10Hz, pulse duration 400 microseconds, duty cycle 10 seconds on and five off, maximum tolerated intensity, 20 minutes twice a week, for 12 weeks[136]

Supervisory intensity (i.e. number of clinic visits/therapist contacts) was the same in PFMT and ES groups in Henalla et al[102] was greater for ES in Hofbauer et al. and Laycock, greater for PFMT in Bø et al [98]. Any differences in supervisory intensity were not clear in the four remaining trials.

PFMT versus bladder training: There were some similarities between the PFMT and bladder training protocols used by the two trials in this comparison. Both Wyman et al.[151] and Yoon et al.[99] used PFMT programs with fast and sustained contractions and some clinic based BF in addition to home PFMT, and both reported bladder training programs in which the voiding interval was extended weekly. The details of the PFMT were:

- five fast (three second holds) and 20 sustained (10 second holds with 10 second rests) VPFMC, twice a day for 12 weeks. Also VPFMC for urge suppression and with increases in intra-abdominal pressure (Wyman)
- 30 VPFMC per day for strength and endurance (12 second holds) for eight weeks (Yoon)

Bladder training comprised:

- Progressive voiding schedule increased by 30 minutes per week for the first six weeks, and urge inhibition techniques (affirmations, distraction and relaxation), for 12 weeks (Wyman)
- Progressive voiding schedule increased weekly for eight weeks (Yoon)

Wyman et al. reported the same number of clinic/therapist contacts in each group. Yoon et al. did not make this clear.

PFMT versus drug: Burgio et al. [104] compared PFMT with oxybutynin in a sample of women with DO or DO with USI. Henalla and colleagues [101, 102] compared PFMT and vaginal oestrogens in women with USI. Ishiko et al.[152] compared B₂-adrenergic agonist and PFMT, while Wells et al. [153] compared alpha-adrenergic agonist with PFMT, in women with symptoms of stress or mixed incontinence. Drug therapy comprised:

- Oxybutynin chloride 2.5mg tid, progressed to maximum 5.0mg tid, for eight weeks [104]
- Premarin (conjugated equine oestrogens) 2g per night for six[101] or 12 weeks [102]
- Clenbuterol 20 micrograms bid, for 12 weeks [152]
- Phenylpropanolamine hydrochloride, 50mg qd for two weeks, increasing to bid for two weeks if leakage continued, for four weeks [153]
- Henalla et al.[101] reported no details of the PFMT program. The PFMT parameters in the other trials were:
 - 15 VPFMC, 10 second hold, three times a day, daily for eight weeks. Also VPFMC with increased intra-abdominal pressure and urge strategies in the Burgio trial
 - Five VPFMC with five second holds, five times an hour, daily for 12 weeks in the Henalla trial
 - 10 minutes VPFMC per day for 12 weeks in the Ishiko trial
 - 90 to 160 VPFMC with 10 second hold and 10 second rest distributed throughout the day, for six months in the Wells trial

Two trials had the same level of supervisory intensity in drug and PFMT groups[104, 152]; in both trials by Henalla and colleagues this is not clear. Wells and co-workers assessed treatment effect after four

weeks in the drug group, and six months in the PFMT group.

PFMT versus surgery: Klarskov and colleagues[154] chose a surgical technique based on the type of defect identified. Women with anterior suspension defects had a Burch colposuspension, women with posterior bladder descent had a vaginal repair, and women with both defects had a combined Burch and vaginal repair procedure. There were no details of the PFMT parameters given; women had five or more group sessions with a physiotherapist.

a) Quality of data

PFMT versus vaginal cones: Bø et al[98] and Cammu and Van Nylen[145] reported adequate random allocation concealment, and Bø et al stated that outcome assessors were blinded. In two trials there were 25 women or less per group[144, 146], in two there were between 25 and 50 per group[98, 145], and Laycock et al [132] randomised women 41 women to cones and 20 to PFMT. Arvonen et al and Bø et al reported drop out rates of 7.5% and 12% respectively, with more dropouts in the other trials (23%[145], 25%[146] and 33% [132]. There were dropouts from both PFMT and cones groups in all trials except Cammu and Van Nylen, where all the dropouts were from the cones group. None of the trials reported follow up beyond the post treatment evaluation.

PFMT versus electrical stimulation: Of the eight trials two reported adequate random allocation concealment and blinding of outcome assessors[98, 136]. Three trials randomised approximately 10 women per comparison group[107, 147, 150], and the remaining trials between 20 and 35 women per group. Four trials appeared to have no dropouts[102, 107, 147, 150], with five percent[149], 12% [98], 13%[136] and 19% [132] in the others. All women were assessed post treatment; Henalla and colleagues and Hahn and co-workers also follow women up longer term, at nine months, and one to four years respectively.

PFMT versus bladder training: It was not clear if random allocation concealment was adequate in either trial. Yoon and colleagues reported blinding of outcome assessors; Wyman and co-workers stated that outcome assessors were not blinded. Wyman et al. [151] randomised nearly 70 women per group. The trial by Yoon et al. [99] was smaller with approximately 15 to 20 women per group. Dropouts were approximately four percent [151] and 12% [99]. All women were assessed post treatment, and

Wyman and colleagues followed women up three months later (i.e. six months after treatment began).

PFMT versus drug: It was not clear if random allocation was adequately concealed in any of the five trials. Outcome assessors were blinded in the Burgio trial. Three randomised 25 women or less per group[101, 102, 152]. Burgio and colleagues randomised approximately 85 women per group, and Wells et al. around 80. The proportion of dropouts ranged from none [102], 14%[104], 16% [152] to 25% [153]. Dropout rates were not reported by Henalla et al. All women were assessed post treatment, and Henalla et al. also followed women up nine months later by questionnaire.

PFMT versus surgery: It was not clear if random allocation was adequately concealed, or if the outcome assessors were blind to group assignment. Klarskov and colleagues randomised approximately 25 women to each comparison group. It appears there were no dropouts at four months (post treatment assessment). There was further long-term follow up at one year, and four to eight years.

b) Results

PFMT versus vaginal cones: Pooled data from two trials in SUI women[98, 144] showed no statistically significant difference in number of self reported cures in PFMT and cones groups (RR 1.33, 95% CI 0.57 to 3.12), but the direction of effect was different in the two trials. Bø et al found a statistically significant difference in favour of PFMT (RR 3.17, 95% CI 1.02 to 9.88), while Arvonen et al did not (RR 0.11, 95% CI 0.01 to 1.83). Similarly, pooled data from three trials in SUI women[98, 144, 146] found no statistically significant difference in the number of women reporting cure/improvement between the groups (RR 1.14, 95% CI 0.90 to 1.45), but Bø and colleagues reported more women with cure/improvement in the PFMT than the cones group (RR 1.46, 95% CI 1.07 to 2.00) while the other two trials did not. Neither individual nor pooled data (WMD -0.54, 95% CI -1.18 to 0.10) from Bø et al and Cammu and Van Nylen showed a statistically significant difference in the number of leakage episodes in 24 hours between the groups. Laycock and colleagues reported reduction in leakage episodes per day in SUI women; there was no statistically significant difference between the groups (WMD 0.13, 95% CI -0.66 to 0.92). Three trials reported different measures of quality of life. Laycock and colleagues used the King's Health Questionnaire, but reported a mean score without variance. Cammu and Van Nylen

used a visual analogue score for psychological distress due to incontinence and did not find any statistically significant differences between the groups. Bø et al used the Social Activity Index and found the PFMT group had significantly higher scores than the cones group after treatment.

Three papers mentioned adverse events [98, 144, 145]. Arvonon and colleagues stated women using vaginal balls reported none, while the other two trials all reported adverse events associated with cone use, e.g. inability to use cones, pain, vaginitis, bleeding, and women finding cones unpleasant to use.

PFMT versus electrical stimulation: Pooled data from three trials in SUI women [98, 147, 150] found self reported cure was more likely for PFMT women (RR 2.67, 95% CI 1.53 to 14.26), although only Bø et al. found a statistically significant difference when data from the trials was considered individually. It was not clear if the cure data reported by Hofbauer et al [107] were derived from a symptom scale or voiding diary; these data were therefore excluded. Pooled data from three trials in SUI women [98, 147, 148] also found self reported cure/improvement was more likely in PFMT women (RR 1.72, 95% CI 1.05 to 2.81); again only Bø and colleagues found a statistically significant difference when trial data were considered individually. Only Bø and colleagues measured leakage episodes and quality of life (Social Activity Index) in SUI women. There was no statistically significant difference between the groups for either outcome. At nine months post treatment, Henalla and co-workers found three of 17 PFMT women and one of eight in the ES group reported recurrent symptoms. Three trials [98, 147, 150] reported side effects related to ES, including vaginal irritation and/or bleeding.

Spruijt and colleagues recruited women with SUI, UI or mixed incontinence, and did not find a statistically significant difference between the groups for self reported cure/improvement (RR 0.99, 95% CI 0.45 to 2.16). These trialists reported that ES produced “physical and emotional stress” in the elderly women in their sample.

Wang et al [136] recruited women with UI, and did not find any statistically significant difference between the groups for self reported cure (RR 0.74, 95% CI 0.38 to 1.42) or cure/improvement (RR 0.84, 95% CI 0.48 to 1.46). PFMT women had statistically significantly fewer leakage episodes per day (WMD -1.22, 95% CI -2.37 to -0.07). Although there were no statistically significant differences in the general health perception, incontinence impact,

role limitation, physical limitation, social limitation, and personal relationship domains of the quality of life measure (Kings Health Questionnaire), the ES group had statistically significantly better scores post treatment for emotions, sleep/energy and severity measures. Some women using ES reported discomfort during treatment.

PFMT versus bladder training: Both trials recruited women with SUI, UI or mixed incontinence. Unfortunately, Yoon et al. [99] did not report any data for the outcomes of interest. While more women reported they were much or somewhat better in PFMT groups than bladder training groups, in the trial by Wyman and colleagues, the difference did not reach statistical significance after treatment (RR 1.73, 95% CI 0.83 to 3.60) or three months later (RR 1.96, 95% CI 0.97 to 3.94). Similarly, while PFMT women had fewer leakage episodes per day than bladder training women the difference was not statistically significant at post treatment (WMD -0.14, 95% CI -0.83 to 0.55) or at six months (WMD -0.09, 95% CI -0.73 to 0.55). With regard to quality of life Wyman et al [151] did not find any statistically significant differences in life impact (Incontinence Impact Questionnaire) or symptom distress (Urogenital Distress inventory) between the groups at either three or six months. No adverse event data were reported in either trial.

PFMT versus drug: In the comparison of PFMT and oxybutynin in women with DO, or DO with UI, Burgio and colleagues reported no statistically significant difference for the number of women who were dry (cured) (RR 1.31, 95% CI 0.73 to 2.34), but PFMT women were more likely to report they were much better than women receiving the drug (RR 1.46, 95% CI 1.08 to 1.97). PFMT women also had fewer leakage episodes per day post treatment (WMD -0.41, 95% CI -0.80 to -0.02). Some women taking oxybutynin reported side effects (dry mouth and inability to void in particular).

Neither of the two trials comparing vaginal oestrogens and PFMT in UI women reported data for the outcomes of interest. Of those that responded to a follow up questionnaire at nine months, three of 17 PFMT women and three or three women using oestrogens reported recurrent symptoms. Adverse events were not reported in either trial.

Two trials compared an adrenergic agonist and PFMT in women with stress or mixed urinary incontinence. Ishiko et al. [152] did not find any statistically significant difference in the proportion of women reporting no leakage episodes (cure) after

treatment (RR 0.68, 95% CI 0.41 to 1.15), and Wells et al. [153] did not find any statistically significant difference for self reported cure/improvement (RR 0.92, 0.77 to 1.10). Wells and colleagues reported data for leakage episodes per day in SUI women only; PFMT women had statistically significantly more leaks per day than women in the drug group (WMD 0.08, 95% CI 0.02 to 0.14). Ishiko and colleagues reported that drug side effects were sufficient in some women that they withdrew from the study; others discontinued the drug, but remained in the trial. Wells and co-workers did not report data on treatment side effects.

PFMT versus surgery: At four months PFMT women with USI were less likely to report cure than women who had surgery (RR 0.20, 95% CI 0.07 to 0.61), although there was no statistically significant difference in the proportions reporting cure/improvement (RR 0.80, 95% CI 0.60 to 1.07). At 12 months 10 of 24 women from the PFMT group were satisfied with initial therapy, versus 19 of 26 women randomised to surgery. Long-term data (four to eight) years were not presented by group allocation. All reported adverse events were associated with surgery; women reported new urge incontinence, retropubic or pelvic pain or dyspareunia.

c) Summary

Five trials compared PFMT with vaginal cones/balls in SUI women. Pooled data demonstrated no statistically significant differences between the groups for self reported cure, cure/improvement or leakage episodes per day, but some trials favoured PFMT and others cones. The direction of effect appeared to relate to supervisory intensity. Four of the five trials reported some women dropped out because they could not or chose not to use cones

Eight trials compared PFMT with ES. Pooled data demonstrated self reported cure and cure/improvement were statistically significantly more likely in PFMT than ES groups for SUI women, although only one trial individually demonstrated a statistically significant difference [98]. Supervisory intensity was greater in the PFMT group in this trial. There were no statistically significant differences between PFMT and ES groups for leakage episodes or quality of life in SUI women, based on a single trial. Self reported cure/improvement rates were not statistically significantly different in a trial in women with SUI, UUI or mixed incontinence. Self reported cure and cure/improvement rates were not statistically

significantly different in a trial in women with UUI, although PFMT women had fewer leakage episodes per day, and women in the ES group had better quality of life in three of nine domains measured. Some women reported adverse events attributable to ES.

Two trials compared PFMT and bladder training in samples of women with SUI, UUI or mixed incontinence. Only one trial reported data for the outcomes of interest, with no statistically significant differences between the groups for self reported cure/improvement, leakage episodes, or quality of life after treatment or three months later.

One trial compared PFMT and oxybutynin in women with DO or DO with USI. It seemed PFMT women were more likely to report improvement and had fewer leakage episodes per day after treatment. Some women taking oxybutynin reported drug side effects. There were no data on the outcomes of interest from the two trials comparing vaginal oestrogens and PFMT in women with USI. Two trials compared adrenergic agonists and PFMT in women with stress or mixed incontinence; while women who took the drug had fewer leakage episodes per day post treatment, the proportion of women reporting cure or cure/improvement was not different. One trial reported drug side effects, sufficient to discontinue treatment, associated with adrenergic agonist.

Based on one trial it seemed self reported cure (at four months) and satisfaction with initial therapy (at 12 months) was more likely after surgery than PFMT for women with USI, although there was no statistically significant difference in the proportion of women reporting cure/improvement in the short term. There was insufficient detail about the PFMT program to make a judgment about how effective this might have been.

d) Recommendations

Where supervisory intensity is similar, PFMT and vaginal cones/balls might have similar effects for SUI women. However, the use of vaginal cones/balls is limited by contraindications to use and/or dislike of cones by some women.

PFMT might be better than ES for SUI women, particularly if PFMT is intensive. However, there is so much variation in the PFMT and electrical stimulation protocols investigated in the available trials, it is difficult to be sure about the relative effects of these treatments. It is not clear if PFMT or ES is better in a sample of women with a variety of incontinence

symptoms, or in UUI women. The use of ES might be limited by contraindication to use and/or side effects of treatment.

There may be no difference in the effect of PFMT or bladder training in a sample of women with a variety of incontinence symptoms (SUI, UUI, or both).

For women with DO, or DO with USI, PFMT might be better than oxybutynin; in addition, PFMT does not have the side effect profile associated with oxybutynin. There is insufficient evidence available to tell if vaginal oestrogen or PFMT is better for women with USI. There might be no difference between PFMT and adrenergic agonists for women with stress or mixed incontinence, and drug therapy appears to be associated with more side effects.

Surgery might be more effective than PFMT for women with USI based on short term follow up.

Larger, good quality trials are needed to address each of the above comparisons if these are of interest to women/clinicians/researchers. In planning comparisons researchers should consider carefully the potential impact of different levels of supervisory intensity between groups, particularly in comparisons of conservative therapies. A comparison of surgery and PFMT might be least useful, because PFMT is usually first line therapy with surgery reserved for those for whom PFMT is not satisfactory or not the treatment of choice.

The following statements should be viewed with caution, in view of the limitations of current evidence (i.e. few trials, poor quality trials, contradictory trial findings)

- **PFMT and vaginal cones might have similar effectiveness for SUI women (Grade B)**
- **PFMT might be better than ES for SUI women (Grade B)**
- **PFMT and bladder training might be similarly effective for women with SUI, UUI or mixed urinary incontinence (Grade B)**
- **PFMT might be better than oxybutynin for women with DO, or DO with USI (Grade B)**
- **PFMT and adrenergic agonists might be similarly effective for women with SUI or mixed incontinence (Grade B)**
- **PFMT might be less effective than surgery for women with USI (Grade B)**

However, when recommending treatment clinicians should consider that adverse events are more common and more severe with cones, electrical stimulation, drugs and surgery than with PFMT.

5. THE ADDITION OF PFMT TO OTHER TREATMENTS

To be included trials needed to investigate the effects of therapy A versus therapy A plus PFMT, to address the additive benefit of PFMT over therapy A. Seven RCTs were found, addressing the additive effect of PFMT over vaginal cones [155], electrical stimulation [107, 141], bladder training [151], drug [152, 156], or urethral occlusive device [157]. Four trials were excluded. Wise et al and Jeyaseelan et al were conference abstracts that did not report any useable data. Millard included men and women; data were not reported separately by sex. Dowell et al used a combination bladder training/PFMT program.

Electrical stimulation comparison: Hofbauer et al gave little detail of either electrical stimulation or PFMT interventions. Electrical stimulation used extravaginal and lumbar electrodes, with sufficient current intensity to provoke a visible contraction to which the patient added their own VPFMC. PFMT comprised a daily home program (not specified) and a twice weekly exercise class. Treatment duration was six weeks.

Bladder training comparison: Women in both groups received the same preliminary education program. Bladder training comprised a progressive voiding schedule and advice on urge inhibition techniques (affirmations, distraction and relaxation). Women who added PFMT were asked to exercise twice per day to a maximum of 10 fast (three second holds) and 40 sustained (10 second holds) VPFMC per day. The combination therapy group began with bladder training and added PFMT in the third week of the 12 week intervention.

Drug comparison: Both groups were prescribed oral beta(2)-adrenergic agonist (clenbuterol) 20 micrograms bid for 12 weeks. Additional PFMT comprised 10 minutes of VPFMC per day, but no further detail of training was given.

a) Quality of data

Electrical stimulation comparison: It was not clear if random allocation concealment was adequate or if assessors were blind to group assignment. There were only 11 women in each comparison group. There did not appear to be any dropouts.

Bladder training comparison: It was not clear if random allocation concealment was adequate. Outcome assessors were not blind to group assignment. There were 68 women in the bladder training group and 67 in combination therapy. There were less than 10% dropouts after 12 weeks treatment, and further follow up was reported at 6 months and approximately three years after study entry.

Drug comparison: It was not clear if random allocation concealment was adequate or if assessors were blind to group assignment. There were 18 women in the drug group, and 23 in the combination therapy group. Five and four women dropped out of these groups respectively, principally because of drug side effects.

b) Results

Electrical stimulation comparison: Although Hofbauer and colleagues reported cure/improvement, it was not clear if this was based on data from symptom scale or urinary diary. There were no data reported for the other outcomes of interest, and the paper does not mention adverse events.

Bladder training comparison: Wyman and co-workers recruited women with USI, or USI with DO. After treatment there was no statistically significant difference between the combination versus single therapy in the number of women reporting they were much better (RR 0.70, 95% CI 0.47 to 1.04), but more in the combination group reported they were much better six months after treatment began (RR 0.61, 95% CI 0.39 to 0.94). There was no statistically significant difference in the number of leakage episodes per day between the groups after treatment (WMD 0.54, 95% CI -0.14 to 1.22) or at six months (WMD 0.27, 95% CI -0.35 to 0.89). Condition specific quality of life was measured using the Urogenital Distress Inventory (UDI) and IIQ. The combination therapy group had statistically significantly better scores on UDI (WMD 31.10, 95% CI 13.26 to 48.94) and IIQ (WMD 25.50, 95% CI 1.05 to 49.95) after treatment, but there was no statistically significant difference in either measure six months after treatment began (UDI, WMD 18.90, 95% CI -0.12 to 37.92; IIQ, WMD 5.90, 95% CI -23.73 to 35.53). Approximately three years later a similar number in each group had sought further treatment for urinary incontinence (19 of 48 bladder retraining, 18 of 48 combination). Of the women who had not sought further treatment, fewer were free of leakage episodes in the bladder training group (four of 22 blad-

der retraining versus eight of 16 combination). The paper does not mention adverse events.

Drug comparison: Ishiko and colleagues did not report data for any of the outcomes of interest. They did state that 10 of 13 women in the drug group, and 17 of 19 in the combination therapy group had no leakage episodes per week post treatment. Some women reported drug side effects sufficient to withdraw from treatment.

c) Summary

There were few trials addressing the effect of adding PFMT to another therapy. Only one of the seven trials located reported useable data. While the findings of Wyman and colleagues suggested benefit of adding PFMT to bladder training for women with USI or DO with USI in the short term (three months), there was no statistically significant difference between single and combination therapy groups for leakage episodes per day, or condition specific quality of life after six months. However, more women in the bladder training/PFMT group felt they were much better at six months. Because there were no useable data, it is not clear if there is any benefit in adding PFMT to vaginal cones, electrical stimulation or drug therapy.

d) Recommendations

It is possible that the addition of PFMT to bladder training for women with USI or DO with USI is more effective in the short term, but it is not clear if the benefit is sustained. Otherwise, because there are so few trials, it is not possible to make recommendations about the possible benefits of adding PFMT to other therapies. If clinicians/researchers are interested in the additive effects of PFMT, further large good quality trials are needed.

For women with stress or mixed incontinence, a combination of PFMT/bladder training may be more effective than PFMT alone in the short term (three months), but any additional benefit may not be maintained longer term (six months) (Grade B).

III. OTHER LUTS

PFMT trials, included above, seldom reported data for other LUTS, e.g. frequency, nocturia, bladder pain. Data were so sparse it was not possible to summarise these in a reasonable manner.

IV. FACTORS AFFECTING OUTCOME OF PFMT

Apart from differences in effect attributed to PFMT or comparison interventions, there might be other factors affecting treatment outcome. Of particular interest is the effect of older age; this and other factors are considered here.

1. AGE

To address the effect of age on outcome, included trials were screened for those that specifically recruited older women and contributed data to the analyses. There were five trials that restricted inclusion to older women. Women were aged 55 or more [100, 104, 105, 153], or 65 or more [149]. The average age of women in these trials was between 60 and 70 years [100, 104, 105, 153], or over 70 years [149], compared with a mean age of 40 to 55 in most other included studies. The five trials contributed data to the following comparisons: PFMT versus no treatment [100], PFMT versus placebo, sham or control treatment [104, 105], biofeedback assisted PFMT versus PFMT alone [100], PFMT versus electrical stimulation [149]), and PFMT versus drug [104, 153].

For three comparisons (PFMT versus no treatment, PFMT versus placebo/sham/control, biofeedback assisted PFMT versus PFMT alone) there were no clear differences in size or direction of effect when the data from the trials in older women were compared with data from other trials. Therefore, the two recommendations arising from these comparisons are inclusive of older women. Namely, that PFMT should be offered, as first line therapy, to all women with stress, urge or mixed incontinence, and that there does not appear to be any post treatment benefit of biofeedback assisted PFMT over PFMT alone.

Burgio and colleagues were the only trial to compare PFMT with oxybutynin, while Wells and co-authors were the only trial to compare PFMT with alpha-adrenergic agonist. Spruijt and co-workers were the only trial to compare PFMT and ES in women with SUI, UI or mixed incontinence. It was not possible to compare the data from older women with data from younger women for these comparisons.

To further address the association of age and treatment outcome, the methods of included trials were checked for use of regression or other methods to investigate association between baseline characteris-

tics (specifically age) and outcome. The literature search had also located some papers that reported secondary analyses of data from included trials. Papers that reported an association between age and outcome, but did not describe the methods used to test this were not considered.

Two reports detailed the testing of independent associations between patient characteristics (including age) and outcome [112, 139]. Burgio et al [112] used data from PFMT groups in three RCTs [104-106]. The individual trials restricted entry to women 55 years and older [104, 105] or 40 years and over [106]. In multivariate analysis, age was not a significant predictor of reduction in leakage episodes for PFMT women with urge or mixed incontinence, or PFMT women with stress or mixed incontinence. Hay-Smith [139] investigated the associations between leakage on paper towel test and patient characteristics using data from a trial that compared two approaches to PFMT for SUI women. Older age was associated with more leakage in univariate models, but was not significant in multivariate analysis.

One further trial used correlation methods, and two categorised women as successes or failures, to investigate the association between age and outcome. In a secondary analysis of data from the trial by Wyman et al. [151], there was no statistically significant correlation between age and reduction in leakage episodes or change in PFM activity after PFMT or bladder training in women with stress, urge or mixed incontinence [158]. Bø and colleagues characterised participants in the intensive PFMT group from their 1990 trial as treatment responders and non-responders [159]. Treatment responders were statistically significantly older than borderline responders; there were no non-responders. Similarly, Wilson et al. [125] classified participants as successes (much improved on self-report) or failures (no better). The average age of treatment failures was statistically significantly older than average age of treatment successes, in this trial comparing intensive versus less intensive supervision in women with USI.

Considering the number of included trials, there were few that restricted entry to older women and/or investigated the association between age and treatment outcome. Only two studies have used the most appropriate methods to test independent associations. More research is needed to investigate the association between age and treatment outcome. Neither study using multivariate models found an association between age and outcome, nor was there a reported correlation in another. The two studies that

categorised women as treatment successes or failures had conflicting results.

There is no good evidence to suggest that older women with urinary incontinence do not benefit from PFMT as much as younger women.

2. OTHER

Aside from age, other factors have the potential to mediate treatment outcome, e.g. baseline incontinence severity, and duration of symptoms. Trial reports, and subsequent publications of included trials, were checked for methods investigating the association between baseline characteristics and treatment outcome. Some included studies reported predictors of outcome that appeared to be based on researcher observation, but did not describe the methods for checking the association; these data are not discussed here. One paper presented the association between PFM strength and baseline characteristics [160]; these data are not discussed because the outcome is not a direct measure of self reported symptom change, leakage, or quality of life. Seven reports of interest were found [100, 112, 125, 139, 153, 158, 159]. A wide range of patient characteristics were considered in these papers; it is not clear if it is more important to know which baseline characteristics might be significant, or which ones might not. To eliminate long lists of non-significant variables, a pragmatic choice was made to report only significant associations here.

Two reports described the testing of independent associations between patient characteristics and outcome [112, 139]. Burgio et al [112] used data from PFMT groups in three RCTs [104-106]. In multivariate analysis of data from PFMT women with urge or predominant urge incontinence, a 75% reduction in leakage episodes was more likely if women did not use protection (e.g. pads) prior to treatment. Continence (100% reduction in leakage episodes) was more likely if women had fewer incontinence episodes at baseline, had lower educational level, but less likely if they had prior incontinence surgery. For PFMT women with stress or predominant stress incontinence a 75% reduction in leakage episodes was less likely if women had previously been evaluated for incontinence or had more than 10 leakage episodes per week pre-treatment. Hay-Smith [139] investigated the associations between patient characteristics and two outcomes (leakage on paper towel test, self reported improvement) using data from a

trial that compared two approaches to PFMT for SUI women. In multivariate models increasing parity was associated with less improvement in leakage symptoms and more risk of leakage on paper towel test. Shorter symptom duration and higher body mass index were both associated with more improvement in symptoms. Leakage once or more per day was associated with greater risk of leakage paper towel test; the reverse was true for women with a history of constipation.

Theofrastous et al [158] used correlation methods to investigate the association between patient characteristics and outcome in a secondary analysis of data from the trial by Wyman et al. [151]. There was no statistically significant correlation between any of the baseline characteristics listed and the two outcomes (reduction in leakage episodes or change in PFM activity).

Two studies categorised women as successes or failures, to investigate the association between patient characteristics and outcome. Bø and colleagues characterised participants in the intensive PFMT group from their 1990 trial as treatment responders and non-responders [159]. Treatment responders had statistically significantly longer symptom duration, higher body mass index, stronger PFM, and were more motivated (clinician judgement) than borderline responders; there were no non-responders. Similarly, Wilson et al. [125] classified participants as successes (much improved on self-report) or failures (no better) in a trial comparing intensive versus less intensive supervision in women with USI. Treatment successes had statistically significantly lower rates of previous incontinence surgery, lower grade of SUI, and were using fewer pads in 24 hours.

Few included studies investigated association between patient characteristics and treatment outcome. Even fewer used appropriate methods. More research is needed to test for independent associations between patient characteristics and outcome. No consistent pattern emerged from the available data. Given the few data available, and the methodological limitations of some papers, any patient characteristic described above that was associated with outcome should be considered as possible rather than established prognostic factor.

It is not clear if there are any reliable predictors of PFMT outcome. Too few trials have appropriately investigated the association between patient characteristics and outcome to be sure.

B3 . PHYSICAL THERAPIES – WEIGHTED VAGINAL CONES

Weighted vaginal cones were developed as a method of strengthening and testing the function of the PFM [161]. (**Figure 3**) Theoretically, the sensation of ‘losing the cone’ from the vagina might provide strong sensory feedback and prompt a PFM contraction in order to retain the cone. Since their introduction, a variety of cones have been developed (i.e. different sizes, shapes and weights). They have been in widespread use in the past, and directly marketed to women through mail order companies. A review that questions the theoretical framework and effects of vaginal cones on PFM strength has been published [162]

This section will examine the evidence for the use of vaginal cones (VC) for the prevention and treatment of urinary incontinence in women of all ages. Questions addressed are:

- Can training with VC prevent urinary incontinence?
- Are VC better than no treatment, placebo or control treatments for urinary incontinence?
- Is one type of training with VC better than another?
- Are VC better than other treatments?
- Does the addition of VC to other treatments add any benefit?
- What factors might affect the outcome of training with VC?
- What is the effect of VC on other LUTS?

To address these questions, the literature was searched for reports of relevant systematic reviews and



Figure 3. Vaginal cones

reports of randomised controlled trials (RCTs) and quasi-randomised (qRCTs), e.g. alternate assignment (see appendix x). Therefore, only Level 1 evidence is considered in this section. Recommendations are based on the findings of existing systematic reviews, or systematic review of RCTs undertaken by the author of this section (JHS).

Pre-specified outcomes of interest were urinary continence (for prevention studies), self reported cure and cure/improvement in incontinence symptoms (treatment studies), leakage episodes (treatment studies), and quality of life (prevention and treatment studies). For a more detailed explanation regarding choice of outcome measures, and assessment of quality of data, readers are referred to the section on PFMT.

I. PREVENTION

The literature search revealed two previous systematic reviews addressing prevention of urinary incontinence [75, 76]. Harvey did not include any trials investigating the effects of training with VC. Hay-Smith and colleagues did include some VC studies, but all these measured the effect of VC on measures of PFM activity. Because no continence related outcomes were measured, these trials are not considered here.

No trials investigating the primary/secondary prevention effects of training with VC for women with urinary incontinence were found.

II. TREATMENT

The literature search revealed one systematic review that specifically addressed the effects of VC for urinary incontinence [163]. The review was the basis of this subsection, because no further RCTs of VC were found during the literature search.

1. VAGINAL CONES (VC) VERSUS NO TREATMENT, PLACEBO OR CONTROL TREATMENTS

Three RCTs compared VC with no treatment, placebo or control treatments for women with urinary incontinence [93, 98, 164]. The trial by Burton was excluded; this was a conference abstract with no useable data (mean without measure of variance). Bø and colleagues recruited women with USI, and compared VC with control treatment (i.e. offered use of

continence device). Wilson and Herbison recruited women with urinary incontinence three months postpartum, and compared VC with standard care.

Women in the trial by Bø and colleagues used cones for 20 minutes per day, progressing through three cone weights (20, 40, 70g) according to ability to hold the cones. Women in the control group were discouraged from using any treatment during the six-month intervention period, and offered the use of a continence device (Continence Guard). Postnatal women in the trial by Wilson and Herbison used cones for 15 minutes twice a day, increasing cone weight as able, for up to nine months. Women in the control group had standard antenatal/postnatal care, which included advice on PFMT.

a) Quality of data

Both trials reported adequate randomisation concealment, and blinded outcome assessors. Both trials randomised about 30 women to VC; Bø and colleagues randomised a similar number to the control group, but Wilson and Herbison had about 100 women in the control group (factorial design). Drop out rates were 12% [98], and 40% [93]. There were more dropouts from VC (42%) than control group (22%) in the trial by Wilson and Herbison. Wilson and Herbison assessed women again at two to four years postpartum.

b) Results

Data from the two trials were not pooled, because the two sample populations were considered to be different. In postnatal women with urinary incontinence, self reported continence was more likely in the VC than standard care group (RR 2.17 95% CI 1.25 to 3.74). No other outcomes of interest were reported for postnatal women.

In women with USI there was no statistically significant difference in the proportion in VC and control groups reporting their incontinence was unproblematic (RR 2.22 95% CI 0.21 to 23.15), but self-reported cure/improvement was more likely after training with VC (RR 18.89 95% CI 2.69 to 132.58). However, there was no statistically significant difference in number of leakage episodes in 24 hours (WMD 1.16 95% CI -1.43 to 1.63), or in quality of life (Social Activity Index) (WMD 0.5 95% CI -0.53 to 1.53). Of the twenty-nine women allocated to VC, one reported abdominal pain, two vaginitis, one vaginal bleeding. Fourteen had problems using cones, principally due to lack of motivation.

c) Summary

While there is some evidence that training with VC

might be better than control treatments (for self-reported outcome), the data are not consistent. Some women training with VC reported adverse events.

d) Recommendations

It is not clear if training with VC is better than control treatments, for postnatal women with urinary incontinence or women with USI. VC are not suitable for some women due to adverse events. With only two trials reporting outcomes of interest, more research is needed to be sure about the effect of VC versus no treatment, placebo or control treatments.

2. ONE APPROACH TO CONES VERSUS ANOTHER

No studies were found addressing this question.

No trials comparing approaches to training with VC were found. Research is needed if this is a comparison of interest for women and clinicians.

3. VC VERSUS OTHER TREATMENTS

Trials that compared VC with PFMT are included in the subsection on PFMT. Otherwise, six trials were found comparing VC with another stand-alone therapy [98, 143, 155, 165-167]; all of these compared VC with electrical stimulation. Four of these trials were excluded. Two because they used VC combined with another treatment[166]; VC with PFMT versus electrical stimulation with PFMT and biofeedback; VC with PFMT versus electrical stimulation[143]. One was a conference abstract and did not present any useable data[155]. Another gave means, but no measure of variation [165].

In the trial by Bø and colleagues, women with USI used VC for 20 minutes per day for six months, progressing through three cone weights (20, 40, 70g) according to ability to hold the cones. The electrical stimulation group used a stimulator with vaginal probe for 30 minutes a day, for six months. Stimulation parameters were biphasic intermittent current, 50 Hz, pulse width 0.2 milliseconds, intensity as high as tolerated to a maximum of 120 mA.

In the trial by Olah and colleagues, SUI women trained with VC for up to 15 minutes twice day for four weeks, with the heaviest cone possible (nine cones, 20 to 100g), progressing to the next heaviest cone when successful on two consecutive occasions. The electrical stimulation group had clinic-based stimulation for 15 minutes three times a week for four weeks, using two abdominal and two thigh vacuum electrodes. Stimulation parameters were interferen-

tial current from 0 – 100 Hz, with maximum intensity tolerated.

a) Quality of data

Bø et al [98] reported adequate random allocation concealment, and blinding of outcome assessors. Both studies randomised about 30 women to each comparison group. Dropout rates were 10% [167] and 12% [98]. Olah and colleagues evaluated response post treatment and again at six months[167].

b) Results

Pooled data found no statistically significant difference between VC and electrical stimulation groups for self reported cure (RR 1.13 95% CI 0.39 to 3.25), self reported cure/improvement (RR 0.95, 95% CI 0.75 to 1.19) or leakage episodes in 24 hours (WMD 0.25, 95% CI –0.59 to 1.08). When considered individually, neither trial found any of these comparisons to be statistically significantly different. Bø and colleagues did not find any statistically significant difference between the groups in quality of life (Social Activity Index) (WMD –0.4, 95% CI –1.15 to 0.35). Both VC and electrical stimulation groups reported adverse events in the trial by Bø and colleagues. Olah and co-workers had to exclude some women from their trial prior to randomisation because they could not use cones in the vagina (e.g. wedging of cones).

c) Summary

In SUI women there does not seem to be a statistically significant difference in effect between VC and electrical stimulation. Women may report adverse events using either treatment.

d) Recommendations

Either VC or ES appear to be equally effective for SUI women, but either treatment may be precluded by side effects.

VC and ES appear to be equally effective for SUI women (Grade A), but either treatment may be precluded by side effects.

4. THE ADDITION OF VC TO OTHER TREATMENTS

To be included trials needed to investigate the effects of therapy A versus therapy A plus VC, to address the

additive benefit of VC over therapy A. One RCT was found, addressing the additive effect of VC over PFMT [168]. Delete hard return to make single paragraph. Women with USI trained with cones 15 minutes per day with heaviest cones possible (five cones, 20 to 70g), progressing as able. Women in both comparison groups did PFMT, with an individualised program of up to 100 VPFMC per day.

a) Quality of data

It was not clear if random allocation was adequately concealed, nor if outcome assessors were blind. There were between 20 and 25 women per comparison group, with 40% dropouts. Women were assessed post treatment (six weeks) and also six weeks later.

b) Results

There was no statistically significant difference in the proportion of SUI women reporting cure/improvement after combination VC/PFMT versus PFMT alone (RR 0.51, 95% CI 0.24 to 1.09). No other outcomes of interest were reported.

c) Summary

Based on a single outcome, from one trial, there may be no further benefit from adding VC to PFMT for SUI women.

d) Recommendations

More research is needed to determine if there is any further benefit from adding VC to PFMT.

III. OTHER LUTS

There were too few data available to comment on the effect of VC on other LUTS.

IV. FACTORS AFFECTING OUTCOME

None of the trials, included in this subsection on VC, reported factors affecting outcome. None of the trials specifically recruited older women.

None of the included trials addressed the effect of age, or any other factor, on outcome of training with VC.

B4. PHYSICAL THERAPIES - ELECTRICAL STIMULATION

The literature concerning electrical stimulation in the management of urinary incontinence is very difficult to interpret, due to the lack of a well-substantiated biological rationale underpinning the use of electrical stimulation. However, the theoretical basis of stimulation interventions is emerging with increasing understanding of the neuro-anatomy and physiology of the central and peripheral nervous systems. It is also becoming clear that the mechanisms of action may vary depending on the cause(s) of incontinence and the structure(s) being targeted by electrical stimulation, e.g. pelvic floor muscle or detrusor muscle, peripheral or central nervous system. In general, the aim of electrical stimulation for women with stress incontinence appears to be to improve the function of the pelvic floor muscles, while for women with urge incontinence the objective seems to be to inhibit detrusor overactivity. Overall, studies poorly report the biological rationale underpinning the application of electrical stimulation being tested.

Electrical stimulation is provided by clinic based mains powered machines or portable battery powered stimulators (**Figure 4**). Electrical stimulation also offers a seemingly infinite combination of current types, waveforms, frequencies, intensities, electrode placements etc. (**Figure 5**). Without a clear biological rationale it is difficult to make reasoned choices of electrical stimulation parameters. Additional confusion is created by the relatively rapid developments in the area of electrical stimulation and a wide variety of stimulation devices and protocols have been used even for the same condition. For example, in the last 20 years or so women with stress incontinence have been treated using anything from a single clinic based episode of maximal stimulation under general anaesthetic for 20 minutes with vaginal and buttock electrodes[169], to 10 sessions of interferential therapy at 10 to 40 Hz with perineal body and symphysis pubis electrodes [143], to eight weeks of home-based stimulation using a 'new pattern of background low frequency and intermediate frequency with an initial doublet', for an hour a day [170, 171], to six months of low intensity stimulation at 10 Hz using a vaginal electrode[172].

Finally the nomenclature used to describe electrical stimulation has been inconsistent. Stimulation has sometimes been described on the basis of the type of current being used (e.g. faradic stimulation, interfe-



Figure 4. Mains and portable battery powered electrical stimulators

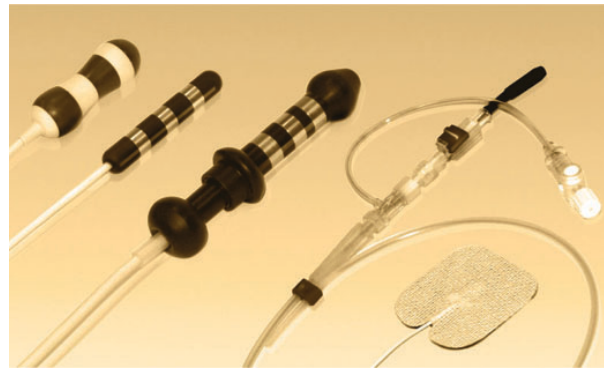


Figure 5. Vaginal, rectal and external electrical stimulation probes

rential therapy), but is also described on the basis of the structures being targeted (e.g. neuromuscular electrical stimulation), the current intensity (e.g. low-intensity stimulation, or maximal stimulation), and the proposed mechanism of action (e.g. neuromodulation). In the absence of agreement of how best to classify electrical stimulation the authors of this chapter have made no attempt to do so. The authors were also reluctant to use any existing system to group the electrical stimulation protocols in the trials as many were poorly described and could therefore be erroneously classified.

This section reviews the evidence in women comparing non-surgical electrical stimulation (ES) with no treatment, placebo ES and comparisons of different ES protocols. It also includes trials comparing non-surgical ES with any other single intervention (e.g. magnetic stimulation, PFMT, weighted vaginal cones, surgery, medication, etc) and trials comparing

ES with any other combined intervention versus that other combined intervention alone. For results of trials comparing ES and PFMT readers are referred to the section on PFMT, and for ES versus weighted vaginal cones to the section on vaginal cones. Three systematic reviews [85, 91, 173] have been published that include trials relevant to this section. The following qualitative summary of the evidence regarding electrical stimulation is based on the trials included in all of the previous systematic reviews with addition of trials performed after publication of the reviews and/or located through additional searching (see Appendix 1). To be included in this section a trial needed to (a) be a RCT, (b) include women with urinary incontinence, and (c) investigate the effect of electrical stimulation versus no treatment, placebo treatment, any other single treatment, with any other combined intervention versus that other combined intervention or compare different electrical stimulation protocols. Published abstracts were included but reporting trials in progress were excluded.

I. PREVENTION

To our knowledge ES has not been investigated for either the primary or secondary prevention of incontinence and lower urinary tract symptoms, i.e., urgency, frequency and nocturia as no published studies have been identified.

II. TREATMENT

The aim of this subsection is to address the following questions:

- What is the most appropriate electrical stimulation protocol?
- Is electrical stimulation better than no treatment, placebo or control treatments for urinary incontinence?
- Is electrical stimulation better than other treatments?
- Does the addition of other treatments add a benefit to electrical stimulation or does the addition of electrical stimulation to other treatments add any benefit?
- What is the effect of electrical stimulation on other LUTS?
- What factors might affect the outcome of electrical stimulation?

1. WHAT IS THE MOST APPROPRIATE ELECTRICAL STIMULATION PROTOCOL?

Some ES protocols were poorly reported, lacking detail of stimulation parameters, devices and methods of delivery. However, on the basis of the details that have been reported it appeared that there was considerable variation in ES protocols with no consistent pattern emerging.

The variability in the findings of the trials included in this section may in part be due to differences in the effectiveness of the wide range of protocols that have been tested. There are many differences in clinical application that have not yet been investigated. For example, some clinicians suggest that 'active' ES (i.e. the patient voluntarily contracts the PFM during stimulation) is better than 'passive' ES but the effect of these two approaches has not yet been evaluated.

Equally it may be that some populations or subgroups of women benefit from ES more than others. For example, anecdotal evidence suggests that ES is used with particular effect for women who are unable to perform a voluntary pelvic floor muscle contraction on initial assessment. However, this observation has not been investigated to date.

ES protocols for women with stress incontinence: Interferential therapy was used in four trials [102, 143, 148, 167]. Few trials clearly stated whether direct or alternating currents were being used. Two earlier trials [142, 174] used faradic current (low frequency interrupted direct current) and it is assumed that most if not all of the remaining trials used alternating currents. In those trials using alternating current only one trial described the pulse shape – a bipolar square wave [175].

The most commonly used descriptors were frequency and pulse duration. Six trials used a single frequency, ranging from 20 Hz [155, 175, 176] to 50 Hz [98, 147, 177]. Two trials included stimulation at both 10 Hz and 35 Hz [172, 178] although the protocols were different, one at combined low and intermediate frequency [170]. Other protocols included stimulation at 12.5 Hz and 50 Hz [179], 10-50 Hz [169], 0 to 100 Hz [102, 167], and finally a 30 minute treatment including 10 minutes at 1 Hz, 10 minutes 10 - 40Hz and 10 minutes at 40 Hz [143]. Pulse durations ranged from 0.08 milliseconds [178] up to 100 milliseconds [175]. Seven trials also detailed the duty cycle used during stimulation. The ratios ranged from 1:3 [180], and 1:2 [175, 177], to 1:1 [106, 172, 178] and one trial alternated between a ratio of 1:1 and 1:2 [179].

Seven trials asked women to use the maximum tolerable intensity of stimulation [98, 106, 143, 155, 167, 175, 179], and one trial increased output until there was a noticeable muscle contraction [169]. The trial by Knight et al [172] compared “low intensity” and “maximal intensity” protocols. The trials by Hofbauer et al [107] Knight et al [172] and Goode et al [106] also asked women to add a voluntary PFM contraction to the stimulated contraction, although in the trial of Knight et al [172] this was only for the maximal stimulation group.

Current was most commonly delivered via a single vaginal electrode [106, 147, 155, 172, 174, 175, 177, 179, 180]. One trial used both vaginal and buttock electrodes [111]. In four trials external electrodes were used, abdomen and inside thighs [129], perineal body and symphysis pubis [143], perineal and buttock [178], and in three studies the electrode placement was not clearly described [102, 107, 148].

The length and number of treatments was also highly variable. The longest treatment periods included daily treatment at home for six months [98, 147, 172]. Medium length treatment periods were based on one-daily treatment at home for eight weeks every other day [106] and twice-daily treatment at home for eight [175] to 12 weeks [177, 179]. The shortest treatment periods were all for clinic-based stimulation, ranging from 10 [102, 143], 12 [167] to 16 [172], and 18 sessions in total [169].

ES protocols for women with urgency, urge incontinence, detrusor overactivity: Although it appeared all the ES trials in this section used alternating current only three trials specifically stated this to be biphasic: [181]; bipolar [175]; biphasic pulsed current [150]. These same three trials and the trials of Yamanishi were the only ones to detail the pulse shape rectangular [181]; square [175, 182, 183]; asymmetric [150]; balanced with two second ramp up and one second ramp down.

Seven trials gave details of the frequencies used and these ranged from 10 Hz [180, 182, 183] to 20 Hz [175, 184], a combination of 12.5 & 50 Hz [150], 150 Hz [180], and a random frequency of 4-10 Hz [181]. Pulse durations were reported in seven trials, and these were 0.1 milliseconds [175], 0.2 milliseconds [180, 181, 184], 0.3 milliseconds [150] and 1 milliseconds [182, 183]. Two trials used a duty cycle ratio of 1:2 [150, 175].

Intensity of stimulation progressed from five to 25 mA in the trial by Smith [150]. Five trials used the maximum tolerable intensity [175, 180, 181, 183],

and one study increased intensity up to the pain threshold [185]. In the trial of Soomro et al. [184] patients were asked to control the amplitude of intensity to produce a tickling sensation. Current was most commonly delivered by a vaginal electrode [150, 175, 181-183]; or vaginal or anal electrodes [176, 185] although one trial used external surface electrode placements two electrodes over S2-3 sacral foramina or two electrodes just above the symphysis pubis [180]. Transcutaneous electrical stimulation was applied bilaterally over the perianal region using two self-adhesive electrodes [184].

The length and number of treatments was also highly variable. The longest treatment period was four months of daily stimulation [150] [86]. Medium length treatment periods were based on twice daily stimulation for four [182], eight [175], nine [96, 181] or 12 weeks [185]. In the crossover trial of Soomro [184] after randomisation patients received 6 weeks of electrical stimulation for 6 hours daily or oxybutynin. After a washout period of 2 weeks they started in the second arm of treatment for another 6 weeks. The shortest treatment period consisted of a single episode of stimulation after the voiding phase of cystometry before filling was repeated [180]. One trial compared clinic based stimulation once a week versus twice a week for five and up to 10 weeks [176].

ES protocols for women with mixed incontinence: The trial of Amaro [186] was only available as an abstract. The treatment protocol consisted of 3 weekly sessions over 7 weeks, using a frequency of 4 Hz. Intensity was controlled in accordance with patient tolerance. The current was delivered by a vaginal plug electrode.

ES protocols for women with stress, urge and mixed incontinence: In the trial of Spruijt et al. [149] biphasic current was used. Frequencies of 50 Hz in the case of (predominant) stress incontinence or 20 Hz in the case of (predominant) urge incontinence was applied. The authors stated that 20 Hz instead of 10 Hz was used because of the expected high percentage of mixed incontinence in their study group. Pulse duration was 1 millisecond. The duty cycle was 1:2. The current was delivered by a vaginal plug electrode. Intensity of stimulation progressed gradually to the level of tolerable discomfort. Maximal electrical stimulation was applied for 30 min three times a week for 8 weeks. Although percentages of types of incontinence (stress, urge, combined) were given, specified outcome data for each of these subgroups were lacking. This means that this

study has not contributed to the analysis of effects of electrical stimulation in women with either stress, urge or mixed incontinence.

Comparison of ES protocols

Few studies reported comparison of protocols, i.e., one approach to ES vs another, one in women with stress incontinence [172], two in women with detrusor overactivity and sensory urge [176, 180].

a) Quality of Data

Random allocation concealment was adequate in one trial [172]. In another trial the authors did not report if allocation was adequately concealed [176], and in a third one it was simply stated that allocation was at "random" [180]. Blinding of assessors and patients was clearly stated in one trial [180], and in the remainder this was not reported. In one study the size of the study population was based on a power calculation [180]. In all three trials less than 25 women were allocated to each comparison group. Bower et al. [180] had no dropouts or losses to follow up. The proportion of dropouts was 12% in the study of Lobel et al. [176], and 15% in Knight's study [172]. Two trials followed women up beyond the post treatment evaluation [172, 176]. The length of follow-up varied from six months [172] to one and six months after treatment [176].

b) Results

Women with stress incontinence: Knight et al. [172] found a trend, across a range of outcomes including self-report of cure or improvement, pad test, and perineometry, for women who received clinic based maximal stimulation to benefit more than women in the low intensity stimulation group although most differences were not significant. Long term follow up (12 months) suggested that women in both groups continued to improve subjectively, and this was most noticeable in the group of women who had received the combination of PFMT and low intensity stimulation. The trialists speculated that the combination of PFMT and low intensity stimulation was counterproductive, as the low intensity stimulation resulted in conversion of fast to slow twitch fibers to the detriment of fast-twitch fibre activity required in response to rapid changes in intra-abdominal pressure.

Women with detrusor overactivity and sensory urge: Bower et al [180] presented the findings for women with detrusor overactivity and sensory urgency separately. Both stimulation groups (10 Hz, sacral electrodes and 150 Hz, symphysis pubis elec-

trodes) showed significant improvements in the urodynamic measures of first desire to void and maximum detrusor pressure although neither group showed any significant change in maximum cystometric capacity. The same proportion (44%) of women in each stimulation group demonstrated a 'stable' bladder post stimulation and only the 150 Hz group show a significant improvement in the threshold volume.

Lobel et al [176] did not find any significant differences in any outcome measured (including leakage episodes and quality of life) between the groups. Although more than half the women in the study were improved symptomatically post treatment only 25% were sufficiently satisfied with outcome that they did not wish for further treatment.

c) Summary

When reviewing trials comparing electrical stimulation protocols in particular, it appears that some electrical stimulation protocols may be more effective than others. Comparison between ES protocols requires further investigation.

d) Recommendations

There is a marked lack of consistency in the electrical stimulation protocols that implies a lack of understanding of the physiological principles of rehabilitating urinary incontinence through electrical stimulation used in clinical practice to treat women with stress, urge and mixed incontinence. This seems likely to continue until the infinite variation of stimulation parameters available to researchers and clinicians is narrowed by further investigation into the biological rationale underpinning electrical stimulation. Further high quality RCTs, in larger samples and with long term follow up, are urgently needed.

2. IS ELECTRICAL STIMULATION BETTER THAN NO TREATMENT, PLACEBO OR CONTROL TREATMENTS FOR URINARY INCONTINENCE?

• ES Versus No Treatment Or Control Treatment

a) Quality of Data

Effect on Incontinence symptoms (incontinence episodes frequency, volume of urine loss, quality of life)

In this section five papers were reviewed [98, 102, 181, 187, 188]. The first three papers were full publications, the last two were abstracts. These abstracts [187, 188] were other reports of the trial of Berghmans et al. [181]. Random allocation concealment was adequate in two of the trials [98, 181]. Masking of assessors was clearly stated in two of the trials

[98, 181]. One trial stated that outcome assessors were not masked [102]. In two studies the size of the study population was based on a power calculation [98, 181]. In two trials the group sizes ranged from 25 to 49 [98, 102], and the remaining trial allocated less than 25 women to each comparison group. The proportion of dropouts was less than 10% in one trial [102] [78] and in the remainder it varied around 12% [98, 187]. One trial followed women up beyond the post treatment evaluation for six months [102].

b) Results

Women with stress incontinence: A single, small trial has compared ES with no treatment in women with stress incontinence [102]. Eight of the 25 women receiving ES were ‘objectively’ cured or improved (negative pad test or more than 50% reduction in pad test) at three months, versus none of the 25 women in the no treatment group. One trial has compared ES with control intervention (women were offered use of the Continence Guard (Coloplast AS, used infrequently by 14 out of 30 controls) in women with stress incontinence [98]. Bø et al found that ES was better than control intervention for change in leakage episodes over three days, using Social Activity Index and Leakage Index. However, only one of these measures (change in leakage episodes over three days) remained significant ($p=0.047$) with intention to treat analysis. PFM activity was significantly improved in the ES group after treatment, but the change in activity was not significant when compared with controls. Two of 30 controls were cured (≤ 2 g leakage) on pad test with standardized bladder volume on pad test) compared to 7/25 in the ES group. One of 30 women in the control group reported the condition was “unproblematic” after treatment versus 3/25 in the ES group, but 28/30 and 19/25 wanted further treatment respectively.

Women with urgency/frequency, urge incontinence, retention/voiding difficulty:

In a four arm RCT in women with detrusor overactivity, Berghmans et al. investigated the effect of no treatment, lower urinary tract exercises alone (reclassified as PFMT for the purposes of this review), electrical stimulation alone, and electrical stimulation in combination with lower urinary tract exercises. As mentioned before, this RCT has been reported in one full manuscript [181] and two abstracts [187, 188]. The main outcome measures were change in the Detrusor Overactivity Index (DAI) [181], the Incontinence Impact Questionnaire [187] and the adapted Dutch Incontinence Quality of Life questionnaire

[DI-QOL]. Neither the no treatment or combination therapy groups showed any significant change pre to post treatment. There was a significant improvement in the electrical stimulation alone group and a positive (but not significant) trend towards improvement in the PFMT alone group for the DAI [181]. Both the ES alone and the PFMT alone group turned out to have statistically significant lower self-professed impact of incontinence on daily life activities [187]. Using the DI-QOL ES alone improved self-professed incontinence control in daily life activities.

c) Summary

Overall it appeared that electrical stimulation was better than no treatment.

d) Recommendations

There are only single trials of good quality investigating the effect of electrical stimulation versus no treatment (or control treatment) in women with urodynamic stress incontinence or women with detrusor overactivity. Consequently there is insufficient evidence to judge whether electrical stimulation is better than no treatment for women with urodynamic stress incontinence or detrusor overactivity.

• ES versus placebo ES

a) Quality of Data

In four of the 13 trials the placebo stimulation devices provided a limited output that the trialists considered would have no treatment effect [150, 170, 178, 179]. In eight trials the placebo device appeared as though it was working but in fact there was no electrical output [143, 169, 175, 177, 180, 182, 185, 189]. In the last remaining trial placebo stimulation was not described at all [186]. Seven of the 13 trials specifically reported that some attempt was made to remove the participants’ expectations of the physical sensations that might accompany stimulation in an effort to mask participants to their allocation to active or placebo stimulation [143, 175, 177, 179, 180, 182, 189]. In one trial the stimulation was delivered under general anaesthesia [169].

Of the 13 trials contributing to this section random allocation concealment was either unclear if allocation was adequately concealed or the authors simply stated that allocation was “random”. Blinding of assessors was clearly stated in nine trials [169, 177-180, 182, 186, 189]. One trial stated that outcome assessors were not blinded [143] and in the remainder this was not reported.

In four studies the size of the study population was based on a power calculation [170, 177, 179, 180]. Two trials randomised more than 50 women to each comparison group [169, 175]. In three trials the group sizes ranged from 25 to 49 [177, 179, 182], and the remaining 8 trials allocated less than 25 women to each comparison group.

Three trials had no dropouts or losses to follow up [143, 150, 180]. The proportion of dropouts was less than 10% in two trials [178, 189] and in the remainder it varied from 11% [170] to 12% [169, 182] to 21% [185].

Six trials followed women up beyond the post treatment evaluation [143, 150, 169, 178, 182, 189]. The length of follow-up varied from 6 weeks [169] to six months [150, 178]. Yamanishi et al [182, 189] only followed up those participants who had improved with treatment, monthly for several months.

Readers should note that the trial by Yamanishi et al [189] included men and women with urinary incontinence. It is possible that the effects of stimulation might be different between sexes (due to difference in electrode placement for example) so this study has not contributed to the analysis where they do not differentiate the effects of treatment in women versus men.

b) Results

Women with stress incontinence: Five trials compared ES with placebo ES in women with urodynamic stress incontinence [107, 143, 170, 177, 179]. One trial compared ES with placebo ES in men and women with urodynamic stress incontinence [189]. One further trial compared [178] compared ES/PFMT versus placebo ES/PFMT in women with urodynamic stress incontinence and for the purposes of analysis this trial was considered to be a comparison of ES with placebo ES. Hofbauer et al [107] provided minimal detail of participants, methods and stimulation parameters. Laycock and Jerwood [143] used clinic based, short-term (10 treatments) maximal stimulation with an Interferential current applied with external surface electrodes. The treatment regimen of Jeyaseelan [170] consisted of a new stimulation pattern, i.e., background low frequency (to target the slow twitch fibres) and intermediate frequency with an initial doublet (to target the fast twitch fibres) applied with a vaginal probe. Four trials were based on daily home stimulation for four [189], six [178], eight [170] or 12 weeks [177, 179]

The two most comparable trials in terms of stimula-

tion parameters reported contrasting findings. Sand et al [179] found that the ES group has significantly greater changes in the number of leakage episodes in 24 hours, number of pads used, amount of leakage on pad test, and PFM activity (perineometry) than the placebo stimulation group. In addition the ES group had significantly improved subjective measures (e.g. visual analogue measure of severity) than the placebo group. Neither group demonstrated significant change in the quality of life measure (SF 36). In contrast Luber and Wolde-Tsadik [177], did not find any statistically significant differences between ES and placebo ES groups for rates of self reported cure or improvement, objective cure (negative stress test during urodynamics), number of incontinence episodes in 24 hours, or valsalva leak point pressure.

The other trials generally favoured ES over placebo ES. Yamanishi et al [189] reported significant improvement in a range of outcomes in the ES group but not the placebo ES group (i.e. number of leakage episodes, number of pad changes, disturbance in activities of daily living, self report of improvement, pad test). Laycock and Jerwood [143] generally found significantly greater improvements in the ES group (pad test, PFM activity, self reported severity) although the decrease in incontinence episodes was not significantly different between the groups post treatment. Blowman et al [178] found a significant decrease in the number of leakage episodes in the ES group only. Hofbauer et al [107] reported that 3/11 women in the ES group were cured/improved (not defined) versus 0/11 in the placebo ES group.

Jeyaseelan et al [170] did not find statistically significant differences between the two study groups when strength was measured using perineometry, but in contrast when strength was assessed using digital assessment a statistical significant difference was found. When endurance was assessed an improvement in favour of the ES group was found over time in the ES group, but not in the sham ES group. The authors suggested that between-group differences may be not significant as a result of the high degree of variance combined with a small sample size. No changes were reported using a pad test or diaries, but a significant change in favor of the ES group using the UDI-score.

One further trial [175] that compared ES with placebo ES in a group of women with urodynamic stress incontinence, detrusor overactivity or both, conducted a subgroup analysis on the basis of diagnosis and did not find any changes in urodynamic measures for women with USI in either ES or placebo ES groups.

Women with urgency, detrusor overactivity, urge incontinence: Three trials were identified. Due to the considerable difference in stimulation parameters and sample populations it does not seem appropriate to try and combine the findings of these trials in any way.

Abel et al [185] randomized 28 postmenopausal detrusor overactivity incontinent women to either active stimulation (maximal anal or vaginal stimulation for 20 minutes once a week for 12 weeks) or placebo stimulation (no current). The results showed a significant improvement in subjective parameters (VAS) but not in objective measurements (24 hour pad test and incontinence episodes per day).

Bower et al [180] used a single stimulation episode given after the voiding phase of cystometry and before bladder filling was repeated. The results were reported separately for women with detrusor overactivity and those with urgency. For women with detrusor overactivity both stimulation groups (10 Hz, sacral electrodes and 150 Hz, symphysis pubis electrodes) showed significant improvements in urodynamic measures when compared with the placebo stimulation group (i.e. reduction in maximum detrusor pressure, increase in first desire to void, proportion of women with a stable bladder). However there were no significant differences between stimulation and placebo groups for change in maximum cystometric capacity or detrusor pressure at first desire to void. Fewer measures were reported for women with urgency. The only significant findings were a significant increase in first desire to void in the 150 Hz group, and a significant increase in the maximum cystometric capacity in the placebo ES group.

Yamanishi et al [182] investigated maximum intensity stimulation delivered daily for four weeks in men and women with detrusor overactivity. There was significantly more improvement in a number of outcomes in the ES group compared with the placebo ES group post treatment (i.e. nocturia, number of leakage episodes, number of pad changes, quality of life score, urodynamic evidence of improvement in detrusor overactivity, self report of cure or improvement). For a single outcome, self report of cure/improvement, subgroup analysis on the basis of sex was reported. Women in the active ES group were much more likely to report cure/improvement than women in the placebo ES group.

One further trial by Brubaker that compared ES with placebo ES in a group of women with urodynamic stress incontinence, detrusor overactivity or both, conducted a subgroup analysis on the basis of diagnosis and found that women with pretreatment

detrusor overactivity who received active stimulation were significantly less likely to have urodynamic evidence of detrusor overactivity post treatment.

Women with mixed incontinence: In this section only one abstract was available. Amaro et al [186] reported that there was significant improvement in force and perception of the pelvic floor muscles, lower number of micturitions, decreased pad test values and degree of patient's satisfaction in both groups pre- and post treatment, but no between-group differences. Due to the small sample population in this study it does not seem appropriate yet to try to make any conclusion about the efficacy of ES in women with mixed incontinence.

Women with stress, urge or mixed incontinence: ES and placebo stimulation were compared in two trials that included women with symptoms [169] or urodynamic [175] diagnoses of stress, urge or mixed incontinence. Neither trial found any significant differences between the stimulation and placebo stimulation groups post treatment for a range of outcomes including frequency, number of leakage episodes, self report of cure or improvement and quality of life. Brubaker et al [175] did include a subgroup analysis by diagnosis and these findings have been reported previously.

c) Summary

Due to the variation in stimulation protocols it is difficult to interpret the findings of trials comparing electrical stimulation with placebo stimulation. For women with urodynamic stress incontinence the findings of two good quality trials using similar stimulation protocols are contradictory. For women with detrusor overactivity there is a trend in favour of active stimulation over placebo stimulation. For women with mixed incontinence so far no conclusions can be made.

d) Recommendations

With only few trials reporting outcomes of interest and the variation in stimulation protocols, more research of high quality, using adequate sample sizes and protocols, is needed to be sure about the effect of ES versus placebo ES.

3. IS ELECTRICAL STIMULATION BETTER THAN OTHER TREATMENTS?

a) Quality of data

In this sections four trials are reviewed.

The two trials by Yamanishi et al [183] and Soomro et al. [184] included men and women with urinary incontinence. It is possible that the effects of stimulation might be different between sexes (due to dif-

ference in electrode placement for example) so these studies have not contributed to the analysis where they do not differentiate the effects of treatment in women versus men. In the single, small trial of the section on ES versus magnetic stimulation[183] random allocation concealment was adequate. In the remainder it was either unclear if allocation was adequately concealed or the authors simply stated that allocation was at “random”.

Blinding of assessors was reported in none of the studies except in one that stated that outcome assessors were not masked[102]. In none of the trials was a power calculation performed. In one study group sizes were between 25 to 49 [102]and three trials[183, 184] allocated less than 25 women to each comparison group.

Two trials did not report whether or not they had any dropouts or losses to follow up [183, 184]. The proportion of dropouts was less than 10% in the remaining two trials [102, 150].One trial followed women up beyond the post treatment evaluation for six months [102]. There was no post treatment follow-up in the other studies.

b) Results

ES versus magnetic stimulation: Yamanishi compared electrical stimulation using a vaginal electrode, with magnetic stimulation. The magnetic stimulator unit was set on an armchair type seat and had a concave-shaped coil. Stimulation was applied continuously at 10 Hz in both groups. The bladder capacity at the first desire to void and the maximum cystometric capacity increased significantly during stimulation compared with prestimulation levels in both groups. However, the (mean +/- sd) amount the maximum cystometric capacity increased was significantly greater in the magnetic stimulation group (than that in the ES group (114.2 +/- 124.1 ml vs 32.3 +/- 56.6 ml). The authors concluded that, although both treatments were effective, the inhibition of detrusor overactivity appeared to be greater in the magnetic stimulation group than in the ES group. Because of the small numbers in this trial and the fact that both women and men were included and no subgroup results were reported this conclusion seems to be premature.

With only one single small trial comparing electrical stimulation with magnetic stimulation there is insufficient evidence to determine if electrical stimulation is better than magnetic stimulation in women with detrusor overactivity.

ES versus PFMT: (Readers are referred to the section on PFMT. p29 of this chapter) including [149] Spruijt 2003.

ES versus vaginal cones: (Readers are referred to the section on Weighted Vaginal Cones page 39 of this chapter).

ES versus medication: Women with stress incontinence: A single trial [78] compared electrical stimulation (Interferential) with vaginal oestrogens (Premarin). Eight of 25 women in the stimulation group reported they were cured or improved versus 3/24 in the oestrogen therapy group. There was a significant reduction in leakage on pad test in the stimulation group but not the oestrogen group. In contrast the maximum urethral closure pressure was significantly increased in the oestrogen group but not the stimulation group. Long-term follow-up (nine months) found that subjectively one of the eight women in the stimulation group who had reported cure/improvement post treatment had recurrent symptoms, as did all three women in the oestrogen group once oestrogen therapy ceased.

Women with detrusor overactivity: The trial of Smith[150] compared electrical stimulation and medication (propantheline bromide) in women with detrusor overactivity with or without urodynamic stress incontinence. He did not find any statistically significant differences in outcome (self reported improvement and urodynamic parameters) between the two groups.

Another trial of Soomro et al.[184] with a crossover design compared transcutaneous electrical nerve stimulation (TENS) with oxybutynin in both men and women with detrusor overactivity. Functional capacity had increased and number of daily voids had decreased significantly compared with before treatment in both arms. The volume to first desire to void and first unstable contractions had increased significantly with oxybutynin but not with TENS. Total bladder capacity did not change significantly with either treatment but patients noticed side effects more commonly with oxybutynin.

There was no separate presentation of results according to gender, which made it very difficult to draw any conclusions from this study about the effect of TENS in women with detrusor overactivity.

With only few small trials comparing electrical stimulation with medication there is insufficient evidence to determine if electrical stimulation is better than vaginal oestrogens in women with urodynamic stress incontinence, or electrical stimulation is better

than anticholinergic or antimuscarinic therapy in women with detrusor overactivity.

c) Summary

Because of low number of trials, there is insufficient evidence to determine if electrical stimulation is better than magnetic stimulation in women with detrusor overactivity.

There is also insufficient evidence to determine if ES is better than medication for women with urodynamic stress incontinence or detrusor overactivity.

d) Recommendations

Further high quality RCTs, in larger samples and with long term follow up, are urgently required to investigate the added value of the use of ES compared to other treatments, in women with urinary incontinence.

4. DOES THE ADDITION OF OTHER TREATMENTS ADD A BENEFIT TO ELECTRICAL STIMULATION OR DOES THE ADDITION OF ELECTRICAL STIMULATION TO OTHER TREATMENTS ADD ANY BENEFIT?

ES with biofeedback assisted PFMT versus biofeedback assisted PFMT alone versus self-administered PFMT (control group)

a) Quality of Data

In this section only one study was found, investigating ES with biofeedback assisted PFMT versus biofeedback assisted PFMT alone versus a control group (self administrated PFMT)[106]. As both intervention arms in this trial received the same PFMT the trial is essentially investigating the added benefit of ES. Random allocation concealment was adequate, masking of assessors was not reported. Goode et al. used a power calculation and randomized more than 50 patients to each comparison group[106]. The dropout rate was 22.5%. There was no post treatment follow-up.

b) Results

Intention-to-treat analysis showed that incontinence was reduced by a mean of 68.6% with biofeedback assisted PFMT, 71.9% with ES with biofeedback assisted PFMT, and 52.5% with the control condition. In comparison with the control group both interventions were significantly more effective, but they were not significantly different from each other ($p=.60$). The ES with biofeedback assisted PFMT had significantly better patient self-perception of outcome ($p<0.001$) and satisfaction with progress ($p=.02$).

c) Summary

For comparisons of electrical stimulation with biofeedback assisted PFMT versus biofeedback assisted PFMT alone versus a control condition reporting was limited to one single trial. Goode et al.[106] concluded that treatment with additional ES did not increase effectiveness of a comprehensive PFMT program for women with stress incontinence.

d) Recommendations

At present it seems that there is no extra benefit in adding electrical stimulation to biofeedback assisted PFMT but this hypothesis needs to be investigated in further high quality trials.

ES with PFMT versus PFMT alone

a) Quality of data

Of the five trials contributing to this section random allocation concealment was adequate in two [172, 181], and in the remainder it was either unclear if allocation was adequately concealed or the authors simply stated that allocation was at "random". Masking of assessors was clearly stated in one of the five trials [181]. In the remaining four trials blinding of participants or assessors was not reported. Berghmans et al. used a power calculation, the other studies had no report on this. In one trial the group sizes ranged from 25 to 49 [142] and the remaining four trials allocated less than 25 women to each comparison group.

Two trials had no dropouts or losses to follow up [107, 174]. Two trials followed women up beyond the post treatment evaluation [107, 172]. The length of follow-up was six months in both studies.

b) Results

Women with stress incontinence: Four trials compared ES in combination with PFMT versus PFMT alone in women with stress incontinence [107, 142, 172, 174]. As both arms in these trials received the same PFMT the trials are essentially investigating the effect of ES. Tapp's two small trials, using faradic stimulation, were reported only as abstracts and another small trial gave minimal detail of participants, methods and stimulation parameters [107]. In a three arm RCT Knight et al [172] compared PFMT versus PFMT with home based low intensity ES versus PFMT with clinic based maximal intensity stimulation. Ten of 21 women in the PFMT group, 9/25 women in the low intensity stimulation group, and 16/24 in the maximum intensity stimulation group reported cure or great improvement. All three groups

had significant improvements in pad test after treatment, with no significant differences in the percentage reduction between the groups. Similarly all three groups had improvements in vaginal squeeze pressure, but there were no significant differences in improvement.

Overall Knight et al did not find any clear benefits of ES in addition to PFMT. This finding is similar to that of the three small poorly reported trials [107, 142, 174] which found no significant differences between the groups receiving combined ES/PFMT and PFMT alone.

Women with detrusor overactivity: In a four arm RCT in women with detrusor overactivity Berghmans et al [181] investigated the effect of no treatment, PFMT exercises alone (reclassified as PFMT for the purposes of this review), electrical stimulation alone, and electrical stimulation in combination with PFMT. The main outcome measure was change in the Detrusor Overactivity Index (DAI). The combination therapy group did not demonstrate any significant changes pre to post treatment. There was a positive (but not significant) trend towards improvement in the PFMT group for the DAI. These findings do not suggest added benefit from stimulation. It is important to note that Berghmans et al [181] theorise that the combination of stimulation/PFMT used in their trial may be counterproductive because the former is targeted at the supraspinal reflexes while the latter may work on central inhibition.

c) Summary

For comparisons of electrical stimulation with PFMT versus PFMT alone the reporting was very poor in three of the four trials in women with stress incontinence, and only a single trial was found for women with detrusor overactivity. At present it seems that there is no extra benefit in adding electrical stimulation to PFMT.

d) Recommendations

Although it seems that at present there is no extra benefit in adding electrical stimulation to PFMT, also this hypothesis needs to be investigated in further high quality trials.

III. OTHER LUTS

No studies were identified that analysed the effect of ES on lower urinary tract symptoms alone, i.e, frequency of voiding, urgency and/or nocturia.

Although in the study of Berghmans et al. baseline values of frequency of voiding were provided they did not analyse the pre- and post treatment data of this symptom separately, because the variable 'voiding behaviour' (mean number of voids/hr) was included in the combined parameter DAI [181].

IV. FACTORS AFFECTING OUTCOME

1. AGE

Urinary incontinence is a social and disabling problem affecting large numbers of elderly people, mostly women. Urinary incontinence is treated with a variety of surgical and non-surgical treatments. Electrical stimulation is one of the non-surgical treatment modalities that are applied in the elderly [149]. Unlike biofeedback-assisted PFMT, which requires active participation of the patients to be successful, electrical stimulation is a passive exercise of the pelvic floor musculature. It is used in patients with stress incontinence aiming to improve the urethral closing pressure during the increase of intraabdominal pressure [190] and in case of detrusor overactivity to inhibit involuntary bladder contractions [181]. ES does not have any serious side-effects (apart from interfering with pacemaker activity) but can give an unpleasant vaginal, anal and perineal sensation [149]. This kind of discomfort together with patient's doubt about effect of therapy in general can easily lead to a lesser degree of cooperativeness, informed consent and motivation, especially in the elderly.

a) Quality of the included studies:

There is one prospective, uncontrolled study including frail elderly incontinent women i.e., cognitively impaired long term care women residents with urinary incontinence[191]. This study will be discussed in the section dealing with frail elderly people with urinary incontinence. Readers are referred to Chapter 18, volume 2.

All other published studies of electrical stimulation have included only independent, community dwelling elderly.

In a randomized clinical trial [149] compared in a eight-week study program the effectiveness of vaginal electrical stimulation of the pelvic floor in elderly women (> 65 years) with symptoms of stress, urge, or mixed incontinence with a daily pelvic floor muscle training (PFMT).

Objective outcome parameters were urinary leakage (during a standardized pad test), pelvic floor muscle strength (measured by a perineometer) and detrusor instability (on ambulant urodynamic registration). Subjective parameters were women's subjective assessment of change in urinary symptoms based on the PRAFAB score. The PRAFAB-score which combines the most important objective and subjective elements of the degree of urinary incontinence, i.e., **p**rotection (use of pads), **a**mount of urine loss, **f**requency of the complaint, **a**djustment in behavior due to the complaint and **b**ody image as result of the urine loss are the five elements of the PRAFAB-score[192]. Pelvic floor ES was accomplished by means of a home device and a vaginal probe. The stimulator generated biphasic current pulse with a duration of 1 ms and a frequency of 50 Hz in case of (predominant) stress urinary incontinence or 20 Hz in the case of (predominant) urge urinary incontinence. The other parameters were 2 seconds contraction time, and a duty cycle of 1:2 with stimulation gradually increased to the level of tolerable discomfort. Maximal ES was applied for 30 min three times a week for 8 weeks.

One study of patients with overactive bladder symptoms reported subanalyses of those older and younger than 60 [119]. In a double-blind randomized trial, Yamanishi et al studied electrical stimulation compared to a sham device in 68 patients with urge UI due to detrusor overactivity [189]. Patient recruitment was not well explained. Three women (of 39) had mild stress incontinence. Outcomes included frequency, incontinence episodes and pad changes as assessed by voiding records; subjective urgency; and urodynamic parameters. ES was delivered by surface, anal, or vaginal electrodes 15 minutes twice daily for 4 weeks, using 10 Hz and a maximum output current of 60 milliamps.

Other identified studies with a mean age above 60 years were not randomized clinical trials [193-195] or failed to report whether age influenced outcomes[189].

b) Results

Spruijt et al [149] did not find any significant difference in either objective leakage outcome variables (vaginal electrical stimulation 29.2% versus 36.4% PFMT) nor subjective improvement in leakage (vaginal electrical stimulation 29.2% versus 27.3% PFMT). However, in this study the sample size was small (n=37). Power analysis showed that at least 75 patients were necessary to detect statistical difference between the study groups. So, this study obviously lacks power and the author's conclusions about

negative outcome of ES are debatable.

In the study of Yamanishi et al mean age was 70 years +/- 11. Improvement was compared in those older and younger than age 60. This study found equivalent improvement in older and younger subjects. Also, an uncontrolled study seemed to support this result[196]. Furthermore, a prospective cohort study was conducted on 3198 women treated with home-managed electrical stimulation in Norway during 1992-1994. Analyses showed that according to patients' answers there were no differences between age groups as to improvement after treatment, but according to physicians there were better success rates for younger patients [197].

c) Summary

Older persons may respond to electrical stimulation of the pelvic floor as well as younger (Level of Evidence 4). However, the extent of the effect of ES in the elderly persons in comparison with other treatment modalities has yet to be established. Its non-invasive character and its very limited side effects may make ES an attractive option in the treatment of elderly people, but prognostic or predictive factors for success or failure and adequate patient selection who will benefit and who will not are still lacking.

d) Recommendations

- Cognitively intact older persons respond well to electrical stimulation of the pelvic floor (Grade of Recommendation C).
- Electrical stimulation of the pelvic floor may have equal benefit in older and younger persons.
- However, the evidence for this may reflect publication bias, because most studies do not report the effect of age (Grade of Recommendation C)
- All aspects of electrical stimulation of the pelvic floor in the elderly need further study using adequate methodology and sample sizes.

2. OTHER

Several factors affecting outcome of treatment have been described:

- a) Diagnosis and underlying cause of urinary incontinence,
- b) Patient selection,
- c) ES delivery systems, study design, protocol and procedures,
- d) Outcome parameters,
- e) Patient compliance and cooperation and
- f) Side effects

a) Diagnosis

The question is for whom ES should be chosen? In patients with SUI, if the patient cannot contract the pelvic floor muscles, ES maybe can provide further help. However, most studies focusing on the efficacy of ES do not address the question in this way[198]. In patients with detrusor overactivity ES is focused on inhibition of involuntary detrusor contractions and seemed to be an effective therapy[181].

Patients with detrusor overactivity or symptoms of urgency, frequency and or urge incontinence may respond differently to ES than patients with SUI. For SUI the underlying cause or type (weak pelvic floor muscles, hypermobility of the urethra, intrinsic sphincter deficiency) may have a different influence on the outcome of treatment[199], although it is unclear how ES works in these different types of SUI.

b) Patient selection

ES is reported to be unsuccessful in patients with major descent of the vagina and prolapse of the uterus[177]. Also patients with denervated pelvic floor muscles might not respond to ES[200]. It is unfortunate that little objective testing is available to assess for the application of ES necessary integrity of the sacral arc to provide detrusor inhibition. This means that in patients with less or no integrity of the relevant nerve pathways ES provides no or little change of cure/improvement [201]. It has been reported that ES will fail also in patients without response of ES on urethral pressure profile (UPP) [202]. Age, presence of estrogen, lack of urethral hypermobility are reported to be relevant to therapeutic outcome[202].

c) ES delivery systems, study design, protocol and procedures

The optimal non-implanted ES delivery system, keeping in mind presumed electrical parameters, and patients' preferences, has not yet been established [201]. In electrical stimulation studies many combinations of current types, amplitudes, types of waveforms, frequencies, intensities, electrode placements etc. are reported [88]. The lack of a clear biological rationale seems to hamper reasoned choices of electrical stimulation parameters and even for the same health problem a wide variety of stimulation devices and protocols have been used.

d) Outcome parameters

There are patients with frequency volume charts and urodynamic evidence of 'cure' who request additional treatment while others with unchanged findings are greatly satisfied with their ES treatment. This contradiction may result from measurement of the wrong variable [201].

There is a heterogeneity in outcome measures in this area like different frequency volume charts or micturition diaries, self report of cure/improvement, measurement of leakage (pad test, frequency volume charts), questionnaires of quality of life and urodynamic variables. Depending on the outcome parameters in a particular study, objective and subjective results of ES therapy can be different.

c) Patient compliance and cooperation

As with all conservative therapy modalities one of the key factors to success or failure of ES is adherence to and compliance with the chosen protocol. Full cooperation of the patient is necessary.

d) Side effect

Side effects can have impact on the outcome of ES. In a large Norwegian study Indrekvam and Hunskaaer [197] studied the side effects of ES. They reported that pain (20%), soreness/local irritation (26%) and psychological distress (7%) were the most occurring side effects. Users of maximal stimulators experienced more pain than users of long-term stimulators (25% versus 15 %). A range of various, not serious, degrees of side effects was reported.

Summary: Further research is needed to investigate to what extent all the factors mentioned above affect the outcome of ES plus query incorporate the rest of the comments in the first paragraph. Under b) other - Unfortunately, it is very difficult to interpret this kind of research and -consequently- these results, because of a lack of description and report if, how, and to what extent these factors really affect outcome of treatment.

Recommendations: Research should first focus on identification and proper description of factors affecting outcome of ES. After this, the focus should be on how and to what extent these factors affect outcome of ES-treatment and whether or not these factors can be influenced by ES.

B5. PHYSICAL THERAPIES – MAGNETIC STIMULATION

Magnetic stimulation has been developed for stimulating both central and peripheral nervous systems noninvasively [203]. Magnetic stimulation has been applied to pelvic floor therapy and the treatment of urinary incontinence for the first time in 1999 by Galloway et al [204]. Contrary to electrical stimulation, extracorporeal magnetic innervation (ExMI) aims to stimulate the pelvic floor muscles and sacral roots without insertion of an anal or vaginal probe [205, 206]. For treatment, the patient is positioned in a chair. Within the chair's seat is a magnetic field generator (therapy head) that is powered and controlled by an external power unit (**fig. 6 a-b**). Conventional stimulators deliver, at frequencies of 10 to 50 Hz, repetitive pulses of current between less than 100 Fs [205] and 275 Fs [204] in duration. Size and strength of the magnetic field is determined by adjusting this amplitude by the therapist [204]. A concentrated steep gradient magnetic field is directed vertically through the seat of the chair. When seated, the patient's perineum is centred in the middle of the seat, which places the pelvic floor muscles and sphincters directly on the primary axis of the pulsing magnetic field. Because of this all tissues of the perineum can be penetrated by the magnetic field (fig.2). Galloway indicated that no electricity, but only magnetic flux enters the patient's body from the device. Goldberg indicated that, in contrast to electrical current, the conduction of magnetic energy is unaffected by tissue impedance, creating a major advantage in its clinical application compared to electrical stimulation. In that way structures, such as sacral roots or pudendal nerves, can therefore be magnetically stimulated without patient's discomfort or inconvenience of probe insertion for electrical stimulation.

Therefore advantages of ExMI are that it is performed through full clothing, entailing no probes, skin preparation, or physical or electrical contact with the skin surface. On the other hand, the need for repeated office-based treatment sessions represents an inherent disadvantage. In contrast to electrical stimulation units, this kind of technology lacks portability, and, because both the depth and width of magnetic field penetration is proportional to coil diameter, the present technology according to Goldberg is best suited for stimulation of a field, rather than a narrowly focused target as the sacral roots or the pudendal nerve.



Figure 6 a-b. Magnetic chair showing magnetic field generator and external power unit (courtesy of Prof Kate Moore and Dr Alastair Morris, Sydney)

Only recently, a small electromagnetic device (Pulsgen) was developed for homebound use and tested in women with urinary incontinence to determine its efficacy and safety [207].

Magnetic stimulation of the sacral nerve roots and pelvic floor is suggested to be effective for both urge and stress urinary incontinence [205] although the mechanism of action on the continence mechanism is not fully understood. Some authors suggested that in stress urinary incontinence it stimulates pelvic floor musculature causing external sphincter contraction [208], acting as a passive Kegel exercise [209]. In urge urinary incontinence magnetic stimulation might suppress detrusor overactivity through at least two autonomic effects: activation of pudendal nerve afferents blocking parasympathetic detrusor motor fibres at the spinal reflex arc, activation of inhibitory

hypogastric sympathetic neurons, or a combination of both mechanisms [210]. Stimulation of sympathetic fibres maintaining smooth muscle tone within the intrinsic urethral sphincter and modulation of pudendal nerve afferent branches stimulating an inhibitory spinal reflex at the S3 nerve root, are also suggested to play a role in this mechanism of action [210].

This section will examine the evidence for the use of magnetic stimulation for the prevention and treatment of urinary incontinence in adult women. Questions addressed are:

- Can magnetic stimulation prevent urinary incontinence?
- Is magnetic stimulation better than no treatment, placebo or control treatments for urinary incontinence?
- Is one type of magnetic stimulation better than another?
- Is magnetic stimulation better than other treatments?
- What factors might affect the outcome of magnetic stimulation?

A literature search for reports of relevant systematic reviews and reports of randomised controlled trials (RCTs) and quasi-randomised (qRCTs), e.g. alternate assignment (see appendix x) was performed. Only Level 1 evidence is considered in this section. Recommendations are based on the findings of existing systematic reviews, or systematic review of RCTs undertaken by the author of this section (BB).

Pre-specified outcomes of interest were urinary continence (for prevention studies), self reported cure and cure/improvement in incontinence symptoms (treatment studies), leakage episodes (treatment studies), and quality of life (prevention and treatment studies). For a more detailed explanation regarding choice of outcome measures, readers are referred to the section on PFMT.

I. PREVENTION

In this subsection the question ‘Is magnetic stimulation effective for the primary/secondary prevention of urinary incontinence in adult women?’ is addressed. The literature search revealed no systematic reviews or qRCTs addressing prevention of urinary incontinence.

No trials investigating the primary/secondary prevention effects of magnetic stimulation for adult women with urinary incontinence were found.

II. TREATMENT

The aim of this subsection is to address the following questions:

- Is magnetic stimulation better than no treatment, placebo or control treatment for urinary incontinence?
- Is one type of magnetic stimulation better than another?
- Is magnetic stimulation better than other treatments?
- What factors might affect the outcome of magnetic stimulation?

The literature search revealed two reviews, one in the English and one in the German language, that only addressed the indications for and the use of magnetic stimulation and provided an historical overview of the therapeutic application possibilities of this treatment modality for urinary incontinence [163]. These reviews were used to provide some background information of magnetic stimulation, as described in the first paragraphs of this section. Furthermore, in this section seven papers were reviewed [183, 207, 211-214]. The first four papers were full publications, the last three were abstracts. Two of these abstracts [212, 214] were earlier reports of trials later published as full manuscripts [207, 211].

Readers should note that the trial by Yamanishi et al included men and women with urinary incontinence. It is possible that the effects of magnetic stimulation might be different between sexes (due to differences in the underlying causes of detrusor overactivity) so this study has not contributed to the analysis where they do not differentiate the effects of treatment in women versus men.

1. MAGNETIC STIMULATION VERSUS NO TREATMENT, PLACEBO OR CONTROL TREATMENTS

The trials: Four RCTs comparing magnetic stimulation with placebo treatments for women with urinary

incontinence were found [207, 211, 213, 215]. The trial by But [207] compared magnetic stimulation using a home device (Pulsegen) with sham magnetic stimulation using the same –but now inactive– device in women with urinary incontinence, i.e., a mixture of women with stress, urge and mixed incontinence. Fusjhiro and colleagues recruited in one RCT women with stress urinary incontinence and in another women with urinary frequency and urge incontinence, and compared magnetic stimulation with sham stimulation [211]. Gilling et al. recruited women with stress urinary incontinence, and compared active magnetic stimulation of the pelvic floor to sham treatment, using the Neocontrol system [213]. All patients also underwent low-intensity home-based pelvic floor muscle training supervised by a urotherapist.

The interventions: Women in the trial by But and colleagues used in both groups a Pulsegen device, producing a pulsating magnetic field of $B=10$ FT intensity and a frequency of 10 Hz. In the active group the women were asked to wear the Pulsegen device as a *home* device day and night for 2 months. Fusjhiro et al. applied in both trials in the active group 15 Hz repetitive magnetic stimulation of the sacral roots with 50% intensity output for 5 seconds per minute for 30 minutes. Magnetic stimulation was performed with patient prone using a rapid rate stimulator with a Rapid circular coil. The coil was fixed over the sacrum to cover the bilateral third sacral foramina. The sham group received exactly the same manner of treatment except for the use of the sham stimulating coil, which did not induce any electromagnetic field. In the trials investigating magnetic stimulation in women with stress urinary incontinence and in women with urinary frequency and urge incontinence only 1 session was performed in each patient. Gilling et al. used a chair with an inbuilt magnetic coil (Neocontrol system) for 20 minutes in women fully-clothed on the chair. A total of 16 treatments were performed over 6 weeks (3 per week).

a) Quality of data

Random allocation concealment was adequate in one of the trials [207], in the trials of Fujishiro [211, 215] and Gilling [213] random assignment was not specified.

Masking of patients was clearly stated in three of the trials [207, 211, 215], and masking of outcome assessors was also noted in the trial of But.

In none of the studies the size of the study population was based on a power calculation. In two trials the group sizes ranged between 25 to 49 [211, 213], in

the But trial, group sizes were 30 in the active and 22 in the sham group, and the remaining trial allocated less than 25 women to each comparison group.

The proportion of dropouts was less than 10% in one trial [207] and in the remainder this was not reported adequately. No trials followed women up beyond the post treatment evaluation. Only in the abstract of Gilling et al. was it indicated that follow-up with quality of life questionnaire and pad testing after 6 and 12 months post treatment were performed.

b) Results

Data from the four trials were not pooled, because the sample populations were considered to be different, mainly according to indication.

2. STUDIES WITH MIXTURE OF STRESS, URGE AND MIXED INCONTINENCE

But et al. [207] included 52 women of which 21 were diagnosed with mixed (40.4%), 22 with urge (42.3%) and 9 with stress urinary incontinence (17.3%). However, between both research groups they did not make any difference in indication or subgroup analysis related to outcome of magnetic stimulation. In the study of But et al. comparing magnetic stimulation with placebo, the number of pads used was significantly lower ($p=0.0017$), as was the pad weight ($p=0.038$). Power and duration of contractions of the pelvic floor muscles was significantly improved in the active group compared to the placebo. A 56.3% improvement of urinary incontinence symptoms in the active compared to 26.3% in the sham group was seen ($p=0.00012$). The authors concluded that this kind of new home device represents an efficient and safe treatment modality for women with urinary incontinence.

3. STUDIES WITH STRESS URINARY INCONTINENCE

In Fujishiro's study 62 women with stress incontinence were included [211]. All women had 1 session of magnetic stimulation. The number of leaks and the amount of urine loss on a pad test significantly decreased more in the active than in the sham group ($p=0.0023$ and 0.0377 , respectively). Quality of life improved significantly in the active group ($p=0.0006$) in contrast to the sham group. The improvement rate in the active group was 74% vs 32% in the sham group ($p=0.0009$). There were no adverse events. It was concluded that magnetic stimulation of the sacral roots might be useful but that further studies are needed.

Gilling et al. studied 70 women with stress urinary incontinence with a mean (range) age of 55 (27-81) years [213]. The two groups were well matched at baseline. There was no significant difference between the active and sham groups at 8 weeks for any parameter and there was no significant difference between the two groups for any parameter when the change between baseline and 8 weeks was compared (repeated measures ANOVA). However, in a subgroup with poor pelvic floor tone at baseline, Gilling et al did find a significant difference between groups in the number of grams of urinary leakage on the 24 hr pad test and mean abdominal leak point pressure, measured pre and post treatment after 6 weeks. The authors reported that follow-up was ongoing, but provided no data on this.

4. STUDIES WITH URGE URINARY INCONTINENCE

In the study of Fujishiro et al. [215] in women with urinary frequency and urge incontinence all women underwent 1 session with magnetic stimulation.

Intergroup comparison showed that mean urine volume per void, mean number of leaks and mean quality of life score improved more significantly in the active than in the sham stimulation group (23.5 +/- 25.6 ml. vs 6.2 +/- 22.5, $p=0.04$, 3.6 +/- 4.1 vs 0.4 +/- 1.4, $p=0.04$ and 1.4 +/- 1.3 vs 0.4 +/- 0.8, $p=0.01$, respectively). No adverse effects were noted in any patients. It was also concluded that magnetic stimulation of the sacral roots might be useful for treating this kind of health problem, but that further studies are needed.

a) Summary

Only sparse evidence of the effect of magnetic stimulation vs no treatment, placebo or control treatment in women with urinary incontinence is available. There was considerable variation in the regimen, protocols, intensity and duration of treatment. Sample sizes were small, outcomes were contradictory. Only short term results were available. At the moment there is not enough evidence for the efficacy of magnetic stimulation in women with urinary incontinence. Women did not report adverse events using this treatment.

b) Recommendations

Magnetic stimulation might be effective in the treatment of women with urinary incontinence (Grade C). There are no reported adverse events using this treatment modality. Further high quality studies with adequate sample sizes are needed. Homogeneity of study populations is warranted.

5. ONE APPROACH TO MAGNETIC STIMULATION VERSUS ANOTHER

No studies were found addressing this question.

No trials comparing approaches to magnetic stimulation were found. Research is needed if this is a comparison of interest for women and clinicians.

6. MAGNETIC STIMULATION VERSUS OTHER TREATMENTS

Only one study was found that compared magnetic stimulation vs other treatment, i.e., magnetic stimulation with electrical stimulation of women with detrusor overactivity[182]. This comparison is described and evaluated in the section of electrical stimulation in women (see p49 in this Chapter).

III. OTHER LUTS

IV. FACTORS AFFECTING OUTCOME

None of the trials specifically recruited older women. None of the trials, included in this subsection on magnetic stimulation, reported factors affecting outcome.

However, in a study of Sand et al. [216] risk factors predicting success of magnetic stimulation were evaluated. A successful response to therapy was statistically associated with the absence of four risk factors: prior hysterectomy, prior anti-incontinence operations, incontinence of greater than 10 years' duration and the use of medications known to cause incontinence.

Other factors that might influence success or failure of magnetic stimulation are body habitus (thin patients have more significant detrusor responses, presumably due to a shorter distance between the stimulating coil and the sacral nerve roots), and bladder volume (in 11 spinal-injured patients the detrusor response to magnetic stimulation dampened with increasing bladder volumes) [217]. Finally, the most effective treatment parameters and protocols are not yet determined [205].

None of the included trials addressed the effect of age, or any other factor, on outcome of magnetic stimulation. A few authors indicate the relevance of some factors but the causal relationship between these factors and the outcome of magnetic stimulation has yet to be determined

B6. SCHEDULED VOIDING REGIMENS

This section examines the evidence on use of scheduled voiding regimens in cognitively intact, non-institutionalised women with urge, stress, and mixed incontinence and provides recommendations for their use in clinical practice. A summary of the search strategy and inclusion/exclusion criteria for selecting studies for review is provided in the Appendix. See the chapter on the Frail Elderly for a detailed discussion of scheduled voiding regimens that are used in the management of urinary incontinence in cognitively impaired, institutionalised, or homebound older adults, and the section on Neurogenic Patients for those voiding regimens appropriate for individuals with incontinence secondary to central nervous system or spinal cord disease.

Scheduled Voiding Regimens: Bladder training is a term that has been broadly and sometimes inaccurately applied to any type of a scheduled toileting intervention. This has created conceptual confusion in interpreting research reports where few details are provided other than the statement that bladder training was used. The types of scheduled voiding regimens can be categorized as: bladder training, timed voiding, habit training, and prompted voiding [218]. Although these regimens share a common feature of a toileting schedule, they differ on the basis of adjustments to the voiding schedule; the active or passive involvement of the patient; the nature of patient education including the teaching of strategies to control urgency and prevent stress leakage, the use of reinforcement techniques, and the nature of the interactions between clinicians and patients. In practice, however, scheduled voiding regimens may share aspects of one or more of these features.

Bladder training (also referred to as bladder drill, bladder discipline, bladder re-education, and bladder retraining) involves a program of patient education along with a scheduled voiding regimen with gradually progressive voiding intervals. Specific goals of bladder training are to correct faulty habit patterns of frequent urination (if present), improve control over bladder urgency, prolong voiding intervals, increase bladder capacity, reduce incontinent episodes, and restore patient confidence in controlling bladder function. The underlying mechanism of how bladder training achieves its effect is poorly understood. Several hypotheses have been proposed including improved cortical inhibition over detrusor

contractions; improved cortical facilitation over urethral closure during bladder filling; improved central modulation of afferent sensory impulses; altered behavior resulting from better individual awareness of the lower urinary tract function and circumstances that cause incontinence, and increasing the “reserve capacity” of the lower urinary tract system [151, 219, 220].

Timed voiding is a fixed voiding schedule that remains unchanged over the course of treatment [218]. The goal of timed voiding is to prevent incontinence by providing regular opportunities for bladder emptying prior to exceeding bladder capacity. Timed voiding has been recommended for patients who cannot participate in independent toileting [221]. It has been primarily used in institutional settings as a passive toileting assistance program where a caregiver takes the patient to void every 2-4 hours including at night, and for patients with neurogenic bladders associated with spinal cord injuries (see chapter related to management of incontinence associated with neuropathic conditions) [222]. However, it has applicability for use in outpatient settings with incontinent women who have infrequent or irregular voiding patterns [223] (and men who are independent in their voiding function [224]).

Habit training is a toileting schedule that is matched to the patient’s voiding pattern. Using the patient’s voiding chart, a toileting schedule is assigned to fit a time interval that is shorter than the patient’s normal voiding pattern and to precede the time period when incontinent episodes are expected. Thus, the voiding interval may be lengthened or shortened throughout the day depending on the patient’s voiding pattern with the goal to pre-empt incontinence. Patients may also be encouraged to suppress the urge to void until the assigned time. Habit training has primarily been used in institutional settings with cognitively and physically impaired adults; more recently, it has been tested with the homebound elderly population [225]. It also has applicability for use in unimpaired adults who have a consistent pattern of incontinence [223].

Prompted voiding refers to a caregiver education program in combination with a scheduled voiding regimen, typically every two hours. It is used to teach people with or without cognitive impairment to initiate their own toileting through requests for help and positive reinforcement from caregivers when they do so [226]. Although it has been used primarily in institutionalized settings with cognitively and physically impaired older adults, prompted voiding has applicability for use with homebound elders.

(See the section on conservative management of the frail elderly chapter 18, volume 2 for a full review).

This section will examine the evidence for the use of timed voiding, habit retraining and bladder training for the prevention and treatment of urinary incontinence in non-institutionalised women of all ages without cognitive or mobility impairments. Because of scant evidence with the use of timed voiding and none on habit retraining in this population, the majority of this review will focus on bladder training.

Questions addressed are:

- Can scheduled voiding regimes prevent urinary incontinence?
- What is the most appropriate bladder training protocol?
- Is bladder training better than no treatment, placebo or control treatments for urinary incontinence?
- Is bladder training better than other treatments?
- Does the addition of other treatments add a benefit to bladder training or does the addition of bladder training to other treatments add any benefit?
- What is the effect of bladder training on other LUTS?
- What factors might affect the outcome of bladder training?

I. PREVENTION

a) Quality of data

No trials were located that examined scheduled voiding regimens as a sole intervention in the prevention of urinary incontinence.

b) Results

No trials were identified.

c) Summary

There is no evidence (Level 4) on the effect of scheduled voiding regimens as sole interventions in the prevention of urinary incontinence.

d) Recommendations

Grade of Recommendation: D

There is no evidence available documenting the effect of scheduled voiding regimens in the prevention of urinary incontinence (Level 4).

II. TREATMENT

1. TIMED VOIDING

Although a Cochrane review on timed voiding is planned [222, 227], the last literature review was published in 1986 [218]. There are anecdotal reports that timed voiding involving a 2 or 3 hour schedule may be beneficial for patients in clinical practice.

a) Quality of Data

Two reports were located that presented findings related to timed voiding in women with urinary incontinence associated with detrusor overactivity, mixed urinary incontinence, and stable bladders with urge incontinence [228, 229]. The voiding schedule consisted of either a 2 hour [228] or 3 hour [229] voiding interval. One case series report involved 20 women ages 24 to 94 years [228] and the other report involved a consecutive series of 20 women ages 27 to 75 years in a double-blinded crossover study comparing anticholinergic drug therapy (terodiline) with timed voiding to placebo with timed voiding [229]. Women in both groups were given the instruction to perform triple voiding, suppress urgency (no details on how they were instructed to do this), and to void more frequently if voided volume exceeded 200-400 ml.

The outcome measures used were subjective categorization of incontinence status (dry, improved, or unchanged) [228, 229]; voiding charts and urodynamics [229]. Follow-up periods ranged from 6 weeks to 8 months after treatment (Godec), and after each 3 week period (run-in, placebo, and drug) and at 3 months (Klarskov).

b) Results

Two hour timed voiding in women with a mild degree of urinary leakage, irregular voiding patterns, and normal urodynamic parameters (incontinence type not clearly reported), resulted in a 79% success rate (not objectively quantified): 15 patients became totally dry, 1 patient had less leakage, 3 patients with neurogenic diseases remained unchanged, and 1 patient was lost to follow-up. In the protocol involving 3 hour timed voiding with placebo or terodiline in women with stable detrusor function and urge incontinence, the drug group did significantly better than the placebo group. In the first period, 50% more patients in the drug therapy and timed voiding group had greater subjective and objective improvement than the placebo and timed voiding group; frequency

and incontinent episodes measured by a voiding chart decreased significantly, in contrast to patients in the placebo group who had a nonsignificant deterioration [229].

c) Summary

There are no high quality trials providing evidence on the effect of timed voiding on urinary incontinence in women. Based upon the data from one small uncontrolled study, there is some suggestion that a 2 hour timed voiding schedule may be beneficial in treating women with mild urinary incontinence, infrequent voiding patterns, and stable bladder function. A 3 hour voiding interval appears to be too long to be beneficial. RCTs are needed that include standardized outcome assessment. (Level of evidence: 3)

d) Recommendations

Timed voiding with a 2 hour voiding interval may be beneficial as a sole intervention for women with mild incontinence and infrequent voiding patterns. It may also be helpful as an adjunct to other treatment. Further research is required. (Grade C)

2. HABIT TRAINING

A Cochrane review on habit training has recently been published [227]. Prior to this, the last literature review was published in 1986 [218]. There are anecdotal reports that habit training may be beneficial for noninstitutionalized women with a consistent pattern of incontinence [223].

a) Quality of included studies

No studies were located that investigated habit training in non-institutionalised women.

b) Results

No studies were identified.

c) Summary

There are anecdotal reports that habit training may be beneficial for women who have a consistent pattern of urinary incontinence such as diuretic induced incontinence. However, there is insufficient evidence to come to any conclusion regarding the role of habit training in women. Research is needed on habit training in women with a consistent pattern of urinary incontinence who are cognitive intact.

d) Recommendations

There is no evidence regarding the benefit of habit training in women. It may be useful as sole or adjunct to other treatments when there is a consistent

pattern of urinary incontinence. Research is recommended. (Grade D)

3. BLADDER TRAINING

Four systematic reviews on bladder training were located that provided qualitative synthesis with evidence grading ([91, 221, 230, 231]; . The Cochrane Collaboration recently published an updated review that included a quantitative analysis of trial data [230].

Since the *Second International Consultation on Incontinence*, there have been four reports [36, 99, 232, 233] and one research abstract [234] published on bladder training. A restructuring of the categories of trials led to changes in this review as compared to the previous review [88]. This review also varies from the recent Cochrane review because of differences in inclusion criteria and trial categorization.

• WHAT IS THE MOST APPROPRIATE BLADDER TRAINING PROTOCOL?

a) Quality of Data

No trials that were located that compared two or more approaches to bladder training. In the absence of trials comparing two or more approaches, a content analysis of bladder training protocols in other RCTs investigating the effects of bladder training was performed.

b) Results

Fourteen trials on bladder training involving a total of 1,567 women were located. Six of the 14 RCTs provided no or minimal details regarding the bladder training protocol used [99, 234-238]. In trials that did provide some description, bladder training protocols were implemented in several ways.

All protocols involved some type of patient education:

- Brief verbal instruction[235, 236]
- Brief written instructions[232]
- Verbal, written, and audiovisual instruction[151, 220]
- If specified, the education was provided by nurses [99, 151, 220, 233] [234]; or general practitioners[109]
- Participants were introduced to an individual who successfully completed bladder training [237]

Scheduling regimen variations included:

- Assignment of the initial voiding interval varied from 30 minutes to 2 hours, with 1 hour being the

most common interval based upon the participant's voiding pattern or 30 minutes beyond the participant's average voiding interval [239]

- Adjustments to the voiding interval varied from 15 to 30 minutes, with 30 minutes the most common interval. Increases were made daily for inpatient regimens [238], after 48 hours of dryness [240], to every 4-5 days [239] to weekly if schedule was well-tolerated [151, 220]

- Goals for optimal voiding interval varied from 3-4 hours

Voiding regimen varied from use of a mandatory regimen with restriction of voiding in between assigned toileting times even if incontinence occurred [238] to a scheduled voiding regimen that allowed interruptions in the schedule if urgency became unbearable [151, 220, 233] to self-scheduling of voiding with a target goal to reach [232].

- Voidings were not scheduled (allowed) during sleeping hours [238]; all other protocols did not identify how voidings were handled during sleeping hours.

Several protocols included use of adjunctive treatments:

- Fluid and caffeine adjustments [36, 233]
- Fluids allowed up to a certain level (1,500 ml [240])
- No fluid modifications [109, 151, 220, 232]
- Advice on constipation prevention [233]

Specific strategies taught to control urgency and/or stress leakage included:

- Distraction and relaxation [151, 220, 232, 233]
- Pelvic floor muscle contraction [151, 234] Encouraged participants to suppress urgency but did not identify suggested strategies [36, 109, 236]

Several protocols described use of reinforcement techniques through:

- Self-monitoring [151, 220, 233, 235, 237]
- Positive reinforcement [151, 220, 239]

Outpatient bladder training programs involved: Weekly follow-up visits [99, 220], biweekly [239], weekly for 6 weeks with biweekly telephone calls for 6 additional weeks [151], or monthly follow-up visits [240].

Early inpatient bladder training programs involved:

- 5-13 days of hospitalisation to ensure strict protocol adherence [238]

c) Summary

There is no evidence indicating what is the most effective bladder training protocol to use. The literature suggests several variables that could be investigated in future trials including the instructional approach, supervisory intensity, adjunctive treatments, scheduling parameters, and length of treatment.

d) Recommendations

Clinicians should provide the most intensive bladder training supervision that is possible within service constraints. It is not clear what the most effective bladder training parameters are, and whether they might vary based upon patient characteristics. Clinicians and researchers should refer to the operant conditioning and educational literature to provide a rationale for their choice of training parameters or approach. More research is needed to investigate which bladder training parameters, supervisory intensity, and adjunctive treatments are most effective. Future trials should include outcomes that matter to patients including the length and frequency of supervisory contact. (Grade C)

There is a lack of consistency in bladder training protocols. On the basis of extrapolation from the bladder training literature, an outpatient training protocol should include an initial voiding interval typically beginning at 1 hour during waking hours, which is increased by 15-30 minutes per week depending on tolerance of the schedule (i.e., fewer incontinent episodes than the previous week, minimal interruptions to the schedule, and the woman's feeling of control over urgency), until a 2-3 hour voiding interval is achieved. A shorter initial voiding interval, i.e., 30 minutes or less, may be necessary for women whose baseline micturition patterns reveal an average daytime voiding interval of less than 1 hour. Education should be provided about normal bladder control and methods to control urgency such as distraction and relaxation techniques and pelvic floor muscle contraction. Self-monitoring of voiding behaviour using diaries or logs should be included in order to determine adherence to the schedule, evaluate progress, and determine whether the voiding interval should be changed (Figure 7, a and b: Bladder training self-monitoring log). Clinicians should monitor progress, determine adjustments to the voiding interval, and provide positive reinforcement to women undergoing bladder training at least weekly during the training period. If there is no impro-

vement after 3 weeks of bladder training, the patient should be re-evaluated and other treatment options considered. Inpatient bladder training programs may follow a more rigid scheduling regimen with progression of the voiding interval on a daily basis. Grade C.

Monday

Continence Program For Women
Treatment Log

Chart No. _____ Date ____/____/____

MIDNIGHT TO NOON

NOON TO MIDNIGHT

WEEKLY VOIDING INTERVAL 1 1/2 hours

Treatment Number <u>2</u>	No. of Scheduled Voidings Interrupted <u>2</u>
No. of Scheduled Voidings <u>12</u>	Nocturnal Frequency <u>1</u>
No. of Scheduled Voidings Missed <u>1</u>	Incontinent Episodes <u>2</u>
	Day Missed (Y/N) <u>N</u>

A

Instructions Use this side to indicate all unscheduled voidings including interruptions in schedule, nighttime voidings, and incontinent episodes.

TIME	URINATE IN TOILET	LEAKING ACCIDENT	COMMENTS
12-1 AM			
1-2 AM			
2-3 AM	✓		
3-4 AM			
4-5 AM			
5-6 AM			
6-7 AM			
7-8 AM			
8-9 AM			
9-10 AM	✓	✓	<i>strong urge</i>
10-11 AM			
11-12 NOON			
12-1 PM	✓		
1-2 PM			
2-3 PM			
3-4 PM		✓	<i>cough</i>
4-5 PM			
5-6 PM			
6-7 PM			
7-8 PM			
8-9 PM			
9-10 PM			
10-11 PM			
11-12 PM			

Awake Time 6:30 A Bed Time 11 P # of Pads Used 2

B

Figure 7 a&b : Bladder training self monitoring

• BLADDER TRAINING VERSUS NO TREATMENT, PLACEBO OR CONTROL TREATMENTS

Bladder training as the sole therapy has been used in the treatment of detrusor overactivity, urodynamic stress incontinence, mixed incontinence, urge incontinence, urge incontinence with a stable bladder, and urgency-frequency syndrome. Individual RCTs that met inclusion criteria and the Cochrane review [230] were used to address the question is bladder training better than no treatment, placebo, or control treatments for urinary incontinence.

a) Quality of data

Five RCTs involving 515 women were found that compared the effect of bladder training to no treatment [99, 109, 220, 233, 238]. In one trial, it was not possible to identify the effect of bladder training alone as results of participants in the treatment group who received bladder training (those with urge or mixed incontinence) are combined with those who also received PFMT (stress incontinent participants) [109]. In another trial with three consecutive treatments (self-monitoring, bladder training, PFMT; decision for which treatments taken based on participants' goals), it was difficult to discern the effect of bladder training alone as compared to a control group as some participants had already undergone lifestyle modifications (caffeine and fluid modifications and constipation advice) and diary keeping in a prior self-monitoring condition[233]. Thus, the quality of these two trials is not discussed further in this section.

In the three trials with analysable data, Jarvis and Millar [238] investigated the effect of an in-patient bladder training program in women ages 27-79 years with a diagnosis of detrusor overactivity or coexisting stress incontinence, whereas two trials[99, 220] examined the effect of an outpatient program. Fantl et al. [220] studied the effect of a 6 week outpatient program in women ages 55-90 years with urodynamic stress incontinence, detrusor overactivity; or both who reported at least one incontinent episode on a weekly voiding diary; and Yoon et al. [99] examined the effect of an 8 week outpatient program in women ages 35 to 55 years with urinary incontinence (type not identified) who had pad test weights at least 1.0 g or more and 14 or more voids during a 2-day diary.

Although all three RCTs reported random assignment, only one RCT reported the method of how randomisation was accomplished, e.g., use of a list of random numbers [99]. One trial used stratification

based on urodynamic diagnosis of urodynamic stress incontinence and/or detrusor overactivity [220]. No trial reported how random allocation concealment was accomplished.

Sample sizes in the three analyzable RCTs were 44 [99], 60 [238], and 123 [220]. Fantl reported a power calculation although details were not described.

Outcome measures used included self-reported symptoms [238], voiding diaries [220] [99]; a self-rated incontinence severity measure (Yoon et al), pad tests (Fantl et al; Yoon et al); quality of life instruments [151, 220]; and voided volumes or other urodynamics parameters [99, 220, 237, 241], Cure was defined as 0 incontinent episodes over 7-days and improvement as a reduction of 50% or more of incontinent episodes [220]. Masking of outcome assessors was described in only one RCT [99].

Follow-up periods ranged from 6 weeks [220], 8 weeks [99], 12 weeks [238], with an additional evaluation 6 months [238], and 9 months [220] from initiation of treatment. Two trials noted whether there were adverse events with bladder training [238], [220]. No trial reported a compliance assessment. Losses to follow-up were 0% in one trial although it was not clear if this was due to no drop-outs or due to lack of reporting [237]. In the other two analyzable RCTs, it was 8% -15% [220] and 14% [99]. Drop-out rates at the immediate follow-up between the bladder training and the control groups seem similar; they ranged from 8% vs 5%, respectively [220] and 10% vs 14%, respectively [99]. No trials reported whether analyses were based on intent to treat principles.

All of these RCTs with the exception of the one by Yoon et al. [99] were considered in the Cochrane review [230]. The Cochrane review based their conclusions on data available from 149 women from two trials [220].

b) Results

Two of the three RCTs reported significant improvements in the bladder training group as compared to an untreated control group with respect to incontinent episodes [220] [238]; the third RCT [99] did not report data on incontinent episodes. Jarvis and Millar [238] reported that 90% of the participants in the treatment group were continent and 83.3% were symptom free at 6 months (method for determination of continence and symptom status was not specified but probably self-report) as compared to 23.3% of the control group who were both continent and symptom free. All women who were symptom free after treatment reverted to a normal cystometrogram.

Fantl et al. [220] reported that 12% of participants in the treatment group were continent and 75% had reduced their incontinent episodes at least 50% or more at 6-weeks as measured by a 7-day voiding diary as compared to 3% with no incontinent episodes and 24% with at least 50% reduction in their incontinent episodes. These results were maintained at 6 months. Women with detrusor overactivity and those with urodynamic stress incontinence with and without detrusor overactivity had similar improvement rates. Participants in the treatment group also significantly decreased the grams of fluid lost on a retrograde pad filling test by 54% with results maintained six months later; this was more pronounced in those who had detrusor overactivity with or without urodynamic stress incontinence. While some women did revert back to normal bladder function following bladder training, no relationship was found between changes in urodynamic variables and the number of incontinent episodes [241]. Yoon et al. [99] reported that there was no difference between the bladder training and control groups in the amount of leaked urine at an immediate follow-up; however, it was not clear if this referred to pad test weights solely or a urinary incontinence severity score. Conclusions from this trial are uninterpretable because of insufficient power.

The Cochrane review [230] found that although point estimates of effect favoured bladder training, confidence intervals were wide with no statistically significant differences observed for any of the prespecified outcome variables.

c) Summary

From the few trials available, there is scant Level 1 evidence that bladder training as compared to no treatment may be an effective treatment for women with urge, stress, and mixed urinary incontinence

Additional studies involving a no treatment control group are needed.

d) Recommendations

Bladder training is recommended as a first line treatment of urinary incontinence in women (Grade A). Additional high quality studies are needed that examine the effect of bladder training in treatment of women with urge, stress, and mixed incontinence.

• BLADDER TRAINING VERSUS OTHER TREATMENTS

The next sections will examine the evidence on whether bladder training is better than other treatments in the management of urinary incontinence. Questions addressed are:

- Is bladder training better than other treatments?

- Does the addition of other treatments add a benefit to bladder training?
- Does the addition of bladder training to other treatments add any benefit?
- **IS BLADDER TRAINING BETTER THAN OTHER TREATMENTS?**

To be included trials needed to investigate the effects of bladder training versus therapy A.

Bladder Training versus PFMT

Refer to PFMT versus Bladder Training, see Physical Therapies.

Bladder Training versus Drug Therapy

Individual RCTs that met inclusion criteria and the Cochrane review [230] were used to address the question is bladder training better than drug therapy in the treatment of urinary incontinence.

a) Quality of data

Three RCTs were located that compared bladder training to drug therapy in 203 women [238], [234] [abstract only]. Two trials used drugs available prior to 1995: a combination of flavoxate hydrochloride and imipramine [238], and oxybutynin chloride [239]. A more recent trial presented in abstract form only involved tolterodine as one of a 3-arm trial (bladder training, tolterodine, or both) [234]. One trial randomised by using computer allocation and reported adequate random allocation concealment [239]. Sample sizes were: 50 [238], 74 [234], and 79 [239]. No trial reported a power calculation.

Follow-up periods varied from 4 weeks [238], 6 weeks [239], 12 weeks [238] (Jarvis, 1981; [234] to 6 months [239]. Outcome measures included self-report of benefit urodynamic parameters [238], subjective urgency score ([234], subjective perception of bladder condition (e.g., 5-point from cure to aggravated) [234] and voiding diary [239]; [234]. All RCTs evaluated drug tolerability and adverse events. Drop-outs were 0% in two trials; however, it is not clear whether this is a reporting issue [238]. In the third trial, drop-out was 25.3% but due to the abbreviated abstract reporting, it is unclear where the drop-outs occurred [234]. No trial identified whether intent to treat principles were followed.

The Cochrane review [230] based their conclusions on two trials including 125 women comparing bladder training with drugs: one with oxybutynin (immediate release) [239] and one with flavoxate hydrochloride imipramine [238].

b) Results

Two RCTs conducted with drugs available prior to

1995 suggest that bladder training may be superior to drug therapy in women with detrusor overactivity [238]. Jarvis [238] compared inpatient bladder training to outpatient treatment of 200 mg of flavoxate hydrochloride (three times a day) and 25 mg of imipramine (three times per day) in 50 women ages 17-78 years with detrusor overactivity, and concluded that bladder training was more effective. In the bladder training group, significantly more patients (84%) patients became continent and symptom free (76%) assessed by self-report, as compared to the drug group where 56% became continent and 48% were symptom free at 4 weeks. Patients who were symptom free at 4 weeks were able to maintain their outcomes at 12 weeks. In the analysis by the Cochrane review group, the only outcome demonstrating a statistically significant difference were participants' perception of cure at six months (RR 1.69; 95% CI 1.21 to 2.34) and adverse events (RR 0.03; 95% CI 0.00 to 0.44), both favouring bladder training [238].

Columbo and his associates [239] reported that a 6-week course of 5 mg oxybutynin chloride (immediate release, IR) (three times a day) had a similar clinical cure rate (e.g., self-reported total disappearance of urge incontinence, no protective pads, or further treatment) as outpatient bladder training (74% vs 73% respectively) in 79 women ages 24 to 65 years with detrusor overactivity. Oxybutynin clinically cured 93% of patients with detrusor overactivity, 67% of those with low compliance bladder, and 60% of those with urgency-frequency syndrome. Bladder training clinically cured 62% of those with detrusor overactivity, 75% of those with low compliance bladders, and 81% of those with sensory urgency. The relapse rate at 6-months was higher for the drug group, whereas, those in the bladder training group maintained their results better. In the analysis by the Cochrane group, participants' perception of cure immediately after treatment just achieved statistical significance (RR 1.50; 95% CI 1.02 to 2.21) favouring bladder training, and this difference was maintained at approximately two months post treatment.

In a more recent RCT (abstract only), Park and colleagues [234] compared a 12-week bladder training program to 2mg tolterodine twice daily in women (ages unknown) with overactive bladders (unclear if incontinence was present), and concluded that both treatments were effective as a first-line therapy in treating women with overactive bladders. Results are discussed in the section on Other LUTS as there were no findings reported on incontinence.

The Cochrane review [230] concluded that there was not enough evidence to determine whether first line

therapy should be bladder training or anticholinergic drugs.

c) Summary

There is scant Level 1 evidence on whether bladder training is more effective than drug therapy available prior to 1995 for women with detrusor overactivity. There is insufficient evidence regarding the comparative effectiveness of bladder training and newer drug therapies (Level 3). Additional RCTs are needed.

d) Recommendations

Since there is insufficient evidence regarding the comparative effectiveness of bladder training and current drug therapies, bladder training which has no adverse effects as compared to drug therapy should be considered as a first line treatment of detrusor overactivity. (Grade B)

• DOES THE ADDITION OF OTHER TREATMENTS ADD A BENEFIT TO BLADDER TRAINING?

To be included trials need to investigate the effects of bladder training versus bladder training plus therapy A to address the additive benefit of therapy A to bladder training.

Trials addressing the additional benefit of three other treatments were found; the added benefit of caffeine reduction; the added benefit of PFMT, the added benefit of drug or therapy. The trial addressing the added benefit of caffeine reduction[36] is considered in the section on Lifestyle Interventions and the trial addressing the added benefit of PFMT [151] is considered in the section on Physical Therapies. The trials addressing the added benefit of drug therapy are considered below.

Bladder Training Versus Bladder Training and Drug Therapy

This section compares bladder training alone or with placebo to bladder training and drug therapy. It is possible that placebo may augment bladder training; therefore, the data is summarized for bladder training arms that involved and did not involve placebo controls.

a) Quality of Data

Three double-blinded RCTs compared bladder training with placebo to bladder training and drug therapy in patients with detrusor overactivity; one trial studied imipramine in 34 patients with detrusor overactivity (28 women ages 30-91 years and 6 men) [240]; one trial studied terodiline (drug no longer available) in 34 patients (30 women, 4 men) aged 70 years and over [236] and one trial used oxybutynin (immediate release) in 57 patients aged 70 years and

over (56 women, 4 men) [235]. Both trials included power calculations.

One RCT compared bladder training alone to bladder training with tolterodine (2 mg, twice daily) in 99 women with overactive bladders (incontinence status unknown) [234]. Details regarding the study methodology were limited (abstract only).

Post-treatment follow-up periods were variable. One trial evaluated participants at 4 and 6 weeks[236]; one trial at 8 weeks[235]; and one trial at 12 weeks [234]. An early trial did not have a clear endpoint but followed participants a range of 1-11 months[240]. Outcome was measured most frequently by subjective report of benefit [234-236] and voiding diaries[234, 236] followed by urodynamic parameters[235, 240]; or self-rated incontinence severity measure or symptom score[234, 240]. Improvement was defined as: mean, median, or any reduction in incontinent episodes [235, 236] bladder symptom score to a specified level [234]. One trial reported analyses based on intent to treat principles[236]. Because of reporting issues, it was not possible to discern the treatment effects in women alone in three trials [235, 236].

b) Results

Three trials comparing different drug therapies available before 1995 with bladder training to bladder training with placebo [235, 236, 240] were inconsistent with respect to the additive benefit when combining bladder training with drug therapy in the treatment of detrusor overactivity in women and a small number of men.

Castleden et al [240] found that more patients became dry on imipramine 25 mg or more per day (74%) than those in the bladder training and placebo group (43%). In a parallel group design, Szonyi et al [235] found no difference between 2.5 mg of oxybutynin 2.5 mg immediate release I.R. twice daily with bladder training versus the bladder training and placebo group in reducing incontinent episodes. Szonyi et al concluded, however, that the drug group was superior to the bladder training and placebo group because it had greater subjective benefit (86% versus 55%). Using a similar research design, Wiseman and colleagues [236] reported no difference between the bladder training and placebo group and the group that received 25 mg of terodiline twice daily with bladder training in reducing incontinent episodes.

Park and colleagues [234] concluded that bladder training and combined therapy (bladder training and tolterodine 2 mg twice daily) were effective first-line treatments but that combined therapy had some bet-

ter effects than bladder training alone. However, significant improvement rates were higher in the combined therapy group (69.3%) as compared to the bladder training group (50%). Based on the limited reporting (abstract only), it was impossible to discern the treatment effects on incontinence separately.

c) Summary

In small placebo-controlled trials using drugs available before 1995 for treatment of detrusor overactivity, outcomes varied based on the medication used. In a more recent trial of a newer drug, it was impossible to discern the treatments effects on incontinence. Thus, there was insufficient evidence to derive a conclusion related to the effectiveness of augmenting bladder training with drug therapy (Level 2/3).

d) Recommendations: B

There is limited Level 2 evidence on the effectiveness of augmenting bladder training with drug therapy. The available evidence is inconclusive, and further RCTs are needed.

• DOES THE ADDITION OF BLADDER TRAINING TO OTHER TREATMENTS ADD ANY BENEFIT?

To be included trials needed to investigate the effects of Therapy A versus Therapy A plus bladder training to address the added benefit of bladder training over Therapy A. Trials were located that investigated the effects of PFMT versus PFMT plus bladder training (addressed in the Physical Therapies section); and drug therapy versus bladder training plus drug therapy.

Drug Therapy Versus Bladder Training and Drug Therapy

a) Quality of Data

Two RCTs were located that compared tolterodine alone (2 mg twice daily) to bladder training with tolterodine (2 mg twice daily) [232]. The single-blinded trial by Mattiasson et al [232] which incorporated a power calculation included 501 participants (378 women and 123 men) ages 18 years and over with overactive bladders with and without urge incontinence. Analyses were based on intent to treat principles. However, because of reporting issues, it was not possible to discern the effect of treatment in women alone. In a three arm trial, Park and colleagues [234] included 99 women (ages unknown) with overactive bladders (unclear if incontinence was present). Post-treatment follow-up periods in both trials were at 12 weeks, with a 24 week follow-up in one trial[232]. Outcome was assessed by subjective report of benefit in both trials; voiding diaries

for incontinent episodes in one trial [232] or frequency and nocturia in another trial [234]; and bladder symptom scores [234]. Additional details regarding the trial by Park were not available.

b) Results

Mattiason and colleagues[232] reported no difference between participants (combined female and male) with overactive bladders with and without urge incontinence who were given brief written bladder training instructions plus tolterodine 2 mg twice daily versus tolterodine alone with respect to reducing incontinent episodes (median reduction 87% vs 81%, respectively). Park et al [234] concluded that tolterodine and combined therapy (tolterodine plus a nurse supervised bladder training program) are effective first-line therapies but that combined therapy had some better effects than tolterodine alone. At the end of treatment, subjective perception of bladder symptom scores were 1.4 in the drug therapy group and 1.3 in the combined therapy group. However, significant improvement rates were higher in the combined therapy group (69.3%) as compared to the drug therapy group (58.3%).

c) Summary

There is conflicting Level 1 evidence whether there is an added benefit of combining bladder training with drug therapy (tolterodine 2mg twice daily) as compared to drug therapy alone. Results might be attributed to differences in study populations, the intensity of the bladder training protocols, and outcome measures. More research is needed using other antimuscarinic drug therapies and incorporating traditional bladder training protocols.

d) Recommendations: D

Augmenting drug therapy with a supervised bladder training program may be helpful in the treatment of overactive bladder with and without urge incontinence

III. OTHER LUTS

There is good evidence that bladder training has a beneficial effect on urgency and frequency (Level 1). Several RCTs reported significant improvements in diurnal and nocturnal micturition frequencies with bladder training alone. Jarvis and Millar [238], reported that 83.3% of participants in the bladder training group were symptom free at 6 months. After bladder training, there were 17% in the treatment group and 77% in the control group who continued to have symptoms of diurnal frequency; 11% and

80% for nocturnal frequency, respectively, 13% and 77% for urgency, respectively; 10% and 77% for urge incontinence; and 14% and 80% for stress incontinence, respectively. Fantl et al., [220] also found significant reductions with diurnal and nocturnal frequency. In subgroup analyses, this occurred in participants with urodynamic stress incontinence with a baseline diurnal micturition frequency of at least 61 per week, and those with detrusor overactivity with or without urodynamic stress incontinence who had at least 57 diurnal micturitions per week. Nocturnal micturitions were only significantly decreased in women with urodynamic stress incontinence alone who experienced at least five episodes of nocturia per week, and not in those who had detrusor overactivity. Yoon et al. [99] reported that bladder training group as compared to a no treatment control group significantly reduced both its diurnal and nocturnal micturitions whereas the control group deteriorated slightly. Similarly, the treatment group was able to significantly increase voided volumes whereas the control group reduced their voided volumes.

In several drug trials using medications available before 1995, bladder training had superior advantages in two trials. Using subjective data, Jarvis [238] reported that the bladder training group as compared to the drug group (flavoxate and imipramine) had 76% vs 48% who were symptom free, 24% vs 48% who continued to experience frequency, 16% vs 44% who continued to experience urgency, and 19% vs 68% who continued to experience nocturia. Columbo et al [239] found that diurnal frequency was resolved by oxybutynin vs bladder training in 18 (56%) of 32 patients vs 20 (69%) of 29 patients, and that nocturia disappeared in 3 (27%) of 11 patients and 11(61%) of 18 patients, respectively. Results in placebo drug trials using bladder training in combination with a placebo group, the findings were less clear. Wiseman and colleagues [236] found no difference in the median frequencies of micturitions which improved slightly in both the bladder training plus placebo group and a terodiline group. Szonyi and associates [235] found that there was a greater reduction in diurnal micturition frequencies in participants taking oxybutynin compared to those on placebo but no difference in nocturnal micturition frequencies. However, in trials using a newer drug, augmenting the drug with bladder training led to greater improvements in micturition frequencies. Mattiasson et al [232] found that bladder training significantly augmented tolterodine effects with respect to voiding frequency (33% vs 25% improvement, respectively),

volume voided, and patients' rating of their bladder problems as minor or less (66.5% vs 61.5%, respectively). There were comparable improvements in urgency. Overall, 76% of those on bladder training and tolterodine improved their bladder symptoms relative to baseline compared to 71% on tolterodine alone. Park et al. [234] found that the tolterodine group augmented with bladder training had greater reductions in diurnal micturition (32.6%), nocturnal micturition (63.2%), urgency scores (63.2%), and bladder symptom improvement rates (69.3%) than those in bladder training alone (27.1%, 55.8%, 48.4%, 50%, respectively) or tolterodine alone (30.3%, 61.9%, 62.5%, 58.3%, respectively). However, only the bladder symptom improvement scores were significantly better in the augmented group.

IV. FACTORS AFFECTING OUTCOME

1. AGE

All trials with the exception of two RCTs [99, 109] included older women in their study populations. Three trials specifically recruited elderly women ages 65-70 and over [235, 236, 240]; and two trials recruited women ages 55 years and over [220, 233]. In conducting analyses of factors predicting outcomes of bladder training alone, two trials reported that age was not a factor in treatment outcome [151]. Similarly, age was also not a predictor of outcome in a trial incorporating an intervention involving the potential of three consecutive interventions based on participant goals (self-monitoring, bladder training, PFMT) [233].

2. OTHER

Few bladder training trials examined predictors of treatment response. Several trials discussed the effect of diagnosis on treatment outcome. Two trials reported that urodynamic diagnosis did not have an effect on the treatment outcome as measured by incontinent episodes and the Incontinence Impact Questionnaire [151, 220]. These RCTs included women with urodynamic stress incontinence, detrusor overactivity, or both diagnoses. Bladder training also led to greater clinical cures in one small drug trial. Women with sensory urgency (81%) and low compliance bladders (75%) versus those on oxybutynin immediate release. (60%, 67%, respectively); however, oxybutynin. led to greater cure rates in patients with detrusor overactivity (93% vs 62%).

B7. COMPLIMENTARY THERAPIES

There is emerging evidence that complimentary therapy may influence both physiologic function and health outcomes. Complimentary therapies include those not part of the traditional biomedical model, such as relaxation, meditation, imagery, hypnosis, acupuncture and naturopathic and herbal remedies. While some consider biofeedback part of complimentary therapy, we have included biofeedback in this chapter as an adjunct to physical therapies. This section will examine evidence for the association and use of Complimentary Therapies in the management of Female Urinary Incontinence. A summary of research strategy and inclusion/exclusion criteria is given in **Appendix 1**.

I. PREVENTION

No articles were identified.

II. TREATMENT

a) Quality of data

In uncontrolled trials, acupuncture was used to treat 13 patients (11 males, 2 females) with detrusor hyperreflexia from chronic spinal cord injuries [242], 15 elderly women with urge or mixed incontinence [243], and 20 patients (3 men, 17 women) with bladder instability or urgency [244]. Number of acupuncture treatment sessions were 4 [242] and 12 [243].

In an uncontrolled trial, 50 women with detrusor overactivity completed 12 hypnosis sessions over one month [245].

b) Results

After 12 weeks of treatment, 77% of patients with “idiopathic detrusor instability” were symptomatically improved, though urodynamic assessment showed resolution of detrusor activity in only 1 of 20 subjects [244]. Three months after completing 12 acupuncture sessions, 12 of 15 women considered themselves improved [243]. In spinal cord injured patients, after 4 acupuncture treatments, incontinence resolved in 2 and improved in 6 of 13 patients [242]. After 12 hypnosis sessions over one month, subjects continued at home with a prerecorded cassette. After 12 sessions, 29 patients were symptom

free, 14 improved and 7 unchanged (of 50 total). Seven patients subsequently relapsed by 6 months [245].

c) Summary

Uncontrolled data suggests that acupuncture and hypnosis improve overactive bladder symptoms. Current studies are limited by the lack of a placebo group and by very short follow-up. Level of evidence: 3,4

d) Recommendation

Given the high placebo response rate in most studies that address overactive bladder symptoms, it is crucial that future studies on complementary therapies have a control group. When placebo treatment is not possible due to the nature of the intervention, a standard treatment control group (for example, bladder training) should be used. Grade of recommendation: C, D

III. OTHER LUTS

a) Quality of data

Chang compared urodynamic measurements in 52 women with urinary frequency, urgency and dysuria before and after one acupuncture treatment session, administered at two different points in each half of the subject group [246]. In a non-randomized trial of women with “urethral syndrome”, Huitian compared urinary frequency, nocturia, symptom scores and urodynamic indices between 128 women treated with acupuncture and moxibustion versus 52 treated with western medicine [247]. Women in the former group were treated every other day for 20 days (in some women, this course was repeated) and women in the latter group were given Hu Quian Lie Pian orally three times daily.

b) Results

Improvements were seen in urodynamic variables after acupuncture at one particular point (Sp. 6), but not at another (St. 36) [246]. After 1-2 months of treatment, 51.6% of women in the acupuncture/moxibustion group reported over 2/3 reduction in symptom scores, compared to 5.8% in the medication group. Before treatment, diurnal and nocturnal frequency were similar between the groups; after treatment, diurnal frequency decreased to 6.4 +/- 2.2 in the acupuncture group (from 12.7 +/- 4.6 pre-treatment) and to 10.6 +/- 4.2 in the medication group (from 11.7 +/- 4.3 pre-treatment) and nocturnal frequency decreased in the acupuncture group from 3.9

+/- 3.0 before treatment to 1.7 +/- 1.4 after treatment while no change was seen in the control group. Of interest, urethral closure pressure, which was similar in both groups before treatment, dropped significantly after treatment in the acupuncture group alone, from 110 +/- 34 cm H₂O to 42 +/- 29 cm H₂O.

c) Summary

There is insufficient information to summarize the effect of complementary therapies on lower urinary tract symptoms in women. Preliminary data suggests a role for such therapies, but highlights the importance of choosing specific acupuncture points or specific complementary treatments.

d) Recommendation

Randomized clinical trials are needed to assess the effect of complementary therapies on lower urinary tract symptoms in women. Various populations will likely respond differently to such therapies. When clinical trials are carried out by physicians inexperienced with various complementary therapies, it is essential that they collaborate with practitioners versed in such therapies.

IV. FACTORS AFFECTING OUTCOME

a) Age

No data delineates the impact of such therapies on older versus younger women.

b) Other

Similarly, no such information was identified.

C. URINARY INCONTINENCE IN MEN

INTRODUCTION

The investigation and management of incontinence in men suffers a gender bias in favour of women. Funded research and publications on incontinence are based predominantly on female samples. Studies on the patient with overactive bladder may include men but data analysis does not separate men from women. Indeed, most articles on urinary incontinence in men focus only on the problem after prostatectomy, implying indirectly the unlikelihood of other causes. Although more prevalent in younger women

than younger men, the prevalence of incontinence in men and women over 65 is similar with equal effects on quality of life, health resources, and personal finances.

A recent survey of men in four different cities in France, England, Korea, and Holland identified an incontinence rate in men over 60 ranging from 8% in Seoul to 23% in Birmingham [248]. The authors posit that it is cultural rather than actual differences that led to the different prevalence rates. In Spain, a population survey and interview of people over 65 indicated a prevalence for incontinence of 14% in men and 30% in women noting that few had sought assistance for the problem [249]. These percentages are similar to those reported in the NOBLE study [250] in which Americans matched for sex and age were surveyed for the prevalence and burden of overactive bladder. Frequency and urgency, with or without incontinence, were equally reported by men and women for an overall rate of 16.5%. The prevalence of lower urinary tract symptoms, post micturition dribble and urinary incontinence are known to increase with age: 10% of men over 75 reported urge incontinence and 22% over the age of 55 reported frequency, nocturia, and urgency, without incontinence, suggesting a protective mechanism of the prostate [251, 252]. Men with urinary symptoms report decreased quality of life scores, higher depression scores, and interrupted sleep. In subgroup analysis, nocturia, traditionally thought to be an indicator of prostatism, was reported equally by older men and women. Loss of sleep from nocturia is correlated with decreased socialization, increased symptom bother and increased seeking of medical care [253].

Despite the prevalence of incontinence and LUTS in older men, the only area which has received systematic consideration with respect to conservative management is associated with prostatectomy.

• Incontinence after prostatectomy

Urinary incontinence after prostatectomy is an iatrogenic condition that can decrease quality of life in those afflicted. It is debilitating and ranked higher than erectile dysfunction as impacting quality of life [254]. When incontinent men who have undergone radical prostatectomy are compared to their continent counterparts there is a significant decrease in health related quality of life, urinary bother and satisfaction scores [255]. Incontinence after radical prostatectomy is primarily due to sphincteric incompetence but overactive bladder, mixed incontinence or decreased contractility [256, 257] should not be overlooked. The problem is not well understood but

it is likely multifactorial [258] and related to neourethral or functional urethral length [259], preservation of the bladder neck [260], preservation of the neurovascular bundles [261, 262], de novo detrusor overactivity [263], and sphincteric injury. The bladder neck sphincter is destroyed in all forms of prostatectomy and continence relies on a competent external urethral sphincter reinforced by pelvic floor musculature [264]. If the pelvic floor muscles are weak leakage may ensue. Incontinence after transurethral resection of prostate (TURP) is most likely to be due to pre-existing abnormalities of bladder function such as poor compliance or detrusor overactivity, rather than direct sphincter injury [265] although 6% of men present with new incontinence [266] after TURP (see also Chapter 19, Surgical Treatment of Male Incontinence).

Two risk factors have been repeatedly identified for incontinence after radical prostatectomy and TURP: abnormalities of detrusor contractility [263] and age [267]. Other related factors include previous TURP, preoperative radiotherapy [256, 268], trauma, spinal cord lesion, new obstruction such as unresected adenoma, bladder neck contracture, or urethral stricture, Parkinsons disease [256, 269], dementia, and medications [270].

The primary conservative treatment of incontinence after prostatectomy is pelvic floor muscle therapy (PFMT) [256, 271]. Anal electrical stimulation, PFMT, biofeedback or transcutaneous electrical nerve stimulation (TENS) have also been utilized and all treatments are reported as modestly successful. However, most studies are non-randomised or not controlled, with small, heterogeneous samples, and no objective outcome measures or long-term follow up. Moreover, the non-controlled nature of the studies does not account for a placebo effect reported as high as 39% when similar conservative management strategies are used for women with incontinence [104, 270] nor for the spontaneous improvement up to 12 months after surgery.

A total of 22 potentially relevant randomised studies on conservative management of post radical prostatectomy (n=20) or transurethral prostate resection (TURP) (n=2) urinary incontinence were identified. Ten were excluded: five were in Spanish with English abstracts and appeared to be descriptive [272-276]; four were abstracts only [277-280], and one in German [281] included the data for the post-prostatectomy patients with a group of post-polio female

participants. The remaining 12 studies all used some aspect of pelvic floor muscle exercise, but varied considerably. Interventions ranged from PFMT in comparison to no treatment or sham; PFMT with biofeedback, anal electrical stimulation or a combination of therapies. Outcome measures varied: pad tests were 20 minute, 1, 4 or 24 hour periods; incontinence was defined as number of pads used, 1 gm or 2 gm of urine loss on pad test. Withdrawals or dropouts were not or inconsistently reported. Only two [282, 283] discussed how this was dealt with in the analysis. Although all studies were identified as randomised controlled trials, only two [282, 284], clearly stated that an adequate technique of concealment of allocation had been used (sealed envelopes). Blinding was not described in the others although some attempted to minimize bias in intervention or outcome measurement. Two [284, 285] had people not involved in provision of the intervention act as outcomes assessors and one [282] indicated that a single therapist, blinded to control group outcomes, provided all treatment. Using the Jadad scale [286] one trial [282] received 2/5 points, three [283, 284, 287] received 1 point, and the rest received a score of zero. Subjects were recruited pre-operatively, post-operatively with the catheter in situ before it was known if they were incontinent or not. None specifically stated that men were continent prior to surgery although this was assumed. Therefore some trials addressed the primary and/or secondary preventive effects of PFMT, and the others did not differentiate between primary/secondary prevention and treatment effects. It was not possible to provide definitive answers for any of the questions.

C1. LIFESTYLE INTERVENTIONS

Lifestyle interventions are frequently recommended by continence advisors for men with LUTS [288] but no trials were found which specifically addressed the effectiveness of lifestyle interventions in men. The topics of prevention, weight loss, physical exercise, smoking, dietary factors, and constipation management are addressed in *Incontinence in Women* with all or predominantly female samples with no subgroup analysis of men.

a) Quality of data

No randomised trials assessing the effect of lifestyle interventions for prevention or treatment of urinary incontinence in men were identified.

b) Results

No trials identified.

c) Summary

It is reasonable to recommend healthy lifestyle choices that will reduce or delay the onset of atherosclerosis, cardiac failure and diabetes, both of which place a man at higher risk of co-morbid conditions that increase the risk urinary incontinence. Level of Evidence: Level 4

d) Recommendation

Lifestyle choices such as smoking obesity, and sedentary lifestyle known to affect health. Whether these factors have a direct impact on urinary incontinence is suggested but not known. Further studies on the effect of caffeine, in particular, would assist in guiding practice; research on the physiological effect of constipation and incontinence would assist in the understanding of the relationship between these two entities.

Grade of Recommendation: D

C2. PHYSICAL THERAPIES – PFMT

No trials were found that specifically addressed the effectiveness of PFMT for incontinence in groups of men other than those having prostatectomy. All types and approaches to prostatectomy were considered (e.g. radical prostatectomy, TURP, open). Two trials addressed the effect of PFMT for post micturition dribble [289, 290]. The following questions guided the review:

1. Does preoperative PFMT prevent urinary incontinence after prostatectomy?
2. Is PFMT an effective treatment for post prostatectomy incontinence?
3. Is one approach to PFMT better than another?
4. Is PFMT better than other treatments for post prostatectomy incontinence?
5. Is PFMT an effective treatment for post micturition dribble?

1. PRIMARY/SECONDARY PREVENTION OF URINARY INCONTINENCE POST PROSTATECTOMY

Trials included in this subsection address the effect of pre-operative PFMT, pre and post-operative PFMT, or post-operative PFMT on the incidence of post prostatectomy incontinence. To be included in this section trials needed to recruit men before sur-

gery or after surgery before it was known whether they were incontinent or not (e.g. whilst the catheter was still in situ). A number of trials used PFMT in conjunction with an adjunct (e.g. biofeedback) or another physical therapy (e.g. electrical stimulation). Because overall there were few trials, these combination therapies have been considered below.

2. PRE-OPERATIVE PELVIC FLOOR MUSCLE TRAINING AFTER RADICAL PROSTATECTOMY

a) Quality of data

Only one study (n=100) was found evaluating preoperative PFMT on post operative continence outcomes after radical prostatectomy. Randomisation and allocation were not described. Urinary continence outcome was assessed by a nurse not involved in the study by interview at 1, 2, 3, 4, and 6 months post surgery. There were three dropouts who did not appear to be included as intention to treat analysis. Last follow up was at 6 months.

b) Results

Men who had undergone two 45 minute biofeedback sessions 2 to 4 weeks preoperatively plus daily home practice (n=50) were compared to those who received only verbal and written teaching materials (n=50) [285]. No difference was found in achievement of continence at 1,2,3,4, or 6 months between the two groups. Continence was assessed by telephone interview, based on reported number of pads used.

c) Summary

It is not clear whether knowledge of and practice of pelvic floor muscle exercises before surgery improves continence recovery. Subjectively, it may help men prepare surgery and give them a sense of control but this concept requires further exploration.

Level of evidence: 2

d) Recommendation

Studies comparing the effectiveness of pre versus post operative exercises are needed so that practitioners may advise men about preoperative preparation and budget conscious health boards can make informed decisions on program funding. In designing such studies, the natural history of incontinence after radical prostatectomy must be taken into account as the majority of men achieve continence by 12 weeks post surgery. This high attrition rate means that sample sizes must be large to detect any differences between protocols.

Grade of Recommendation: C

3. PREOPERATIVE AND POST OPERATIVE PFMT AFTER RADICAL PROSTATECTOMY

a) *Quality of data*

Four trials were found that assessed a combination of pre and post operative PFME for a total of 204 subjects. There was statistical heterogeneity and wide confidence intervals. Outcome measures varied from pad weight, pad count, and subject report. None of the trials described method of randomization or allocation concealment. Three did not provide information on whether outcomes assessors were blinded nor were dropouts described [283, 291, 292]. One trial [285] attempted to control for bias in outcomes assessment by having a nurse not directly involved in the study interview the subjects but it is not clear whether he/she was blinded to allocation group. Follow up in all studies was 1 year or less.

b) *Results*

Bales [285] gave initial instruction on PFMT using biofeedback (surface electrodes) 2-4 weeks prior to retropubic prostatectomy. The control group received only post operative verbal instruction on PFMT, and both groups were encouraged to practice PFMT four times daily once the catheter was removed at two weeks after surgery (N=100). There were no differences between groups at any of the time points. Mathewson-Chapman assigned all subjects (N=50) to one session of preoperative instruction using biofeedback and verbal coaching then randomized them to active or non-intervention groups [291]. Post operatively the intervention group (n=26) practiced PFMT with a home biofeedback unit (anal probe) from weeks 3 to 12 after surgery, whereas the control group (n=24) received no treatment. Both groups completed questionnaires, pad counts, and 24 hour pad test at weeks 2, 5 and 12 post operatively. There were no differences between groups at any of the time points. Another study (n=38) used a non-traditional pelvic floor exercise program plus biofeedback with 2 sessions preop and 4 sessions every three weeks post op plus home exercise[283]. Continence was assessed by patient reported number of pads and continence questionnaires at 6, 12, 16, 20, 28 and 52 weeks post surgery and was achieved more quickly at 12 weeks in the treatment group but this difference was not significant by 16 weeks post surgery. Finally, in a small study of 16 men, Sueppel assessed the benefit of 2 sessions preoperatively and home exercises three times a day compared to PFMT using biofeedback started at 6 weeks post surgery. Both groups had follow up biofeedback sessions at 6, 12,

24, 40, and 52 weeks post op and were asked to do home exercises. At one year post surgery the preoperative group was improved over the post operative only group based on a standardized 45 minute pad test (mean pad weight 2.8 gm vs 33.3 gm) [292]. This was the only trial that found a group difference.

c) *Summary*

The current trials suggest that there may be a modest benefit to preoperative and post operative interventions in early return to continence but that this benefit is not sustained over the long term. **Level of Evidence: 2**

d) *Recommendation*

Further preoperative/postoperative trials are required with adequate sample sizes and standardised protocols, taking into account that most men will achieve continence by 12 weeks post surgery, leaving only 15-20% with significant leakage.

Grade of Recommendation: B

4. POST OPERATIVE PFMT AFTER PROSTATECTOMY

• **PFMT After Radical Prostatectomy**

a) *Quality of data*

Two trials used digital rectal examination only to teach PFMT [282, 293] after radical prostatectomy and one after TURP [293]. There was considerable variation in the type and intensity of interventions and studies involved a heterogeneous group of men ranging from eight weeks to more than a year post operatively. Subjects with persistent incontinence may have more complex underlying reasons for incontinence and may be considerably different from men in the first weeks after surgery. Only one of the trials described the randomization method (sealed envelopes opened by the research in front of the subject), had treatment provided by a therapist blinded to the control group outcomes, and described how withdrawals/dropouts were dealt with in the analysis. Outcomes were assessed by the primary investigator who had a direct involvement in the trial [282]. In both studies follow up was 12 months.

b) *Results*

The two studies used DRE rather than biofeedback to teach PFME for a total of 73 subjects. In the Moore [282] trial, men (n=63) were randomized to control (no active intervention), PFMT taught by a physiotherapist using digital rectal exam and abdominal pal-

pation or PFMT augmented with electrical stimulation. Both treatment groups met with the therapist twice a week for up to 12 weeks. Joseph randomised a mixed group of 11 men (1 TURP, 4 RRP, and 6 radical perineal prostatectomy) to weekly verbal teaching plus digital rectal assessment or biofeedback assisted PFME over a 4 week period [293]. There were no group differences in outcomes measured by 24 hour pad test, voiding diary or quality of life (IIQ-7).

c) Summary

Sample size and heterogeneity mean that no conclusions can be drawn about the benefits on return to continence PFMT taught using DRE. Level of Evidence: 2

d) Recommendation

Well designed studies are required using standardized outcomes and adequate sample sizes to allow across study comparisons.

Grade of Evidence: B

• PFMT after TURP

a) Quality of data

One trial involved 58 patients after TURP [294] and one [293] included 11 patients with either TURP (n=1) or radical prostatectomy (n=10). One non randomized study on TURP patients [295] was also included because of the paucity of research post TURP. Little study has been dedicated to incontinence after TURP. In fact, the issue has been largely ignored, perhaps because the incidence of incontinence after TURP is reported to be very low. Neither of the trials described randomization, allocation concealment, outcome assessment, or dropout data.

b) Results

Porru randomized men preoperatively to no intervention (n=28) or to active treatment (n=30) consisting of verbal instruction, digital rectal assessment of pelvic floor muscle contraction, and pelvic floor muscle contractions at home (varying frequency) starting on the first or second day post catheter removal [294]. Symptom score improved, pelvic muscle strength increased, based on digital rectal assessment, and diarised incontinence episodes were fewer in the active group in the first 3 weeks post TURP. By week 4, the differences between groups was no longer significant. These findings are similar to a non randomized study in which the first 25 subjects were assigned to control and the next 25 to treatment [295].

c) Summary

PFMT after TURP appears to reduce the length of time of incontinence after TURP but over time, the difference is not sustained. **Level of evidence: 2**

d) Recommendation

The natural history of urinary incontinence after TURP requires a systematic assessment using current standardized measures of voiding diaries, pad tests, and quality of life measures.

Grade of Recommendation: C

• PFMT Plus Biofeedback After Radical Prostatectomy

a) Quality of data

Four trials [283, 284, 287, 291] compared PFMT plus biofeedback with a no-treatment or placebo-treatment control group. There was clinical heterogeneity regarding incontinence status at baseline, timing of recruitment and intervention, content of intervention and control treatments. Franke [287] used percentage of participants pad free, while Mathewson-Chapman [291] did not specify whether the incontinence rates were based on objective or subjective data. Parekh based incontinence on pad use [283]. Van Kampen used subjective report and amount of urine lost on pad test (< 2 g). There was a high drop out rate in the Franke [287] study and these data were not accounted for in the analysis nor were randomization, outcomes assessment or blinding described in three of the trials [283, 287, 291]. Van Kampen did not describe randomization method and all treatment and follow up were provided by the investigator. Outcomes however were assessed directly by the patient (pad weight) or by a research nurse not involved with the study. Dropouts were clearly described although analysis did not appear to be on intention to treat [284]. Follow up in these studies ranged from 12 week to 1 year. A recent Cochrane review found that there was a modest benefit of active biofeedback after radical prostatectomy [296]. The reviewers recommended further well designed studies, however, as the pooled benefit was seen in only one of the 4 trials described above.

b) Results

A total of 220 subjects in 4 trials received biofeedback assisted PFMT for incontinence after radical prostatectomy. Franke [287] randomised men (n=30) to treatment with PFMT using biofeedback (perineal patch electromyography through weeks 6, 7, 9, 11 and

16 post operatively), supplemented with home exercises (n=15). The control group (n=15) received no instruction. This was a small trial, with over 50% drop out rate. Mathewson-Chapman (n=50) had the intervention group perform PFMT with biofeedback (anal probe) at home from weeks 3-12 after surgery, whereas the control group received no treatment [291]. Men in the Parekh (n=38) trial had postoperative PFMT, and digital or anal-probe biofeedback [283]. Van Kampen recruited men (n=102) who were incontinent after catheter removal; 7/50 men received additional anal electrical stimulation if their contractions were found to be weak [284]. The control group received placebo (skin) electrostimulation.

c) Summary

Although postoperative treatment of incontinence has received the most attention with 7 randomised trials and several non-controlled studies, only one trial by Van Kampen [284] has shown a significant difference between treatment and control subjects. However, methodological differences and limitations make the results difficult to interpret. The use of biofeedback was the most common modality in the treatment of incontinence after radical prostatectomy. It provides the patient with some visual feedback that may enhance PFME ability. Treatment appeared to improve continence at three months and, to the patient, this improvement may be highly significant in activity, well-being, and socializing. Such concepts require further investigation.

In a 2004 Cochrane Review [296], the combined data from the total of 6 studies using DRE or biofeedback at three months or less favoured the intervention (RR for failure 0.74, 95% CI 0.60 to 0.93), but there were no significant differences at 6 months or 12 months between the treatment and control groups. **Level of Evidence: 2**

d) Recommendation

Future studies must follow the established format for reporting results based on the ICS and CONSORT recommendations and journal editors must insist that trials be reported according to a standard format. Group exercise deserves attention, in part because of the peer support that men may receive from participating in a group [297]. Both Moore [282] and Opsoemer [298] reported that support in the post operative period may be important to healthy recovery.

Grade of Evidence: C

5. ONE APPROACH TO PFMT VERSUS ANOTHER AFTER RADICAL PROSTATECTOMY

• BIOFEEDBACK COMPARISON WITH DRE AFTER RADICAL PROSTATECTOMY

a) Quality of data

One study of 42 subjects was found that compared the addition of biofeedback to digital rectal teaching of pelvic floor muscle exercises [299]. Subjects were randomised in a 2:1 order although allocation concealment is not described. Both groups received therapy from the same therapist. Outcome assessors are not described. Data was analysed on an intent to treat basis. There were no dropouts. The study is limited by the lack of a non intervention control group. Last follow up data was collected at 6 months post surgery.

b) Results

42 men were randomized 1 week after catheter removal to verbal instruction plus digital rectal teaching about PFME and 80-100 home exercises a day or to 15 sessions of EMG biofeedback given over a 3 week period along with 50-100 daily home exercises [299]. Evaluation at 1, 2, 3, and 6 months with diary and 1 hour pad test showed no difference between groups at any of the time points.

c) Summary

The addition of biofeedback did not appear to improve the outcomes of patients receiving PFMT for incontinence after radical prostatectomy. **Level of Evidence: 3**

d) Recommendation

The theoretical basis for teaching pelvic floor muscle exercises should not vary, whether the approach is digitally or assisted by biofeedback. However, provides worthwhile reinforcement of behaviour for the patient [300]. The use of biofeedback is currently a therapist decision, based on economics and preference.

Grade of Recommendation: C

• BIOFEEDBACK COMPARISON WITH ELECTRICAL STIMULATION AFTER RADICAL PROSTATECTOMY

a) Quality of data

Two studies on biofeedback [298, 301] were identified evaluating PFMT plus electrical stimulation, one of which was an abstract only. Neither trial pro-

vided information on randomization, allocation concealment or outcome assessors [298](total subjects 182)In one study, results were difficult to analyse because they were reported in percentages only with no standard deviations [301] and continence was defined broadly as 0 or 1 pad per day. Both authors stated a pad test was done but do not provide details of the pad test (1 hr, 24 hr).

b) Results

Wille reported on a study of 139 men who were randomized to three groups: verbal instructions; verbal instructions plus ES; or verbal instructions, ES, and biofeedback [301]. Treatment began after catheter removal and continued for 12 weeks. Mean percentage differences on 20 minute pad test at 3 and 12 months post surgery were not significant between groups at either of the post op time points, with an overall continence rate of 86% at 12 months post surgery. Opsomer [298] randomised men to biofeedback plus electrical stimulation (n=21) or a single session of verbal instruction with encouragement to do home exercises (n=22). Follow up with pad test at 12 weeks showed no difference between groups.

c) Summary

The addition of biofeedback did not appear to improve outcomes compared to verbal instruction. **Level of Evidence: 2**

d) Recommendation

Further studies on the topic must follow the Consort Guidelines for reporting data and include means, standard deviations, and details of statistical analysis to allow proper comparisons.

Grade of Recommendation: C

6. PFMT FOR POST MICTURITION DRIBBLE

Post micturition dribble (PMD) is an annoying problem experienced by many men of all ages likely due to a failure of the bulbocavernosus muscle to evacuate the bulbar portion of the urethra causing pooling of urine in the bulbar urethra which dribbles with movement

a) Quality of data

Two randomised studies totalling 85 subjects who had not undergone prostatectomy were found [289, 290] in which PFMT and/or urethral milking were compared to verbal instruction and lifestyle changes. One explored directly the relationship between PMD and PFMT and the other had a subgroup of 36 men with PMD who were being treated conservatively for

erectile dysfunction. Randomisation was with computer generated list (not stated if researcher blinded to list sequence) [289] or sealed envelopes which the subject opened [290]. In both studies data collection was done by the researchers but data analysis was done by separate party.

b) Results

Paterson [289] assessed men assigned to daily PFMT, urethral milking, or lifestyle changes, using 4 hour pad test at 5, 9, and 13 weeks. Both PFMT and urethral milking were found to be equally effective and better than lifestyle changes, relaxation therapy, and oedema management. In another study on PFMT to treat erectile dysfunction over 65% (n=36) of subjects also complained of PMD. Subjects were randomized to the PFMT using biofeedback (5 weekly treatments plus home exercises) or lifestyle recommendations. Outcome was based on subject report using a standardized questionnaire administered by an interviewer unaware of group assignment. The PFMT group not only reported a significant improvement in erectile function (p=0.001) but also a significant improvement in PMD (p<0.002)[290].

c) Summary

Both PFME and urethral milking appear to be effective in the control of the annoying symptom of post micturition dribble. **Level of Evidence: 2**

d) Recommendation

Men can be offered instruction to do a strong PFM contraction immediately after voiding or urethral massage to empty urethra and improve symptoms of post micturition dribble.

Grade of Recommendation: C.

C 3. PHYSICAL THERAPIES - ELECTRICAL STIMULATION

Electrical stimulation is reported to be effective in the treatment of both stress and urge urinary incontinence in men [189, 202, 302]. Male detrusor overactivity including urge incontinence is due to neurogenic disorders and to bladder outlet obstruction such as benign prostatic hyperplasia. Male urodynamic stress incontinence is extremely rare but radical prostatectomy and, rarely, transurethral resection of the prostate may cause sphincter injury leading to stress incontinence [282, 303-305]. Detrusor overactivity, poor compliance and decreased contractility may also be factors related to post-prostatectomy incontinence [282, 306].

- **Electrical stimulation for urge incontinence in men**

Similar to women, the etiology of urge incontinence in men is neurogenic, idiopathic and bladder outlet obstruction [307]. Besides this, many elderly men may also have prostatic enlargements with subsequent symptoms of urgency, frequency, nocturia and urinary incontinence [308, 309]. Electrical stimulation can be effective for urge incontinence in both sexes, and is believed to be due to reflex inhibition of pelvic efferents or activation of hypogastric efferents through stimulation of the afferent input in the sacral route [182, 302]. However, there can be differences in the effects of electrical stimulation between men and women because of difference in gender, etiologies and electrodes used.

- **Electrical stimulation for stress incontinence in men**

Stress incontinence in men is rare, caused mostly by surgery (post-prostatectomy) or trauma. The most common cause of post-prostatectomy incontinence is stress incontinence due to sphincter dysfunction. Thus electrical stimulation can be used for post-prostatectomy incontinence by enhancing contractility of the pelvic floor muscles in the same way as female stress incontinence [309, 310].

PFMT is reported to be the mainstay therapy for post-prostatectomy. Electrical stimulation may be used as stand alone therapy, as a second-line treatment when other methods have failed, or in combination with PFMT [296, 301]. It has been postulated that continence is regained more rapidly [275] and the duration of the application of electrical stimulation is reduced when PFMT is augmented with electrical stimulation [275, 311]. Electrical stimulation is also believed to be more effective in patients who are initially unable to identify and contract the correct pelvic floor muscles[85]. Some state that cancer is a contra-indication for ES as it is not known if ES stimulates an increase in abnormal cell activity [264]although there are no research data to support this. Therefore many physiotherapists are unwilling to use ES for patients with cancer and following radical prostatectomy. Although there is insufficient evidence for this proposed contraindication, further research should clarify this potential danger.

I. PREVENTION

There have been no studies on the preventative role of ES for the treatment of urge incontinence or post prostatectomy incontinence in men.

II. TREATMENT

The aim of this subsection is to address the following questions:

- What is the most appropriate electrical stimulation protocol?
- Is electrical stimulation better than no treatment, placebo or control treatments for urinary incontinence?
- Is electrical stimulation better than other treatments?
- Does the addition of other treatments add a benefit to electrical stimulation or does the addition of electrical stimulation to other treatments add any benefit?
- What is the effect of electrical stimulation on other LUTS?
- What factors might affect the outcome of electrical stimulation?
- **WHAT IS THE MOST APPROPRIATE ELECTRICAL STIMULATION PROTOCOL?**

ES protocols for men are almost similar to women. Usually intermittent, short-term stimulation (maximal electrical stimulation: MES) using a portable stimulation device in home-use has been used. In males ES can be applied by rectal or surface electrodes. Although both kinds of electrodes have been reported to be safe [182], sometimes patients do not tolerate rectal plug electrode because of pain, discomfort, mucosal injury or exacerbation of haemorrhoids. Surface electrode (Transcutaneous electrical neurostimulation: TENS) are less invasive, and are preferred by some for the treatment of urge incontinence in men. The surface electrodes were positioned over the dorsal nerve of penis or peri-anal region, both at the S3 dermatome [311-313], tibial nerve [314, 315], the quadriceps and hamstring muscles[316], suprapubic region or the skin directly over the third sacral foramina [313]. For the treatment of post-prostatectomy incontinence, ES has been usually used in combination with PFMT. Usually a rectal electrode is used, and the stimulation artificially stimulates the pudendal nerve and its branches to cause direct reflex responses of the urethral and periurethral striated muscles.

Frequencies of 5 to 20Hz are recommended for urge incontinence, and 20 to 50 Hz is used for stress (post-prostatectomy) incontinence [179, 199, 202]. Although a wide range of values has been claimed to

be successful, the optimum has not been determined [317]. Duration of the stimulation varies according to investigators, from 15 minutes [315, 318] to 20 minutes each [195], from twice daily [179, 315], every other day [318] to twice weekly [195]. As for the number of sessions needed, some suggest at least ten treatments before the clinical effect should be assessed [199, 319] and a session of 4-6 weeks [315, 317, 320] to 14 weeks [318] of stimulation might be necessary before significant objective improvements are seen.

• SUMMARY

ES protocols for men have been developed from the female literature. It is not clear if any particular ES protocol is more effective than any other. The variability in the findings of the trials included in this section may in part be due to differences in the effectiveness of the wide range of protocols that have been tested. There are many differences in clinical application that have not yet been investigated. For the treatment of post-prostatectomy incontinence, ES using a patch or rectal electrode has been usually used in combination with PFMT. Some populations or subgroups of men may benefit from ES plus PFMT more than others. However, this observation has not been fully investigated to date.

• IS ELECTRICAL STIMULATION BETTER THAN NO TREATMENT, PLACEBO OR CONTROL TREATMENTS FOR URINARY INCONTINENCE?

ES versus no treatment or control treatment

No studies were identified which addressed this comparison.

ES versus placebo ES

For ES in post-prostatectomy incontinence, most studies suggest that electrical stimulation is successful but suffer from lack of control groups, have only small sample sizes, and do not include objective measures of incontinence. Moreover, long-term follow-up is lacking and the uncontrolled nature of the studies does not account for a placebo effect or for spontaneous improvement that may occur up to 12 months after surgery [296, 310].

a) Quality of data

There is no study of electrical stimulation versus placebo in urinary incontinence reported exclusively in

men. Two placebo controlled-studies were identified including both sexes: one for urge incontinence and the other for stress incontinence [182, 189]. These studies were blinded for both patients and doctors. For ES in urge incontinence, 3 patients (8%) in the active group and 1 patient (3%) in the sham group dropped out, and 2 patients (5.4%) and 2 (6.5%), respectively, discontinued the treatment due to adverse events. The number of male patients (n=29) is relatively small, and stratified analysis between men and women was not performed [182]. For ES in post-prostatectomy incontinence, 2 of 35 patients (6%) dropped out and none of the patients had adverse events. However, the number of male patients (n=5) is too small to draw any conclusions [189].

b) Results

Men with urge incontinence: There is one placebo-controlled study including both sexes. A placebo-controlled randomized study by Yamanishi et al [182] included 29 men and 39 women with urge incontinence. They demonstrated significant superiority of active electrical stimulation to sham device, the cure and improvement rates being 22% and 81%, respectively, in the active group, and 4% and 35%, respectively, in the sham group.

Men with stress (post-prostatectomy) incontinence: Yamanishi et al [189] performed a placebo-controlled randomized study in 35 patients (30 women and 5 men) with stress incontinence. Four men had post-prostatectomy incontinence and one had sphincter deficiency due to sacral cord tumor. One of 5 men was cured and a second was improved by the active ES but nobody was cured or improved by sham ES.

c) Summary

There has been no study of electrical stimulation versus placebo in urge incontinence for men exclusively. There are only two placebo-controlled studies including both sexes, and the number of male patients is too small to draw any valid conclusion whether ES is better than placebo or not in men. (Level of Evidence: 2)

d) Recommendation

Further randomized controlled study in large samples and long-term follow up may be necessary for the treatment of urinary incontinence in men exclusively.

Grades of recommendation: D

- **IS ELECTRICAL STIMULATION BETTER THAN OTHER TREATMENTS?**

There are three randomized-controlled studies comparing ES vs other treatments. Two studies compared electrical stimulation with magnetic stimulation; one study included both men and women for urge incontinence [183], and another study included men with post-prostatectomy incontinence [206]. One study had a crossover design comparing ES with medication including both men and women with urge incontinence [184].

ES VERSUS MAGNETIC STIMULATION

a) Quality of data

Two RCTs were identified. One study is an investigational urodynamic study on the inhibition of detrusor overactivity comparing electrical stimulation with magnetic stimulation in both sexes [183]. In this small trial, random allocation concealment was adequate, but no subgroup results between men and women were reported. Another study included men with post-prostatectomy incontinence and compared ES, magnetic stimulation and PFMT [206]. Treatment sessions were 20 minutes, twice a week for two months and followed up for six months.

b) Results

Yamanishi et al [183] compared the effects of functional magnetic stimulation on the inhibition of detrusor overactivity with electrical stimulation in 32 patients (15 males, 17 females; aged 62.3 ± 16.6 years). Although bladder capacity at first desire to void and maximum cystometric capacity increased significantly in both groups, the increase in maximum cystometric capacity was significantly greater in the magnetic stimulation group ($105.5 \pm 130.4\%$ increase compared with the pretreatment level) than that in the electrical stimulation group ($16.3 \pm 33.9\%$ increase).

Yokoyama treated 36 men with post-prostatectomy incontinence and randomly allocated into ES, magnetic stimulation and PFMT group (12 men in each group) [206]. They found that the leakage weight during the 24 hours after removing the catheter was 684, 698 and 664 g for the ES, magnetic stimulation and PFMT groups, respectively. At 1 month, it was 72, 83 and 175 g (ES vs PFMT, $p < 0.05$), and at 2 months was 54, 18 and 92 g (magnetic stimulation vs PFMT $p < 0.05$), respectively. Finally, 6 months later, the average 24-hour leakage weight was less than 10 g in all groups. No complications were noted in any of the groups. They concluded that both magnetic and electrical stimula-

tion offered earlier continence compared with PFMT after radical prostatectomy.

c) Summary

Only two RCTs were identified for ES vs magnetic stimulation. One RCT compared ES with magnetic stimulation in urge incontinence including both sexes, but studied only urodynamic effects on the inhibition of detrusor overactivity. Another RCT included post-prostatectomy incontinence in men. The sample size of men in these two studies was small and there is insufficient evidence to determine whether ES is better than magnetic stimulation in men. (Level of Evidence:2)

d) Recommendation

High quality RCT's with an appropriate sample size and with long-term follow up are urgently required to investigate these comparisons.

Grades of recommendation: D

- **ES VS MEDICATION**

a) Quality of data

One RCT was identified which had a crossover design comparing ES with medication for urge incontinence in both sexes [184].

b) Results

Soomro et al [184] compared the effects of transcutaneous electrical nerve stimulation (TENS) over the perianal region with oxybutynin in 43 patients (13 men, 30 women) with detrusor overactivity, and reported that both treatments improved subjective parameters but that only oxybutynin showed significant improvements in objective urodynamic parameters such as bladder volume at first desire to void and at first overactive detrusor contraction.

c) Summary

This RCT comparing ES vs medication showed that both treatments were equally effective subjectively but that only oxybutynin improved urodynamic parameters for urge incontinence including both sexes. However, the number of men is too small to draw any conclusions whether medication is better than ES or not. (Level of Evidence:2).

No studies were identified ES vs other treatments for stress incontinence.

d) Recommendation

Since there are no randomized trials of electrical stimulation vs other therapies in urinary incontinence reported exclusively in men, high quality RCT's with an appropriate sample size and with long-term follow up are urgently required to investigate these

comparisons.

Grades of recommendation: D

- **DOES THE ADDITION OF OTHER TREATMENTS ADD A BENEFIT TO ELECTRICAL STIMULATION OR DOES THE ADDITION OF ELECTRICAL STIMULATION TO OTHER TREATMENTS ADD ANY BENEFIT?**

a) Quality of data

There are no studies of addition of electrical stimulation to other treatments in urge incontinence in men.

Three randomized controlled studies have been identified on addition of electrical stimulation to other treatments for men with post-prostatectomy incontinence [282, 301] [298]. Moore et al [282] compared standard treatment, versus intensive PFMT versus intensive PFMT plus rectal electrical stimulation in 63 men. Wille et al [301] compared PFMT alone, PFMT plus electrical stimulation and PFMT plus electrical stimulation plus biofeedback in 139 men. Opsomer et al [298] compared intensive PFMT plus electrical stimulation plus biofeedback training, with simple PFMT in 43 men.

b) Results

Men with post-prostatectomy incontinence: Moore et al [282] compared standard treatment (verbal and written instructions about PFMT), versus intensive PFMT versus intensive PFMT plus rectal electrical stimulation (twice a week) in 63 men with urinary incontinence ≥ 8 weeks after radical prostatectomy. Incontinence improved greatly in all three groups, but no differences were noted among the three groups in terms of the amount of urine loss at 16 and 24 weeks, or the QOL scores with IIQ-7 or QLQ C30. Wille et al [301] randomized 139 patients who underwent radical prostatectomy into three groups: those received PFMT alone (n=47), those who received PFMT plus electrical stimulation (n=46) and those PFMT plus electrical stimulation plus biofeedback (n=46). Overall subjective continence percentage (questionnaire) was 21.4% immediately after catheter removal, 59.2% after 3 months and 85.9% after 12 months, and there was no significant difference between groups. Overall objective continence percentage (pad test) was 32.9% immediately after catheter removal, 65% after 3 months and 83% after 12 months without any significant difference between groups. Opsomer et al [298] compared intensive PFMT plus electrical stimulation once a week plus biofeedback training (n=21), with simple PFMT (n=22). No statistical significant difference

was found between the two groups in terms of cure.

c) Summary

There is no study of the addition of electrical stimulation to other treatments in urge incontinence on men. Three randomized controlled studies have been identified regarding the addition of electrical stimulation to other treatments for men with post-prostatectomy incontinence. From these three randomized trials, electrical stimulation did not show any additional improvements compared to PFMT alone, however the numbers were relatively small. (Level of Evidence:2)

d) Recommendation

Although it seems that at present there is no extra benefit in adding electrical stimulation to PFMT, this hypothesis needs to be investigated in further high quality trials.

Grades of recommendation: B

III. OTHER LUTS

No studies were identified which addressed this comparison in men.

IV. FACTORS AFFECTING OUTCOME

a) Age

Incontinence is a common condition that increases markedly with advancing age [321]. In elderly men, urge incontinence is the most frequent type of incontinence, but co-morbid conditions, either related or unrelated to the lower urinary tract as well as prior prostate surgery are significant factors [322]. Resnick et al reported that, in 94 of the 245 incontinent patients (77 women and 17 men), detrusor overactivity was the predominant cause in 61%, with concomitant impaired detrusor contractility present in half these patients. Up to 30% of elderly men in long term care may have bladder outlet obstruction, and 50 to 75% of men with bladder outlet obstruction may have detrusor overactivity symptoms [308, 321].

Device-based conservative therapies for urinary incontinence have been studied very little in older persons. Elderly men may have more co-morbid conditions than young men, such as dementia, changes in the secretion of vasopressin, venous

insufficiency, renal disease, heart failure, drug intake, restricted mobility and constipation many studies of electrical stimulation for urinary incontinence include young-elderly and some middle elderly subjects [319]. The efficacy of electrical stimulation for urge incontinence in elderly men might be the same as that of women. Mean age of the patients reported in the studies of electrical stimulation for post-prostatectomy incontinence is 65-67 years old, thus these studies mostly included elderly men but with incontinence primarily as a result of sphincter incompetence rather than pure overactive bladder symptoms.

• **RECOMMENDATIONS**

Although studies of electrical stimulation for post-prostatectomy incontinence mostly included elderly men, there are no studies comparing the effects of electrical stimulation for urinary incontinence between young and elderly men. Further RCTs comparing the effects of electrical stimulation for urinary incontinence between young with elderly men may be necessary.

Grades of recommendation: D.

b) Other

Many other factors, such as types of electrodes, intensity, frequency and duration of stimulation, electrode positioning, diagnosis and underlying cause, patient selection, study design, outcome parameters and side effects may be factors affecting outcome.

As already has been stated in the ES protocols section, rectal or surface electrodes are used in males. Interferential therapy, another type of stimulation, which is generated by interferential waves, has also been reported to be effective in older references [125, 323]. The positioning of surface electrodes was various: over the dorsal nerve of penis or peri-anal region, both at the S3 dermatome [311-313], tibial nerve [314, 315], the quadriceps and hamstring muscles[316], suprapubic region or the skin directly over the third sacral foramina [313]. The intensity of stimulation is recommended to be up to the maximum tolerable level, because many authors report that the stronger the intensity, the better the outcome [179, 183, 189, 195, 199, 202, 302]. Frequencies and duration of the stimulation, and the number of sessions varies according to investigators. These factors as well as patient selection and compliance may affect outcome. However, there are no studies comparing these factors in male patients.

• **RECOMMENDATIONS**

There are no studies investigating these factors affecting outcome in male patients.

Research should first focus on identification and proper description of factors affecting outcome of ES. After this, the focus should be on how and to what extent these factors affect outcome of ES-treatment and whether or not these factors can be influenced by ES.

Grades of recommendation: D

C4. PHYSICAL THERAPIES – MAGNETIC STIMULATION

Background information, advantages and use of magnetic stimulation for urinary incontinence in women have already been discussed (ref ii) subsection 6). Magnetic stimulation has also been used in men however it unclear whether the mode of action and effects of magnetic stimulation are similar in men as in women.

Magnetic stimulation is used to treat urinary incontinence after radical prostatectomy [206, 324] and for the inhibition of detrusor overactivity [183].

I. PREVENTION

In this subsection the question ‘Is magnetic stimulation effective for the primary/secondary prevention of urinary incontinence in adult men?’ is addressed. The literature search revealed no systematic reviews or (q)RCTs addressing prevention of urinary incontinence.

No trials investigating the primary/secondary prevention effects of magnetic stimulation for adult men with urinary incontinence were found.

II. TREATMENT

The aim of this subsection is to address the following questions:

- Is magnetic stimulation better than no treatment, placebo or control treatment for urinary incontinence?
- Is one type of magnetic stimulation better than another?
- Is magnetic stimulation better than other treatments?

- What factors might affect the outcome of magnetic stimulation?

Only 3 RCTs were identified, two full manuscripts and 1 abstract [183, 206, 324]. Readers should note that the trial by Yamanishi et al [183] included both men and women with urinary incontinence. It is possible that the effects of magnetic stimulation might be different between sexes (due to differences in the underlying cause of detrusor overactivity) so this study has not contributed to the analysis where they do not differentiate the effects of treatment in women versus men.

The study of Nehra is still ongoing, no data are yet available.

- **MAGNETIC STIMULATION VERSUS NO TREATMENT, PLACEBO OR CONTROL TREATMENTS**

No studies were found addressing this question.

No trials comparing approaches to magnetic stimulation were found. Research is needed.

- **ONE APPROACH TO MAGNETIC STIMULATION VERSUS ANOTHER**

No studies were found addressing this question.

- **MAGNETIC STIMULATION VERSUS OTHER TREATMENTS**

Two studies were identified. One study was found that compared magnetic stimulation with electrical stimulation in men (and women) with detrusor overactivity [183]. This comparison is described and evaluated in the section of electrical stimulation in women above. The magnetic stimulator unit was set on an armchair type seat and had a concave-shaped coil. For electrical stimulation, a surface electrode on the dorsal part of the penis was used. Stimulation was applied continuously at 10 Hz in both groups.

Another study compared effects of magnetic vs electrical stimulation in men with urinary incontinence after radical prostatectomy [206].

Yokoyama used 3 research groups [206]. Magnetic stimulation was given with the Neocontrol system. Treatment sessions were for 20 minutes, twice a week for 2 months. Frequency of the pulse field was 10 Hz for 10 minutes, followed by a second treatment at 50 Hz for 10 minutes. For electrical stimulation, an anal electrode was used. Pulses of 20 Hz square waves at a 300 Fs pulse duration were used for 15 minutes twice daily for 1 months. The control group received only pelvic floor muscle exercises.

a) Quality of data

In the single, small trial of Yamanishi [183] allocation concealment was adequate. In the other study the authors simply stated that allocation was at “random”.

Blinding of assessors was reported in none of the studies. In none of the trials was a power calculation performed. In both studies group sizes were less than 25 men to each comparison group.

The two trials did not report whether or not they had any dropouts or losses to follow up. One trial followed men up beyond the post treatment evaluation for six months [206]. There was no post treatment follow-up in the other study.

b) Results

1. URINARY INCONTINENCE AFTER RADICAL PROSTATECTOMY

Yokoyama found that the leakage weight during the 24 hours after removing the catheter was 698, 684 and 664 g for the magnetic stimulation, electrical stimulation and control groups, respectively [206]. At 1 month, it was 83, 72 and 175 g (electrical stimulation vs controls, $p < 0.05$), and at 2 months was 18, 54 and 92 g (magnetic stimulation vs controls $p < 0.05$), respectively. Finally, at 6 months, the average 24-hour leakage weight was less than 10 g in all groups. Quality-of-life measures decreased after surgery, but gradually improved over time in all groups. No complications were noted in any of the groups. It was concluded that both magnetic and electrical stimulation offered earlier continence compared with the control group after radical prostatectomy.

With only one single small trial comparing magnetic stimulation with electrical stimulation there is insufficient evidence to determine if magnetic stimulation is better than electrical stimulation in men with urinary incontinence after radical prostatectomy.

2. DETRUSOR OVERACTIVITY

In the trial of Yamanishi [183] bladder capacity at first desire to void and the maximum cystometric capacity increased significantly during stimulation compared with prestimulation levels in both groups. However, the (mean \pm sd) amount the maximum cystometric capacity increased was significantly greater in the magnetic stimulation group (than that in the electrical stimulation group (114.2 \pm 124.1 ml vs 32.3 \pm 56.6 ml). The authors concluded that, although both treatments were effective, the inhibition of detrusor overactivity appeared to be greater in the magnetic stimulation group than in the electrical stimulation group. Because of the small numbers in

this trial and the fact that both women and men were included and no subgroup results were reported this conclusion seems to be premature.

With only one single small trial comparing magnetic stimulation with electrical stimulation there is insufficient evidence to determine if magnetic stimulation is better than electrical stimulation in men with detrusor overactivity.

c) Summary

For comparisons of magnetic stimulation with electrical stimulation reporting was limited to two relevant trials, one in men with urinary incontinence after radical prostatectomy, another in men with detrusor overactivity, providing insufficient evidence for the effect of magnetic stimulation in men with these kind of health problems.

d) Recommendations

Further high quality RCTs, using adequate sample sizes, are necessary.

III. OTHER LUTS

No studies were found.

IV . FACTORS AFFECTING OUTCOME

None of the trials specifically recruited older men. None of the trials, included in this subsection on magnetic stimulation, reported factors affecting outcome.

However, in a study of Sand et al. [216] risk factors predicting success of magnetic stimulation in *women* were evaluated. A successful response to therapy was statistically associated with the absence of risk factors as prior anti-incontinence operations, incontinence of greater than 10 years' duration and the use of medications known to cause incontinence.

Other factors that might influence success or failure of magnetic stimulation are body habitus (thin patients have most significant detrusor responses, presumably due to a shorter distance between the stimulating coil and the sacral nerve roots), and bladder volume (in 11 spinal-injured patients the detrusor response to magnetic stimulation dampened with increasing bladder volumes) [217]. Finally, the most effective treatment parameters and protocols are not yet to be determined [205].

None of the included trials addressed the effect of age, or any other factor, on outcome of magnetic stimulation. A few authors indicate the relevance of some factors but the causal relationship between these factors and the outcome of magnetic stimulation has yet to be determined

C5. SCHEDULED VOIDING REGIMES

Scheduled Voiding Regimes include bladder training, timed voiding, habit training and prompted voiding. They are frequently combined to achieve maximum benefits. Although there is evidence to indicate that scheduled voiding regimens, especially bladder training and timed voiding, are commonly used in the treatment of men with urinary incontinence and other lower urinary tract symptoms, there has been substantially less literature that addresses their use in men as compared to the vast literature on their use in women

I. PREVENTION

No trials investigating the prevention effects of scheduled voiding regimens for men with urinary incontinence were found

II. TREATMENT

Since the last review by the Second International Consultation on Incontinence, there have been two reports involving bladder training that have included men in the study population [36]. Three earlier reports were also located, although these included only a small number of men in the sample [235, 236, 240].

a) Quality of data

1. BLADDER TRAINING

A total of 5 RCTs involving 142 men met the criteria for inclusion in this review. All trials which were previously described in the section on Quality of Included Studies under Scheduled Voiding Regimens in Women had predominantly female participants; one RCT compared bladder training to bladder training and caffeine reduction (7 men, 86 women) [36]; and three RCTs compared bladder training and placebo

to anticholinergic drug therapy available prior to 1995 (Castleden et al., 6 men, 28 women [240]; Wiseman et al., 4 men, 30 women [236]; Szonyi et al., 2 men, 58 women [235]). The largest RCT compared bladder training plus anticholinergic drug therapy to drug therapy available after 1995 (123 men, 378 women) [8]. A sixth study comparing bladder training supplemented with drug therapy after 3 months was located but was excluded from review because the full length report was only available in Japanese [325].

2. TIMED VOIDING

There was only one case series report located on timed voiding in men [224]. In this study, 20 men who were awaiting behavioural therapy for persistent post-prostatectomy incontinence were instructed to void every two hours and keep a daily bladder record. Outcomes were measured by a 2-week voiding diary kept at baseline and during 2 weeks of timed voiding by patients diagnosed with stress incontinence, urge incontinence, and continual leakage.

3. HABIT TRAINING

There are no articles reporting this method exclusively in men.

4. PROMPTED VOIDING

There are no articles reporting this method exclusively in men.

b) Results

1. BLADDER TRAINING

Mattiasson et al [232] reported that, in a single-blind study in 501 patients (25% men) with overactive bladder, bladder training plus tolterodine (2mg) was more effective than tolterodine alone, in terms of reduction in voiding frequency and the increase in volume voided per void, but that the reduction of incontinence episodes was not significantly different between the two treatment groups.

2. TIMED VOIDING

There is limited evidence on the effect of timed voiding in men. Sogbein et al [326] applied timed voiding in incontinent men in a geriatric hospital with an 85% improvement rate. In a case series report [224], 2 hour timed voiding was used with only 12 out of 20 men aged 55 to 89 years with persistent post-prostatectomy incontinence because the men were either already on or unwilling to go on a voi-

ding schedule or results were not presented because the patient was noncompliant. In five men with stress incontinence, timed voiding resulted in a 28.5% decrease of incontinent episodes; in three men with urge incontinence, two improved and one dramatically regressed producing a 33.1% increase in incontinent episodes; and in 4 patients with continual leakage, there was no reduction in % wet intervals.

3. HABIT TRAINING

There are no articles reporting this method exclusively in men.

4. PROMPTED VOIDING

There are no articles reporting this method exclusively in men. Although published studies generally concluded the technique had a favourable effect, these studies are usually not adequately controlled [226]. Other disadvantages of this method are that it requires considerable manpower and compliance from nursing staff [327].

c) Summary

There is insufficient evidence to comment on the effect of bladder training, timed voiding and prompted voiding either alone or in combination with other treatments in men suffering from urinary incontinence. No evidence is available relating to habit training in men.

d) Recommendations

High quality RCTs with an appropriate sample size and with long-term follow up are urgently required to look at the effects of bladder training, timed voiding, habit training and prompted voiding in men suffering from urinary incontinence

Grades of recommendation: C.

III. OTHER LUTS

No studies were identified in men.

IV. FACTORS AFFECTING OUTCOME

a) Age

The 5 RCTs involving bladder training included older men as well as women in their study populations. Three trials specifically recruited elderly

adults ages 65-70 and over [235, 236] [240]. The largest trial of men recruited adults age 18 and over with a median age of 62 years.

There were no subgroup analyses related to age and gender effects so it is not possible to draw conclusions regarding the effect of bladder training in older men [232]. Voiding regimens are of particular interest vis-à-vis the elderly, but some are effective in younger patients with urge incontinence [218].

b) Others

Five of the 15 trials reported on factors affecting the outcomes of bladder training; none of these trials were with men. No studies were identified on other factors affecting outcome of timed voiding and prompted voiding in men.

Patients who appear to benefit most are highly motivated individuals without cognitive deficits. Men and women with stress and urge incontinence have benefited, whereas patients with severe sphincter damage (e.g. after radical prostatectomy) generally do not benefit [218].

C 6. COMPLIMENTARY THERAPIES

Similar to women, complimentary therapies including acupuncture are used for the treatment of male incontinence. Acupuncture is a traditional Chinese modality and has been used for the treatment of urinary disturbances. Acupuncture has been reported to relieve overactive bladder symptoms including urinary incontinence due to spinal cord injury [242], and idiopathic detrusor overactivity or mixed incontinence [243, 244, 328]. Other trials include relaxation, meditation, imagery, hypnosis and naturopathic and herbal remedies. However, only trials of acupuncture therapy have been found in men with urinary incontinence.

I. PREVENTION

No studies were identified on the preventative role of complimentary therapies in men.

II. TREATMENT

Acupuncture of urge incontinence in men: It has been shown to improve urodynamic parameters such

as bladder capacity [242, 328]. Acupuncture is a form of somatic sensory stimulation[243]. The mechanism by which acupuncture inhibits detrusor overactivity remains unclear, but suppression of the spinal and supraspinal reflexes that lead to bladder contractions is considered one of the most important mechanisms of acupuncture stimulation. In an experimental study with anesthetized rats, an acupuncture-like stimulation of the perineal skin and muscles inhibited detrusor contraction [329, 330]. A release of neuropeptides (e.g. endorphins) by acupuncture may be another possible mechanism of increasing the bladder storage [243].

Acupuncture of stress incontinence in men: Acupuncture may also change sphincter activity. Urethral electromyography in rats showed excitation when acupuncture-like stimulation was applied to the skin and underlying structures in the rostral half of the body, the hind paw, the perineal area, testis or urethra, while a reduction of this electromyography was seen when the bulbocavernosus, sacrococcygeus or pubococcygeus muscles were stimulated [331]. Kubista et al [332] showed a significant increase in the urethral closing pressure. However, there has been no report on the effects of acupuncture for male stress or post-prostatectomy incontinence.

Acupuncture protocols

Acupuncture was carried out with disposable stainless steel needles (0.3mm in diameter, 60mm in length) inserted into the bilateral BL-33 (Zhongliao) points on the skin of the third posterior sacral foramina [242, 244, 328] or several other points (BL-31,32, 21, 23, SP-6, KI-3, LI-11,CV-1,2,4,5 according to [333], usually performed once or twice weekly [242-244, 328, 334]. Thus the acupuncture protocols are determined depending on the investigators, and there is no evidence indicating what is the most effective acupuncture protocol (Level of evidence: 4).

Acupuncture Treatment for Urinary Incontinence

a) Quality of data

Only one RCT has been identified including both men and women[335], but there is no study exclusively for men. No reports were found on the effects of acupuncture for male stress or post-prostatectomy incontinence.

b) Results

In an uncontrolled study, Kitakoji et al [328] treated 11 patients (9 males 2 females) with overactive bladder including 3 with benign prostatic hyperplasia.

Improvement of symptom was noted in 9 patients (82%), overactive detrusor contractions disappeared in 6 (55%) and significant improvements in both maximum cystometric capacity and bladder compliance were obtained after the treatment. Acupuncture was found effective in all 3 patients with benign prostatic hyperplasia. Honjo et al [242] have reported an improvement of urinary incontinence due to neurogenic detrusor overactivity in 13 patients (11males, 2 females) with chronic spinal cord injury. The treatment was repeated once a week for four weeks. Incontinence disappeared in 2 (15%) and decreased to 50% or less compared to baseline in 6 (46%). Maximum cystometric capacity increased significantly from 76.2±62.3 to 148.1±81.5 ml 1 week after the 4th acupuncture.

In randomized controlled study, Ellis et al [335] showed that the frequency of voiding at night was reduced after acupuncture in a randomized-placebo-controlled single-blind study among 20 elderly patients (3 males, 17 females).

c) Summary

Most studies suggest that acupuncture is effective and can be an alternative to the pharmaceutical therapy, for both men and women, for the treatment of urge incontinence. Its use is, however, limited due to difficulties in the skill, and the lack of controlled studies. However, control groups are missing, sample sizes are small, objective measures of incontinence are not included and long-term follow-up is lacking. (Level of Evidence: 4)

d) Recommendations

Further randomized controlled study comparing acupuncture with no therapy, sham-puncture, medication and other complimentary study, in large samples and long-term follow up may be necessary for the treatment of urinary incontinence in men exclusively.

Grades of recommendation: D

III. OTHER LUTS

Honjo et al [242] reported the effects of acupuncture on monosymptomatic nocturnal enuresis. Fifteen (10 males, 5females) patients with monosymptomatic nocturnal enuresis were treated, and nocturnal enuresis was improved in 6patients (40%) just after the treatment and 7 (45%) 2 months after. In 6 responders, the nocturnal bladder capacity increased signi-

ficantly, from 201 to 334ml ($p<0.05$). In a randomized controlled study in patients with sensory urgency after transurethral resection of the prostate, Ricci et al [334] reported significant improvements by acupuncture reflexotherapy (electrical stimulation of somatic and auricular points) in terms of IPSS, QOL scores, decrease of daytime frequency and nocturia, but no improvements with the use of placebo or oxybutynin.

IV. FACTORS AFFECTING OUTCOME

a) Age

Only one randomized-placebo-controlled single-blind study in elderly has been found for acupuncture. Ellis et al [335] showed, in a randomized-placebo-controlled single-blind study among 20 elderly patients (3 males, 17 females), that the frequency of voiding at night was reduced after acupuncture.

b) Other

No trials have been found on other factors affecting outcome of complimentary therapies in men.

D. CONSERVATIVE MANAGEMENT PROGRAMMES FOR WOMEN AND MEN

Conservative management comprises non-surgical, non-pharmaceutical, intervention for urinary incontinence. Common elements of conservative management are lifestyle interventions, physical therapies, scheduled voiding regimes, continence devices and product. Within each category there may be a number of single therapies. For example pelvic floor muscle training, electrical stimulation and vaginal cones are all physical therapies, and lifestyle intervention might address obesity, constipation or excessive physical forces. Although each may be used alone as an intervention for urinary incontinence (the efficacy of single components is addressed elsewhere in this chapter), single therapies are commonly combined as a conservative management programme in clinical practice. Based on clinical anecdote, the most common conservative management programme is probably a combination of bladder training with pelvic floor muscle training.

To be eligible for inclusion in this subsection a study

had to offer a conservative management programme (CMP) that included, at a minimum, one or more single therapies from two or more of the following conservative management categories; lifestyle interventions, physical therapies, and schedule voiding regimes. Thus, a trial that offers pelvic floor muscle training with bladder training was eligible, but a trial that offered combination pelvic floor muscle training/electrical stimulation was not. Further, for inclusion in this subsection a trial could not specifically recruit the frail elderly, or be set only in a nursing home or other institutionalised care environment. The effectiveness of treatment for urinary incontinence in the frail elderly is considered in a separate chapter (see chapter x). In addition, trials that recruited from selected population groups (e.g. men following prostate surgery, postpartum women) were not considered.

This subsection addresses three questions about the effectiveness of CMPs, namely:

- Can a CMP prevent urinary incontinence?
- Is a CMP better than no treatment, or control, for women and/or men with urinary incontinence?
- Is one CMP better than another?

To address these questions, the literature was searched for reports of relevant systematic reviews, and reports of randomised controlled trials (RCTs) and quasi-randomised controlled trials (qRCTs), e.g. alternate assignment (appendix x). Therefore, only Level 1 evidence is considered in this subsection. Recommendations are based on the findings of a new systematic review of RCTs undertaken by the author of this subsection (JHS).

There was little consistency in the outcome measures used and reported by trialists. The three most common outcome measures were leakage episodes, number of voids per day and number of voids per night. Some trials used pad tests, but the type of test varied. There is sufficient doubt about the comparability of data between different pad tests, and the interpretation of pad test data, that these data are not presented [70]. Nor are PFM activity data discussed; these data are a surrogate for the primary outcomes of interest. The pre-specified primary outcomes of interest were urinary incontinence, self reported cure and/or improvement in incontinence symptoms (treatment studies only), leakage episodes, number of micturiations per day an/or per night, and quality of life.

With regard to quality of data there are many quality checklists available, but no gold standard [71].

Attempting to weight primary studies in meta-analysis by quality score is problematic; the choice of scale can dramatically influence the effect estimate [72]. However, there is empirical evidence that two elements of trial quality, allocation concealment and double blinding, are important in the precision of estimating treatment effect; trials with inadequate or unclear concealment of allocation appear to overestimate treatment effect by about 30%, and trials that are not double blind overestimate effect by about 15% [73]. Therefore, trials that reported adequate allocation concealment are noted. It is often difficult, or not possible, to blind treatment providers and patients to conservative treatments, but trials that reported blinding of outcome assessment are also noted. Readers may wish to consider these factors in their interpretation of the data.

I. CONSERVATIVE MANAGEMENT PROGRAMMES (CMP) FOR PREVENTION OF URINARY INCONTINENCE

Only trials addressing the primary/secondary prevention of urinary incontinence were considered. Two trial reports were found, an abstract and full report of the same trial [336, 337]. Diokno and colleagues recruited continent community dwelling women aged 55 to 80 years. Continence was defined as absolute continence (no leakage episodes), or continence (five or less leakage episodes in the previous 12 months). At baseline 39% were absolutely continent, and 61% continent. The women were randomised to a behavioural modification program or no treatment. Behavioural modification comprised a two hour group session on PFMT and bladder training from continence specialists; women also received an audiotape of PFMT instructions. An individual visit with a nurse took place two to four weeks later to test understanding, and correct any misunderstandings.

a) Quality of data

Random allocation concealment was probably adequate. Data on the primary outcomes was collected by questionnaire. The trial randomised 480 women (242 control, 238 treatment). About 25% of participants dropped out, or were eliminated by the investigators (e.g. for missing data, lack of VPFMC, severe prolapse) at the clinic visit two to four weeks after treatment. Of the remaining 359 women, 11% were lost to follow up over the succeeding 12 months.

Women were evaluated two to four weeks after the education program, then at four monthly intervals, up to 12 months (primary endpoint).

b) Results

In the treatment group 37% reported absolute continence at every assessment after treatment, compared to 28% of controls (RR 1.31 95% CI 0.95 to 1.80). Fifty six percent of the treatment group, and 41% of controls, reported the same or better level of continence at 12 months (RR 1.36 95% CI 1.08 to 1.71). Data on frequency and nocturia were presented without a measure of variation.

c) Summary

For some participants this trial investigated the primary/secondary prevention effect of a CMP. For those who had five or less leakage episodes in 12 months, this may or may not be considered a primary/secondary prevention trial; it depends how the reader defines continence. However, in a sample of older community dwelling women, a two hour group presentation on good bladder habits, PFMT and bladder training, followed by a single clinic visit, was more likely to maintain or improve existing continence status than no treatment.

d) Recommendations

Community based group sessions, taught by continence specialists, might be an effective way to maintain or improve continence status in older women who are already continent, or are rarely incontinent. (Grade B)

II. CMP FOR TREATMENT FOR URINARY INCONTINENCE

1. CMP VERSUS NO TREATMENT, PLACEBO, SHAM OR CONTROL TREATMENTS

Trials were considered for inclusion if they compared a CMP with no treatment, or a CMP with control treatment (e.g. advice on protective pads). Nine trials were found; three were excluded [103, 337-339]. Borrie et al. [338] was reported in three conference abstracts, none of which contained any useable data. O'Brien et al [103] and Fonda et al [339] combined the data from control and treatment groups in their reports.

Five of the six studies recruited only women, with symptoms of stress, urge or mixed urinary inconti-

nence [1, 109, 233, 340, 341]. One recruited women with idiopathic detrusor overactivity only [187]. Four trials recruited only older women, 50 years and older [340], 55 and older [1, 233], and 65 and older [341]

The CMP's comprised:

- Education, PFMT, and toileting behaviour. Nine individual clinic visits, one per week, with physiotherapist [342]
- Self monitoring, scheduled voiding and PFMT with biofeedback. Individual home visits as needed over six months [233]
- Instruction about protective aids, scheduled voiding, and PFMT). Individual clinic visits over three months [109]
- Advice on protective aids, bladder training, PFMT, electrical stimulation, and oestrogen if appropriate. Up to six individual clinic visits with physiotherapist, over six months [340]
- Education, changes in types and amounts of fluid if appropriate, scheduled voiding and urge suppression, and PFMT. Five group sessions, alternate weeks, over nine weeks [341]
- Education, daily urinary diary, scheduled voiding, and PFMT. Six group sessions, one a week, with nurse educator [1].

The comparison groups were offered no treatment [340, 342], home visit with nurse educator including suggestions for improving bladder control [233], instruction on protective aids [109], printed educational materials [341], and daily urinary diary [1]

a) Quality of data

Random allocation concealment was adequate in four trials [233, 340, 342, 343]. Assessors were blind in two [111, 342]. Berghmans and colleagues [342] randomised about 20 women per comparison group; other trials were bigger with about 40 [340], 50 [111], 70 [1, 341, 343] and 100 women per group [340]. Dropout rates ranged from four percent [111], to 26% [341]. All the trials reported longer term follow up (of up to two years); one reason was that controls were offered treatment and further follow up was needed to assess their response.

b) Results

Only Holtedahl and colleagues [340] gave data for self-reported cure; cure was more likely after treatment than control (RR 2.54, 95% CI 1.23 to 346.46). Pooled data from two trials [111, 340] suggested self

reported cure/improvement was even more likely (RR 11.59, 95% CI 5.21 to 25.81). Pooled data from four trials [1, 111, 233, 341] showed statistically significantly fewer incontinence episodes in 24 hours in the treatment than the control group (WMD -0.81, 95% CI -0.53 to -0.24). Pooled data from three trials [1, 233, 341] showed fewer diurnal (WMD -0.70, 95% CI -1.13 to -0.27), but not nocturnal micturitions (WMD 0.04, 95% CI -0.12 to 0.20) in the treatment group. Three trials used the long [340] or short form [341, 342] of the same quality of life measure, the Incontinence Impact Questionnaire (IIQ). All reported statistically significantly less impact of incontinence in the CMP group compared to controls after treatment.

c) Summary

There were no studies, with useable data, that addressed the effect of a CMP in a sample of men alone, or combined sample of men and women. A CMP is more effective than control treatments for women with stress, urge or mixed urinary incontinence, with improved symptoms, reduced leakage episodes, fewer daytime micturitions, and less impact of urinary incontinence on condition specific quality of life. There might not be an effect on nighttime voiding. These findings are particularly applicable to older women; five of the six included trials specifically recruited older women.

d) Recommendations

Women with stress, urge or mixed urinary incontinence should be offered a CMP as first line therapy for urinary incontinence. More research is needed to investigate the effect of CMPs, particularly in men.

Women with stress, urge or mixed urinary incontinence should be offered a CMP as first line therapy for urinary incontinence (Grade A). Most of this evidence comes from trials in older women.

2. ONE CONSERVATIVE MANAGEMENT PACKAGE (CMP) VERSUS ANOTHER

Seven trials were found. Four investigated the effect of adherence strategies in addition to a CMP [113, 344-346]. Neither Dowd et al [344] nor Gunthorpe et al [346] reported any data; these trials were excluded. Three trials compared two methods of CMP delivery [114, 347, 348]. All the included trials recruited only women. In contrast with the comparisons of CMP with no treatment, placebo, sham or control treatments, none of them specifically recruited older women.

Additional adherence strategies: In the trial by Alewijnse and colleagues [113] women with stress, urge or mixed incontinence were randomised to a control group (CMP), or one of three groups who received the CMP with additional adherence strategies. The adherence strategies comprised (a) reminders (e.g. stickers), or (b) reminders and self-help guide (i.e. written information about urinary incontinence, the CMP, and tips to tackle adherence problems), or (c) reminders with self-help guide and counselling (i.e. structured oral feedback from physiotherapist).

Kim [345] randomised women with stress or mixed incontinence to a standard care, or standard care with compliance measures. The standard care appears to have been a CMP because the outcome measures asked women to rate their adherence to sufficient fluid intake, weight control, diet for control of constipation, bladder training and PFMT. The additional adherence strategies were an audiovisual tape, exercise diary, cues to exercise and phone calls for motivation.

Methods of delivery: Demain and colleagues [114] compared individual (one 45 minute appointment) and group delivery (three one hour sessions), Moore and co-workers [347] compared nurse continence advisor (about seven clinic visits) versus urogynaecologist led treatment (about three visits), and Ramsay et al. [348] randomised women to inpatient (five days) or outpatient care (two hours once a week for two weeks). The content of the CMP was the same in both comparison groups in two trials [114, 348], with some variation in the trial by Moore and colleagues (i.e. urogynaecologist led treatment was more likely to include drug therapy in addition to the CMP). All three trials included women with stress, urge or mixed urinary incontinence.

a) Quality of data

Additional adherence strategies: Both trials were small (30 women or less per group) and neither trial reported adequate random allocation concealment or blinding of outcome assessors. Primary endpoints were three [345] and 12 months [113].

Methods of delivery: Random allocation concealment was probably adequate in two trials [114, 347], and both these trials blinded outcome assessors to group assignment. The size of the comparison groups was approximately 20 [114], 35 [348] and 70 women [347]. All three trials measured post treatment effect at about three months, and Moore and co-workers followed up a portion of their sample two or more years later.

b) Results

Additional adherence strategies: There was no overlap in pre-specified outcomes reported by the two trials. Kim [345] did not find any statistically significant difference self reported cure between the two groups, although the measure of adherence was statistically significantly greater at three months in the group receiving additional strategies (WMD 2.50, 0.58 to 4.42). Alewijnse and colleagues [113] did not find any statistically significant difference between any of the three groups receiving additional strategies and the control group in the number of leakage episodes per week, quality of life (I-QoL), or adherence measure at 12 months. Alewijnse and co-workers surveyed the physiotherapists providing treatment, and it seemed that in practice that all four comparison groups received the counselling intervention, because these strategies were an inherent part of the physiotherapists' practice.

Methods of delivery: The differences in comparisons in the three trials precluded pooling of data. Demain and colleagues [114] reported median (IQR) for average number of micturitions in 24 hours, incontinence episodes in seven days, and quality of life (IIQ-7), and found no statistically significant differences between individual and group delivery of a CMP. Moore and co-workers also presented their data as median (IQR) for number of voids/day, number voids/night, leakage episodes/week, and quality of life (UDI and IIQ), and reported no statistically significant differences between these outcomes in nurse continence advisor and urogynaecologist led treatment [347]. Ramsay and co-authors [348] did not find any statistically significant differences between inpatient and outpatient care for self reported cure/improvement, voids/day, voids/night, or leakage episodes per week.

c) Summary

With only two trials, and limited data, it is not clear if the addition of adherence strategies improves continence outcomes or long-term adherence to the content of CMPs.

None of the three trials comparing differences in CMP delivery found any statistically significant differences between the comparison groups, individual versus group contact, nurse continence advisor versus urogynaecologist led treatment, or inpatient versus outpatient care.

d) Recommendations

Given the few trials to date, larger good quality trials are needed to determine the effect of additional adhe-

rence strategies on continence outcomes, and further comparisons of methods of CMP delivery are probably warranted.

To date, there is no convincing evidence that one CMP is better than another, or one method of CMP delivery is better than another. At present, it seems that CMPs are effective (see above), and the approach to delivery doesn't matter much.

E. PELVIC ORGAN PROLAPSE

INTRODUCTION

Pelvic organ prolapse is common and is seen in 50% of parous women [349]. Women with prolapse can experience a variety of pelvic floor symptoms. Treatments include surgery and conservative management. Choice of treatment depends on the severity of the prolapse and its symptoms, and the woman's general health. Conservative treatment is generally considered for women with a mild degree of prolapse, those who wish to have more children, the frail or those unwilling to undergo surgery. Conservative treatment is defined here as lifestyle interventions, physical therapies, complementary therapies, rings and pessaries.

The aims of conservative treatment in the management of pelvic organ prolapse include:

- to increase strength, endurance and support of the pelvic floor muscles;
- to prevent the prolapse becoming worse;
- to help decrease the frequency or severity of symptoms caused by prolapse (vaginal, backache, bladder, bowel and sexual symptoms);
- to avert or delay the need for surgery;
- to provide a therapeutic/diagnostic trail (e.g. to establish, when it is not clear, whether a patient's symptoms are caused by prolapse; to determine whether urodynamics are indicated prior to prolapse surgery; or to confirm suspected incontinence).

This section will examine the evidence for the use of conservative treatments in the management of pelvic organ prolapse utilising information from two recent Cochrane Systematic Reviews [350, 351]. A summary of the search strategy used to identify relevant studies is given in Appendix 1.

E 1. LIFESTYLE INTERVENTIONS

Lifestyle interventions include weight loss, reducing exacerbating activities (e.g. lifting, coughing) and treating constipation. These interventions seek to avoid exacerbation of the prolapse by decreasing intra-abdominal pressure. The extent to which any of these lifestyle interventions are effective in managing prolapse is unknown [352].

I. PREVENTION

a) Quality of data

No body of literature about the effects that changes in lifestyle can have on preventing pelvic organ prolapse could be found. However, several studies were identified that addressed the association between occupations involving heavy lifting/strenuous physical activity, bodyweight and pelvic organ prolapse. These studies are reported here.

Two case control studies addressed the association between occupation and surgery for pelvic organ prolapse [19, 353]. Jørgensen compared the incidence of surgery for a non-specified degree of prolapse among 28,619 Danish nursing assistants, whose occupation exposed them to repetitive heavy lifting, with 1,652,533 female population controls of similar age. No adjustment for parity was made in this study. Chiaffarino [353] compared 100 control women with 108 women admitted to undergo surgery for second or third degree uterovaginal prolapse and/or third degree cystocele. Adjustments were made in this study for potential confounding effects although occupation was collected as a social class indicator and yielded no information about physical effort.

Other studies addressed the association between occupation and pelvic organ prolapse identified via physical examination although none appeared to use validated outcome measures. Spornol [354] and Bao [355] conducted case control studies in the 1980's of 200 and 364 women respectively to assess whether occupations involving hard physical labour were associated with the risk of development of pelvic organ prolapse. In the Bao study women were classified according to weight carried however in the Spornol study past work history was subjectively assessed as light, medium or heavy work. These parameters were not further quantified nor were the study questions validated. Spornol also investigated the

association between bodyweight and risk of pelvic organ prolapse. In a more recent cross-sectional study of 27,342 postmenopausal women [356] questionnaires and a pelvic examination were used to investigate factors (including occupation as assessed in four broad categories and bodyweight) associated with pelvic organ prolapse. Although the large study population allowed examination of numerous associations the study was not designed specifically to determine risk factors for pelvic organ prolapse. Similarly despite the examination for prolapse being standardised no validated grading system was used to measure prolapse e.g. POP-Q examination. Four other epidemiological studies, designed to analyse risk factors for prolapse, explored the influence of bodyweight on risk of prolapse [357-360].

b) Results

Although Hendrix [356] found no association between occupation and prolapse, all other studies outlined above reported some link. Danish nursing assistants were 1.6 times (95% CI 1.3-1.9) more likely to undergo surgery for pelvic organ prolapse than general population control women [19]; Italian housewives were 3.1 times (95% CI 1.6-8.8) more likely to undergo surgery for pelvic organ prolapse than professional/managerial women [353] [6]; 68% of women with uterine prolapse reported a history of medium/heavy work compared to 40% of control women without prolapse ($p=0.0001$) [354], the increased risk remaining after controlling for childbirth; and female workers that generally lifted more than 20kg were more likely to have uterine prolapse than other workers [355].

With respect to the association between bodyweight and risk of pelvic organ prolapse, Spornol [354] reported that 77% of women with pelvic organ prolapse were overweight compared with 45% of women with no prolapse ($p<0.001$). Hendrix [356] reported that being overweight was associated with a significant increase in the occurrence of uterine prolapse by 31%; rectocele by 38% and cystocele by 39% and obesity was associated with a significant 40%, 75% and 57% increase in each of these conditions respectively. Overweight women were also reported to be at increased risk of prolapse in both the British Oxford Family Planning Association Study [357] and the cross-sectional study in menopausal clinics in Italy [13]. This finding however was not confirmed by Samuelsson [359] or Rinne [358] who concluded that bodyweight/obesity did not predispose women to genital prolapse.

c) Summary

There is some evidence that occupations involving heavy lifting/hard physical labour or being overweight may play a role in the development of pelvic organ prolapse. Existing studies however are hampered by their cross-sectional nature, inconsistent definitions of pelvic organ prolapse, failure to adjust for potentially important variables (such as parity and socioeconomic status), failure to account for past occupational history, and use of broad occupational codes to determine level of activity.

Level of evidence: 3

d) Recommendations

Many studies are needed to fully investigate the association between both occupation/heavy lifting and bodyweight, and pelvic organ prolapse. These studies should ensure that occupation or physical activity is assessed as rigorously as possible, and that potential confounding variables are considered. Studies will also need to overcome some of the obstacles in research in this area, such as recall bias inherent in assessing lifetime occupational history or healthy worker bias, a problem when attempting to compare pelvic organ prolapse in women currently employed in heavy labour type jobs versus others. Only when the link between various lifestyle factors and pelvic organ prolapse has been more clearly established can good randomised controlled trials be set up to investigate the effects that changes in these lifestyle factors can have on preventing pelvic organ prolapse.

Grade of recommendation: C

II. TREATMENT

a) Quality of data

No studies have been identified to date that evaluate the effectiveness of lifestyle interventions in the treatment of women with pelvic organ prolapse.

b) Results

There are no results to report.

c) Summary

Currently, there is no evidence regarding the effectiveness of lifestyle interventions in the treatment of women with pelvic organ prolapse.

Level of Evidence: non-existent

d) Recommendations

Given the dearth of information in this area, many studies are needed. Regardless of study type, it is essential that the definition of pelvic organ prolapse be made in a standardised fashion using a validated outcome measure (such as the POP-Q examination).

Grade of recommendation: D

E 2. PHYSICAL THERAPIES

Physical therapies consist of methods grouped under the heading of pelvic floor muscle training. These include pelvic floor muscle assessment, pelvic floor muscle training, pelvic floor muscle bracing against increased intra-abdominal pressure when coughing and sneezing for example (termed “The Knack” [361], electrical stimulation and biofeedback. These therapies aim to improve pelvic floor muscle function.

The promotion of pelvic floor muscle training for prolapse varies between treatment centres with some providing only a patient information leaflet and others giving individual instruction from a physiotherapist [362]. Research shows that verbal teaching of pelvic floor exercises alone is insufficient [363]. It is suggested that 15% of women are incorrectly ‘bearing down’ when trying to carry out these exercises [363]. In women with prolapse, this could further add to the strain on the area and increase the degree of prolapse.

Pelvic floor muscle training appears to be effective in the treatment of urinary stress and mixed incontinence [364]. However, its role in managing prolapse is not established [365]. Some authors have extrapolated the results of trials relating to urinary incontinence, implying for example that pelvic floor muscle training would be effective for prolapse. An article published in 2002 highlighted the importance of clarifying the place of conservative treatment in the prevention and management of prolapse, particularly in relation to the role of pelvic floor muscle training [366].

I. PREVENTION

a) Quality of data

No studies have been identified to date that evaluate the role of pelvic floor muscle training in prevention

of pelvic organ prolapse in women. This lack of evidence was also noted by Harvey in a recent systematic review of pelvic floor muscle training [75].

b) Results

There are no results to report.

c) Summary

Currently, there is no evidence regarding the role of physical therapy interventions in the prevention of pelvic organ prolapse in women.

Level of Evidence: non-existent

d) Recommendations

Many studies are needed to fully investigate the role of physical therapy in the prevention of pelvic organ prolapse. Such studies should consider the exact nature and timing of any physical therapy training programme and ensure that the effects of lifestyle factors and other potential confounding variables are taken into account.

Grade of recommendation: D

II. TREATMENT

a) Quality of data

Two randomised controlled trials were found that evaluated the effects of pelvic floor muscle training [367, 368]. Piya-Anant [367] assessed the effect of pelvic floor muscle training on elderly women (aged 60 years or more) with genital (anterior) prolapse. This trial compared 324 control group women with 330 intervention group women. Details of the randomisation procedure were not provided although each group included women classified as having no prolapse, mild prolapse or severe prolapse. The intervention group women received unspecified training in pelvic floor exercises to strengthen the levator and perineal muscles and were instructed to exercise after one meal every day for 24 months. They were also given dietary advice. Women were followed-up every 6 months for 24 months allowing comparison with baseline measurements. The main outcome measure in the study, worsening of genital prolapse, does not appear to have been determined using a recognised objective measure. No allowance appears to have been made in the study for the presence of other types of prolapse i.e. posterior vaginal wall prolapse or prolapse of the apical segment of the vagina.

Jarvis [368] investigated the effect of pelvic floor

muscle, bladder and bowel training on continence, quality of life and general health symptoms of 30 women undergoing surgery for urinary incontinence and/or prolapse compared with 30 control women who received no training alongside their surgery. The intervention group received pre-operative training in pelvic floor muscle exercises, and correct voiding and defaecation techniques with reinforcement post-operatively. Degree of prolapse was not measured as a study outcome. Results presented to date include both women with prolapse and/or incontinence.

One other small cohort study assessed the effectiveness of biofeedback therapy in 32 women with a rectocele of two cm or more who were complaining of impaired rectal evacuation [369]. Each patient was given a course of biofeedback therapy consisting of approximately five outpatient sessions with a biofeedback therapist. Each session was individually tailored to the patient's needs but included counselling, health education, biofeedback techniques using surface electromyographic equipment, co-ordination exercises and behavioural therapy. The outcome measures in the study were subjectively determined by a self-administered questionnaire before, immediately after treatment, and at follow-up (median 10 months). Measurement of the prolapse was not considered as a study outcome and no control group was included in the study.

Two trials were found. One was an ongoing randomised controlled trial by Frawley and colleagues [370] and one, a feasibility study for a randomised controlled trial [371] both of which contain physical therapy interventions and include women with prolapse. In the Frawley study the physical therapy intervention is an adjunct to surgical treatment whereas the Hagen study focuses on the effect of pelvic floor muscle training alone on pelvic organ prolapse. Both studies aim to recruit 50 women.

A number of randomised controlled trials included in the review of pelvic floor muscle training for urinary incontinence in women appear to have included women with co-existing prolapse although no specific effects on prolapse were reported [364].

b) Results

Piya-Anant [367] reported that pelvic floor muscle training was effective in elderly women who had a severe degree of genital prolapse. After 24 months of pelvic floor muscle training, the rate of worsening of genital prolapse was 72.2% in the control group and 27.3% in the intervention group ($p=0.005$). In women with a mild degree of genital prolapse, the

pelvic floor muscle training intervention did not affect the rate of worsening of prolapse at 24 months ($p=0.1$). However, the rate of worsening at 12 months was significantly less for women with a mild degree of prolapse in the pelvic floor muscle training group ($p=0.02$). Jarvis[368] reported a significant improvement in both quality of life ($p=0.004$) and symptom specific problems ($p=0.02$) when pre-operative physiotherapy was given to women undergoing surgery for urinary incontinence and/or prolapse compared with women who received no physiotherapy[368].

At follow-up, in the Mimura study [369], 18 patients (72%) felt that their constipation had improved with complete resolution of symptoms reported by three of these patients. Frequency of bowel movements normalised after biofeedback and this improvement was maintained at follow-up.

Results are not yet available from the ongoing studies.

c) Summary

Currently the research evidence regarding the effectiveness of physical therapies for the treatment of pelvic organ prolapse is particularly weak. **Pelvic floor muscle training may prevent deterioration of anterior prolapse** however the one existing randomised controlled trial in this area is limited by its failure to utilise a recognised objective measurement of degree of prolapse and its application to an elderly population only. **Pre-operative pelvic floor muscle training may help to improve quality of life and symptom specific problems in women undergoing surgery for prolapse** however the evidence available is based on a study sample that includes women undergoing surgery for urinary incontinence and/or prolapse.

Level of evidence: 2/3.

d) Recommendations

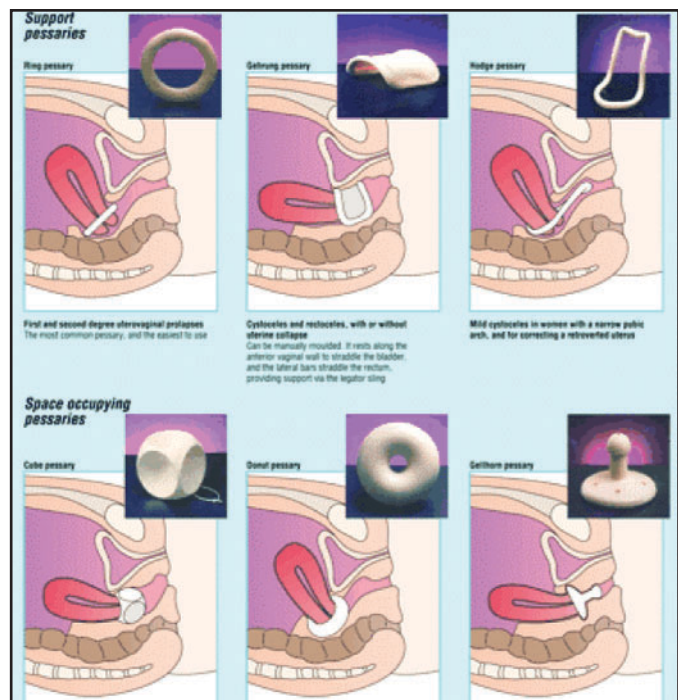
Given the prevalence of pelvic organ prolapse in women and the fact that physical therapies may already be part of the treatment offered to women in many centres [350], the lack of evidence of effectiveness is disconcerting. There is a need therefore for further research regarding the effectiveness of pelvic floor muscle training which is costly in terms of therapist time. It is crucial that such studies have a control group, are randomised and use recognised objective measurements of prolapse severity. At least two such studies are now underway, one of which is a feasibility study that may lead to a multi-centred

randomised controlled trial [371]. The other study may lead to evidence regarding the effectiveness of pelvic floor muscle training used in conjunction with surgery [370]. Future studies should also aim to reach a consensus on the optimal physical therapy intervention programme prescribed in terms of the number of repetitions, type and duration of exercises and should also consider outcome measures that compare individualised training with group training. Finally, there is a need for studies of the effectiveness of physical therapies in comparison with surgery and rings and pessaries.

Grade of recommendation: C/D

E3. RINGS AND PESSARIES

Rings and pessaries aim to manage pelvic organ prolapse by supporting the pelvic area. Various shapes and sizes of pessary are available for use in the treatment of prolapse, a range of which is illustrated by Zeitlin and Poma [365, 372]. (Figure 8) These modern pessaries are made from a variety of materials including rubber, clear plastic, soft plastic with metal reinforcements and silicone [372]. These shaped devices are inserted into the vagina and rest against the cervix. They hold the prolapse inside the vagina, provide support to related pelvic structures and can relieve pressure on the bladder and bowel.



Figures 8. Types of pessaries

Pessaries have been used for many years in the management of pelvic organ prolapse but their efficacy in treating this condition is unknown [373]. Recent surveys of pessary usage have shown that 86% to 98% of gynaecologists/urogynaecologists prescribe pessaries [373, 374]. In the Cundiff survey of members of the American Urogynecologic Society 77% of physicians reported using pessaries as a first line therapy. Ninety two percent of physicians believed that pessaries relieve symptoms associated with pelvic organ prolapse, while 48% felt that pessaries also had therapeutic benefit in addition to relieving symptoms.

Whilst there are identifiable trends in pessary use there are clear practice differences with respect to choosing a pessary for a specific patient. Similarly there are no clear prevailing removal regimes [374]. Many physicians receive little or no training in the use of pessaries[373] and have limited experience with pessary selection and fitting.

This sub-section examines the evidence for interventions utilising rings and pessaries for the treatment of pelvic organ prolapse.

I. TREATMENT

a) *Quality of data*

Much of the evidence relating to pessaries originates from case reports describing complications arising from pessary use [375-378] and review articles that provide advice, primarily based on clinical experience, on the indications for pessary use, pessary selection, fitting, care and replacement [366, 372, 379-386].

No published randomised controlled trials of rings and pessaries used for the treatment of women with pelvic organ prolapse were identified. Several retrospective and prospective observational studies were identified, however, that evaluated factors contributing to successful pessary fitting and usage and/or the therapeutic impact of pessary use [387-392]. Sulak [387] evaluated the therapeutic usefulness of pessaries in a retrospective study of 101 women with pelvic relaxation. Wu [388] performed a prospective study of 110 women with symptomatic pelvic organ prolapse to evaluate a protocol for pessary treatment. Handa [389]described prospectively the course of pelvic organ prolapse amongst 56 women who used a supportive vaginal pessary for at least one year. Both Hanson [390] and Clemons [391] conducted observational studies of 1043 and 100 women with prolapse respectively to analyse the factors that

contributed to successful pessary use. Kapoor [392]addressed the effectiveness of pessaries in alleviating symptoms associated with pelvic organ prolapse in a prospective study of 126 patients attending a dedicated pessary clinic. Follow-up periods for observational studies varied from two weeks [391] to three years [388]. Only in two studies[389, 391] was a recognised measure of prolapse used i.e. POP-Q examination, to objectively assess and evaluate the prolapse. No consistent measure of pessary fitting “success” was used throughout studies.

b) *Results*

Clinical experience suggests a substantial proportion of women with prolapse may be managed safely and effectively with a pessary [372, 379, 382].

Study results show that pessary fitting “success” rates ranged from 56%[388] to 73% [391] of women with pelvic organ prolapse. Higher success rates for specific types of prolapse, 83% for uterine prolapse and 82% for cystocele, were recorded by Hanson[390]. Comparison of fitting success rates by pessary type was difficult due to use of differing protocols for pessary selection within studies. Wu [388] used ring pessaries in 96% of women who were successfully fitted. Similarly, ring pessaries were the primary choice of treatment in the studies by Handa [389] and Clemons [391]whereas the Gellhorn pessary was primarily used in the Sulak study[387]. Of women who had a successful pessary fitting, ring pessaries were used more often in women with stage II (100%) and stage III (71%) prolapse whereas Gellhorn pessaries were used more often with stage IV (64%) prolapse [391]. Hanson found no significant relationship between success of pessary fitting and type of pessary used.

Parameters reported as associated with a “successful” pessary fitting were often contradictory. Both Hanson [390]and Clemons[391] reported that neither patient age nor previous surgical intervention was significantly related to the “success” of pessary fitting whereas Wu reported that women who were fitted successfully tended to be older ($P<0.05$) and that a history of pelvic surgery reduced the probability of a successful pessary fitting from 79% to 67%, although this result was not significant ($p=0.2$). Current hormone use did not predict greater likelihood of fitting success [388, 391] whereas local HRT was felt to play an important role in successful pessary fitting [390]. Wu [388] reported that women with stress incontinence before pessary fitting had a significantly lower success rate ($p=0.03$) whereas Clemons [391]did not find stress incontinence to be a

risk factor for unsuccessful fitting ($p=0.60$). Increasing severity of prolapse was not associated with an unsuccessful pessary [388, 391]. Neither was large genital hiatus size nor severe vaginal atrophy. Shorter vaginal length and wider vaginal introitus were associated with an unsuccessful fitting [391]. No comparative results for these parameters are reported elsewhere.

Comparison of long term pessary usage rates was difficult due to differing follow-up periods used in the studies reported. In the Sulak study [387] the average length of use was 16 months. Fifty percent of women continued to use the pessary at an unspecified follow-up period and 21% discontinued pessary use despite having no surgery. In the Wu study [388] 66% of those who used a pessary for more than one month were still users after 12 months and 53% were still users after 36 months. Thirty four percent of women in the Handa study [389] continued pessary use for at least one year. Women with greater degrees of pelvic support loss were more likely to continue using the pessary than were those with less support loss [387]. The main complaint of patients who discontinued using the pessary was dissatisfaction because symptoms were not adequately relieved or pessary use was inconvenient [387].

With regard to the effect of pessaries on pelvic organ prolapse symptoms and prognosis 21.1% (95% CI - 0.2% to 43.7%) of women had an improvement in stage of prolapse (measured via POP-Q with pessary removed) and none had worsening after using a pessary for at least one year although improvement was limited to women with anterior vaginal prolapse [389]. Similarly, four months after pessary insertion Kapoor [389] concluded that pessaries were successful in reducing prolapse (especially grade III) in two thirds of women and seem to be more effective in relieving symptoms of urinary voiding and faecal evacuation rather than urgency symptoms. After four months 75% of pessary users were able to resume physical activity and lead fulfilling lives. In the Sulak study [387] 82% of women still using the pessary at an unspecified follow-up period described their degree of satisfaction with their symptomatic relief as excellent.

Despite Cundiff [374] reporting that use of pessaries was associated with potential complications no major complications were observed in the studies conducted by Sulak [387] or Wu [388]. Based on clinical experience many authors advocate the use of local oestrogen to prevent or treat sores [391] [381-386] Indeed physicians thought that oestrogen was a necessary adjunct "most times" to pessary

usage [373]. Differing advice however was apparent with regard to the frequency and amount of oestrogen applied.

c) Summary

Despite the fact that pessaries are commonly used today to treat symptomatic pelvic organ prolapse there is little available evidence behind recommendations for their use. Whilst pessaries are cheap and complications are rare there is no consensus regarding various aspects of pessary management including indications for different types of pessary, appropriate choice of pessary, pessary fitting procedures, replacement intervals, follow-up care and treatment of complications. Similarly, **there is relatively little research on the therapeutic benefits of long term use of pessaries for pelvic organ prolapse although data suggest that they provide effective symptomatic relief and may prevent worsening of prolapse or indeed promote improvement in prolapse stage.**

Level of evidence: 4

d) Recommendations

Given the lack of studies in this area, there is a pressing need for well-designed randomised controlled studies to examine the effects of using rings and pessaries in the treatment of pelvic organ prolapse. Such studies need to address optimal pessary effectiveness, including the symptomatic and therapeutic benefits of pessaries as well as the indications for use, pessary fit, replacement and care.

These studies need to adopt consistent protocols regarding choice of pessary and allow sufficient follow-up periods. There is also a need for studies of the effectiveness of rings and pessaries in comparison with surgery, which is a more expensive option that may have additional morbidity, and in comparison with physical therapies.

Grade of recommendation: C/D

E 4. COMPLIMENTARY THERAPIES

Section II, 7 Urinary Incontinence in Women: Complementary Therapy discusses the evidence found for the use of complementary therapies for the treatment of women with bladder symptoms. **No studies have been found that evaluate the role of complementary therapies in the prevention and treatment of pelvic organ prolapse in women.** There is evidently a great need for well designed randomised controlled trials to evaluate the role of such therapies for women with pelvic organ prolapse.

F. GENERAL CONCLUSIONS AND SUMMARY OF RECOMMENDATIONS

Conservative treatment (lifestyle interventions, physical therapies, scheduled voiding regimes, complimentary therapies, anti-incontinence devices, supportive rings/pessaries for pelvic organ prolapse and pads/catheters) should be included in the counselling of both women and men with urinary incontinence and women with pelvic organ prolapse, regarding treatment options. The effectiveness of the various interventions (excluding anti-incontinence devices and pads/catheters discussed chapter) regarding their ability to prevent and treat urinary incontinence and prolapse is summarised below. Comment is also made on the effect of conservative management on other lower urinary tract symptoms and also factors affecting outcome, in particular age.

URINARY INCONTINENCE IN WOMEN

1. LIFESTYLE INTERVENTIONS

I. PREVENTION

- No randomised trials assessing the effect of lifestyle interventions and urinary incontinence prevention were identified.

II. TREATMENT

Studies to date regarding lifestyle interventions have reported associations and only a relatively small number of randomised trials have been carried out to assess the effect of a specific lifestyle on incontinence treatment. However, there is evidence that:

- Obesity is an independent risk factor for the prevalence of urinary incontinence and weight loss would appear to be an acceptable treatment option for morbidly and moderately obese women. Smo-

king appears to increase the risk of more severe urinary incontinence. Smokers may have a different mechanism causing their incontinence than non-smokers. No data has been reported examining whether smoking cessation resolves incontinence.

- Regarding dietary factors, fluid intake plays a minor if any role in the pathogenesis of incontinence. The data on caffeine intake and incontinence are conflicting. While large cross sectional surveys indicate no association, small clinical trials suggest that decreasing caffeine intake improves continence.

Consuming carbonated drinks appears to increase the risk of overactive bladder.

- Chronic straining may also be risk factor for the development of urinary incontinence, however there have been no intervention trials that have examined the effect of resolving constipation on incontinence.

- Strenuous exercise is likely to unmask the symptom of stress incontinence during the provocation. There is scant level 2 and 3 evidence that suggest that active women may be more likely to report incontinence than sedentary women, and that heavy occupational work may be associated with pelvic organ prolapse and urinary incontinence.

There is no evidence that strenuous exercise causes the condition of incontinence, however extreme provocation, such as parachute jumping, may cause incontinence. There are no trials that assess the role alteration in activity plays in treating urinary incontinence.

- Apart from postural changes, there is no scientific evidence about whether other lifestyle changes affect the treatment of urinary incontinence.

III. OTHER LUTS

- There is little published data on the effect of lifestyle interventions on other lower urinary tract symptoms in women only. The data is insufficient to draw any firm conclusions.

IV. FACTORS AFFECTING OUTCOME

- Published data is sparse in this area and the data is insufficient to draw any firm conclusions regarding the impact of age or other variables on the outcome of lifestyle interventions for treating incontinence.

2. PHYSICAL THERAPIES – PELVIC FLOOR MUSCLE TRAINING

I. PREVENTION

- Although a small number of trials have investigated the effect of pelvic floor muscle training (PFMT) on pelvic floor muscle activity, no trials investigating the primary/secondary prevention effects of PFMT for urinary incontinence in non-childbearing women were found.
- The methods of most trials investigating PFMT for prevention of urinary incontinence in childbearing women have allowed inclusion of women with prior incontinence symptoms. Therefore, it is usually not possible to differentiate primary/secondary prevention effects from treatment effects.
- Intensive supervised PFMT should be offered to antenatal women and/or individual postnatal PFMT instruction with adherence strategies to women after instrumental delivery and/or delivery of a large baby, to reduce the prevalence of postnatal incontinence.
- It is not clear whether either antenatal or postnatal training has a greater effect, nor are the long-term effects of training established.

II. TREATMENT

- Supervised PFMT is more effective than standard postnatal care for the treatment of urinary incontinence at three months postpartum.
- There is Level 1 evidence to suggest that for women with the range of urinary incontinence

symptoms (stress, mixed, urge), pelvic floor muscle training (PFMT) is better than no treatment. For those women with mixed and urge incontinence, it may be beneficial to offer PFMT in combination with bladder training.

- It is not clear what the most effective PFMT parameters are; clinicians and researchers should refer to exercise physiology literature to provide a biological rationale for their choice of training parameters. PFMT parameters can be selected based on the aim(s) of treatment, e.g. muscle strength, endurance, co-ordination and function.
- Therefore programs might comprise small numbers of maximal or near maximal contractions held for short periods, repeat once or more daily, at least three days a week (suggests strength training), and/or a moderate number of, daily, sub-maximal contractions held for long periods (suggests endurance training), and/or voluntary contractions timed with activities, in different body positions, and with varying levels of task difficulty (suggests co-ordination and functional training).
- Prior to PFMT, a person with skills in the assessment and training of pelvic floor muscles should assess each woman to ensure that a correct voluntary pelvic floor muscle contraction is being performed and to determine what facilitation, techniques or adaptations, if any, are required to the recommended training programme to ensure an appropriate training intensity. Clinicians should provide the most intensive PFMT supervision that is possible within service constraints. Supervision could be provided in individual or group settings.
- On the basis of the limited evidence currently available there is no apparent difference in the effectiveness of PFMT with or without biofeedback (home or clinic) or intravaginal resistant devices over PFMT alone. Clinicians may have or find occasions when these would be useful adjuncts to treatment for the purposes of teaching, motivation and compliance.
- Regarding PFMT versus other treatment the following statements should be viewed with caution, in view of the limitations of current evidence (i.e. few trials, poor quality trials, contradictory trial findings)
 - PFMT and vaginal cones might have similar effectiveness for SUI women (Grade B)
 - PFMT might be better than ES for SUI women (Grade B)

- PFMT and bladder training might be similarly effective for women with SUI, UUI or mixed urinary incontinence (Grade B)
- PFMT might be better than oxybutynin for women with DO, or DO with USI (Grade B)
- PFMT and adrenergic agonists might be similarly effective for women with SUI or mixed incontinence (Grade B)
- PFMT might be less effective than surgery for women with USI (Grade B)

However, when recommending treatment clinicians should consider that adverse events are more common and more severe with cones, electrical stimulation, drugs and surgery than with PFMT.

- It is possible that the addition of PFMT to bladder training for women with USI or DO with USI is more effective in the short term, but it is not clear if the benefit is sustained. Otherwise, because there are so few trials, it is not possible to make recommendations about the possible benefits of adding PFMT to other therapies. If clinicians/researchers are interested in the additive effects of PFMT, further large good quality trials are needed.

III. OTHER LUTS

- PFMT trials seldom reported data for other LUTS, e.g. frequency, nocturia, bladder pain. Data were so sparse it was not possible to summarise these in a reasonable manner.

IV. FACTORS AFFECTING OUTCOME

- There is no good evidence to suggest that older women with urinary incontinence do not benefit from PFMT as much as younger women.
- It is not clear if there are any reliable predictors of PFMT outcome. Too few trials have appropriately investigated the association between patient characteristics and outcome to be sure.

3. PHYSICAL THERAPIES – WEIGHTED VAGINAL CONES

I. PREVENTION

- No trials investigating the primary/secondary prevention effects of training with vaginal cones (VC) for women with urinary incontinence were found.

II. TREATMENT

- It is not clear if training with VC is better than control treatments, for postnatal women with urinary incontinence or women with USI. VC are not suitable for some women due to adverse events. With only two trials reporting outcomes of interest, more research is needed to be sure about the effect of VC versus no treatment, placebo or control treatments.
- No trials comparing approaches to training with VC were found. Research is needed if this is a comparison of interest for women and clinicians.
- VC and ES appear to be equally effective for SUI women (Grade A), but either treatment may be precluded by side effects.
- Based on a single outcome, from one trial, there may be no further benefit from adding VC to PFMT for SUI women.

III. OTHER LUTS

- There were too few data available to comment on the effect of VC on other LUTS.

IV. FACTORS AFFECTING OUTCOME

- None of the included trials addressed the effect of age, or any other factor, on outcome of training with VC.

4. PHYSICAL THERAPIES – ELECTRICAL STIMULATION

I. PREVENTION

- ES has not been used for either the primary or secondary prevention of incontinence and lower urinary tract symptoms, i.e., urgency, frequency and nocturia,

II. TREATMENT

- There is a marked lack of consistency in the electrical stimulation protocols that implies a lack of understanding of the physiological principles of rehabilitating urinary incontinence through electrical stimulation used in clinical practice to treat women with stress, urge and mixed incontinence.
- There is no apparent difference in either electrical stimulation or placebo treatment in women with urodynamic stress incontinence. For women with detrusor overactivity there is a trend in favour of active stimulation over placebo stimulation.
- There is insufficient evidence to determine if electrical stimulation is better than magnetic stimulation in women with detrusor overactivity.
- There is insufficient evidence to determine if electrical stimulation is better than vaginal oestrogens in women with urodynamic stress incontinence, or if electrical stimulation is better than anticholinergic or antimuscarinic therapy in women with detrusor overactivity.
- At present it seems that there is no extra benefit in adding electrical stimulation to PFMT.

III. OTHER LUTS

- No studies were identified that analysed the effect of ES on lower urinary tract symptoms alone, i.e., frequency of voiding, urgency and/or nocturia.

IV. FACTORS AFFECTING OUTCOME

- Cognitively intact older persons respond well to electrical stimulation of the pelvic floor and electrical stimulation may have equal benefit in older and younger persons.
- However, the evidence for this may reflect publication bias, because most studies do not report the effect of age.

5. PHYSICAL THERAPIES – MAGNETIC STIMULATION

I. PREVENTION

- No trials investigating the primary/secondary prevention effects of magnetic stimulation for adult women with urinary incontinence were found.

II. TREATMENT

- There is considerable variation in the regimen, protocols, intensity and duration of magnetic stimulation. At present there is insufficient evidence to determine the efficacy of magnetic stimulation in women with urinary incontinence. Women did not report adverse events using this treatment.

III. OTHER LUTS

- No studies were found addressing this question

IV. FACTORS AFFECTING OUTCOME

- None of the included trials addressed the effect of age, or any other factor, on outcome of magnetic stimulation. A few authors indicate the relevance of some factors but the causal relationship between these factors and the outcome of magnetic stimulation has yet to be determined.

6. SCHEDULED VOIDING REGIMES

I. PREVENTION

- There is no evidence available documenting the effect of scheduled voiding regimens in the prevention of urinary incontinence.

II. TREATMENT

- Timed voiding with a 2 hour voiding interval may be beneficial as a sole intervention for women with mild incontinence and infrequent voiding patterns. It may also be helpful as an adjunct to other treatment.
- There is no evidence regarding the benefit of habit training in women.
- There is Level 1 evidence to suggest that for women with urge, stress and mixed urinary incontinence, bladder training is more effective than no treatment. Evidence is inconsistent about expected cure rates, which maybe dependent on when and how the outcome was measured or reflect differences in the bladder training protocol.
- There is a lack of consistency in bladder training protocols. On the basis of extrapolation from the bladder training literature, an outpatient training protocol should include an initial voiding interval typically beginning at 1 hour during waking hours, which is increased by 15-30 minutes per week depending on tolerance of the schedule (i.e., fewer incontinent episodes than the previous week, minimal interruptions to the schedule, and the woman's feeling of control over urgency), until a 2-3 hour voiding interval is achieved. A shorter initial voiding interval, i.e., 30 minutes or less, may be necessary for women whose baseline micturition patterns reveal an average daytime voiding interval of less than 1 hour. Education should be provided about normal bladder control and methods to control urgency such as distraction and relaxation techniques and pelvic floor muscle contraction. Self- monitoring of voiding behaviour using diaries or logs should be included in order to determine adherence to the schedule, evaluate progress, and determine whether the voi-

ding interval should be changed. Clinicians should monitor progress, determine adjustments to the voiding interval, and provide positive reinforcement to women undergoing bladder training at least weekly during the training period. If there is no improvement after 2-3 weeks of bladder training, the patient should be re-evaluated and other treatment options considered. Inpatient bladder training programs may follow a more rigid scheduling regimen with progression of the voiding interval on a daily basis.

- There is insufficient evidence regarding the comparative effectiveness of bladder training and current drug therapy. However, bladder training, which has no adverse effects as compared to drug therapy, should be considered as first line treatment for detrusor overactivity.
- The additional benefit of combining drug therapy with bladder training and vice versa was not consistently noted and further investigation is warranted.

III. OTHER LUTS

- There is level one evidence that bladder training reduces urgency, frequency and nocturia.

IV. FACTORS AFFECTING OUTCOME

- Cognitively intact older persons respond well to bladder training and bladder training may have equal benefit in older and younger persons

7. COMPLIMENTARY THERAPY

I. PREVENTION

- No articles assessing the effect of complimentary therapy preventing urinary incontinence were identified.

II. TREATMENT

- Uncontrolled data suggests that acupuncture and

hypnosis improve overactive bladder symptoms, however current studies are limited by the lack of a placebo group and by very short follow-up.

III. OTHER LUTS

- There is insufficient information to summarize the effect of complementary therapies on lower urinary tract symptoms in women.

IV. FACTORS AFFECTING OUTCOME

- No data delineates the impact of such therapies on older versus younger women.

URINARY INCONTINENCE IN MEN

- Despite the prevalence of incontinence and LUTS in older men the only area, which has received consideration with respect to conservative management, is associated with prostatectomy. No trials were found on prevention of incontinence in men other than those undergoing prostatic surgery.

1. LIFESTYLE INTERVENTIONS

- No randomised trials assessing the effect of lifestyle interventions on either the prevention or treatment of urinary incontinence in men were identified.

2. PHYSICAL THERAPIES – PELVIC FLOOR MUSCLE TRAINING

I. PREVENTION

- It is not clear whether PFMT either before or both before and after radical prostatectomy surgery reduces the prevalence of post operative urinary incontinence.

II. TREATMENT

- There is modest support for the use of pelvic floor muscle therapy compared to no active intervention for reducing the incidence of incontinence after radical prostatectomy surgery. It is unclear whether the addition of biofeedback enhances the effectiveness of PFMT compared to digital rectal examination (DRE) alone.
- PFMT after TURP may reduce the incidence of incontinence in the first three weeks post operatively but this effect is not sustained thereafter.
- Both PFMT and urethral milking appear to be effective in the control of post micturition dribble.

3. PHYSICAL THERAPIES – ELECTRICAL STIMULATION

I. PREVENTION

- There have been no studies on the preventative role of ES for the treatment of urge incontinence in men.

II. TREATMENT

- ES protocols for men are similar to women and the marked lack of consistency in electrical stimulation protocols also applies. It is not clear if any particular ES protocol and mode of application is more effective than any other (rectal electrodes are usually used).
- There has been no study of ES versus no or control treatment, nor versus placebo treatment exclusively in men. It is therefore not possible to draw any valid conclusions regarding these comparisons.
- There is insufficient evidence to determine whether ES is better than magnetic stimulation or oxybutynin in men.
- Electrical stimulation has not shown any additional improvements compared to PFMT alone, however the numbers in the study were relatively small.

III. OTHER LUTS

- No studies were identified which addressed this comparison in men.

IV. FACTORS AFFECTING OUTCOME

- Studies of electrical stimulation for post-prostatectomy incontinence have mostly included elderly men and there are no studies comparing the effects of electrical stimulation for urinary incontinence between young and elderly men.

4. PHYSICAL THERAPIES – MAGNETIC STIMULATION

I. PREVENTION

- No trials investigating the primary/secondary prevention effects of magnetic stimulation for adult men with urinary incontinence were found.

II. TREATMENT

- No trials comparing approaches to magnetic stimulation were found. Further research is needed.
- With only single trials comparing magnetic stimulation with electrical stimulation there is insufficient evidence to determine if magnetic stimulation is better than electrical stimulation in men with urinary incontinence after radical prostatectomy and also in men with detrusor overactivity.

III. OTHER LUTS

No studies were found.

IV. FACTORS AFFECTING OUTCOME

- None of the included trials addressed the effect of age, or any other factor, on outcome of magnetic stimulation.

5. SCHEDULED VOIDING REGIMENS

I. PREVENTION

- No trials investigating the prevention effects of voiding regimens for men with urinary incontinence were found.

II. TREATMENT

- There is insufficient evidence of the effect of scheduled voiding regimes either alone or in combination with other treatments in men suffering from urinary incontinence.

III. OTHER LUTS

- No studies were identified in men.

IV. FACTORS AFFECTING OUTCOME

- No subgroup analyses related to age have been carried out regarding bladder training in men, therefore it is not possible to draw conclusions regarding the effect of bladder training in older men.

6. COMPLIMENTARY THERAPIES

I. PREVENTION

- No studies were identified on the preventative role of complimentary therapies in men.

II. TREATMENT

- Most studies suggest that acupuncture is effective for the treatment of urge incontinence in both men and women. However, there has been no study reported exclusively for men and studies to date have suffered from small sample size with no long term follow up.

III. OTHER LUTS

- Single trials have showed an improvement in nocturnal enuresis, daytime frequency and nocturia. Further research is recommended to confirm these findings.

IV. FACTORS AFFECTING OUTCOME

- No subgroup analysis related to age and gender effects has been carried out so it is not possible to draw any conclusions.

CONSERVATIVE MANAGEMENT PACKAGES FOR WOMEN AND MEN

I. PREVENTION

- Community based group sessions taught by continence specialists might be an effective way to maintain or improve continence status in older women who are already continent or are rarely incontinent.

II. TREATMENT

- There is Level 1 evidence that for women with stress, urge or mixed urinary incontinence a Conservative Management Package (CMP) is better than no treatment. (Grade A). Most of this evidence comes from trials in older women.
- To date, there is no convincing evidence that one CMP is better than another, or one method of CMP delivery is better than another. At present, it seems that CMPs are effective and the approach to delivery doesn't matter much.

PELVIC ORGAN PROLAPSE

I. PREVENTION

- There is some evidence that occupations involving heavy lifting/hard physical labour or being

overweight may play a role in the development of pelvic organ prolapse. No studies have been identified to date that evaluate the effectiveness of lifestyle interventions in the prevention of women with pelvic organ prolapse.

- No research evidence was found regarding the effectiveness of physical therapies for the prevention of pelvic organ prolapse.
- No studies have been found that evaluate the role of complimentary therapies in the prevention of pelvic organ prolapse.

II. TREATMENT

- No studies have been identified to date that evaluate the effectiveness of lifestyle interventions in the treatment of women with pelvic organ prolapse.
- Currently the research evidence regarding the effectiveness of physical therapies for the treatment of pelvic organ prolapse is particularly weak. Pelvic floor muscle training may prevent deterioration of anterior prolapse however this evidence arises from a single RCT which has several limitations.
- Currently, there is little rigorous research evidence behind recommendations for the use of rings and devices in the management of pelvic organ prolapse. There is no consensus on the use of different types of device, the indication, fitting procedures, nor the pattern of replacement and follow-up care. Similarly, there is relatively little research on the therapeutic benefit of long term use of pessaries although data suggest that they provide effective symptomatic relief and may promote improvement or prevent worsening of prolapse.
- No studies have been found that evaluate the role of complimentary therapies in the treatment of pelvic organ prolapse in women.

G. RECOMMENDATIONS FOR FUTURE RESEARCH

G1. LIFESTYLE INTERVENTIONS

Further research is needed to evaluate the effect of several currently recommended lifestyle interven-

tions on incontinence and whether their cessation can alleviate or prevent this condition. These include: weight loss, heavy exertion/exercise, smoking, caffeine intake, fluid intake, constipation on incontinence.

G2. PHYSICAL THERAPIES

High quality RCTs with long term follow up are required to investigate:

- the effectiveness of PFMT in comparison to other interventions and to compare the effectiveness of different PFMT programmes in the management of urinary incontinence.
- the effectiveness of PFMT with other adjuncts in comparison to PFMT alone and effectiveness of different biofeedback protocols.
- all aspects of the use of electrical stimulation in the treatment of urinary incontinence.
- all aspects of the use of magnetic stimulation in the treatment of urinary incontinence.
- the effectiveness of physical therapies to prevent incontinence in women at risk or in the general female population.
- the subgroups of patients who would derive the greatest benefit from physical therapies.

G3. SCHEDULED VOIDING REGIMENS

- High quality RCTs with long term follow-up are needed to determine the effect of the various scheduled voiding regimens, especially timed voiding and bladder training, as compared to no treatment in the management of stress, urge, and mixed incontinence and other lower urinary tract symptoms in women; studies are especially needed in men.
- High quality RCTs with long term follow up are required to compare timed voiding, habit retraining, and bladder training alone and in combination with lifestyle interventions, physical therapies and drug therapies in the management of stress, urge, and mixed incontinence and other lower urinary tract symptoms in women and men.
- Research is needed that compares bladder training

to other scheduled voiding regimens (timed voiding and habit training) as well as compares different bladder training protocols, e.g., intensive vs less intensive.

- Research is needed to determine the subgroups of patients who will derive the greatest benefit from timed voiding, habit retraining, and bladder training alone or in combination with lifestyle interventions, physical therapies and drug therapies.
- Research is needed to determine whether the long-term effect of bladder training can be maintained by booster interventions.
- Research is needed to determine whether scheduled voiding regimens especially timed voiding and bladder training can prevent the development of urinary incontinence in women and men at risk for its development.
- RCTs are needed on timed voiding and habit retraining as sole intervention or as an adjunct intervention to lifestyle interventions, PFMT, drug therapy, and anti-incontinence devices in women with urinary incontinence and other LUTS. Further RCTs are needed that compare bladder training alone and in combination to lifestyle interventions, PFMT, and drug therapies in the management of stress, urge, and mixed incontinence and other LUTS. Studies are also needed to determine the long-term efficacy of bladder training, and strategies that can assist in maintaining long-term benefit.

G4. COMPLIMENTARY THERAPIES

- High quality RCT's with long term follow up are required to investigate the effect of all complimentary therapies on lower urinary tract symptoms in both men and women.

G5. PELVIC ORGAN PROLAPSE

- Good quality epidemiological research is needed to establish the relationships between lifestyle factors and the occurrence of pelvic organ prolapse. Only then can the effects of altering these lifestyle factors, in terms of preventing and treating prolapse, be researched in randomised controlled trials.

- Prospective studies of the preventative effects of physical therapy could be undertaken although these would be costly, involving lengthy follow-up of women who at outset do not have pelvic organ prolapse. More pressing is the need to increase the evidence regarding treatment of existing pelvic organ prolapse with physical therapy, building on trial work that is ongoing.
- There is an urgent need for well-designed randomised controlled trials to address the effectiveness of rings and pessaries in treating pelvic organ prolapse. Such trials need to address the symptomatic and therapeutic benefits of pessaries as well as various aspects of pessary management such as indications for use and replacement and care.
- There have been no studies of the effects of complementary therapies in preventing or treating pelvic organ prolapse. There is therefore scope for controlled trials to assess effectiveness in both these respects. This should be preceded by exploratory work to establish potential mechanisms for such therapies to impact on prolapse.

ACKNOWLEDEMENT

We would like to acknowledge the Secretarial assistance of Debbie Moore in the coordination and preparation of this Chapter.

SEARCH STRATEGIES

Lifestyle Interventions

We searched Medline (languages English, Scandinavian, German) and the Cochrane Register of Controlled Trials from 1966-February, 2004 using the following keywords which were linked to “urinary incontinence” or “urination disorders” or “overactive bladder” or “urinary urgency”: lifestyle interventions, weight, obesity, weight loss, exercise, work, physical activity, smoking, tobacco, coffee, caffeine, posture, constipation, bowel function, fluids, fluid restriction, timed voiding, clothing, pulmonary status, cough, and diet.

Physical Therapies – PFMT & Weighted Vaginal Cones

Relevant trial and systematic review reports were identified from the Specialised Register of Controlled Trials of the Cochrane Incontinence Group. Date of search: January 2004. The register contains trials and systematic reviews identified from MEDLINE, CINAHL, the Cochrane Controlled Trials Register (CENTRAL), and handsearching of journals. The search strategy used to identify trials for inclusion on the Specialised Register is documented in Cochrane Incontinence Review Group section of The Cochrane Library. Further trial reports were sought through consultation with co-authors and experts in the field.

Physical Therapies – Electrical Stimulation

Relevant trials were identified from the Specialised Register of Controlled Trials of the Cochrane Incontinence Group. The register contains trials identified from MEDLINE, CINAHL, the Cochrane Controlled Trials Register (CENTRAL) and handsearching of journals. Additional trials were sought from the reference lists of included studies and a broader search of computerized bibliographic databases (EMBASE, EXCERPTA MEDICA, DUTCH NATIONAL INSTITUTE OF ALLIED HEALTH PROFESSIONS), from 1980 – February 2004, was undertaken. In addition, published abstracts presented at the International Continence Society, the European Association of Urology, the American Urogynaecology Society, and the American Urological Association were reviewed from 2000 to 2004, and cross-referenced to find if a full-length report had been published. Keywords were incontinence, urinary incontinence, detrusor instability, detrusor overactivity, bladder, overactive bladder, stress incontinence,

urge incontinence, mixed incontinence, urgency, frequency, nocturia, physiotherapy, physical therapy, conservative management, conservative therapy, non-surgical stimulation, electrostimulation, neuromuscular stimulation, electrical stimulation, electrotherapy, RCT’s, controlled trials, evaluation, effectiveness, efficacy, and outcomes.

Physical Therapies – Magnetic Stimulation

Relevant trials were identified from the Specialised Register of Controlled Trials of the Cochrane Incontinence Group. The register contains trials identified from MEDLINE, CINAHL, the Cochrane Controlled Trials Register (CENTRAL) and handsearching of journals. Additional trials were sought from the reference lists of included studies and a broader search of computerized bibliographic databases (EMBASE, EXCERPTA MEDICA, DUTCH NATIONAL INSTITUTE OF ALLIED HEALTH PROFESSIONS), from 1995 – February 2004, was undertaken. In addition, published abstracts presented at the International Continence Society, the European Association of Urology, the American Urogynaecology Society, and the American Urological Association were reviewed from 2000 to 2004, and cross-referenced to find if a full-length report had been published. Keywords were incontinence, urinary incontinence, detrusor instability, detrusor overactivity, bladder, overactive bladder, stress incontinence, urge incontinence, mixed incontinence, urgency, frequency, nocturia, physiotherapy, physical therapy, conservative management, conservative therapy, non-surgical stimulation, magnetic stimulation, neuromuscular stimulation, electromagnetic stimulation, extracorporeal magnetic, magnetic therapy, magnetic chair, RCT’s, controlled trials, evaluation, effectiveness, efficacy, and outcomes.

Scheduled Voiding Regimes

Reports of scheduled voiding regimens were obtained by searching MEDLINE, CINAHL, BIOSIS, and the Cochrane Register of Controlled Trials from February 1966 to January 2004 using the keywords which were linked to urinary incontinence: bladder, bladder training, behavior therapy, toileting, rehabilitation, and therapy. In addition, table of contents from urological and urogynecological journals were scanned for pertinent articles from October 2003 to January 2004. Reference lists were searched from protocols and systematic reviews published on timed voiding, habit training, and bladder training by the

Cochrane Collaboration, the Agency for Healthcare Policy and Research (United States) (Fantl, Newman, Colling et al., 1996), review articles, and retrieved manuscripts. In addition, published abstracts presented at the International Continence Society, American Urogynaecology Society, and the American Urological Society were reviewed from 2000 to 2003, and cross-referenced to find if a full-length report had been published.

Inclusion/exclusion criteria (appendix) subheading of above

To be considered for inclusion, studies had to meet the following criteria:

1. Prospective research design: randomised controlled or non-randomised controlled trials. If there were none available, then non-randomised cohort studies, case control studies, and case series were reviewed.
2. Types of participants: cognitively intact, non-institutionalised women and men with stress, urge, and mixed incontinence. Studies involving participants with catheters, urinary tract infections, interstitial cystitis or other pelvic pain syndrome, neurological disorders, or who were pregnant or immediate postpartum were excluded.
3. Type of intervention: timed voiding, habit training, and bladder training used in the management of urinary incontinence or lower urinary tract symptoms. Studies were excluded where it was not possible to establish any direct effects due to a specific scheduled voiding regimen. For example, studies that compared an intervention that used both bladder training and pelvic floor muscle training to another type of intervention such as drug therapy were excluded because it was not possible to determine the effect of bladder training alone.
4. Publication type: full published reports in English.

Complimentary Therapies

To evaluate the literature, we searched Medline using Ovid from 1966-February 2004 using the search terms "acupuncture" or "hypnosis" or "complementary therapies" or "alternative therapies" AND "urinary incontinence" or "urination disorders" or "overactive bladder" or "urinary urgency" or "uterine prolapse". We also examined reference lists of the articles obtained. Manuscripts that included only males or children in the study population were excluded.

Lifestyle Interventions and Physical Therapies in Men

The following electronic data bases were accessed for trials: Cochrane Incontinence Group, MEDLINE,

CINAHL, EMBASE, PsycLit and ERIC (all up to February 2004). Reference lists of relevant articles were searched. The following conference proceedings were also searched: American Urological Association (1989-2003); Society of Urologic Nurses and Associates (1991-2003); Wound Ostomy and Continence Nurses (1996-2003); and International Continence Society (1980-2003). If relevant abstracts were found, a second electronic search was performed for a published paper. Data from abstracts were not included in this update, as per ICI guidelines.

The following search terms were used in each database (no limits were applied to the searches): incontinence, urinary, male, post prostatectomy, stimulation, electrical stimulation, biofeedback, pelvic muscle exercises, Kegel exercises, behavioural, behaviour/or, therapy, behaviour modification, physiotherapy, quality of life, randomised controlled trial, evaluation, effectiveness, efficacy, outcomes.

Conservative Management Programmes

No separate search for trials of conservative management packages (CMP) was done. Trials of CMP were identified from the search strategies for PFMT and scheduled voiding regimes.

Pelvic Organ Prolapse – Lifestyle Interventions, Physical Therapies, Rings and Pessaries

Reports of RCTs evaluating the effect of lifestyle interventions, physical therapies and the use of rings and devices were obtained from a search of the Cochrane Incontinence Group specialised register. This register contains trials identified from MEDLINE, CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL) and handsearching of journals and conference proceedings. The date of the last search was April 2004.

Reports of other studies evaluating the effectiveness of the above treatments in the management of pelvic organ prolapse were obtained by searching MEDLINE (January 1966 to April 2004), PREMEDLINE (15 April 2004), EMBASE (1996 to January 2003), CINAHL (1982 to April 2004) and PEDro (April 2004). Key search terms were: prolapse, pelvic organ prolapse, uterine/uterus prolapse, urogenital prolapse, cervical prolapse, pelvic prolapse, vagina prolapse, rectocele, cystocele, urethrocele, enterocele, proctocele, sigmoidocele, pelvic dysfunction, pelvic disorder, pelvic relaxation, vaginal defects.

The UK National Research Register (Issue 1, 2004), Controlled Clinical Trials (April 2004), ZETOC database of conference abstracts (April 2004) and the reference lists of relevant articles were also searched.

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