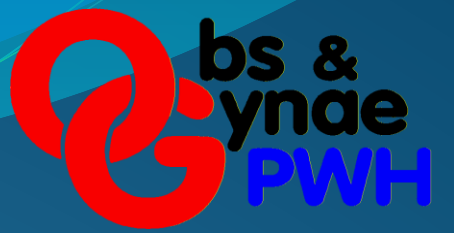


(#23951) Vaginal laser treatment on urinary stress incontinence: a randomized controlled trial



Wan OYK, Cheung RYK, LEE LLL, Wong D, Tam MS, Lee YT, Lee KW, Chan SCC

Department of Obstetrics and Gynaecology, Prince of Wales Hospital, Chinese University of Hong Kong

Hypothesis / aims of study

Stress urinary incontinence (SI) has strong adverse impact on quality of life, which was comparable to those with other chronic diseases. Pelvic floor exercise is known to be the first line treatment. Different continence surgeries are known to have high efficacy yet carry their respective surgical risks. Vaginal laser therapy is relatively minimally invasive and has been reported to have favourable outcome on patients' symptoms of SI with minimal adverse effects. The aim of our study is to investigate the efficacy of vaginal laser treatment on women with SI comparing with control.

Study design, materials and methods

This is a **single-blinded randomized controlled trial** with women recruited from three urogynaecology centres. Women with urodynamically proven urinary stress incontinence (USI) who failed to respond to pelvic floor exercise were recruited. They were randomized in 2:1 ratio (treatment versus control). All vaginal laser treatment was delivered by trained operators using the same machine with erbium-YAG laser technology, in two outpatient sessions at 4-6 weeks apart. Control group of women would have all the same procedures performed except no energy released from the vaginal laser probe. Women were followed up at 3 months, 6 months and 12 months after the first laser treatment with their urinary symptoms, adverse effects if any and validated quality of life questionnaire reviewed. Statistical analysis was performed by SPSS, version 25. Prior sample size calculation was done.

Results

Total 114 women were invited for studies and 76 eligible women were randomized, with **52 in laser treatment group and 24 in sham control group**. All women completed the 2 treatment procedures, except one withdrew after the first placebo treatment and one excluded from study after completion of vaginal laser treatment as found to be pregnant during follow-up. **Overall loss to follow-up rate was 4% (n=3)**.

There was significant **reduction in mean severity of urinary incontinence at 4-6 weeks** follow-up after the first vaginal laser treatment (0.76 ± 0.57 (laser) versus 1.11 ± 0.83 (sham), $p = 0.045$), but not found

at subsequent follow-up visits. A trend of **improvement in Pelvic floor Impact questionnaire, Urinary impact questionnaire, social subscale** score was also noted in laser treatment group, scoring 13.4 ± 13.77 (laser) versus 21.71 ± 19.14 (sham), p -value = 0.05 at 6-month follow-up, yet none at 12-month follow-up. There was also a trend of having **higher Female Sexual Function Index (orgasm)** for women after vaginal laser treatment at 3 months follow-up (1.71 ± 2.10 (laser) versus 0.87 ± 1.41 (sham), p -value 0.05) There is no significant difference of the mean score or mean changes of Urinary distress inventory, stress subscale between the two groups. Vaginal pain score during the procedure and immediately after procedure was higher in laser treatment group (mean score 5.24 ± 2.46 (laser) versus 0.71 ± 1.59 (sham), p -value < 0.01; 1.68 ± 2.02 (laser) versus 0.37 ± 0.90 (sham) respectively, $p < 0.01$). There were more women complaining of vaginal spotting after vaginal laser treatment (31 (59.6% in laser) versus 3 (13.0% in control); 30 (11.5% in laser) versus 1 (4.3% in control) after the first and second treatment respectively, $p < 0.01$. No major adverse effects were noted.

Interpretation of results

Only a **short-term reduction in severity of urinary incontinence** after the first laser treatment was noted. A trend of **improvement of quality of life at 6 months and better female sexual function at 3 months** after 2 sessions of laser treatment were identified. No major adverse events were noted.

Concluding message

Vaginal laser treatment for stress urinary incontinence is minimally invasive and has no major adverse outcome. However, the effect was found to be limited and short term.

Disclosure

None.