

## A RANDOMISED TRIAL OF OVERLAP VS END-TO-END PRIMARY REPAIR OF THE ANAL SPHINCTER

### Hypothesis / aims of study

Anal incontinence can have a devastating effect on a woman's quality of life. Obstetric anal sphincter injury (OASI) is the major cause of anal incontinence. Despite primary end-to-end anal sphincter repair, up to 59% of women suffer anal incontinence and sonographic sphincter defects have been demonstrated in about 85% of women. In a non-randomised study using the overlap technique better results has been demonstrated<sup>1</sup>. We aimed to perform a randomised study to determine the outcome of primary repair of OASI comparing the end-to-end to overlap technique.

### Study design, materials and methods

A prospective multicentre randomised controlled study was designed to compare overlap and end-to-end techniques for primary external sphincter repair of OASI. The primary outcome of the study was anal incontinence, which include faecal urgency, faecal urge incontinence, flatus incontinence, liquid and solid faecal incontinence at twelve months. The secondary outcomes were perineal pain, dyspareunia, quality of life, anal sphincter defects detected by endoanal scans and ano-rectal manometry at twelve months. To show any significant difference with adequate power, 24 patients were required in each arm of the study. Ethical approval was obtained from the local ethics committees of the participating centres.

A total of 64 patients with OASI of 3b, 3c and 4<sup>th</sup> degrees were recruited for the study during a 24 month period from two hospitals. All repairs were carried out by two trained obstetricians and a specialist midwife according to an ethically approved study protocol. Patients were followed-up with questionnaires at 6 weeks, 3, 6 and 12 months and invited to have endoanal scans and anal manometry at 6 and 12 months. Specialists reporting endoanal scans and the technician performing anal manometry were blinded to the technique of repair.

### Results

The baseline characteristics were comparable in both groups. The mean duration of overlap repair was 39 minutes compared to 29 minutes for end-to-end repair ( $p=0.003$ ). The mean blood loss associated with overlap repair was 259 ml compared to 203 ml in the end-to-end group ( $p=0.05$ ). None required blood transfusion. Twenty percent of the patient in the end-to-end group complained of perineal pain whereas none of the patients in the overlap group complained of perineal pain at 12 months ( $p=0.04$ ). Thirty two percent of the end-to-end group noted that faecal urgency & faecal urge incontinence symptoms either became worse or not improved over the 12 months whereas all the patients in the overlap group noted an improvement ( $p=0.01$ ). There were no statistically significant differences between the two techniques in terms of dyspareunia, quality of life, anorectal manometry and endoanal scan findings. None of the patients from either group complained of suture migration. There were no statistically significant differences in the primary and secondary outcomes between the operators. A summary of primary outcome results is shown in Table 1.

**Table 1: Primary outcome at 12 months**

Outcome	Overlap (n=27)	End-to-end (n=25)	p value
Overall anal incontinence	5 (18.5%)	10 (40%)	0.13
Faecal urgency	1 ( 3.7%)	8 (32%)	0.02
Faecal urge incontinence	0	6 (24%)	0.01
Flatus incontinence	4 (14.9%)	4 (16%)	1.00
Liquid faecal incontinence	0	1 ( 4%)	0.48
Solid faecal incontinence	0	0	-

### **Interpretation of results**

This is the first randomised controlled study to show a significant improvement in faecal urgency and faecal urge incontinence with primary overlap repair at twelve months. There was a 22% reduction of overall anal incontinence in the overlap group compared to end-to-end group although non significant. There is only one published randomised controlled study<sup>2</sup> that reported no difference in outcome at 3 months follow-up. However they did not analyse the different components of anal incontinence separately (external sphincter injury is associated with urgency and urge incontinence) and did not exclude Type 3a OASI (partial tears), where an overlap repair is not possible without completely dividing the rest of the sphincter. In our study all repairs were carried out by only three experienced operators and this may have contributed to the better outcome in the overlap group. In addition the overlap group showed a rapid improvement of symptoms over one year. A possible explanation may be that with the overlap there is better apposition whereas with end-to-end repair there may be ischaemia of the muscle ends and possible scarring. The steady improvement of symptom severity with time highlights the necessity for longer term follow-up with OASI repair. This study also demonstrates that outcome of primary overlap repair is more favourable than secondary overlap repair<sup>3</sup>.

### **Concluding message**

Primary overlap repair of OASI is a feasible technique and is associated with a lower prevalence of long-term anal incontinence. Use of this technique by trained operators can minimise the risk of anal incontinence following obstetric anal sphincter injury.

### **References**

1. Primary repair of the obstetric anal sphincter rupture using the overlap technique. Br J Obstet Gynaecol 1999;106:318-323
2. A randomised controlled trial comparing primary overlap with approximation repair of third degree obstetric tears. Am J Obstet Gynaecol 2000;183:1220-4.
3. Long term results of overlapping anterior anal sphincter repair for obstetric trauma. Lancet 2000;355:260-65.

**FUNDING: REMEDI, Bath, UK**