

AFTER THE TRIAL IS OVER- A STUDY OF THE MANAGEMENT OF ANAL SPHINCTER TEARS IN A TERTIARY REFERRAL UNIT 5 YEARS FOLLOWING A RANDOMISED CONTROLLED TRIAL (RCT).

Hypothesis / aims of study

An RCT was undertaken in our tertiary referral unit to compare two surgical techniques and two suture materials for anal sphincter repair after childbirth(1). The trial reported no difference in outcomes between the four groups of women sustaining third degree tears in terms of bowel symptoms or defects on endoanal ultrasound.

The management protocol in our hospital is the same as that used in the RCT. 5 years following the trial; our aim was to review the patient outcomes and compare the results with the data from the RCT.

Study design, materials and methods

Retrospective case note review of women with anal sphincter injury was undertaken for delivered in 2007.

Results

115 women underwent anal sphincter repair in 2007. 104 case notes were reviewed. 42% underwent end-to-end and 56% overlap repairs.

Table 1: Number of women attending follow-up appointments, anal incontinence symptoms and ultrasound findings following anal sphincter in 2007 and randomised controlled trial (RCT).

	2007	RCT
Follow up at 6 weeks		
Attendance	91 (87%)	103 (92%)
Anal incontinence symptoms	59 (65%)	34 (30%)
Follow up at 6 months		
Attendance	64 (62%)	79 (71%)
Anal incontinence symptoms	31 (48%)	30 (38%)
Defects on endoanal ultrasound		
External anal sphincter	21 (33%)	19 (21%)
Internal anal sphincter	4 (6%)	6 (7%)

Interpretation of results

Anal incontinence is more common than the rates reported in the RCT from our hospital despite adopting the same protocol. Our ultrasound data suggests this is due to increased persistent sphincter defects rates rather than the Hawthorne effect.

Concluding message

Counselling of women following anal sphincter injury should be undertaken using accurate data from the audit of local practice rather than RCT, even when that RCT has been undertaken in the same unit. The increased rate of persistent sphincter defects highlights both training and clinical governance issues.

References

1. How to repair an anal sphincter injury after vaginal delivery: results of a randomised controlled trial. Br J Obstet Gynaecol. 2006;113 201-7

Specify source of funding or grant	None
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	No
This study did not require ethics committee approval because	Audit of standard clinical care
Was the Declaration of Helsinki followed?	Yes

Was informed consent obtained from the patients?

No
