412

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FEASIBILITY STUDY FOR A RANDOMISED CONTROLLED TRIAL EVALUATING THE USE OF ABSORBABLE MESH, POLYDIOXANONE AND POLYGLACTIN SUTURES FOR ANTERIOR AND POSTERIOR VAGINAL WALL PROLAPSE REPAIRS.

Hypothesis / aims of study

We aimed to answer the following questions:

1. Is absorbable mesh (polyglactin) effective in treatment of pelvic organ prolapse surgery?
2. Is polydioxanone (PDS) or polyglactin (Vicryl) a better suture material to use for pelvic prolapse surgery?
3. What are the effects of mesh and different suture material on short-term and long-term morbidity, recurrence of prolapse symptoms, and quality of life?

Our objective was to establish whether it was feasible to mount a randomised controlled trial to meet these aims.

Study design, materials and methods

Trial design: a randomised controlled trial using a 2x2 factorial design of absorbable mesh compared with no mesh, and two types of sutures for anterior or posterior pelvic organ prolapse repair. Ethics approval was obtained.

Women scheduled for anterior or posterior repair for pelvic organ prolapse were identified from the waiting lists of the consultants participating in the trial: 83 women were identified, of whom 78 were willing to participate and 5 were ineligible. Each woman was counselled and consented for the trial by the research assistant or the gynaecologist. The 73 women were then randomised to having mesh or not, and to having a polydioxanone or polyglactin suture used for the repair of the pubocervical and/or the rectovaginal fascia using a secure method of concealment of randomisation (remote computer allocation using telephone access).

The women completed a preoperative and 3 day postoperative questionnaire. They were seen 3 months postoperatively for objective assessment of their prolapse, and were finally followed up at 6 months using a postal questionnaire. The surgeons participating in the study were also asked to fill in a peri-operative questionnaire describing their experience of the use of mesh and sutures in the study and other operative details.

Outcomes included a prolapse symptom score (range 7 = no symptoms to 35 = maximum score for all 7 symptoms) and a quality of life score ('how much do your prolapse symptoms interfere with everyday life, score 0 (not at all) to 10 (a great deal)).

Results

Ten surgical colleagues were involved in the study and were happy to allow their patients to be randomised. They were willing to be trained in the use of mesh if not already familiar with it. Of the 73 randomised women, 7 were excluded after randomisation as they were found to be unfit for surgery or did not have a prolapse operation within the study period. Thus 66 women were eligible for follow up, of whom 61 returned a 6 month questionnaire (92%). Some women had concomitant operations (14 vaginal hysterectomy; 18 cervical amputation, 13 TVT) in addition to their prolapse repairs (47 anterior repair; 2 paravaginal repair; 32 posterior repair). Nine women had a secondary repair. 33 women each were randomised to PDS or Vicryl, and 32 to mesh, 34 to no mesh. There were no baseline differences between the groups.

At 3 month outpatient review (92% of women seen), 6 women had a residual Stage 2 prolapse (2 in the mesh group and 4 in the no mesh group; 4 in the PDS group and 2 in the Vicryl group). The 7 most common prolapse symptoms decreased significantly: at baseline the mean symptom score was 20.3 (SD 6.5) but 6 months after surgery this had fallen to 11.1 (4.8), 95% CI for difference 7.1 to 11.1. Similarly the quality of life score improved from 4.6 (3.8) at baseline to 1.4 (2.6) after surgery. However, there were no significant differences between the groups treated with mesh or no mesh, or PDS suture versus Vicryl suture (Table).

At baseline, 49 women (74%) reported some urinary incontinence. At 6 months, this had fallen to 67%, with 35 remaining incontinent at both time points, and 11 remaining dry. The proportion of women wet did not differ according to their randomised treatments (78% wet after mesh versus 58% after no mesh, 69% wet after PDS versus 65% when Vicryl was used).

Table Prolapse symptom score and quality of life due to prolapse symptoms at 6 months after prolapse surgery

	Symptom Score at 6 months	**95% CI for difference**	**Quality of Life Score**	**95% CI for difference**
Mesh (n=27)	10.9 (3.9)	-2.9 to +2.1	1.4 (2.5)	-1.6 to +1.2
No mesh (n=33)	11.3 (5.4)		1.5 (2.8)	
PDS (n=29)	12.0 (4.7)	-0.7 to +4.2	2.0 (3.1)	-0.4 to +2.4
Vicryl (n=31)	10.3 (4.7)		1.0 (2.0)	

There were few adverse events (post operative bleeding requiring reoperation 1; recatheterised 4; blood transfusion 1; MRSA 1). Nine women (15%) were dissatisfied with the results of their operation, but the numbers were too few to attribute this to their randomised treatment.

Interpretation of results

This was a feasibility study in preparation for larger randomised controlled trials in women having prolapse surgery. Although the numbers were too few to identify systematic differences between mesh and no mesh, or PDS and Vicryl, we established that the methods of the study were successful: recruitment (94% willing), randomisation and retention (over 90% followed up) of the women was excellent. In addition, we were able to demonstrate changes over time using a prolapse questionnaire developed for use in RCTs.

Concluding message

Our study has demonstrated that it is feasible and practical to run randomised controlled trials in women having prolapse surgery when new materials such as the use of mesh or PDS are introduced.

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