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TRANS-VAGINAL MESH TECHNIQUE FOR TREATMENT OF PELVIC ORGAN PROLAPSE: 5 YEARS OF PROSPECTIVE FOLLOW UP

Hypothesis / aims of study

The Trans-Vaginal Mesh (TVM) technique involved a polypropylene mesh of specific size and shape that was secured tension free by extension arms that passed through the arcus tendineous via a transobturator approach anteriorly, and through the sacrospinous ligament via a transgluteal approach posteriorly. The objective of the study was to evaluate the long-term safety and effectiveness of the TVM technique for vaginal prolapse. In 2006 and 2008, one and three year results were reported; here we present our final 5 year results.

Study design, materials and methods

Women from eight French centres with symptomatic pelvic organ prolapse (ICS POP-Q Stage II-IV) were invited to participate in this ethics committee-approved study. It was a prospective single-arm, non-comparative design involving routine, standardised, pre-operative assessment, surgery and follow-up care at 6 weeks, 6 months, 1, 3 and 5 years. Patients with a uterus were required to undergo concurrent hysterectomy to limit the number of different factors that could influence anatomic success, mesh exposure, and pain. Uncontrolled diabetes or coagulation disorders were considered to be exclusion criteria. The primary effectiveness endpoint was prolapse recurrence, defined as a POP-Q stage II or more (=leading edge of the prolapse ≥-1 cm) or surgical intervention to repair recurrence of vaginal prolapse at 1 year post-surgery. Pre-operatively, patients' demographic details, medical and surgical history were recorded. Other secondary outcome parameters that were prospectively recorded were the impact of the prolapse on sexual activity, the clinical examination of the vaginal mucosa and any vaginal pain reported by the patient, categorized as unprovoked or provoked through examination or activity. The Prolapse-Specific Inventory and Quality of Life (QoL) questionnaire (PSI-QOL) was used to evaluate pelvic symptoms and QoL. Complications were collected throughout the study.

Results

Between January and December 2004, 90 women were enrolled into the study. Mean age at time of surgery was 65.2 years; 18 had prior hysterectomy and 72 underwent concurrent hysterectomy. Total mesh repair was performed in 89 women; one women had anterior repair only. Eighty-two patients were available for 5 years follow up. Two patients had died prior to the 5 year visit. Two patients withdrew consent from the study on day 46 and 361 after the study procedure; a further 4 patients did not wish to attend the 5 year follow up visit.

At five years, the anatomic failure rate was 20.7% (90% CI 13.7%– 29.5%). Of the 13 women with Stage II prolapse, the leading edge remained at or inside the hymen in all but one case. The POP-Q stages and failure rates for 1, 3 and 5 years are presented in Table 1. Over the course of the five year follow up, there were four re-interventions for recurrent prolapse. Statistically significant improvements in mean scores for PSI and QoL reported at 1 and 3 years were maintained at 5 years (baseline to 5 years: 13.9 to 2.1 and 3.4 to 0.0, respectively). At 5 years, unprovoked vaginal pain and pain provoked during pelvic examination were reported in 1.2% and 6.1% patients, respectively; only one of these was *de novo* at 5 years. Of the 33 women who were reported being sexually active, there was 1 new case of *de novo* dyspareunia reported at five years. Two patients continued to report *de novo* symptoms of dyspareunia from earlier follow up, and 1 who had pre-existing symptoms before surgery. At the 3 year assessment, we reported mesh exposure in 13 patients; one further patient was reported with mesh exposure by 5 years, bringing the total incidence of mesh exposure over the five year follow up to 15.6%. In total, 7 required excision of the exposed mesh; 6 were ongoing at the time of the 5 year follow-up evaluation.

Interpretation of results

The overall anatomic failure was 20.7% at 5 years, with a low re-operation rate for recurrence of 4.8%. These longer-term results remain consistent with one year results reported in other multicentre studies with this polypropylene mesh system.[1,2] The substantial improvements observed in symptoms and QoL were significant and sustained over time. The rate of mesh exposure remained relatively unchanged between 3 and 5 years, with an overall rate of 15.6% at 5 years. Similarly, new reports of dyspareunia and vaginal pain reported at 5 years were limited to one new case of each.

Concluding message

Here we report the first five year results following TVM for vaginal prolapse. These results indicate that TVM provided a stable anatomical repair to five years following surgery, with associated improvements in specific prolapse symptoms and QoL which were sustained over time. Moreover, it was encouraging that there were so few new reports of specific mesh related morbidities between three and five years.

Table 1: Anatomical outcome measures

	Baseline N=86*	**1 year N=87**	**3 years N=85**	**5 years N=82**
Stage 0	-	38 (44.2%)	37 (43.5%)	34 (41.5%)
Stage I	-	33 (38.4.0%)	31 (36.5%)	31 (37.8%)

Stage II	14 (16.3%)	13 (15.1%)	14 (16.5%)	13 (15.9%)
Stage III	49 (57.0%)	1 (1.2%)	-	-
Stage IV	23 (26.7%)	-	-	-
Re-intervention		1 (1.2%)	3 (3.5%)	4 (4.8%)
Anatomic failure (90% CI)		**1 year**	**3 years**	**5 years**
		17.4% (11.1%-25.6%)	20.0% (13.2%-28.5%)	20.7% (13.7%–29.5%)

* For 4 patients, actual baseline stage was unknown but at least Stage II.

References

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Lille Consultation Committee for the Protection of Persons in Biomedical Research**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**