

PORCINE VERSUS POLYPROPYLENE SLING FOR STRESS URINARY INCONTINENCE – RESULTS OF A 10 YEAR RANDOMISED CONTROL STUDY.

Hypothesis / aims of study

Mid-urethral sling vaginal tape procedures, using polypropylene are the most commonly performed procedures worldwide for stress urinary incontinence. Recently there have been concerns regarding the safety of polypropylene meshes, especially with respect to chronic pain and mesh extrusion or erosion. Alternative, more bio-compatible materials have been used in the past, but there is a paucity of long-term follow up studies. In this study we present a 10 year follow up randomised control trial, comparing polypropylene Tension-free Vaginal Tape (TVT™)(Ethicon Inc., Somerville, USA) and porcine (Pelvicol™) slings, with comparison to earlier 3 year published data.

Study design, materials and methods

The TVT™ sling uses a synthetic, type 1 Polypropylene mesh, whilst Pelvicol™ sling uses a natural, non-allergenic, biological matrix derived from porcine dermis. 142 patients were randomised to either a Pelvicol™ or TVT™ sling procedure, over a 24 month period. The group demographics were comparable in terms of age, parity and duration of stress urinary incontinence. The study was approved by our local research ethics committee and informed, written consent was obtained. 128 patients completed the postal questionnaire follow-up at 3 years and 98 patients at 10 years. The primary outcome was cure rates of stress incontinence. Success was defined as a patient determined continent status of 'cured' or 'at least 90% improved', whilst an improvement was defined as more than 75% improved.

Secondary outcomes included if repeat continence surgery had been performed, use of incontinence pads, adverse events such as pelvic pain and dyspareunia; and patient satisfaction rating in the form of 2 questions - would the patient undergo the procedure again if required and would they recommend the procedure?

Results

TVT™ was associated with significantly higher cure rates at 10 years follow-up compared to Pelvicol™ slings (61.8% vs. 47.1% $p=0.03$). 14 patients in the Pelvicol™ group compared to 4 TVT™ patients had undergone further anti-incontinence surgeries. Excluding cases of repeat surgery, there was no observed difference in pad usage at 10 years. More women in the TVT™ group (13%) described difficulty in voiding compared to the Pelvicol™ group (5.4%), but no patients required intermittent self-catheterisation.

Pelvic pain reporting had increased at 10 year follow up in both groups, compared to the 3 years results (TVT™: 1.7% – 9.3% vs. Pelvicol™: 1.5% – 8.1%). Rates of dyspareunia were comparable in both groups. None of the patients reported being diagnosed or treated for mesh erosions. The majority of patients would have the operation repeated again if needed (62.2% Pelvicol™ vs. 76.7% TVT™) and also would recommend the procedure (62.2% Pelvicol™ vs 72% TVT™).

Patient determined continence	3 Year Follow-Up		10 Year Follow-Up	
	Pelvicol™ N=68	TVT™ N=60	Pelvicol™ N=51	TVT™ N=47
Success (≥90%)	56 (82.4%)	53 (88.3%)	24 (47.2%)	29 (61.8%)
Improved (≥75 <90%)	7 (10.3%)	3 (5.0%)	9 (17.5%)	9 (19.1%)
Failed (<75%)	5 (7.3%)	4 (6.7%)	18 (35.3%)	9 (19.1%)

Interpretation of results

In 2015, the Cochrane review concluded that the synthetic mesh sling procedure had established effectiveness and a good safety profile. However, numerous reports in response to the recent controversy have highlighted the lack of long-term outcome data for sling procedures, especially in regards to using different sling materials. Some examples of long-term follow-up studies of TVT sling procedures include Groutz et al⁽¹⁾ who reported success rates of 65%. Aigmuller et al⁽²⁾ reported a cure rate of 57% with a further 23% reporting overall improvement and Svenningsen et al⁽³⁾ showed slightly higher patient-reported cure rates of 76% at 10-years, for a large cohort of 483 women. Our results are comparable with these studies, with our cure rate of 62% and more than 75% improvement of 81%.

The long term follow up studies for porcine dermis are generally poor and there are questions over its durability for sling procedures. In our study, results for long-term cure rates mirrors this concern. The cure rates significantly declined at 10 year

follow-up compared to 3 years, within both groups but the decline is greater in the Pelvicol group. Our experience was that Pelvicol slings failed after 3 years and this failure was noted by patients to be a sudden deterioration in urinary incontinence.

The re-operation rate for the TVT group of 8.5% is comparable to that reported in other studies, for example Aigmueller et al⁽³⁾ reported a re-operation rate of 7.8%. However, the re-operation rate of 27.5% in the Pelvicol group is significantly higher. The Pelvicol sling is no longer commercially available, however with increasing interest in use of other allogenic materials, our results can be useful information for patient counselling.

Concluding message

Overall, our study has shown that at 10 year follow-up, synthetic TVT™ slings are superior to Pelvicol™ porcine slings in the surgical management of stress urinary incontinence.

References

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Disclosures

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