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A RANDOMISED CONTROL TRIAL COMPARING TVT, PELVICOL AND AUTOLOGOUS FASCIAL SLINGS FOR THE MANAGEMENT OF STRESS URINARY INCONTINENCE IN WOMEN.

Hypothesis / aims of study
Insertion of a midurethral sling is now widely accepted as the standard surgical approach for stress urinary incontinence (SUI). Uncertainty remains about the optimum material. This randomised controlled trial compares three materials: Tension-free vaginal tape (Gynecare TVT), Porcine Dermis (Bard Pelvicol) and autologous rectus fascia.

Study design, materials and methods
Women requiring primary surgical treatment for urodynamic SUI were recruited in 4 centres and randomised into 3 arms. Assessments were performed preoperatively, at 6 weeks, 6 and 12 months. Assessments included operative details and complications, dry / improved rates, BFLUTS / EuroQol, catheterisation and re-operation rates. To detect a clinically significant difference of 15% between the groups 76 women were needed in each arm (with 80% power). The aim was to recruit 100 women in each arm.

Results
201 women were randomised ranging in age from 31 – 80 years (mean 52 years). Interim analysis was performed after the first 50 patients in each group. High re-operation rates were observed in the Pelvicol group so this arm was closed. Recruitment continued in the other 2 arms. However the study was closed after 6 years, before the target number of women had been reached. This was due to tailing off in recruitment. 50 women had a Pelvicol sling, 72 women had TVT and 79 women had autologous slings by the time the study was closed. Over 85% of women were available for follow-up at 1 year.
The results and complications are summarised in the table.
1 woman (2%) in the Pelvicol group required urethral dilatation. 1 woman (1.3%) in the autologous group had urethrolysis, both before the 6 week assessment. At 1-year, 1 in 5 women who had a Pelvicol sling had undergone a further continence procedure for SUI, as opposed to none in the other 2 arms.

Interpretation of results
Autologous slings take longer to perform and have higher self catheterisation rates than TVT or Pelvicol slings. Women who had TVT procedure went home sooner than those who had autologous or Pelvicol slings. There are no significant differences in peri-operative morbidity between the 3 arms.
There are no significant differences in continence results for TVT and autologous slings. Pelvicol slings however have significantly lower improved and dry rates, with significantly higher re-operation rates.
Recruitment was felt to have tailed off due to increasing popularity of the TVT.

Table showing results and complications.

	TVT	Pelvicol	Autologous
Median theatre time (min)	30	35	50
Median length post-op stay (days)	2	4	4
Bladder Injury	5.5%	2%	2.5%
Dry Rate 6 / 52	52%	60%	66%
Dry Rate 6 / 12	51%	44%	48%
Dry Rate 12 / 12	55%	22%*	48%
Improved Rates 6 / 52	**91%**	**91%**	**94%**
Improved Rates 6 / 12	**92%**	**73%***	**95%**
Improved Rates 12 / 12	**93%**	**61%***	**90%**
Re-operation Rate	0%	20%*	0%
Self – Catheterisation Rate 6 / 52	1.5%	0%	9.9%
Self - Catheterisation Rate 6 / 12	0%	0%	1.5%
Self - Catheterisation Rate 12 / 12	0%	0%	0%

* denotes statistically significant results. *p< 0.0015 throughout.

Concluding message
Pelvicol is an inferior material for midurethral sling support and cannot be recommended.
There is no detectable difference in clinical outcome between TVT and autologous fascia but TVT consumes less hospital resources in terms of operating time and length of stay.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Swansea Local Research Ethics Committee. The Business services Committee.LREC reference number 2000.117**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**