637

Khan Z[1], Nambiar A[1], Emery S[1], Lucas M[1]
1. *ABMU-health Board*

LONG TERM FOLLOW-UP OF A MULTICENTRE RANDOMISED CONTROLLED TRIAL COMPARING TVT, PELVICOLTM AND AUTOLOGOUS FASCIAL SLINGS FOR THE TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN.

Hypothesis / aims of study

Many procedures for the treatment of stress urinary incontinence (SUI) have been described. Although no strong evidence favours any particular one, the best available data supports the use of mid-urethral tape procedures, colposuspension and autologous fascial slings.

In 2010, we published the 12 month results of a multi-center randomised study comparing autologous fascial sling (AFS), Pelvicol™ and TVT in the definitive management of SUI.(1) The current study reports the follow-up of the same study population analyzing the efficacy, durability and long-term outcomes of these slings at a median follow-up of 10 years.

Study design, materials and methods

A multicenter randomised controlled trial carried out in four centres across the UK from 2001-2006. 201 women requiring primary surgery for SUI, with urodynamically proven SUI. Women were randomly assigned to receive TVT, AFS or Pelvicol™.

Primary outcome was surgical success defined as “women reporting being completely ‘dry’ or ‘improved’ at the time of follow-up”. Secondary outcomes included completely ‘dry’ rates, changes in the Bristol Female Lower Urinary Tract Symptoms (BFLUTS) and Euro-QoL scores.

Results

162 (80.6%) women were available for follow-up with a median duration of 10-years (6.6-12.6 years).‘Success’ rates at 12-months were 93%, 90% and 61% for TVT, AFS and Pelvicol™ respectively. The 10-year ‘success’ rates weren’t statistically different in any group. (TVT: 73%; AFS: 75.4%; Pelvicol™: 58%;). Comparing the 12-month and 10-year ‘success’ rates, a reduction from 93% to 73% (p=<0.05) in the TVT and from 90% to 75.4% (p=<0.05) in the AFS group was noted. These rates remained steady for PelvicolTM (61% vs. 58%, p=1.00). (Table 1)

‘Dry’ rates at 12-months were 55%, 48% and 22% for TVT, AFS and Pelvicol™, which at 10-years were 31.7%, 50.8% and 15.7% respectively. ‘Dry’ rates significantly favoured women who underwent an AFS [PelvicolTM (p=<0.001), TVT (p=0.036)]. Comparing the 12-month and 10-year ‘dry’ rates, they remained stable for both AFS (p=0.157) and Pelvicol™ (p=0.157) but deteriorated for TVT (p=<0.001) and this difference persisted in the ITT analysis. (Table 1) Figure 2 demonstrates the graphical representation of the deterioration in the ‘success rates’ and ‘dry rates’ over the 10 year period.

Re-operation for persistent SUI was 3.2% (n=2) in the TVT arm, 13.1% (n=5) in the Pelvicol™ arm while none of the patients in the AFS arm required further intervention. (Table 2)

Interpretation of results

Our study indicates that both TVT and AFS appear to have equivalent long-term success rates, in our hands, as defined by results of postal questionnaire including non-validated measures and urinary incontinence scores in BFLUTS questionnaire.

The dry rates for AFS appear more durable compared to TVT. There is time dependent deterioration with all slings and the results support the view that xenograft material should not be routinely used for treating SUI.

Concluding message

Autologous slings should certainly be considered as a valid alternative to synthetic sling material for implantation.

	TVT			**AFS**			**Pelvicol™**			**Pelvicol™ vs TVT**	**Pelvicol™ vs AFS**	**TVT vs AFS**
	1 year (n=69)	10 year (n=63)	p- value	1 year (n=67)	10 year (n=61)	p-value	1 year (n=46)	10 year (n=38)	p-value	p-value	p-value	p-value
Improvement Rate	93%	73%	<0.001	90%	75.4%	0.004	61%	58%	1.000	0.089	0.055	0.461
Dry Rate	55%	31.7%	<0.001	48%	50.8%	0.157	22%	15.7%	0.157	0.042	<0.001	0.036
ITT* (Improvement rate)	89%	63.8%	<0.001	71.4%	54.7%	<0.001	51%	40%	0.005	0.031	0.050	0.161
ITT (Dry rates)	53%	27.7%	<0.001	38%	37 %	0.500	18%	11%	0.125	0.008	<0.001	.188

Table 1: ‘Dry’ and ‘Improvement’ rates at 12-months and 10-years

	TVT (n=63)	AFS (n=61)	Pelvicol™ (n=38)
Re-operations			
SUI	2 (3.2%)	0 (0%)	5 (13.1%)
Other Gynaecological Surgery	5 (7.9%)	7 (11.4%)	4 (10.5%)
Urgency Incontinence			
De-novo Urgency	1 (1.6%)	0 (0%)	0 (0%)
Anti-cholinergics	5 (7.9%)	6 (9.8%)	6 (15.7%)
Botox	1 (1.6%)	5 (8.2%)	2 (5.2%)
Complications			
Use of self catheterization	3(4.7%)	4(6.5%)	0(0%)
Sling release	2 (3.2%)	2 (3.3%)	1 (2.6%)
Exposure	1 (1.6%)	0 (0%)	0 (0%)
Scar pain	0 (0%)	2 (3.2%)	0 (0%)

Table 2: Re-operation and complication rates

References

1. Guerrero KL, Emery SJ, Wareham K, Ismail S, Watkins A, Lucas MG. A randomised controlled trial comparing TVT, Pelvicol and autologous fascial slings for the treatment of stress urinary incontinence in women. BJOG : an international journal of obstetrics and gynaecology. 2010;117(12):1493-502. Epub 2010/10/14.

Disclosures

Funding: The initial study was partially funded by BARD limited. No subsequent funding was available for long-term follow up. **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov (Reg.No: NCT01057550) **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** South-West Cornwall and Plymouth National Research Ethics Service (NRES) committee (Ref:12/SW/0362). **Helsinki:** Yes **Informed Consent:** Yes