

Author(s)) S.Emery, M.Lucas, T.Stephenson*, I Cheung, K.Wareham,

Institution, city, country: SWANSEA NHS TRUST, SWANSEA, UNITED KINGDOM,
UNIVERSITY HOSPITAL OF WALES*, CARDIFF, UNITED KINGDOM

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TENSION FREE AUTOLOGOUS FASCIAL SLING; A RANDOMISED TRIAL TO COMPARE FULL LENGTH TECHNIQUE WITH THE SHORT SUSPENDED "SLING ON A STRING" IN TREATING FEMALE STRESS INCONTINENCE

Aims of Study

To compare, in a randomised trial, the conventional full length autologous fascial sling (Gp A) with the short, suspended sling, or "Sling on a String" (Gp B) in terms of subjective and objective outcomes, including quality of life. We present results with twelve month follow up for 165 evaluable patients.

Methods

The trial was conducted in two centres recruiting over two years. 168 patients were randomised to the study of whom 165 were evaluable at follow up. Patients with GSI were included regardless of previous surgery but patients with detrusor instability were excluded. All operations were undertaken by one of the investigators (two urologists and one gynaecologist) who standardised their operative technique, or under their strict supervision. Pre and postoperative evaluations (by an independent research team) included one hour pad test, pain and symptom scores together with validated quality of life questionnaires (UDI and IIQ), and videourodynamics. All adverse events during admission and post discharge up to one year were collected.

Results

Baseline demography and past surgical history was similar for both groups. The mean operating time for Group B (Sling-on-a-string) was significantly shorter than that of the Group A (53 minute vs 61 minutes, $p=0.003$). There was no other significant difference between the groups in terms of blood loss, post operative pain, length of stay or return to natural voiding.

The subjective clinical outcomes are summarised in the table.

	Group A	Group B	
No	n = 81	n = 84	
Cured of GSI	83%	87%	
Urge syndrome pre op	83%	87%	
Urge syndrome post op	33%	33%	
De novo Urge syndrome	7%	2%	
Overall satisfaction	78%	76%	No significant differences

Quality of life improved for most patients assessed by both UDI and IIQ. Mean improvements by comparison with UDI at recruitment were 114.15 points at 12 months ($p<0.001$) and mean improvement by comparison with IIQ at recruitment were 146.72 at 12 months ($p<0.001$). There was no significant difference in the rate of improvement between the two groups according to the UDI and the IIQ at three and six months. At 12 months the observed rate of improvement was higher for Group A patients. For the UDI, the observed difference in the relative improvements between the two groups was statistically significant ($p<0.05$). Covariance and regression analysis showed that the observed difference in relative improvement in UDI between the two groups was probably due to different scores at recruitment, hence a statistical artefact. For the IIQ, the observed difference in relative improvement between the two groups did not reach statistical significance.

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Conclusions

These results show no significant clinical difference in outcome between the two procedures (95% confidence). However the shorter "Sling on a String" procedure is easier and marginally quicker to perform (p=0.003). These results justify the adoption of the tension free, short suspended "Sling on a String" as a first line treatment for women with GSI

This trial used independent evaluation to exclude observer bias. The results of this study should only be compared to other studies that have used similar methods of independent evaluation.