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A RANDOMIZED CONTROLLED STUDY TO COMPARE TENSION FREE VAGINAL TAPE (TVT) AND MONARC TRANS-OBTURATOR TAPE IN THE TREATMENT OF WOMEN WITH URODYNAMIC STRESS INCONTINENCE (USI) AND INTRINSIC SPHINCTER DEFICIENCY (ISD): THE THREE YEAR FOLLOW UP.

Hypothesis / aims of study

To compare TVTTM retropubic and MonarcTM trans-obturator sling in the treatment of women with urodynamic stress incontinence (USI) and intrinsic sphincter deficiency (ISD) in the long term.

Study design, materials and methods

A prospective, randomized controlled trial was conducted of women with USI and ISD, defined as maximum urethral closure pressure < 20cm H₂O and/or ΔALLP <60 cm H₂O. The pre- and post-operative protocol included: complete urogynaecological history, physical examination, multi-channel urodynamics testing, 24-hour pad test and a three day bladder diary. UDI 6 SF, IIQ7 SF and visual analog score (VAS) were used for subjective assessment of quality of life (QOL) and treatment success. The early results of the 6 months follow up were published in 2008 (1). Yearly follow up has occurred with main outcome measure being the need for repeat surgery. Urogynaecological history, physical examination and QOL assessment (UDI 6 SF, IIQ 7 SF, VAS) were recorded.

Results

From Feb 2004 to Feb 2007 181 women were eligible to participate in this study and 162 were enrolled with 82 randomized to TVT and 82 to Monarc sling. Informed consent was obtained and ethical approval was obtained by the ethics committees of both participating centers. Demographic data, additional surgery to correct prolapse and results of 6 months follow up have already been reported.(1) The main outcome measure at median follow up time of 37.0 [23.3 to 47.9] months revealed that fifteen (18.3%) repeat sling procedures (TVT) were required for recurrent stress urinary incontinence in the Monarc group compared with one (1.2%) in the TVT group ($p < 0.001$). Repeat stress incontinence surgery was required in the TVT group 1/82 (1.2%) versus the Monarc group 15/82 (18.3%). The difference in proportion is 0.17 [95%CI 0.26 to 0.08] or 17% [95%CI 8% to 26%] $p < 0.001$, higher in Monarc compared to TVT. The relative risk of failure is 1.2 [95%CI 1.09 to 1.34] times greater with Monarc sling compared to the TVT sling. The time to repeat surgery given as median [25th to 75th percentile] was 15.6 months [11.8 to 41.4] in the 15 Monarc patients compared to 43.7 months in the one TVT failure. The difference in failure times was tested using the log-rank test for equality of survivor function, $p < 0.001$. Repeat surgery with TVT was performed in all women with symptomatic recurrent stress incontinence except for 1 woman in the Monarc group who developed a groin infection requiring partial Monarc sling removal, drainage and antibiotic treatment; and subsequently had a pubovaginal sling. Of the 15 women in the Monarc group who received further surgery: 5 women were cured, 4 women reported persistent bothersome stress urinary incontinence and 3 did have SUI with minimal leakage. The remaining 3 women have not reached six months postoperative follow up as yet. The one woman who received a repeat TVT following initial TVT has reported not bothersome persistent SUI at 4 months review. The analysis of the QOL questionnaires showed no difference between the groups at follow-up, but within groups there was again an overall significant improvement comparing pre- to postoperative assessment at 24, 36 and 48 months. Assessing the symptom of stress urinary incontinence in particular (UDI6q3) the same was found (Table 1).

Interpretation of results

The results of our three follow up confirm the earlier results reported after 6 months follow up (1). There appears to be a significantly better success rate in women with ISD undergoing the TVT compared with the Monarc procedure. Failure occurred earlier in the Monarc group. If TVT was performed rather than Monarc in women with ISD one in six [95%CI 4 to 13] failures would have been prevented. As there were 8 women (7 Monarc group/ 1 TVT group) that had persistent SUI following repeat sling, this may indicate that repeat surgery has a lesser success rate than primary surgery. However 8/14 (57%) were much improved or cured in the Monarc group following TVT insertion. In the QOL assessment with UDI 6 and IIQ 7 there was no difference demonstrable between the two groups, which may be due to the fact that the patients with significant stress incontinence received a further sling procedure and were therefore analysed separately after the second procedure.

Concluding message

Women with USI and ISD are significantly less likely to require further SI surgery with the retropubic TVT sling than the trans-obturator Monarc sling. On the basis of our findings, we conclude that in the treatment of USI with ISD the insertion of a TVT is the preferable surgical option. Further follow-up will be continued long term.

Table 1: Stress urinary incontinence, QOL questionnaires and VAS
 Results for 24, 36 and 48 months

	TVT			MONARC			Between group		
	n	Preop	Postop	n	Preop	Postop	Adjusted mean group difference	95%CI diff	p-value
24 MONTHS									
SUI	42	1.79	0.31	39	1.86	1.02	0.76	0.12 to 1.40	0.02

IIq7	56	8.25	1.60	47	9.86	1.14	-0.58	-1.68 to 0.52	0.30
UDI6	60	9.58	3.68	49	10.42	3.58	-0.04	-1.38 to 1.30	0.96
UDI6 q3	60	2.46	0.40	49	2.65	0.66	0.20	-0.19 to 0.58	0.32
VAS	33	N/A	89	36	N/A	80	8.4	-1.9 to 18.7	0.11
36 MONTHS									
SUI	39	1.79	0.18	27	1.86	1.10	0.95	0.32 to 1.60	0.004
IIq7	53	8.25	2.80	44	9.86	1.07	-2.05	-3.56 to -0.53	0.009
UDI6	54	9.58	3.69	43	10.42	3.43	-0.25	-1.47 to 0.97	0.68
UDI6 q3	54	2.46	0.45	43	2.65	0.48	-0.15	-0.57 to 0.26	0.47
VAS	30	N/A	82	21	N/A	86	-4.3	-17.1 to 8.46	0.50
48 MONTHS									
SUI	26	1.79	0.42	23	1.86	1.46	1.10	0.16 to 2.03	0.02
IIq7	31	8.25	2.71	28	9.86	1.60	-0.94	-3.17 to 1.29	0.40
UDI6	32	9.58	4.27	29	10.42	4.17	-0.06	-1.84 to 1.73	0.95
UDI6 q3	32	2.46	0.39	29	2.65	0.63	0.10	-0.45 to 0.65	0.71
VAS	14	N/A	88	14	N/A	90	-1.2	-13.9 to 11.5	0.84

* mean group difference after adjustment for preoperative value using change score ANOVA.

Within group change highly statistically significant for all comparisons $p < 0.0001$

References

- Schierlitz, L. Dwyer, P. L. Rosamilia, A. Murray, C. Thomas, E. De Souza, A. Lim, Y. N. Hiscock, R. Effectiveness of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency: a randomized controlled trial. *Obstet Gynecol.* 2008 Dec;112(6):1253-61

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Is this a Randomised Controlled Trial (RCT)?	Yes
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Institutional Research Ethics Committee, Mercy Hospital for Women, Heidelberg, VIC Australia Institutional Research Ethics Committee, Southern Health, Monash Medical Centre, Clayton, Vic Australia
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes