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LAPAROSCOPIC COLPOSUSPENSION OR TENSION-FREE VAGINAL TAPE FOR RECURRENT STRESS URINARY INCONTINENCE AND/OR INTRINSIC SPHINCTER DEFICIENCY - A RANDOMISED CONTROLLED TRIAL

Hypothesis / aims of study

Over the past decade there has been a significant shift towards less invasive continence surgeries including the Tension-free Vaginal Tape (TVT) and laparoscopic colposuspension (LC). The outcomes of these surgeries in high-risk incontinence groups including recurrent stress urinary incontinence and Intrinsic Sphincter Deficiency (ISD) remain unproven.
The aim of the paper is to compare the LC and TVT in women with recurrent stress urinary incontinence (previous retropubic surgery) and/or ISD.

Study design, materials and methods

Between 2001 and 2002, 82 women with recurrent SUI and/or ISD (MUCP$\leq$ 20cmH_20) were randomly allocated to the laparoscopic colposuspension (42) or TVT (40). A computer generated randomisation list was held by the non-surgical coauthor. Lists were stratified for ISD and concomitant prolapse surgery to ensure equal distribution. Women presenting primarily with pelvic organ prolapse, rigid urethra and those unfit for general anaesthesia were excluded.
Prior to enrolment, all women completed standardised pelvic floor proforma, including vaginal staging using the Pelvic Organ Prolapse Quantification (POP-Q), multichannel subtracted urodynamics, transperineal ultrasound to record bladder neck mobility, Short Urinary Distress Inventory (SUDI), short Incontinence Impact Questionnaire (SIIQ) and SF-36 Health Survey (SF-36).
Postoperative reviews were conducted by the non-surgical co-authors at 6 weeks, 6 months and at 6 monthly intervals. At 6 months the complete pre-operative evaluation was repeated. All women were treated on an intention to treat basis and the study conducted according to Consort guidelines.
Using a significance level of 5%, the study had an 80% power to detect a difference in success rates previously reported (1) between the groups in women with primary SUI.

Results

No eligible women refused participation in the trial and 1 failed to complete meaningful review. Preoperative details including age, parity, BMI, smoking, menopausal status, previous hysterectomy, previous continence or prolapse surgery, bladder overactivity, voiding dysfunction, MUCP, pelvic organ prolapse, dyspareunia and scores on quality of life and validated pelvic floor questionnaires were similar between the groups except women in the LC group were significantly older and women in the TVT group had a higher SIIQ score.
In the LC group 65% and in the TVT group 61% had recurrent SUI (p= 1.00).Table 1 reports important perioperative details and outcomes.
On logistic regression analysis no single factor was independently associated with outcome. In the LC arm 9 women underwent open procedures due to BMI $\geq$ 35. In the TVT group one woman had her procedure converted to open colposuspension due to inability to traverse retropubic space without bladder perforation and 1 had an incidental grade 1 transitional cell carcinoma of the bladder identified. Complications and re-operation rates were similar in each group.

Interpretation of results

In the medium term the LC and TVT are equally effective in women with recurrent SUI and or ISD. The TVT is associated with a statistically significant reduced operating time, catheter days, inpatient days and a quicker return to activities of daily living.

Concluding message

The LC and TVT are equally effective in women with recurrent SUI and or ISD.

Table 1. Perioperative details and outcomes

	Lap. colposuspension				**TVT**		
	n	***X***	***(%)***	***N***	***x***	***(%)***	***P***
Subjective success rate	42	34	(81)	40	35	(85)	0.77
Objective success rate	40	31	(78)	40	34	(85)	0.56
De novo OAB	40	4	(10)	0	0	(0)	0.09
De novo voiding dysfunction	40	2	(5)	0	0	(0)	0.43
Aware of prolapse	42	3	(7)	40	2	(5)	1.00
Sexually active	41	18	(44)	40	21	(53)	0.51
Dyspareunia	18	1	(6)	21	3	(14)	0.61
Concomitant prolapse surgery	42	7	(17)	40	6	(15)	0.77
	n	***mean***	***SD***	***N***	***mean***	***SD***	***P***
Operating time (mins)	42	44	17	40	30	16	<0.001
Blood loss (mls)	42	105	79	40	96.9	92	0.2
Days in hospital	42	3.4	1.2	40	2.4	1.2	<0.001*
Catheter days	4.1	2.7	2.6	40	1.4	2.1	<0.001*
Return normal activity (day)	29	25.0	9.7	33	17.9	9.7	0.002*
Review length (months)	42	19.1	10.1	39	18.0	8.4	0.79*
Cost Aus $	42	3,388	718	40	3,633	684	0.11
Patient Satisfaction (0-10)	42	9.0	1.1	40	8.6	1.9	0.45
Postop. increase MUCP	37	7.9	25	38	4.6	19.6	0.69*
Change in SUDI	41	40	31	40	43	25	0.97*
Change in SIIQ	41	48	39	40	62	32	0.85*
Change SF-36	25	4.0	11.9	31	4.3	9.8	0.37*

P-values calculated using Fishers exact test unless specified otherwise.
* Wilcoxon's two-sample test

1. Neurourol Urodyn 2003;22(5): 487-8.
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