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FACTORS INFLUENCING THE OUTCOME AFTER MID-URETHRAL SLING PROCEDURES IN FEMALE URINARY INCONTINENCE

Hypothesis / aims of study

There are few data on factors predicting the outcome after these operations and the effect of patient characteristics on the outcome has not been systemically addressed. Identifying factors that can be associated with the persistent urinary incontinence (UI) after the surgery would be of utmost importance because postoperative incontinence undermines the success rate perceived by the patient and physician. We evaluated the outcome at least 6 months after TVT or TOT procedure in women with UI, and identified factors predicting persistent stress UI after the surgery in these patients. <u>Study design, materials and methods</u>

Between January 2000 and March 2006, clinical records of 506 women with complaints of UI who underwent midurethral sling procedures (TVT or TOT) were retrospectively reviewed. The first case of the TVT procedure at our institution was performed on March 1999. From May 2004, we performed TOT procedure for patients with UI. A total of 464 women 28 to 80 years old (mean age 56) were included in the study. TVT (n = 252) and TOT (n = 212) procedures were performed by the same surgeon. The mean follow-up time was 10.8 months (range 6 to 52). The sample size calculation was performed assuming a 90% cure rate with TVT, and that a 10% difference in cure rate between procedures would be clinically important. To detect this level of difference with 80% power would require 197 patients in each arm of the trial.

Results

Bladder perforations were noted in 12 (4.8%) in the TVT group, but there was no bladder perforation occurred after the TOT procedure (p = 0.001). The rate of urinary retention in the TVT group was significantly higher than that in the TOT group (15.1% versus 6.6%; p = 0.004). The overall cure rate was significantly higher in the TVT group than in the TOT group (92.1% versus 84.9%, p = 0.015) (Table). In the multivatiate analysis, four variables were independent risk factors for persistent stress UI: (odds ratio 2.37; 95% confidence interval 1.26-4.47; p = 0.008) for co-morbid disease; 1.95 (1.02-3.74; p = 0.044) for urge UI; 2.73 (1.43-5.20; p = 0.002) for severe grade of cystocele; 2.87 (1.50-5.47; p = 0.001) for the TOT procedure.

Interpretation of results

The sling axis in the TVT is roughly perpendicular to the urethral axis, while the axis of TOT is less acute to the urethral axis. Therefore, one would expect the higher failure rate with TOT in women with intrinsic sphincter deficiency due to less circumferential compression of the urethra. Miller et al found that the TOT was nearly 6 times more likely to fail than TVT at 3 months after surgery in women with MUCP \leq 42 cmH₂O.¹ A recent study revealed that the odds of continued stress UI following TOT were 12 times greater for women with VLPP \leq 60 cmH₂O compared to those with VLPP >60 cmH₂O.² To date, the effect of patient characteristics on the outcome of mid-urethral sling procedures has not been systemically addressed. In the multivariate model used, severe grade of cystocele was one of independent risk factors for persistent stress UI. Recognition of the severity and types of pelvic organ prolapse in a given patient may be imperative in devising an appropriate operative approach. In addition, we found the presence of combined urge UI as another risk factor of persistent stress UI. It is also possible that patients with mixed UI symptoms do not really have two separate pathologic conditions. Rather mixed symptoms may be due to a more severe form of stress predominant UI.³ This may be an explanation of why mixed symptoms may resolve after successful anti-incontinence procedures.

Concluding message

The cure rates in women with UI are not similar after TVT and TOT procedures. Our findings suggest that patient characteristics including the type of procedure, co-morbid diseases, mixed UI and severe grade cystocele should be considered to be at high risk of persistent stress UI in these patients.

<u>References</u>

1. Am J Obstet Gynecol (2006) 195; 1799-1084.

- 2. Neurourol Urodyn (2006) 25; 685-688.
- 3. Obstet Gynecol (2003) 102; 76-83.

Table. Postoperative results

	TVT	TOT	p Value
No.	252	212	
Bladder injury	12 (4.8%)	0 (0.0%)	0.001**
One-hour pad test (g)	3.9 ± 2.0	2.9 ± 0.9	0.706
Maximum flow rate (ml/s)	21.7 ± 0.7	25.7 ± 0.8	<0.001 [*]
Post-void residual (ml)	47.3 ± 5.6	29.9 ± 5.5	0.028 [*]
Urinary retention	38 (15.1%)	14 (6.6%)	0.004^{+}
Cure rate	232 (92.1%)	180 (84.9%)	0.015^{+}

FUNDING: None CLINICAL TRIAL REGISTRATION: trials registry.

This clinical trial has not yet been registered in a public clinical

HUMAN SUBJECTS: This study was approved by the Internal Review Board of the Seoul National University Hospital and followed the Declaration of Helsinki Informed consent was obtained from the patients.