Bratisl Lek Listy 2010; 111 (12)
647 – 652

CLINICAL STUDY

Critical appraisal of prognostic factors for transobturator tape implantation

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Abstract: *Objectives:* The aim of the study was (1) to compare early results of transobturator tape (TOT) implantation in women with lower and higher Valsalva leak point pressure (VLPP) and (2) to find out significant and independent prognostic factors of TOT implantation.
Material and Methods: 97 female patients (pts) underwent TOT implantation between March 2004 and September 2007. We observed preoperative parameters including VLPP, urine leakage (PWT1), quality of life (IQOL1), age, BMI, parity, previous anti-incontinence surgery, hysterectomy status (HYE) and symptoms of OAB. According to VLPP value, pts were divided into two groups, namely those with lower VLPP values (≤60 cmH_2O) and those with higher VLPP values (> 60 cmH_2O). Two different tapes were used for TOT implantation (resorbable and non-resorbable). Six months after surgery, urine leakage (PWT2) was reassessed and pts were classed into two main categories as 'cured' (PWT2 ≤2 g), or 'not cured' (PWT2 >2 g).
Results: Pts with lower VLPP values had significantly lower cure rates than those with higher VLPP values (43.8 % vs 81.5 %, p <0.001, respectively). Univariate logistic regresion analysis identified VLPP, PWT1, IQOL1, age, HYE, and TOT type parameters as significant factors for cure. Of these significant parameters, the multivariate logistic regresion analysis identified PWT1 and TOT type as the only independent ones.
Conclusions: Pts with lower VLPP values are at a five-fold greater risk of not being cured than those with higher VLPP values. Preoperative urine leakage and TOT type are the only independent prognostic factors for cure after TOT implantation *(Tab. 5, Fig. 3, Ref. 32)*. Full Text in free PDF *www.bmj.sk.*
Key words: urinary incontinence, prostheses and implants, treatment outcome, urodynamics, valsalva manoeuvre.

Stress urinary incontinence (SUI) is a devastating condition affecting 15 % to 35 % of females in general population (1). Many surgical procedures for relieving SUI have been introduced and most of them stabilise the bladder neck and/or urethra. In 1996, Ulmsten proposed a new surgical technique called tension-free vaginal tape (TVT) for treatment of SUI (2). Pioneered by Delormed in 2001, the transobturator approach was developed with an aim to reduce the side effects of this retropubic sling procedure without entering the space beyond the endopelvic fascia (3). The mechanism of action of these sling procedures differs from that of conventional slings since the latter slings were usually placed beneath the bladder neck to elevate this area according to Enhoerning's pressure transmission theory (4). Using tension-free or low-tension slings, the bladder neck is not displaced backwards into the abdomino-pelvic pressure zone but the defective pubo-urethral ligaments are replaced. In addition, the defective connection between the urethra and vagina is restored and thereby the suburethral hammock is reinforced/restored. In this way, the threedimensional vector forces can open and close the bladder neck again according to the Integral Theory by Petros and Ulmsten (5). The transobturator suburethral tape (TOT) implantation has recently gained in popularity in the treatment of all types of SUI, i.e. SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency (6). So far however, the extent of sphincteric impairment which can be cured or improved by TOT implantation has not been specified (7, 8). Additionally, there is no prospective study evaluating the prognostic factors for TOT implantation.

Currently, the definition and diagnosis of intrinsic sphincter deficiency (ISD) is still unclear and there are no data in literature supporting the suggestion that ISD can influence either the outcomes or the type of surgical treatment (9, 10). In spite of this, maximal urethral closure pressure (MUCP) of less than 20 cmH_2O or Valsalva leak point pressure (VLPP) of less than 60 cmH_2O have been the urodynamic criteria for the diagnosis of ISD (11, 12). The former shows passive urethral tone generated by urethral and paraurethral tissues while the latter determinates active urethral resistance during stress. Thus, one would expect that VLPP was relatively more important than MUCP for the result of TOT procedure. Nevertheless, the clinical value of VLPP in predicting the outcomes of TOT implantation has not been systematically evaluated in previous studies (13). In this study,

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we compared the treatment outcomes in terms of the cure rate, success rate, objective improvement, subjective improvement, postoperative leakage, and postoperative quality of life in patients with higher and lower VLPP values. Parameters such as urine leakage, quality of life, age, BMI, parity, previous anti-incontinence surgery, hysterectomy status, symptoms of OAB and TOT type may also influence the outcome of TOT implantation. For this reason, we evaluated the outcome of TOT implantation taking into account the influence of each and every parameter separately.

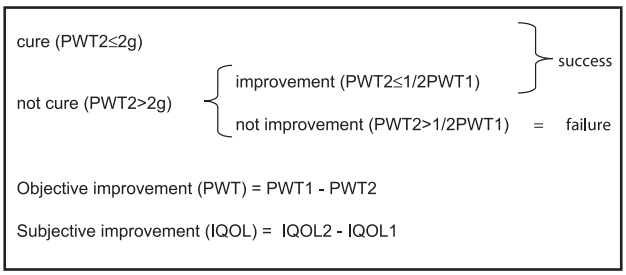

Fig. 1. Assessment of treatment outcomes.

Material and methods

We prospectively evaluated 97 female patients with urodynamic SUI who underwent the TOT implantation between March 2004 and September 2007. Before surgery, all patients underwent a three-day bladder diary, one-hour pad weight test (PWT1) (Tab. 1) (14), assessment of urinary incontinence-specific quality of life (IQOL1) (15, 16, 17) and urodynamic investigation with establishment of VLPP value according to the standard protocol (Tab. 2). Patients with detrusor overactivity, detrusor underactivity, significant post-void residuum (higher than 40 ml) and genital prolapse were excluded from this study. Patients were divided into two groups according to the preoperative VLPP value, while the first group included patients with lower VLPP values (≤60 cmH_20) and the second group included patients with higher VLPP values (> 60 cmH_2O).

Tab. 1. Schedule of a one-hour pad weight test (PWT).

1. Test was started without the patient voiding (bladder was filled at approximately 1/2 of maximum voided volume, checkup was done by ultrasound)
2. Preweighed collecting device was put on and one-hour test period began
3. Patient drank 500ml sodium free liquid with a short period (maximum 15 minutes), then sat and rested
4. Half hour period: patient walked, including stair climbing
5. During the remaining 15 minutes period the patient performed the following activities:
   – standing up from sitting, 10 times
   – coughing vigorously, 10 times
   – running on the spot for 1 minute
   – bending to pick up small object from floor, 5 times
   – washing hands in running water for 1 minute
6. At the end of the one-hour test the collecting device was removed and weighed. The gain in weight of the collecting device was considered as the urine loss

Tab. 2. Protocol of VLPP measurement.

1. The patient was positioned in the semivertical position (45°). A 6Fr dual lumen vesical catheter and 9Fr rectal balloon catheter were placed after both were zeroed to atmospheric pressure at the level of symphysis.
2. The bladder was filled with saline at room temperature at the 50ml per minute to approximately 200ml. The patient was instructed to perform progresive Valsalva manoeuvre until leakage occurs. Leakage was identified visually. If no leakage was detected at 200ml bladder filling, the test was repeated at higher volume with stepwise 50ml increments until maximum voided volume was attained. Investigation was prerformed by two persons. One person observed the urine leakage and one person observed the pressure curve.
3. The VLPP was reported as the intravesical pressure at which urine leakage occured subtracted from baseline vesical pressure

The TOT implantation was carried out with an outside-in approach according to the standard operation technique as orriginaly described by Delorme (18). Two different tapes were used for TOT implantation: polypropylene tape (type I) with suburethral segment made of polydioxanone (hereinafter resorbable tape) and homogenous polypropylene tape (type I) (hereinafter non-resorbable tape). Six months after surgery, urine leakage (PWT2) and urinary incontinence-specific quality of life (IQOL2) were reestablished using the same instruments as before the surgery. Additionally, complications of surgery were assessed at the same time. Surgery complications were reckoned as follows:

1. Excessive or prolonged bleeding (defined as blood loss greater than 200 ml or bleeding lasting more than three days),
2. Transient bladder catheterisation or permanent urinary retention (defined as post-void residuum higher than 200 ml),
3. *De novo s*torage symptoms (increased daytime frequency, nocturia, urgency),
4. *De novo* voiding symptoms (slow stream, splitting or spraying, intermittent stream, hesitancy, straining, terminal dribble),
5. Paraurethral inflammation,
6. Tape erosion into the urethra or vagina,
7. Peroperative anterior vaginal wall perforation,
8. Peroperative injury of the urethra,
9. Peroperative bladder perforation.

The treatment outcome of TOT implantation was assessed according to criteria as follows. Patients after TOT were considered cured should PWT2 be smaller or equal to 2 g, All other patients (i.e. those with PWT2 > 2 g) were considered not cured and were further separated into a group of patients with improved symptoms (PWT2 ≤1/2 PWT1) or those with no improvement (PWT2 > 1/2PWT1). 'Success' was considered should the patient be cured or symptoms improved, while 'failure' was considered should the symptoms stay not improved. 'Objective im-

provement' was measured as the difference between leaked amounts measured prior to and after surgery (PWT1-PWT2), while 'subjective improvement' as the difference in quality of life before and after surgery (IQOL2-IOQL1) (Fig. 1) (19).

Entire terminology used in this paper conforms to the standards recommended by the International Continence Society, while urodynamic investigations were performed respecting the recommendations of Good Urodynamic Practices (20, 21). The distributions of preoperative variables were compared using the descriptive statistics. Continuous variables were evaluated with Student's t-test. Categorical variables were evaluated with the Chi-Square test. Predictive modeling was performed with logistic regression. Step-wise models were created to assess the potential impact of preoperative measures other than the primary stratification variable. Variables that were significant on univariate analysis were considered significant prognostic factors and were further included in the multivariate logistic model. Variables that were significant on multivariate analysis were considered independent prognostic factors. The receiver operating characteristics (ROC) curve was used to provide predicting ability while areas under ROC curves were estimated. A significance level of 5 % was used for all statistical testing and all statistical tests were two-sided. The analysis was performed using statistical software SaS Enterprise Miner 5.2, SaS Enterprise Guide, STATGRAPHICS Plus 3.0 and statistic calculator EXCEL.

Results

A total of 97 patients underwent the TOT implantation for the treatment of SUI. Mean age was 51.7 years (range 30–74), mean parity was 2.0 (range 0–4), mean BMI was 24.9 kgm^{-2} (range 18.6–32), mean PWT1 was 13.2 g (range 4–48), mean IQOL1 was 60.1 p (range 22.7–87.5), 15 patients (15.5 %) previously underwent hysterectomy, 15 patients (15.5 %) previously underwent another surgery for urinary incontinence, 15 patients (15.5 %) suffered from OAB symptoms before the surgery. The first group included 32 patients while the second group included 65 patients. The overall cure rate was 69.1 %, success rate 90.7 %, objective improvement +10.4 g (range 2–38), subjective improvement +27 p (range 0–24), mean postoperative urine leakage 2.8 g (range 0–24), mean postoperative quality of life 87.8 p (range 45.5–100).

Tab. 3. Comparison of preoperative characteristics and type of implanted TOT in patients stratified by VLPP value.

	VLPP≤60cm H_2O (32 patients) average±SD	VLPP>60cm H_2O (65 patients) average±SD	p value
PWT1 (g)	19,4±8,1	10,1±3,5	<0,001
IQOL1 (p)	53,0±11,0	63,8±10,4	<0,001
age (year)	60,4±8,0	47,4±8,3	<0,001
BMI (kgm-2)	25,4±2,7	24,7±2,9	0,274
parity	2,4±1,1	1,8±0,8	0,002
HYE	37,50%	4,60%	<0,001
AIS	28,10%	9,20%	0,016
OAB1	12,50%	16,90%	0,571
TOT	resorbable 34,4% non-resorbable 65,6%	resorbable 24,6% non-resorbable 75,4%	0,313

Tab. 4. Comparison of postoperative characteristics and complications of surgery in patients stratified by VLPP value.

	VLPP≤60cm H_2O (32 patients) average±SD	VLPP>60cm H_2O (65 patients) average±SD	p value
cure rate	43,80%	81,50%	<0,001
success rate	84,40%	93,80%	*
objective improvement (g)	13,9±6,9	8,6±3,4	<0,001
subjective improvement (p)	28,2±12,6	27,6±11,0	0,236
PWT2 (g)	5,5±5,4	1,5±2,1	<0,001
IQOL2 (p)	81,0±12,2	91,3±9,1	<0,001
complications (total)	11x	14x	0,174
bleeding	2x(6,3%)	2x(3,1%)	*
retention	4x(12,5%)	5x(7,7%)	*
storage symptoms "de novo"	2x(6,3%)	5x(7,7%)	*
voiding symptoms "de novo"	1x(3,1%)	1x(1,5%)	*
paraurethral inflamation	0x(0%)	0x(0%)	*
tape erosion	0x(0%)	0x(0%)	*
vaginal wall perforation	2x(6,3%)	0x(0%)	*
urethral laesion	0x(0%)	1x(1,5%)	*
bladder perforation	0x(0%)	0x(0%)	*

* there was not fulfill the condition of chi-square test for minimal frequency in each unit, i.e. it is not possible to compare properly the difference in the observed parameter between both groups

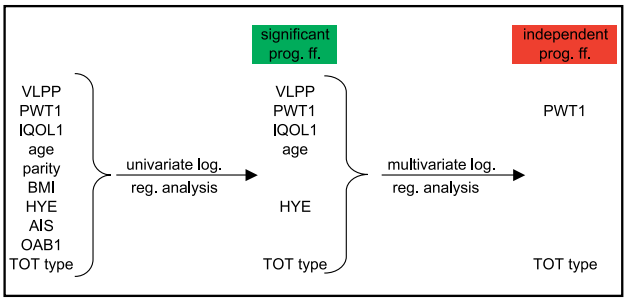

Fig. 2. Detection of significant and independent prognostic factors for cure after TOT implantation.

The comparison of preoperative variables, TOT type and postoperative characteristics of patients stratified by VLPP values are shown in tables (Tabs 3 and 4). Patients with lower VLPP values had significantly higher preoperative urine leakage, lower quality of life, higher age and parity. These patients were significantly more often after hysterectomy and had a previous antiincontinence surgery than those with higher VLPP values. Patients with lower VLPP values were at a 5.68-times greater risk of not being cured and at a 2.82-times greater risk of failure than those with higher VLPP values. There was found no significant difference in total complications of surgery among patients stratified by VLPP value.

Univariate logistic regresion analysis identified VLPP, PWT1, IQOL1, age, HYE and TOT type to be significant factors for cure. Of the latter significant parameters, the multivariate logis-

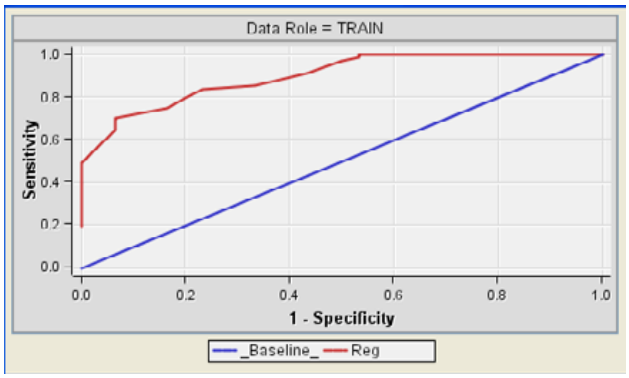

Fig. 3. Multivariate logistic regression analysis model predicting cure according to PWT1 a TOT type.

tic regresion analysis identified only PWT1 and TOT type to be independent ones (Fig. 2). The logistic regresion analysis model predicting the cure according to both PWT1 and TOT types had an area under the ROC curve of 0.896 (sensitivity 85.1 %, specificity 66.7 %, PPV 85.1 %, NPV 66.7 %) (Fig. 3). Interactive correlation between observed preoperative variables reflects their correlation coefficient and it is shown in table (Tab. 5).

Discussion

Urodynamic studies are considered the gold standard for the assessment of female stress urinary incontinence, although the extent to which it influences the treatment outcomes is controversial (22). According to a questionnaire mailed to gynecologists in five developed countries with the exception of UK, almost 50 % of them would consider doing surgery for non-complex stress urinary incontinence without performing urodynamic studies (23). According to a prospective study conducted by Rodriguez, no statistical difference was observed in surgical results, although the number of pads was significantly higher in patients with lower VLPP. The authors conclude that VLPP has no bearing on the outcome of synthetic midurethra sling procedures (24). The role of urodynamics when considering TOT is still an unanswered question as conflicting results are available in literature (25, 26, 27).

Confusing results in previous studies comparing the treatment outcomes in patients stratified by VLPP may be due to the methodology of VLPP measurement. VLPP is not consistently defined and techniques for its measurement are not standardized. This renders any comparison of findings between studies diffucult. ICS allows calculation of VLPP value from three different commonly used baseline values, namely the true zero of intravesical pressure ($VLPP_{tot}$) (1), the value of vesical pressure immediately before the Valsalva manoeuvre (ΔVLPP) (2), or the value of vesical pressure measured at zero bladder volume ($VLPP_{orig}$) (3) (14). In women in the standing position, ΔVLPP is much smaller than $VLPP_{tot}$, namely by about 33 cmH_2O on average (28). Other elements contributing to the confusion include the location of catheter (urethra, vagina, rectum), catheter caliber, shift in catheter location during Valsalva or cough, whether Valsalva or cough is used to produce leakage, technique to confirm urine loss (visual, electronic, uroflowmetric, fluoroscopic), type of pressure sensor, volume in bladder during the test, rate of prior bladder filling and patient position (horizontal, semivertical, vertical), pelvis organ prolapse and the way of its correction (10).

The operation technique may also influence the outcome of TOT implantation. However, the assessment of tape tension during TOT implantation includes an inevitable bias and there is no consensus for the diagnosis of bladder outlet obstruction in

Tab. 5. Correlation matrix. Correlation coefficient between observed preoperative variables is shown in the first line. "P value" testing hypothesis that correlation coefficient = 0 (H0: p≠0, H1: p?0) is shown in the second line.

Pearson Correlation Coefficients, N = 97 Prob > |r| under H0: Rho=0						
	VLPP	IQOL1	PWT1	VEK	BMI	PARITA
VLPP	1,00000	0,59530 <0,0001	-0,77758 <0,0001	-0,62781 <0,0001	-0,11400 0,2662	-0,28355 0,0049
IQOL1	0,59530 <0,0001	1,00000	-0,66609 <0,0001	-0,35027 0,0004	-0,07317 0,4763	-0,08707 0,3964
PWT1	-0,77758 <0,0001	-0,66609 <0,0001	1,00000	0,55018 <0,0001	0,12939 0,2066	0,21677 0,0330
VEK	-0,62781 <0,0001	-0,35027 0,0004	0,55018 <0,0001	1,00000	0,35481 0,0004	0,20878 0,0401
BMI	-0,11400 0,2662	-0,07317 0,4763	0,12939 0,2066	0,35481 0,0004	1,00000	0,05319 0,6049
PARITA	-0,28355 0,0049	-0,08707 0,3964	0,21677 0,0330	0,20878 0,0401	0,05319 0,6049	1,00000

women (30). TOT implantation with too much tension can probably cause continence in all patients regardless to their VLPP value.

In the current study, we found a significant difference between patients stratified by VLPP values in terms of cure rate, objective improvement, postoperative leakage and quality of life. These findings mean that results after TOT implantation in patients with intrinsic sphincter deficiency seem to be worse than in those without sphincteric impairment. Although no significant difference was found in subjective improvement and total complications of surgery, it cannot be stated that the TOT procedure is efficient equally in patients with and without impaired intrinsic urethral resistance. We do not recommend to use resorbable TOT as this tape significantly increases the risk of not being cured and we found no benefit resulting from its use.

There is no consensus for assessment of results after anti-incontinence surgery. Surgeons have tended to assume that the most significant outcome measure for surgery for SUI is whether complete continence is achieved. This is despite the evidence that patients may be satisfied with the outcome without complete continence (28). Taking into account that surgery for stress incontinence does not always produce continence and that this procedure can produce significant complications, it may be more relevant to consider the overall impact of the surgery on the quality of life rather than on the single issue of continence. Although the cure rate in patients with lower VLPP values may seem relatively low, we considere patient satisfaction the most important goal of surgery. Even there are other possibilities of how to achieve higher cure rate in patients with lower VLPP values, these procedures are associated with greater side effects (especially voiding dysfunction, constipation, need of repeated procedures). Even though a female patient is treated for the condition of SUI, her general quality of life may drop down and if she had been aware of all these consequences, she might have never agreed with such a surgery (31). Jeon at al. compared the treatment outcomes of three sling procedures (pubovaginal sling, TVT and TOT) in women with SUI due to ISD. Two years after surgery, the cumulative cure rates of the pubovaginal sling (PVS), TVT and TOT groups were significantly different (87.25 %, 86.94 % and 34.89 %, respectively). The seven-year cumulative cure rates are so far available only in PVS and TVT groups and are as follows: PVS group 59.10 % and TVT group 55.09 % (no significant difference) (32).

Conclusions

VLPP was found to be a significant but dependent prognostic factor for TOT implantation. Urine leakage and TOT type were found to be the only independent prognostic factors for cure after TOT implantation. TOT implantation improves both, continence status and quality of life in patients with SUI regardless of their VLPP value. Patients with lower VLPP values are at a five-fold greater risk of not being cured and at a two-fold greater risk of not being improved than those with higher VLPP values. Resorbable TOT significantly increases the risk of not being cured. PVS and TVT seem to be more efficacious in women with SUI due to ISD, however the long-term cure rates are not as high. Best treatment modality should be chosen for each patient individually taking into account her expectations. Moreover, the patient should be aware of potential complications resulting from the chosen surgery.

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Received November 12, 2009.
Accepted September 20, 2010.