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CRITICAL APPRAISAL OF PROGNOSTIC FACTORS FOR TRANSOBTURATOR TAPE IMPLANTATION

Hypothesis / aims of study

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) values
2.) to find out significant and independent prognostic factors for TOT implantation

Study design, materials and methods

97 female patients (pts) underwent TOT implantation between March 2004 and September 2007. Their inclusion criterion was urodynamic stress urinary incontinence. The exclusion criteria were detrusor overactivity or underactivity, neurogenic voiding dysfunction, pelvic organ prolapse and post-void residuum higher than 40ml. Following preoperative parameters were observed: VLPP, urine leakage (PWT1), quality of life (IQOL1), age, body mass index (BMI), number of deliveries (parity), previous anti-incontinence surgery (AIS), previous hysterectomy (HYE) and symptoms of overactive bladder (OAB1). Pts were introduced into two groups according to their preoperative VLPP value: pts with lower VLPP values (≤60cm H_2O) and pts with higher VLPP values (>60cm H_2O). Two different tapes were used for TOT implantation (resorbable and non resorbable). Six months after surgery urine leakage (PWT2) and quality of life (IQOL2) were reassessed and complications of surgery were established. Pts were classified into two main categories: “cured” (PWT2≤2g) or “not cured” (PWT2>2g). Not cured pts were further separated into “improved” (PWT2≤1/2PWT1) or “not improved” (PWT2>1/2PWT1). Cure or improvement were considered as a “success”, not improvement as a “failure”. “Objective improvement” was defined as the difference between preoperative and postoperative leakage (PWT1-PWT2), “subjective improvement” as the difference between postoperative and preoperative quality of life (IQOL2-IQOL1). Statistical analysis was done using the Student’s t–test for continuous data and the Chi-Square test for categorical data. Odds ratio (OR) and p values of the observed parameters were estimated by logistic regresion analysis (LRA). Those parameters that were significant on univariate model were considered as „significant prognostic factors“. Only these factors were further included into multivariate model. Significant factors of multivariate model were considered as „independent prognostic factors“. A receiver operating characteristic (ROC) and an area under the ROC curve (AUC) were used to provide predicting ability of the observed parameters. Values of sensitivity, specificity, positive predictive value and negative predictive value were counted for a cut-off value of probability 0,5 (i.e. pts whose probability of cure predicted by model is >0,5 are considered by model as cured, pts whose probability of cure predicted by model is ≤0,5 are considered by model as not cured). 5% level of significance was used for all statistical testing and all statistical tests were two sided.

Results

Comparison of preoperative and postoperative characteristics in pts stratified by VLPP value are shown in tabules (Figure 1, Figure 2). Pts with lower VLPP values were at 6-fold greater risk for not being cured and at 3-fold greater risk for failure than those with higher VLPP values. Univariate LRA identified as significant prognostic factors for cure after TOT implantation following parameters: VLPP, PWT1, IQOL1, age, HYE and TOT type. Multivariate LRA identified from these significant factors only PWT1 and TOT type as independent prognostic factors. Predicting ability of VLPP alone and predicting ability of PWT1 together with TOT type are shown in Figure 3. Pts with resorbable TOT were at 4-fold greater risk for not being cured than those with non-resorbable TOT (OR 4,583, 95%CI 1,773-1,849).

Interpretation of results

Pts with lower VLPP values had significantly lower cure rates than those with higher VLPP values (43,8% versus 81,5%). Objective improvement was significantly higher is pts with lower VLPP values that those with higher VLPP values. There was no significant difference in subjective improvement between pts stratified by VLPP value. VLPP value alone had low specificity for prediction of cure (about 50%). Resorbable TOT significantly increases the risk for not being cured. Preoperative urine leakage and TOT type were identified as the only independent prognostic factors for cure after TOT implantation.

Concluding message

Pts with lower VLPP values do not fare as well as those with higher VLPP values. Pts with lower VLPP values should be informed accordingly prior to a TOT implantation. Implantation of resorbable TOT significantly increases the risk for not being cured.

Figure 1. Comparison of preoperative characteristics and type of implanted TOT in patients stratified by VLPP value

Figure 2. Comparison of postoperative characteristics and complications of surgery in patients stratified by VLPP value

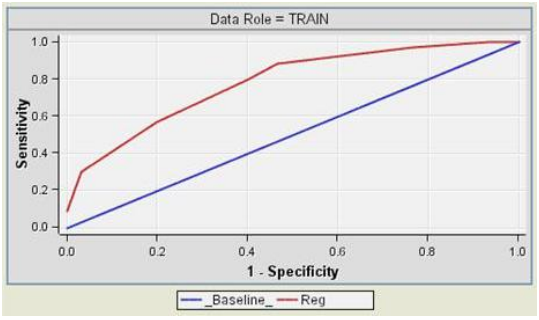
		VLPP		p value
		≤60cm H2O (32 patients) average±SD	>60cm H2O (65 patients) average±SD	
PWT1 (g)		19,4±8,1	10,1±3,5	<0,001
IQOL1 (p)		53,0±11,0	63,8±10,4	<0,001
age (year)		60,4±8,0	47,4±8,3	<0,001
BMI (kgm-2)		25,4±2,7	24,7±2,9	0,274
parity		2,4±1,1	1,8±0,8	0,002
HYE		37,50%	4,60%	<0,001
AIS		28,10%	9,20%	0,016
OAB1		12,50%	16,90%	0,571
TOT	resorbable	34,40%	24,60%	0,313
	non-resorbable	65,60%	75,40%	

	VLPP		p value
	≤60cm H2O (32 patients) average±SD	>60cm H2O (65 patients) average±SD	
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%)	*

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

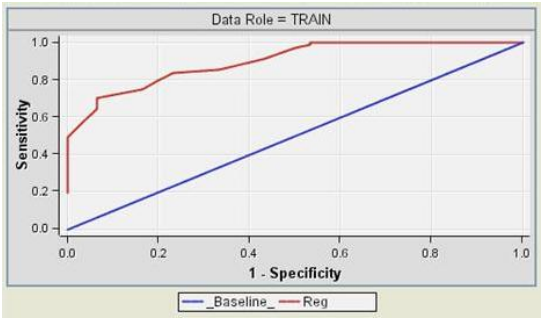
Figure 3. LRA for prediction of cure after TOT implantation

Univariate LRA model predicting cure according to VLPP



AUC: **0,77861**
(sensitivity 88,1%, specificity 53,3%, positive predictive value 80,8%, negative predictive value 66,6%)

Multivariate LRA model predicting cure according to PWT1 and TOT type



AUC: **0,89627**
(sensitivity 85,1%, specificity 66,7%, positive predictive value 85,1%, negative predictive value 66,7%)

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**This study was proceeded within conventional evaluation and treatment in our real life practice**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**