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RISK FACTORS OF TREATMENT FAILURE AFTER SURGERY FOR URINARY STRESS INCONTINENCE

Hypothesis / aims of study

The main aim for our study is to explore independent risk factors associated with the treatment failure after urinary stress incontinence surgery.

Study design, materials and methods

The study includes a total of 322 women with urodynamic stress incontinence, operated between 2004 and 2008 in our Hospital. 97 patients underwent Contasure-Needleless[®] and 225 underwent Obturator TVT[®].

Failure was defined as positive stress test during the examination 12 months after surgery.

Potential variables thought to be associated with treatment failure included medical/surgical history (age, body mass index (BMI), vaginal parity, prior pelvic prolapse surgery, menopausal status/hormone replacement treatment (HRT), use of vaginal estrogens, diabetes, smoking status, family history of stress urinary incontinence (SUI)); characteristics of urinary Incontinence (UI) (presence of urge symptoms, severity and duration of symptoms) and surgical factors (sling type, concomitant prolapse surgery and surgeon's experience)

Statistical analysis was performed using SPSS version 17.0 Chi-square tests and independent t student tests were used to compare the two groups (success vs failure) by baseline characteristics and clinical factors. When the assumption of the chi-square test was violated, the Fisher's exact test was used.

Multivariate analysis for the prediction of events was performed with logistic regression models. The analyses included independent variables that had a p<0.2 in the univariate analysis.

Results

UNIVARIATE ANALYSIS

	Success (n=263)	Failure (n=59)	P value
Age	58.97	57.85	0.43
Smoking Status	23 (8.7%)	10 (16.9%)	0.06
Menopausal Status	205 (77.9%)	46 (78%)	0.99
HRT	29 (14.1%)	4 (8.7%)	0.32
Diabetes	19 (7.2%)	8 (13.6%)	0.12
BMI >25	52 (19.8%)	7 (11.9%)	0.15
Vaginal Parity	2.49	2.49	0.99
Family History of SUI	61 (23.2%)	21 (35.6%)	0.04
Prior pelvic prolapse surgery	16 (6.1%)	5 (8.5%)	0.55
Use of vaginal estrogens	124 (47.3%)	25 (43.1%)	0.55
Duration of symptoms (years)	5.82	6.45	0.55
Pre-surgery Slight Sandvik Index	31 (11.8%)	5 (8.5%)	0.07
Pre-surgery Severe Sandvik Index	90 (34.2%)	19 (32.2%)	
Urge Symptoms	79 (30%)	19 (32.2%)	0.74
Concomitant prolapse surgery	177 (67.3%)	25 (42.4%)	0
Sling type: Contasure-Needleless [®]	77 (79.4%)	20 (20.6%)	0.48
Sling type: Obturator TVT [®]	186 (82.7%)	39 (17.3%)	
Expert surgeon	94 (35.7%)	15 (25.4%)	0.29
Novel surgeon	126 (47.9%)	34 (57.6%)	

LOGISTIC REGRESSION MODEL

	P value	OR
Smoking Status	0.346	
BMI >25	0.099	
Diabetes	0.018	0.25
Family History of SUI	0.09	
Pre-surgery Slight Sandvik Index	0.07	
Pre-surgery Severe Sandvik Index	0.56	
Concomitant prolapse surgery	0.002	0.33

Interpretation of results

In the present study, the success rate at follow-up of 12 months was 79.4% in the Contasure-Needleless® group and 82.7% in the Obturator TVT® group.

12 months after surgery, risk factors for recurrent or persistent SUI were similar in women undergoing Contasure-Needleless® and Obturator TVT®.

Our data suggest that addressing prolapse at the time of the sling procedure may provide better protection against recurrent SUI with an OR of 0.33. A possible theory for this protection is that concomitant prolapse repair creates anatomical changes that result in better restoration of continence.

Patients without diabetes mellitus had protective effect against recurrent SUI with an OR of 0.25, 13.6 percent of the patients in the failure group had diabetes mellitus compared to 7.2% in the success group ($p=0.12$).

Concluding message

We found that diabetes mellitus is an independent risk factor for midurethral sling failure. Correcting significant vaginal prolapse at the time of the sling procedure may provide protection against recurrent SUI.

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<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	We analyze results of our patients
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes