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ORIGINAL ARTICLE

Outcome of transobturator sling for treatment of female stress urinary incontinence applied as a single procedure or concomitantly with pelvic organ prolapse surgery

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Abstract

Introduction and Objective. The aim of the study was to check the safety and efficacy of transobturator tape (TOT) combined with various prolapse procedures. The results were compared with outcomes of sling performed as an alone surgery. Risk factors for TOT failure were also identified.

Materials and method. The study comprised 219 patients with sling alone (Group SUI) and 221 after TOT combined with concomitant prolapse surgery (Group POP/SUI). Medical records were carefully reviewed to obtain demographic and clinical data, details of surgery, including intra-and postoperative complications.

Results. Subjective cure rate was slightly, but statistically significantly, higher in POP/SUI group (89.6% vs 82.6%; $ch^2 = 4.44$; $p = 0.035$). There was no significant difference in sling efficacy dependant of type of POP surgery. Post-operative urine retention was more frequent in POP/SUI group compared to SUI group (18.6% vs 3.2%; $ch^2 = 34.36$; $p < 0.001$). Logistic regression showed that age, BMI and prolonged pos-operative urine retention are independent factors affecting TOT outcome. Age ≥65years and BMI ≥30kg,m^2 more than doubled the risk of failure: OR 2.348, CI 95% (1.330–4.147); $p = 0.003$ and 2.030, (95% CI 1.148–3.587); $p = 0.015$; respectively. Interestingly, post-operative urine retention appeared to be a positive prognostic factor OR 0.145, (95% CI 0.019–1.097); $p < 0.05$.

Conclusions. Subjective efficacy of TOT used concomitantly with POP procedures is slightly higher than TOT alone. Better sling outcomes can be expected both for POP procedures involving both the anterior and posterior compartments. Age and obesity are independent factors of TOT failure, whereas prolonged post-operative urine retention is a positive predictive factor of TOT success.

Key words

Sub-urethral sling, pelvic organ prolapse, stress urinary incontinence, transobturator tape, sling efficacy, urine retention

INTRODUCTION

Stress urinary incontinence (SUI) and pelvic organ prolapse (POP) are very common conditions affecting 20% -25% of the female population. Both ailments share aetiological factors, mainly parity and vaginal delivery, which often develop concomitantly [1–3]. It is estimated that SUI may co-exist with POP in around 40–60% of patients [4, 5]. SUI and POP produce many unpleasant symptoms and significantly decrease the quality of life. Other recognized risk factors of SUI and POP are age, obesity, pelvic surgery, comorbidities like asthma or constipation, as well as some genetic and constitutional characteristics [6–9].

Both conditions can be successfully corrected by the vaginal approach; however it is still controversial if concomitant prolapse surgery may affect the outcome of anti-incontinence treatment. The gold standard of contemporary anti-incontinence surgery are various procedures with synthetic tapes implanted under the mid-urethra (sub-urethral slings). Slings can be used alone or in combination with other surgeries. Some recommendations advise that treatment of SUI and POP may be completed during one operation, disregarding the higher risk of complications [10, 11]. On the other hand, some studies show that correction of POP may successfully treat SUI in 30–50% of patients indicating that a delayed two-step approach is also acceptable [12].

The aim of the study was to check the safety and efficacy of transobturator tape (TOT) applied for treatment of SUI combined with various prolapse procedures. The results were compared with outcomes of sling preformed as an alone surgery. Moreover, an attempt was made to identify risk factors for TOT failure.

MATERIALS AND METHOD

The study comprised a total of 577 patients who underwent transobturator sling procedure in the 2nd Department of Gynaecology at the Medical University of Lublin, Poland. Data for analysis were available for 219 patients with sling

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alone (SUI group) and for 221 when tape was combined with concomitant prolapse surgery (POP/SUI group). Information on surgery outcome was unavailable for 137 (23.7%) of the patients. Among them, 120 did not answer the phone call, 8 rejected participation in the study and 9 had died (Fig. 1). All participants were given a paper copy of the study protocol and provided informed consent by regular mail.

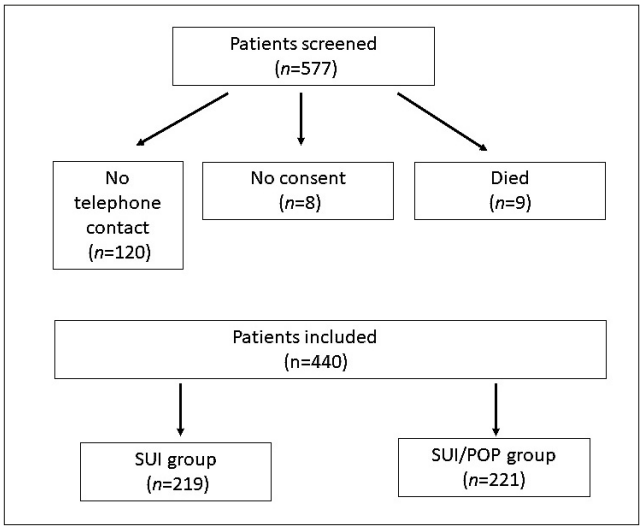

Figure 1. Flow chart of the study

Medical records were carefully reviewed to obtain demographic and clinical data, and details of surgery, including intra- and postoperative complications.

Before surgery, the patients were evaluated by medical history, pelvic examination, cough test and post-void residual (PVR) measurement by means of ultrasound. Type and severity of prolapse were assessed using Pelvic Organ Prolapse Quantification (POP-Q) system [13]. Types of prolapse diagnosed were as follows: combined anterior and posterior in 122 patients, only anterior in 10 patients, only posterior in 66 patients, total uterine prolapse in 25 patients, and vaginal cuff prolapse in 7 patients.

All patients underwent transobturator tape (TOT), as described previously [14]. Concomitant prolapse procedures included: anterior and posterior transvaginal mesh (TVM) (n=85), anterior TVM and posterior colporrhaphy (n=37), posterior colporrhaphy (n=44), posterior TVM (n=20), anterior TVM (n=8), anterior colporrhaphy (n=2), modified TVM for prolapse of vaginal cuff (n=7), vaginal hysterectomy (n=7) and LeFort colpocleisis (n=11) [15].

Data regarding continence status were obtained by telesurvey. The primary goal was to establish whether the patient was continent. When incontinence was reported, a detailed enquiry focused on stress and urgency symptoms was carried out. To maximize the reliability of data, selected questions from the Polish versions of the Gaudenz Questionnaire, Urinary Distress Inventory-6 (UDI-6) and Sandvic Scale were incorporated into the telesurvey [16]. The reason for using questionnaires was to differentiate between stress and urge incontinence, as well as to establish the actual severity of incontinence, which enabled the identification of patients with incidental incontinence episodes. The mean observation period was 27 months. The patients were regarded cured in the absence of incontinence or resolution of stress component in the case of mixed urinary incontinence. Post-operative urine retention was diagnosed when prolonged problems with bladder emptying required clean intermittent catheterization and the ultrasonographical post-void residue (PVR) exceeded 150ml. *De-novo* urgency was defined as the development or persistence of urge symptoms 6 months after surgery, excluding patients with a pre-operative urgency problem.

Statistical analyses were performed with Statistica.Statsoft wersja 13 (Tulusa, OK, USA). Student t-test, Mann-Whitney U test, chi-square test and logistic regression were used as appropriate. A p value of <0.05 was considered statistically significant.

The study was approved by the Institutional Review Board (KE-0254/223/2018).

RESULTS

Demographic and clinical data. Women in the POP/SUI group were older, more frequently post-menopausal, had higher parity, and underwent more vaginal deliveries compared to the SUI group of patients, whereas the mean BMI was slightly lower in POP/SUI group. The only relevant clinical data was a higher incidence of previous anti-incontinence surgery in the SUI group (Tab. 1).

Table 1. Demographic and clinical data of study groups

Parameter	SUI group (n=219)	POP/SUI group (n=221)	Statistical significance
Age (years, mean±SD)	5.8,0 ± 12.1	61.4 ± 11.2	p=0.0025
BMI (kg/m^2, mean±SD)	29.1 ± 5.4	28.0 ± 4.3	p=0.019
Parity (n, mean±SD)	2.2 ± 1.0	2.9 ± 1.4	p<0.001
Vaginal delivery (n, mean±SD)	2.0 ±1.0	2.8 ±1.4	p<0.001
Menopause n (%)	158 (72.1%)	185 (83.7%)	chi^2 = 8.56 p=0.0034
Mixed urinary incontinence n (%)	22 (10.1%)	15 (6.8%)	NS
Previous SUI surgery n (%)	31 (14.2%)	11 (5.0%)	chi2 = 10.73 p = 0.0011
Previuos POP surgery (%)	19 (8.7%)	21 (9.5%)	NS
Previous hysterectomy	28 (12.8%)	23 (10.4%)	NS

SD - standard deviation; SUI – stress urinary incontinence; POP – pelvic organ prolapse.

Sling efficacy. Subjective cure rate was slightly, but statistically significantly higher in the POP/SUI group (89.6% vs 82.6%; chi^2=4.44; p=0.035). There were no significant differences in sling efficacy dependant on the type of POP surgery (Tab. 2). In the case of surgeries involving both the

Table 2. Efficacy of transobturator sling depending on type of pelvic organ prolapse surgery

Type of surgery	Efficacy % (n)
Anterior and posterior mesh (n=85)	87.1% (74)
Anterior mesh and posterior colporrhaphy (n=37)	97.3% (36)
Posterior colporraphy(n=44)	88.6% (39)
Posterior mesh (n=20)	95.0% (19)
Anterior mesh (n=8)	75.0% (6)
Anterior colporraphy (n=2)	100% (2)
Modified anterior mesh for vaginal prolapse (n=7)	100% (7)
Vaginal hysterectomy (n=7)	100% (7)
LeFort colpocleisis (n=11)	72.7% (8)

anterior and posterior compartments, or, interestingly, only the posterior compartment, the cure rate exceeded 90% (90.7% and 90.6%, respectively). TOT was effective in all patients who underwent vaginal hysterectomy and in 72.7% of women after LeFort colpocleisis.

Complications. The most common complication associated with SUI and POP surgery were post-operative urine retention and development of *de-novo* urgency.

Post-operative urine retention occurred more frequently in the POP/SUI group, compared to the SUI group (18.6% vs 3.2%; $ch^2=34.36$; $p<0.001$), mainly due to the high incidence of this complication when the surgery involved the anterior compartment (25.2%). In the case of procedures involving solely the posterior vaginal wall, this complication was very rare (4.7%)

The prevalence of *de-novo* urgency did not differ between the POP/SUI and SUI groups (16.3% vs 17.4%); however, it was twice as frequent when the surgery involved the anterior vaginal wall (18.0% vs 9.4%).

Other complications, such as bladder injury, bleeding or graft protrusion, were rarely observed. None of the patient required blood transfusion or early re-operation. Only one case of intraoperative bladder injury (in POP/SUI group) occurred. Seven cases of graft extrusion in the POP/SUI group and one in the SUI group were identified. However, it is acknowledged that data regarding this complication may not be reliable, since up to 30% of protrusions may be free of symptoms and can be detected only at the objective evaluation [18].

Risk factors for sling failure. Also analysed were the influence of age, menopausal status, BMI, parity, previous anti-incontinence surgery, previous POP surgery, previous hysterectomy, mixed urinary incontinence, combined POP/SUI surgery, and post-operative urine retention on the risk of sling failure.

Univariate logistic regression showed that age, BMI, combined POP/SUI surgery and post-operative urine retention might have an impact on sling efficacy. OR for age was 1.031; CI 95% (1.007 – 1.056); $p = 0.027$, suggesting that risk of failure rises by 3% with each year. However, detailed analysis showed that the increase was not linear, and a significant risk of sling failure was observed from 65 years of age (Fig. 2). The risk actually doubles when the age of 65 is taken as a predictor: OR 2.353; CI 95% (1.362 – 4.066); $p < 0.001$. Furthermore, unfavourable sling outcome was associated with patients BMI: OR 1.066, (95% CI 1.012 – 1.124); $p = 0.017$. Risk of failure significantly increased in patients with BMI ≥30 kg/m^2 (Fig. 3) – OR 2.402, (95% CI 1.389 – 4.155); $p = 0.0017$.

Interestingly, concomitant POP surgery and prolonged post-operative urine retention appeared to be favourable predictors: OR 0.553, (95% CI 0.317 – 0.964); p=0,037 and OR 0.118, (95% CI 0.016 – 0.870); $p < 0.036$, respectively.

Multivariate logistic regression showed that age, BMI and prolonged post-operative urine retention are independent factors affecting sling outcome. Age ≥65years and BMI ≥30kg,m^2 more than doubled the risk of failure: OR 2.348, CI 95% (1.330 – 4.147); p=0.003 and OR 2.030, (95% CI 1.148 – 3.587); p=0.015; respectively. Interestingly, post-operative urine retention appeared to be a positive prognostic factor: OR 0.145, (95% CI 0.019 – 1.097); $p < 0.05$.

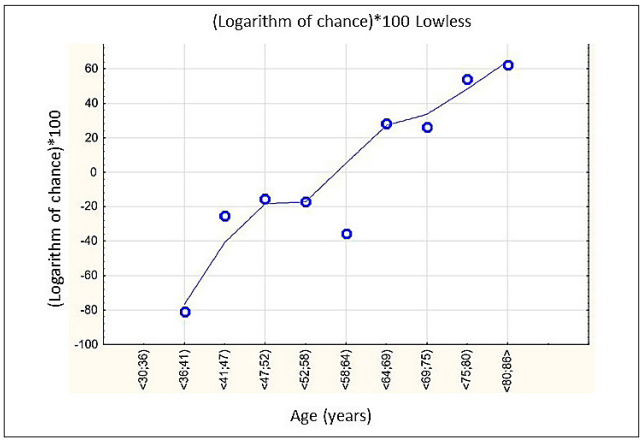

Figure 2. Logistic regression analysis of age as a risk factor of transobturator risk failure

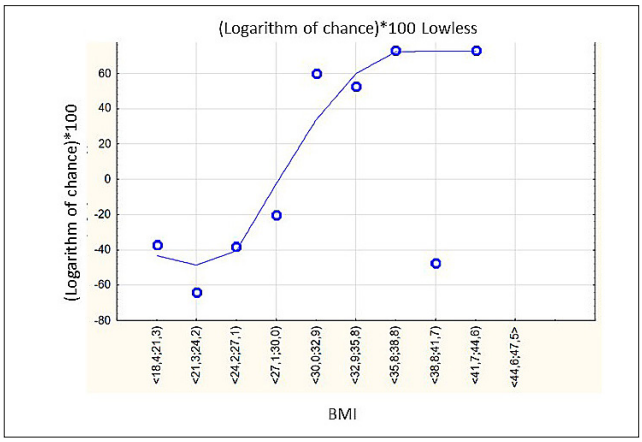

Figure 3. Logistic regression analysis of BMI as a risk factor of transobturator risk failure

DISCUSSION

Most published studies show equal efficacy of TOT used as a single procedure or combined with prolapse surgery [18–21]. Only the results of 2 studies revealed a better outcome for sling performed concomitantly with prolapse surgery [22, 23]. Due to many variables, such as the number of patients, observation period and, especially, types of concomitant prolapse surgery, direct comparison between studies is problematic. The findings of the current study show a better subjective outcome of combined procedures. However, many aspects need to be considered when interpreting the results of the study. First, in 62% of the patients, prolapse surgery involved mesh reinforcement of the anterior vaginal wall, which during the study period was a standard procedure for an anterior defect [24–26]. This may imply that additional compression of the urethra by mesh could explain better results. Nevertheless, favourable outcomes for slings, exceeding 90%, were observed when the surgery involved only the posterior compartment. It can be speculated that correction of the prolapse, anterior or posterior, restores proper urethra mobility which is crucial for adequate tape functioning [27].

Most of the authors did not focus on the relationship between sling efficacy and different types of prolapse surgery. Similarly to Chai et al. [18], no such coincidence was observed in the current study.

Among the many analysed risk factors of sling failure, age and obesity appeared to be the most significant, with the failure rate notably increased in patients aged ≥65 years. This is in line with observations of other authors [14, 24, 28, 29].

Obviously, anatomical and functional deterioration of the pelvic structures associated with ageing, lower mobility of the urethra, are explanations for worse sling results [28]. Therefore, it is worth mentioning that in the current study the patients in the POP/SUI group, on average, were 3 years older than those in the SUI group, but treatment results were even better.

Obesity is a condition which can be modified in pre- and post-operative care. However, the impact of body mass on slings results has not been unequivocally established. Some studies have identified obesity as an important risk factor, whereas others negate that it plays any role [14, 24, 28, 30–33]. In the current study, the risk of failure was more than twice as high in obese women.

An important point of debate is whether SUI and POP procedures should be performed concurrently or separately because of the uncertainty of the risk of complications. Many studies have not shown an increased risk of complications when the procedures are performed concomitantly [21, 34]. Other authors have observed an increased incidence of post-operative urine retention [35, 36]. In the current study, prolonged post-operative retention occurred more frequently in the POP/SIU group (18.6% vs 3.2%), mainly after procedures involving the anterior vaginal wall. Interestingly, this complication considerably decreased the risk of sling failure: OR 0.145 (95% CI 0.019–1.097); $p<0.05$. An association between prolonged urine retention and better sling results were observed by some but not all authors [21, 24, 35–37].

In this study, telephonic interview was used as the method for collecting data from participants. It appears to be an efficient method although its reliability in urogynaecology has not been extensively investigated. Balzarro et al. found that telesurvey is sufficient to establish continence status; however, patients tended to wrongly interpret *de-novo* urge urinary incontinence as a recurrence of SUI [17]. Thus, to maximize reliability of the study, questions from the validated questionnaires were used, which mainly focused on discrimination between stress and urge episodes. It is believed that this significantly improved the quality of data [38].

Obviously, the study has certain limitations. It is a retrospective non-randomized study in which some data bias could not be avoided. The POP group was heterogenous in terms of types of surgeries which, however, reflected the clinical presentation of patients. No data was obtained regarding POP surgery outcome due to, as mentioned above, the expected poor efficacy of telesurvey in this area.

CONCLUSIONS

The study showed that the subjective efficacy of TOT used concomitantly with POP procedures is slightly higher than TOT alone. Better sling outcomes can be expected both for POP procedures involving the anterior and posterior compartments. *De novo* urgency and post-operative urine retention are the most frequent complications of sling surgery; however, the combination of TOT with POP procedures does not increase the risk of *de novo* urgency. Age and obesity are independent factors of TOT failure, whereas prolonged post-operative urine retention is a positive predictive factor of TOT success.

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