

Research Article

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TVT-Exact and midurethral sling (SLING-IUFT) operative procedures: a randomized study

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Abstract: Objectives: The aim of the study is to compare results, effectiveness and complications of TVT exact and midurethral sling (SLING-IUFT) operations in the treatment of female stress urinary incontinence (SUI).

Methods: A single center nonblind, randomized study of women with SUI who were randomized to TVT-Exact and SLING-IUFT was performed by one surgeon from April 2009 to April 2011. SUI was diagnosed on coughing and Valsalva test and urodynamics (cystometry and uroflowmetry) were assessed before operation and 1 year after surgery. This was a prospective randomized study. The follow up period was 12 months. 76 patients were operated using the TVT-Exact operation and 78 patients – using the SLING-IUFT operation. There was no statistically significant differences between groups for BMI, parity, menopausal status and prolapsed stage (no patients had cystocele greater than stage II).

Results: Mean operative time was significantly shorter in the SLING-IUFT group (19 ± 5.6 min.) compared with the TVT-Exact group (27 ± 7.1 min.). There were statistically significant differences in the effectiveness of both procedures: TVT-Exact – at 94.5% and SLING-IUFT – at 61.2% after one year. Hospital stay was statistically significantly shorter in the SLING-IUFT group (1.2 ± 0.5 days) compared with the TVT-Exact group (3.5 ± 1.5 days). Statistically significantly fewer complications occurred in the SLING-IUFT group.

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Conclusion: the TVT-Exact and SLING-IUFT operations are both effective for surgical treatment of female stress urinary incontinence. The SLING-IUFT involved a shorter operation time and lower complications rate., the TVT-Exact procedure had statistically significantly more complications than the SLING-IUFT operation, but a higher effectiveness.

Keywords: TVT- exact, SLING-IUFT, MUS, stress urinary incontinence

1 Introduction

Female stress urinary incontinence (SUI) is a common disease with a huge impact on the patient's quality of life [1, 2].

Several reports show that urinary incontinence affects emotional, physical, as well as sexual aspects of well-being and can be a cause of anxiety and depression [3-7].

Surgical procedures are standard for women who have failed conservative management strategies such as lifestyle changes, physical therapy, scheduled voiding regimes, and behavioral therapies [5].

Surgical techniques for the correction of stress incontinence have evolved during the past 100 years and have included Kelly plication, retropubic urethropexy (Marshal-Marchetti-Krantz, Burch operations), needle urethropexy, fascial and synthetic bladder neck, and, more recently, midurethral slings (MUS), which can be placed using either a retropubic or a transobturator approach [9]. Midurethral tension-free slings are minimally invasive procedures that have been shown to have high success rates and low overall complication rate [10].

The tension-free vaginal tape procedure only is the best studied and documented procedure with excellent long-term outcome data. The transobturatoric approach

seemed to be equally effective according to the patient's subjective point of view. Promising new techniques, like the minislings, needs further evaluation [8].

The Urinary Incontinence Treatment Network has published a landmark multicenter randomized controlled trial (RCT) of 597 women who underwent either a retropubic or a transobturator midurethral sling (MUS) procedure [11]. Retropubic and transobturator MUS demonstrated equivalent objective success rates. Vaginal mesh exposure and mesh exposure were listed as serious adverse events in 2.7 and 0.3% of women in the retropubic group, respectively. This compared with vaginal mesh exposure and mesh erosion rates of 0.3% and 0.3% in the transobturator group, respectively. These differences were not statistically significant [12, 13].

A recent Cochrane review of MUS concluded that the MUS is as effective as the pubovaginal sling and retropubic colposuspension, but with fewer postoperative complications [14].

Although transobturator MUS was associated with less postoperative voiding dysfunction, it did result in more groin pain (12%) than retropubic MUS (1.7%).

The updated American Urologic Association (AUA) guideline for the surgical management of female stress urinary incontinence (SUI) also concluded that synthetic MUS is appropriate treatment with similar efficacy and less morbidity than conventional nonmesh slings [15].

Retropubic sling systems, especially TVT, are the best studied and well documented procedures. Both have excellent long-term outcome data, with low rate of complications. Significantly higher objective cure rates were reported for TVT than TOT, but both procedures are equally effective according to the patient's subjective point of view. In comparison with different types of TOT, no significant differences were identified [8].

2 Materials and methods

A randomized, nonblinded, clinical study was done, with all operations performed at Kaunas clinic of Lithuanian university of health sciences by one surgeon. Informed consent was obtained preoperatively from each subject. Women were randomized by 1:1 to midurethral sling-SLING-IUFT (transobturator) and TVT-Exact (retropubic) operations. The envelopes were sealed at the same day of surgery. Patients were not blinded to the procedure postoperatively as they were made aware of differences between procedures. This study was undertaken to compare prospectively the TVT-Exact procedure concerning the

effectiveness, safety and simplicity with the midurethral sling-SLING-IUFT procedure.

78 patients were subjected to TVT-Exact procedure and 76 to SLING-IUFT procedure. All those patients were available for follow-up at 12 months.

Inclusion criteria were a history of SUI with a demonstrable impact of SUI upon coughing and Valsalva tests during urodynamic (cystometry and uroflowmetry) testing [16].

Exclusion criteria were: previous suburethral sling, predominant overactive bladder symptoms, prolapse (cystocele) greater than stage 2, elevated postvoid residual (PVR >100 mL), urinary retention, progressive neurological disease, psychiatric disease and evidence of systematic infection.

The degree of the incontinence was 2–3 according to Ingelman-Sundberg scale [52]. The degree of vaginal defects was evaluated using the pelvic organ prolapse quantification (POP-Q) system [17].

Cystoscopy during operation was routinely performed only in the TVT-Exact group.

Antibiotic prophylaxis was performed for all operations during surgery.

Surgical procedures (TVT-Exact and SLING-IUFT) were performed by the same surgeon, using standardized protocols.

2.1 Results were estimated using the following criteria

- Excellent – no signs of stress incontinence, no imperative urination, no disuria.
- Good – no signs of stress incontinence, very mild imperative urination, no disuria.
- Medium – no signs of stress incontinence, imperative urination with minimal leakage, very mild disuria.
- Bad – stress incontinence, imperative urination, disuria, woman uses inlays.

Calculation was performed using SPSS-20 for Windows and statistical analysis was performed with the use of Student's t-test and chi-square test, Pearson's correlation coefficient and $p < 0.05$ was considered as statistically significant.

The study was approved by the Ethic Committee of the university hospital. Permission number: BEC-MF-306.

Ethical approval: The research related to human use has been complied with all the relevant national regulations, institutional policies and in accordance the tenets of the

Helsinki Declaration, and has been approved by the my institutional review board.

3 Results

All patients (TVT-Exact group n=76 and SLING-IUFT group n=78) were assessed for eligibility. SUI was diagnosed for all patient, who met the inclusion criteria and signed informed consent. All patients underwent surgery were operated in the Kaunas clinic of Lithuanian University of Health Sciences, Department of Obstetrics and Gynecology (by the same surgeon). The main type of anesthesia in both groups was intravenous (80.2% and 85.8%).

There is no statistically significant differences between the two groups among patients characteristics

for BMI, obesity and prolapse stage., (no patients had cystocele greater than stage II) (Table 1).

Statistically significant older patients were in the MUS group- SLING-IUFT group. Also statistically significant : there were more menopausal women in MUS (SLING-IUFT) group (Table 1).

There was no differences in the duration of stress urinary incontinence between groups (Table 1).

After 12 months, the TVT-Exact procedure is statistically significantly more effective than the SLING-IUFT (TVT-Exact– 94.5%, SLING-IUFT – 61.2%) (Table 2). Mean operative time was shorter in the SLING-IUFT group (19 ± 5.7 min) compared with the TVT-Exact group (21 ± 9.1 min.). Hospital stay was statistically significantly shorter in the SLING-IUFT group (1.5 ± 0.5 days) than in the TVT-Exact group (3.5 ± 1.5 days). Bladder drainage was statistically

Table 1: Patients characteristics

Patients characteristics	TVT-Exact (n = 76)	SLING-IUFT (n = 78)	P
Age ± SD	50 ± 8.9	67 ± 9.5	p<0.05
POP Q system: Stage 1	35	21	NS
Stage 2	41	57	NS
Follow up period (months)	12	12	NS
BMI, kg/m ²	28.5 ± 3.5	28.2 ± 3.8	NS
Parity	2.1 ± 1.1	2.5 ± 1.2	NS
Birth weight > 3500 g	49 ± 1.2	51 ± 1.3	NS
Menopause (1 – 30 years)	38	55	p<0.05
Obesity (BMI > 30)	10	11	NS
Irritated bladder symptoms	6	5	NS
Urinary incontinence period	8.5 ± 2.7	7.5 ± 2.9	NS
Hysterectomy in the past	11	15	NS
Operated incontinence in the past	8	7	NS

NS: non significant

Table 2: Register data of TVT-Exact and SLING-IUFT procedure

Register parameters	TVT-Exact (n = 76)	SLING-IUFT (n = 78)	P
Effectiveness of procedure (cure rate)	94.5%	61.2%	p<0.05
Duration of procedure	21 ± 9.1	19 ± 5.7	NS
Hospital stay (days)	3.5 ± 1.5	1.5 ± 0.5	p<0.05
Anesthesia:			
Lumbar	15 (19.7%)	11 (14.1%)	
Intravenous	61 (80.2%)	67 (85.8%)	
Concomitant surgery	25	26	NS
Bladder drainage:			
- Interrupted catheterization	12 (15.7%)	1 (1.3%)	p<0.05

NS: non significant

significantly rare in the SLING-IUFT group (1.3%) compare with TVT-Exact group (15.7%).

The postoperative results were very different in the groups (Table 3).

Bad results (the patient had stress urinary incontinence, imperative urination, disuria, used inlays) in TVT-Exact group included 4 (5.3%) cases and in the SLING-IUFT group, 31 (39.7%) cases. Medium results (patient didn't have signs of stress urinary incontinence., imperative urination was with minimal leakage and very mild disuria) in the TVT-Exact group (n=1., 1.3%), in SLING-IUFT (n=2., 2.6%), good results (patient didn't have signs of stress urinary incontinence., had very mild imperative urination, no disuria) in TVT-Exact group (n=11., 14.5%) in SLING-IUFT (n=10., 12.9%) and excellent results (patient didn't have signs of stress urinary incontinence, no imperative urination, no disuria) in the TVT-Exact group (n=60., 78.9%) in SLING-IUFT (n=35., 44.8%). The Chi-square test value- was 27.767, $p < 0.0001$.

Statistically significantly fewer complications occurred in the SLING-IUFT group (Table 4). Suprapubic hematoma occurred only in 3.9% of the TVT-Exact group., bladder perforation occurred in 1 case in the TVT-exact group as well. Postoperative urinary retention was statistically significantly higher in the TVT-Exact group (19.7%) than in SLING-IUFT group (1.3%).

Table 3: TVT-Exact and SLING-IUFT procedures follow-up results.

Results (after 1 year)	TVT-Exact N = 76	SLING-IUFT N = 78
Excellent	60 (78.9%)	35 (44.8%)
Good	11 (14.5%)	10 (12.9%)
Medium	1 (1.3%)	2 (2.6%)
Bad	4 (5.3%)	31 (39.7%)

$p < 0.0001$

Table 4: Postoperative complications

Complications	TVTExact (n = 76)	SLING-IUFT (n = 78)	p
None	49 (64.6%)	66 (84.6%)	$p < 0.05$
Suprapubic hematoma	3 (3.9%)	0	$p < 0.05$
Bladder perforation	1 (1.3%)	0	NS
Postoperative urinary retention	15 (19.7%)	1 (1.3%)	$p < 0.05$
Symptoms of irritated bladder	7 (9.2%)	5 (6.4%)	NS
Postoperative groin pain	1(1.3%)	5(6.4%)	$p < 0.05$
Vaginal erosion	0	1(1.3%)	NS

NS- non significant

Postoperative groin pain was more significant in the SLING-IUFT group- (6.4%), compared with the TVT-Exact group – (1.3%). There were no statistically significant differences in such complications as symptoms of irritated bladder. One instance of vaginal erosion was noticed in SLING-IUFT group.

4 Discussion

In the present study no statistically significant differences were noted between the two groups concerning- parity, BMI, obesity, duration of urinary incontinence, and degree of prolapse. Age was the independent risk factor for urinary incontinence [51].

There was a small difference in the mean operative time: it was much longer in the TVT-Exact- procedure than in the SLING-IUFT method, because in the TVT-Exact group intraoperative cystoscopy was necessary [18]. The duration of hospitalisation was statistically significant longer in the TVT-Exact group than in the SLING-IUFT group. These results are not in agreement with other authors [19], where the majority of patients were discharged from the hospital on the first postoperative day.

According to the literature, TVT provides overall subjective cure rates of more than 80% compared with less than 80% with another MUS- SPARC [41-44]. A 2-year follow-up study demonstrated a cure rate of 97% after 12 months and 85% after 24 months concerning TOT [45].

The effectiveness of procedure (or cure rate) in our study was 94.5% in the TVT-Exact group and 61.2% in the SLING-IUFT group. The cure rate of the TVT-Exact procedure is in agreement with other authors with cure rates that range from 84% to 95% [20-23,38]. However, the cure rate of midurethral sling- SLING-IUFT (61.2%) is worse than reported in the literature [18]. The older ages of

women in the SLING-IUFT group was the risk factor for the low cure rate. Severity of the incontinence, bladder hyposensitivity and cognitive deterioration among elderly women are factors that reduce the response to treatment (level 2) evidence [51].

Bladder perforation in our study was only 1.3% in the TVT-Exact- group (no cases in SLING-IUFT group) and it is less than reported in the literature [20, 24, 25].

Postoperative groin pain was more statistically significant in the SLING-IUFT group, compared with TVT-Exact procedure. The data are similar to those reported in the literature [40]. An advantage of the MUS-TOT procedure is the low perioperative complication rate. The transobturator approach is associated with a shorter operation time, less postoperative voiding dysfunction, and fewer bladder perforations than the retropubic route. An adverse effect reported more frequently with the obturatoric approach is postoperative groin pain [40,46-50]. Postoperative groin pain- in our study: in the SLING-IUFT group was higher at 6.4%, like in the TVT-Exact group at 1.3%.

Postoperative urinary retention was statistically significant higher in the TVT-Exact group., our data are not in agreement with the literature report [26]. Therefore, TVT-Exact is a safe and effective surgical treatment for female stress urinary incontinence with a good effectiveness [27-30, 37], but the TVT-Exact operation- is also associated with various perioperative complications [31-34].

Several suburethral tape insertion procedures have been described, such as tension-free trans-obturator tape (TOT) either from outside to inside or inside to outside [34-36]. One retrospective comparative study, investigating retropubic and outside- in transobturator sling, demonstrated that these procedures are equally efficacious to treat female stress urinary incontinence with a cure rate of 90% versus 84% for TOT and TVT, respectively [39].

The increasing number of procedures for the operative treatment of SUI leaves the surgeon not only with the freedom to choose, but also the responsibility to implant a device with which he/she feels confident and has sufficient experience [8].

5 Conclusions

1. The TVT-Exact operation is a very effective procedure, curing female stress urinary incontinence after 12 month of follow-up.
2. The SLING-IUFT operation had a low complication rate, but was less effective compared with the TVT-Exact operation.

3. The SLING-IUFT procedure had a shorter operation time and hospital stay than TVT-Exact procedure.

List of abbreviations

TVT-Exact: tension free vaginal tape exact and retropubic.

MUS: midurethral sling.

TVT-O: tension free vaginal obturator tape.

SUI: stress urinary incontinence.

POP-Q: pelvic organ prolapse quantification system.

NS: non significant.

RCT: randomized controlled trial.

TOT-tension obturator tape.

Authors' Contributions

RA (Rosita Aniuliene)-surgeon of all cases and general inspirator of main idea of the manuscript.

PA (Povilas Aniulis) and DS (Darijus Skaudickas)- participated in the design and coordination of the manuscript, performed the statistic analysis, also helped to draft the manuscript and participated in patients interrogatory before and after operation.

All authors read and approved the final manuscript.

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