

Comparison of the outcomes of the TOT technique using a hand-made TOT material and a commercial one

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Aim: The purpose of this study was to compare the effectiveness of handmade transobturator tape (TOT) devices (tailored polypropylene mesh by the surgeon during the operation) with commercially available ones.

Materials and methods: We included 78 consecutive women with the complaint of pure stress urinary incontinence recalcitrant to lifestyle modifications, pelvic floor muscle training, and medical treatment. The patients underwent TOT procedures either with a commercially available product (I-Stop, CL Medical, Lyon, France) (group 1) or with a device prepared during the operation with polypropylene mesh of 35 × 2 cm in size (Prolen®, Ethicon Inc., Somerville, New Jersey, USA) (group 2). The patients were followed for at least 18 months and cure was defined as the absence of any episodes of involuntary urine leakage during stressful activities and/or the stress cough test.

Results: Thirty-two (group 1) and 46 (group 2) patients underwent TOT surgery. Mean operation time was slightly shorter in group 1 compared to group 2 (20.53 ± 4.88 vs. 22.93 ± 4.84, P = 0.035); however, mean duration of the indwelling catheter was less than 1 day in both groups (P = 0.444). None of the patients had incontinence or urinary retention postoperatively. The cure rates in groups 1 and 2 were not significantly different at the end of the 1st (87.5% vs. 87%, P = 0.944) and 2nd (78.1% vs. 80.4%, P = 0.804) postoperative years.

Conclusion: TOT procedures performed with polypropylene mesh and No. 1 silk line are as effective and safe as commercially available TOT devices.

Key words: Midurethral sling, stress urinary incontinence, transobturator tape

Introduction

Stress urinary incontinence (SUI) is common among middle-aged women and its prevalence rates increase with age, reaching 45% at 60 years (1). Although several treatment modalities have been previously proposed, midurethral slings have radically changed its surgical management and several procedures for midurethral slings have been developed (1,2). In a quest to find a minimally invasive sling that is associated with even less morbidity than the tension-free vaginal tape (TVT), transobturator tape (TOT) surgery was introduced (3). Indeed, this approach

was found to be associated with lower complication rates and shorter operating times. With objective and subjective cure rates of up to 80% and 92%, respectively, the TOT procedure became a mainstay of surgical treatment for SUI (4–6). However, the cost of the commercially available devices used for the TOT procedure is expensive, which limits their widespread use, especially in developing countries.

In this study, we compared the effectiveness of handmade TOT devices (tailored polypropylene mesh) with a commercially available, ready-to-use TOT device.

Received: 02.01.2012 – Accepted: 12.05.2012

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Material and methods

Study population: Between May 2006 and January 2011, 78 consecutive women with the complaint of pure SUI that was recalcitrant to lifestyle modifications, pelvic floor muscle training, and medical treatment were included. All subjects gave their written informed consent before entering the study, which was conducted in accordance with the Declaration of Helsinki. The local medical ethical committee approved the study.

Characteristics such as body mass index (BMI), menopausal status, the number of pads used per day, and history of previous surgery of the patients were recorded. Physical examination (including detailed pelvic examination), urine analysis, and urodynamic evaluation was systematically performed according to the standards recommended by the International Continence Society (7). None of the patients had concomitant urge incontinence, pure intrinsic sphincter deficiency, neurogenic bladder, residual volume over 50 mL, pelvic organ prolapse, or previous radical pelvic surgery.

Surgical procedure: The operation was performed under either general or regional anesthesia as described by Delorme (3). At the beginning, a 16F Foley catheter was inserted into the bladder in the lithotomy position after administration of a prophylactic antibiotic (cefoxitin, 2 g intravenously). The anterior vaginal wall was suspended with Allis clamps and the mucosa was incised horizontally at the midpoint between the Foley balloon and the external urethral meatus. Helical needles designed for the transobturator process were inserted through skin incisions lateral to the labia major on both sides, by tracing a horizontal line at the level of the urethral meatus. Afterwards, these needles were tunneled through the obturator foramina until their tips were seen in the incision made on the anterior vaginal wall.

After this stage, either the commercially available product (I-Stop, CL Medical, Lyon, France) (group 1) or the hand-made tape (group 2) was used. In group 2, a polypropylene mesh of 35 × 2 cm in size (Prolen®, Ethicon Inc., Somerville, New Jersey, USA) was attached to the helical needles with No. 1 silk sutures, and it was pulled out through the transobturator tunnel, similar to the original procedure with care not

to twist the mesh and with no tension as guaranteed by interposing a pair of scissors between the mesh and the urethra so as to leave a space (3) (Figure). The excessive parts of the mesh were cut off at the level of subcutaneous tissue followed by the closure of the skin incision.

The urethral catheter was removed the following morning. The patients were followed for at least for 18 months and cure was defined as the absence of any episodes of involuntary urine leakage during stressful activities and/or the stress cough test. The patients were asked to return for follow-up visits at postoperative months 1 and 3, and every 3 months thereafter. Follow-up visits included a detailed medical interview, clinical examination, urine analysis, and postvoid residual determination.

Peroperative, early postoperative (hematoma, dysuria, infection), and late postoperative (erosions, perineal pain, de novo dyspareunia, de novo urge, or urge incontinence) complications were recorded. The cure of SUI was defined as no leakage of urine during stressful activities and a stress cough test. Patients who did not meet these criteria were considered to have “failed” treatment (8).

Statistical analysis: Statistical analysis of the data was performed by using Student’s t-test, the chi-square test, and Fisher’s exact test, for which SPSS 17.0 (SPSS Inc., Chicago, Illinois, USA) was used. Statistical significance was set at $P < 0.05$. The cost



Figure. Picture of the tailored mesh and helical needles used during TOT procedure.

Table. The characteristics and outcomes of the patients.

	Commercially available product (group 1, n = 32)	Tailored polypropylene mesh (group 2, n = 46)	P-value
Age (years)	55.69 ± 6.89	52.63 ± 7.43	0.066
BMI (kg/m ²)	25.13 ± 1.64	26.51 ± 3.17	0.014
Gravidity	3.50 ± 1.24	3.80 ± 1.43	0.335
Parity	3.19 ± 1.20	3.07 ± 1.16	0.654
Postmenopausal (%)	16 (50%)	21 (45.7%)	0.819
Cystocele (%)	5 (15.6%)	8 (17.4%)	1.000
VLPP (cmH ₂ O)	95.93 ± 9.55	94.58 ± 9.92	0.550
Q _{max} (mL/s)	27.93 ± 5.72	27.63 ± 6.23	0.831
Voided volume (mL)	325.50 ± 65.68	327.23 ± 66.67	0.910
PVR (mL)	29.21 ± 4.64	28.95 ± 4.87	0.909
Operation time (min)	20.53 ± 4.88	22.93 ± 4.84	0.035
Catheterization time (h)	21.22 ± 3.22	20.65 ± 3.17	0.444
Follow-up (months)	20.16 ± 5.82	26.37 ± 3.92	0.532
Postoperative UTI (%)	2 (6.3%)	3 (6.5%)	1.000
De novo urgency	3 (9.4%)	3 (6.5%)	0.685
Urinary retention	3 (9.4%)	2 (4.3%)	0.396
Dysuria	1 (3.1%)	3 (6.5%)	0.640

BMI: body mass index; VLPP: Valsalva leak point pressure; Q_{max}: maximum flow rate; PVR: postvoid residual urine volume; UTI: urinary tract infection.

of the hand-made and commercially available TOT products was also compared.

Results

The characteristics of the patients in groups 1 and 2 are given in the Table. Patients in group 2 had slightly higher BMI scores ($P = 0.014$), and the operation time in group 1 was shorter than in group 2 ($P = 0.035$). Mean duration of the indwelling catheter was less than 24 h in both groups ($P = 0.444$). None of the patients had any episodes of incontinence or urinary retention postoperatively.

The mean follow-up period was 20.16 ± 5.82 and 26.37 ± 3.92 months in groups 1 and 2 ($P = 0.073$). The cure rates in groups 1 and 2 were similar at the end of the 1st (87.5% vs. 87%, $P = 0.944$) and 2nd (78.1% vs. 80.4%, $P = 0.804$) years postoperatively. There were no peroperative complications (e.g., bladder puncture, intestinal perforation, or nerve and vascular damage) in either group. Minor complications such

as urinary tract infections occurred in 2 (6.3%) and 3 (6.5%) patients in groups 1 and 2, respectively, and de novo urgency occurred in 3 (9.4%) and 3 (6.5%), all of which were successfully treated conservatively. One patient (3.1%) in group 1 and 3 patients (6.5%) in group 2 ($P = 0.640$) reported dysuria and/or discomfort, all of whom responded well to nonopioid analgesic treatment. Wound infection was not observed in either group, whereas 2 patients in each group suffered from vaginal erosion during the follow-up period ($P = 1.000$). None of the patients complained of pain 1 month after the surgery.

The commercial sling system costs approximately €180.00 according to our hospital purchasing commission. The hand-made sling used in this study was fabricated from an original Prolen® Ethicon mesh (30 × 30 cm), which costs €250.00. This mesh was divided into 20 segments of 1.5 × 30 cm with 1 segment being used per surgery, corresponding to a cost per patient of approximately €12.50 (€250.00/20 segments).

Discussion

SUI is a prevalent condition that affects approximately 27% of women worldwide with far-reaching physical, psychological, social, and economic implications (9,10). In 1995, Ulmsten and Petros described a new concept of midurethral support without tension for urinary incontinence (1). However, concerns about complications associated with this procedure (11,12) elicited the development of different procedures, such as TOT (8,11–14). These midurethral sling methods are all based on the integral theory, which proposes that the midurethra serves a significant role in urinary continence and that the midurethral sling provides continence by creating a functional kinking of the midurethra during increased intraabdominal pressure and the associated rotational descent of the bladder neck and proximal urethra (15,16).

In 2001, Delorme (3) proposed the insertion of vaginal tape through the obturator foramen, and de Leval (17) reported a surgical success rate of 90.6% with the same procedure. Similar rates were reported by deTayrac (18), with a 1-year cure rate of 84% with the TOT procedure. These successful results popularized this procedure and ready-to-use TOT devices have begun being manufactured by a number of industrial companies.

In this study, we compared the complication rates and long-term outcomes of TOT surgeries performed with the use of either a commercially available product or hand-made mesh. Although perioperative TOT complications such as urethral or bladder perforation and vascular damage have been reported previously, none of these complications occurred in our study (19,20). Urine retention and voiding dysfunction rates were 9.4% and 4.3% in groups 1 and 2, respectively, which are comparable with the findings of previous studies (0% to 15.6%) (16,21). Minor complications related to TOT are urinary tract infections and de novo urgency symptoms, which have a high impact on the quality of life and have been reported to be as frequent as 0.8% to 47.2% (22,23). The incidences of these minor complications were in accordance with previously published series and were not statistically different within groups. Finally, the cure rates at the end of the 1st (87.5% vs. 87%) and 2nd (78.1% vs. 80.4%) years were similar in groups 1 and 2. These rates were not

different from the cure rates previously reported by different authors (17,18).

In our study, 2 women in each group had vaginal erosion. The mean time to erosion varied, which confirms the importance of close follow-up when symptoms like vaginal discharge, pain, or dyspareunia occur postoperatively (24,25). We think that to avoid erosion, not only the material used but also the surgical technique is important. Urethral injuries are believed to occur because of poor surgical technique, local infection, or excessive tension placed on the tape as these damage the integrity of the urethral tissue or its blood supply; the most important step to avoid erosion is to adjust the tape used against any tension or any contact with the urethra (26).

To our knowledge, this is the first study that compared the outcomes of TOT procedures performed with hand-made polypropylene mesh and commercially available products. However, in a recent study, Chen et al. (27) compared the efficacy of TVT and TOT procedures performed with self-tailored monofilament mesh. Although the authors did not find significant difference in success rates (95% vs. 96% in the TVT and TOT groups, respectively), they concluded that the TOT procedure was faster, more economical, and associated with fewer bladder complications. Similarly, our findings suggest that TOT procedures performed with hand-made polypropylene mesh are as safe and effective as those performed with the commercially available TOT devices. Effective and rational management of health care expenditures by reducing costs without compromising safety with the use of economical alternative techniques for common health problems such as SUI would be of great importance. Since commercially available TOT products are approximately 15 times more expensive than the cost of a hand-made polypropylene mesh, tailoring the TOT material would result in a reduction in the cost of surgery done for this common medical problem.

TOT procedures performed with tailored polypropylene mesh are as effective and safe as those using commercially available TOT devices. Significant reduction in the cost of utilized materials can be achieved and this may be considered as an alternative to commercially available products. However, further studies are required to confirm our findings.

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