Are Expensive Materials Really Necessary to Perform Transobturator Tape Operations?

Transobturator Bant Ameliyatlarında Pahalı Materyaller Kullanılmasına Gerek Var Mıdır?

Transobtrator Bant Ameliyatlarında Kullanılan Materyaller / Materials Used for Transobturator Tape Operations

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Özet

Amaç: Amacımız ameliyat esnasında polipropilen meş ile cerrah tarafından yapılan transobturator bant (TOT) materyallerinin maliyetini ve etkinliğini değerlendirmekti. Gereç ve Yöntem: Mayıs 2006 ve Haziran 2009 arasında 41 hastaya TOT operasyonu uygulandı. Stres üriner inkontinansın (SUI) tedavi başarısı öksürük testinde kaçak olmaması ve herhangibir idrar kaçırmanın rapor edilmemesiydi. Bulgular: Ortalama ameliyat süresi 22.3±5.3 dakika(14-33 dakika) idi. Peroperatif komplikasyon izlenmedi. Üriner enfeksiyon, de novo urgency ve postoperatif ateş gibi minör komplikasyonlar %4.8 hastada meydana geldi. 2 hastada (%4.8) üriner retansiyon oldu. 12 ve 24 ay sonunda sırası ile 37 (90.2%) ve 32 (78%) hasta kontinandı. Tartışma: Polipropilen meş ve 1 numara ipek sütür ile uygulanan TOT cerrahisi ticari TOT materyallerine göre daha ucuz fakat benzer güvenlik ve etkinliğe sahiptir.

Anahtar Kelimeler

İnkontinans; Stres; TOT

Abstract

Aim: Our aim was to assess the cost and effectiveness of transobturatuar tape (TOT) devices, made with tailored polypropylene mesh by the surgeon during the operation. Material and Method: Between May 2006 and June 2009, a total of 41 women underwent TOT procedure. The cure of SUI was defined as no urine leakage at cough test and not reporting any event of urinary incontinence. Result: The mean operative time was 22.3±5.3 minutes (range 14 to 33 minutes). No peroperative complications were recorded. Minor complications such as urinary tract infections, de novo urgency and postoperative fever occurred in 4.8% of patients. Two patients (4.8%) showed urinary retention. Overall 37 (90.2%) and 32 (78%) of patients were continent after 12 and 24 months, respectively. Discussion: TOT procedures performed with polipropilene mesh and no.1 silk line are as safe and effective as performing this operation with commercial TOT devices where as they are less expensive.

Keywords

Incontinence; Stress; TOT

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Introduction

Stress urinary incontinence (SUI) is a common disease in middle-aged women and its prevalence rates increase with age and reach 45% at 60 years [1]. A decade ago, the surgical treatment of female SUI radically changed when Ulmsten and Petros et al.[2] described a new, simple and efficient concept of mid-urethral support without tension. In a quest to find a minimally invasive sling associated with even less morbidity than the tension-free vaginal tape (TVT), transobturator tape (TOT) was created [3]. As the transobturator approach was associated with less complication rates and shorter operating time, with an objective and a subjective cure rates up to 80% and 92% respectively, this procedure became a mainstay of surgical treatment for SUI [4-6]. However, the cost of the devices used in TOT procedure is expensive, especially among developing countries.
In this study, we assessed the cost and effectiveness of TOT devices, made with tailored polypropylene mesh by the surgeon during the operation.

Material and Method

Study population: Between May 2006 and June 2009, a total of 41 consecutive women with the complaint of either pure stress or mixed urinary incontinence recalcitrant to lifestyle modifications, pelvic floor muscle training and medical treatment were prospectively enrolled. Our study was approved by the "Ethics Committee" of our institution. The demographic characteristics, medical history and variables such as body-mass index (BMI), menopausal status and history of previous surgery were recorded.

Those patients were further assessed with history including the number of pads used per day, physical examination including pelvic examination, urinalysis and urodynamic evaluation was systematically performed according to the standards recommended by the International Continence Society [7]. The Valsalva leak-point pressure (VLPP) was recorded via an 8-French urethral catheter, and both Valsalva maneuver and coughing were used to provoke SUI. Patients with confirmed SUI via physical examination and urodynamic studies underwent TOT procedure, whereas patients with urge incontinence, pure intrinsic sphincter deficiency, chronic retention or residual volume over 50 ml were excluded.

TOT procedure: The operation was performed under either general or regional anesthesia as described by Delorme et al.[3]. First, 16F Foley catheter was inserted into the bladder of the patient under lithotomy position and prophylactic antibiotic (cefoxitin 2 g intravenously) was systematically administered. The anterior vaginal wall was suspended with the Allis clamps and mucosa was incised horizontally.

Helical needles designed for transobturator process inserted from the two outside entrance points-the points that were identified by tracing a horizontal line at the level of the urethral meatus-were tunneled to through the obturatuar foramens until their tips were seen in the incision made at the vaginal wall.

On the other side, 35x2 cm sized polipropilen mesh was prepared in the operating theater (Prolen® Ethicon Inc. Somerville, New Jersey, ABD). This mesh was attached to the helical needles with no.1 silk suture and it was pulled out through the transobturator tunnel, similar to the original procedure with a care to avoid twisting the mesh and without any tension by interposing a pair of scissors between the mesh and the urethra so as to leave a space [3]. The excess parts of the mesh were cut off in the subcutaneous layer then the incisions were closed. Cystoscopy was not systematically performed. The urethral catheter was removed next morning in order to avoid the peroperatif urinary retention.

Outcome assessments and Follow up: The patients were invited to control visits at postoperative 1st and 3rd months and every 3 months after. Follow-up visit included a detailed medical interview, clinical examination, urine analysis, and postvoid residual determination. Peroperative, early post-operative(hematoma, dysuria, infection) and late post-operative complications (erosions, ischio-rectal abscess, perineal pain, de novo dyspareunia, de novo urge or urge incontinence) were recorded. The cure of SUI was defined as no urine leakage at cough test and not reporting any event of urinary incontinence. Patients who did not meet these criteria were considered to have "failed" treatment [8].

Result

Between May 2006 - June 2009, 41 female SUI patients underwent TOT procedure with the polypropylene mesh prepared during operation. The characteristics of the patients are reported in table 1. The mean age of those patients was 52.5 (range 36 – 68) and the average follow-up duration was 26.1 months (SD = 9.7) (Table 1). A total of 29(70.8%) and 12 (29.2%) patients had the TOT under regional and general anesthesia, respectively. The mean operative time was 22.3 ±5.3 minutes (range 14 to 33 minutes) (Table 1). No peroperative complications were recorded. Mean duration of hospitalization was 1 day (none of the patients stayed more than 1 day) and mean catheter indwelling period was 20.9 hours (range 16 to 28 hours) days. However minor complications such as urinary tract infections, de novo urgency and postoperative fever occurred in 4.8% of patients, all of which were successfully treated with conservative management. Two patients(4.8%) showed urinary retention. These patients, were recatheterized and the retention symptom disappeared. Dysuria or discomfort was reported by 5 patients (12.1%) immediately after the procedure. This symptom usually abated within 2 -3 days and in all patients was controlled by nonopioid analgesics. Pain was not reported by any of the patients 1 month after the operation.

Table 1. Patients' characteristics

	Mean ±SD	Median (minimum-maximum)
Age (years)	52.5 ± 7.6	52.5 (38-68)
BMI(kg/m²)	26.4±3.2	26.4 (21.1-33.2)
Gravity (n)	3.1 ± 0.6	3.0 (2-6)
Parity (n)	3.7 ± 1.5	3.0 (2-8)
Operation time (minutes)	22.3 ± 5.3	20.0 (14-33)
Follow-up time (months)	31.7 ± 31.2	26.0 (20-225)

SD: standartd deviation n:number

Overall 37(90.2%) and 32(78%) of patients were continent after 12 and 24 months, respectively, none of the patients showed

Table 2. Medical history of patients

	n	%
Menopause		
Yes	20	48.8
No	21	51.2
Previous incontinence surgery		
Yes	4	9.8
No	37	90.2
Cystocele		
Yes	36	87.8
No	5	12.2
Rectocele		
Yes	17	41.5
No	24	58.5

n:number %: percentage

worsening of their condition and none of those patients suffered from late post-operative complications such as vaginal erosion, infection or fistulas during the follow up period. Urinary tract infection was detected in 7 patients during follow up and it was successfully treated with oral antibiotics.

Discussion

In 1995, Ulmsten and Petros et al.[2] described a new concept of mid-urethral support without tension for urinary incontinence and elicited the development of several procedures, such as intravaginal slingplasty, transobturator vaginal tape outside-in (TOT) and TVT-O [8-10]. These TVT methods are all based on the integral theory which proposes that mid-urethra serves a significant role in urinary continence and mid-urethral sling provides continence by creating a functional kinking during increased intra-abdominal pressure [11,12]. TVT had a surgical success rate of 85% to 95% [13,14]. Although it is shown to be effective and easy to perform, TVT has been associated with numerous peri-operative and post-operative complications such as bowel, bladder and vascular injuries [15-18]. The mean operation time has been reported to be 26 min for TVT and 19 min for TOT [19,20].

In 2001, Delorme et al. [3] proposed to insert the vaginal tape through the obturator foramen with a surgical success rate 90.6%. Similar rates were reported by deTayrac et al.[13] with a 1-year cure rate of 84% with the TOT procedure. In addition, this approach has a theoretical advantage of less obstruction and less postoperative voiding dysfunction, as well as avoiding some of the complications, such as bladder perforation and bowel perforation [13].

In this study, we performed TOT procedure with ordinary polypropylene mesh and silk suture, and the cure rates were 90.2% and 78% at the 1st and 2nd year of surgery, respectively. Just as in the transobturator procedure of de Leval [21], there were no serious complications, defined as visceral injury, massive bleeding need for transfusion or hematoma. Minor complications, defined as urinary tract infections, and de novo urgency occurred in 2(4.8%) and 2(4.8%) of patients. There were 2 cases of transient urinary retention, and both recovered with conservative management. There was no vaginal erosion or mesh-related complication during the follow-up period. Urethral injuries are believed to occur because of poor surgical technique, local infection or excessive tension placed on the tape and these damages the integrity of the urethral tissue or its blood supply [22,23]. The most important step to avoid erosion and voiding dysfunction was found to be tape adjustment without any tension or any contact with the urethra [24]. We think that to avoid erosion and voiding dysfunction, not only the material used that allows for good fibroblasts colonization of the tape but also the surgical technique, application without tension and contact with the urethra is important.

These cure rates, duration of operation, incidence of early and late post-operative complications were similar with the previously reported studies suggesting that TOT procedures performed with a device prepared with polypropylene mesh and no.1 silk line is as

safe and effective as the commercially-available TOT devices [6,12,25]. Furthermore, preparing TOT device during operation reduces the economical burden of this operation since commercially-available TOT products are more expensive than the cost of polipropilene mesh and silk suture.

Our study is not without limitation. First of all, the results obtained from another group of SUI patients who had been treated with commercial TOT products should have been compared. Due to the small amount of our study sample we could not randomized our patients into two groups. In our opinion further studies performed in this manner will strengthen our conclusions.

Conclusions

TOT procedures performed with polyprolyene mesh and no.1 silk line are as safe and effective as performing this operation with commercial TOT devices where as they are less expensive. However, further studies are required to confirm our findings.

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