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Handmade Transobturator Polypropylene Mesh as a Low-Cost Alternative for Stress Urinary Incontinence Treatment

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Abstract

Brief summary: In this article the authors evaluate the use of a handmade polypropylene mesh as a transobturator sling for the treatment of female stress urinary incontinence.

Introduction and Hypothesis: Stress urinary incontinence (SUI) is a prevalent disorder that affects women's quality of life. Epidemiological studies reported a high prevalence of SUI, (25 to 55% of women). The goal of this is to report the experience and potential advantages of using a handmade polypropylene mesh as a transobturator sling in the treatment of female SUI from South-Brazil

Methods: We performed a retrospective cohort study at Irmandade Santa Casa de Misericórdia of Porto Alegre, Brazil, analysing all women treated for SUI by transobturator sling surgery with handmade polypropylene mesh (HMPM) between April 2005 and December 2014. Institutional Review Board approval was obtained. All patients were assessed at the 15th and 45th day of the postoperative period and scheduled to return for follow-up in 3, 6 and 12 months. Afterwards, the follow-up was annual. Patient follow-up consisted in identifying the stage of relief from the symptoms present before surgery, the complications and the new symptoms emerged after surgery, by anamnesis and physical examination. Early and late postoperative complications were record.

Result: 96 patients were submitted to this procedure and have been followed since then for 5 years. The average follow-up was 24,3 months (percentiles 25-75: 11,3-39,1). Complications were observed in few cases, the most prevalent were urinary retention and mesh extrusion. Of all the patients, 76 (76,8 %) were cured and 12 (12,1%) improved, while failure was detected in 11 (11%). Previous surgery for SUI and urodynamic showing VLPP < 60cm H20 had statistical association with failure.

Conclusion: Hand-made sling is a useful, safe and accessible alternative for treating SUI.

Keywords: Urinary stress incontinence; Polypropylene mesh; Transobturator sling

Abbreviations: ALPP: Abdominal Leak Point Pressure; CST: Cough Stress Test; DO: Detrusor Overactivity; ISD: Intrinsic Sphincter Deficiency; MUI: Mixed Urinary Incontinence; Pdet Qmax: Detrusor Pressure At Maximum Flow Rate; PVRU: Post-Void Residual Urine; Qmax: Maximum Flow Rate; QOL: Quality Of Life; SUI: Stress Urinary Incontinence; SUIQQ: Stress And Urge Incontinence And Quality Of Life Questionnaire; UUI: Urgency Urinary Incontinence

Introduction

Stress urinary incontinence (SUI) is a prevalent disorder that affects women's quality of life. A large number of epidemiological studies reported a high prevalence of SUI, (25 to 55% of women) [1,2]. Additionally, the financial cost for prevention and treatment can be high, ranging up to 4-6% of the family income, as suggested by a population survey in a developing country [3].

There are a variety of surgery techniques for SUI treatment [4]. Among them, the tension-free vaginal tape (TVT), developed with biological or synthetic material, is highly validated [5]. Since the transobturator approach has been described by Delorme et al. [6], and after de widespread adoption of the technique, a great number of studies corroborated the levels of success and low frequency of complications when compared to the retropubic TVT [7,8].

Unfortunately, the ready-to-use sling kits high-costs often make the surgery inaccessible for the patients, especially those in the public health system or in developing countries [9]. The widespread knowledge of the benefits of the transobturator slings leads to the indication of the technique for an extensive number of patients [10]. With that in mind, it is necessary to identify low-cost alternative materials that can offer similar results and safety for all patients. The goal of this is to report the experience and potential advantages of using a handmade polypropylene mesh as a transobturator sling in the treatment of female SUI from South-Brazil.

Materials and Methods

We performed a retrospective cohort study at Irmandade Santa Casa de Misericórdia of Porto Alegre, Brazil, analysing all women treated for SUI by transobturator sling surgery with handmade polypropylene mesh (HMPM) between April 2005 and December 2014. Institutional Review Board approval was obtained (number 1.351.095). Data was collected from the database of our outpatient urogynecology clinic from the Gynecology Department.

Ninety-six patients underwent the TOT procedure and wore observed for the next 5 years. The surgeries were performed by fourth-year Gynecology resident supervised by a licensed Gynecology surgeon. After that, they were referred to a primary health care center for follow-up. According to the medical reports the primary indication criterion to surgery was the complaint of SUI. The diagnosis was reached by physical exam (testing the involuntary loss of urine caused by cough or Valsalva) in lithotomy position, or by urodynamic testing. The urodynamic test was requested for patients with previous surgery for SUI and also when it was not possible to identify urinary stress loss by the physical examination or for the evaluation of occult SUI in cases of severe genital prolapses.

Patients with associated prolapse of pelvic organs (POP) and other urinary disorders, such as mixed urinary incontinence or previous pelvic surgery for the treatment of POP or SUI were also eligible for the surgery.

The preoperative evaluation included complete urogynecological history and pelvic examination. Positive urinary cultures were treated with specific antibiotics before any intervention. The associated POP was measured with the Baden-Walker classification [11]. All patients were provided with current information about the risks and benefits of mesh-augmented incontinence and POP treatment, with full written Informed Consent obtained. When symptomatic prolapse was concomitantly present, the repair of the prolapse was accomplished using native tissues, without use of meshes. The TOT surgery was performed similarly in patient with or without prolapse.

All patients were assessed at the 15th and 45th day of the postoperative period and scheduled to return for follow-up in 3, 6 and 12 months. Afterwards, the follow-up was annual. Patient follow-up consisted in identifying the stage of relief from the symptoms present before surgery, the complications and the new symptoms emerged after surgery, by anamnesis and physical examination. Early and late postoperative complications were record. The success of the treatment was defined as no urine leakage at cough test (negative stress test) and no report of any SUI event. One or two episodes of SUI reported in a week was considered as "symptom relief". Patients who did not meet these criteria during the interview were considered treatment faillure.

Statistical Analysis

Quantitative variables were described by mean and standard deviation or median and interquartile range. Categorical variables were described by absolute and relative frequencies. To compare means between groups, the one-way analysis of variance (ANOVA), complemented by Turkey's test, was applied. In case of asymmetry, the Kruskal-Wallis test was used. To evaluate the association between categorical variables, Pearson's chi-squared test, complemented by the adjusted residuals analysis, was applied. The Kaplan-Meier method was used to evaluate the probability of failure. For control of confounding factors, the Cox proportional hazards model or the multivariate Poisson Regression model were applied to the variables that presented $p < 0.20$ in the univariate analysis. The significance level adopted was 5% ($p < 0.05$) and the analyses were performed using SPSS program version 21.0.

The handmade mesh and modified needles

The mesh used in this procedure was made of macroporous and multifilament polypropylene (PROLENE* Mesh, ETHICON*) with 30x30cm, cut in the width of 1x30 cm. Each end of polypropylene tape was anchored with a zero polypropylene suture (Figure 1). The polypropylene suture was then inserted into the orifice of the TOT needle. The modified needles were made of resterilizable and spiral surgical steel, with similar specifications to the commercial product designed by DeLeval [12] (Figure 2). The needle is fenestrated at the tip, which allows the insertion of polypropylene sutures that were attached to both ends of the polypropylene mesh strip (Figure 3).

Surgical technique

The procedure was done under spinal anesthesia in the lithotomy position. Antibiotic prophylaxis with 1g of a first-generation cephalosporin was administered before the beginning of surgery. During induction of anesthesia and positioning of the patient, the polypropylene tape was prepared. The bladder was

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emptied by a Foley catheter. A point about 1.5cm to 2cm below the urethral meatus, and another about 2.0cm further down below, was held with Allis clamps. A vertical incision was made between the two clamps. The paraurethral tissue was then dissected laterally with Metzenbaum scissors, bilaterally. Dissection was large enough to fit an index finger, pushing towards the back of the pubic ramus. Hydrodissection was not performed.

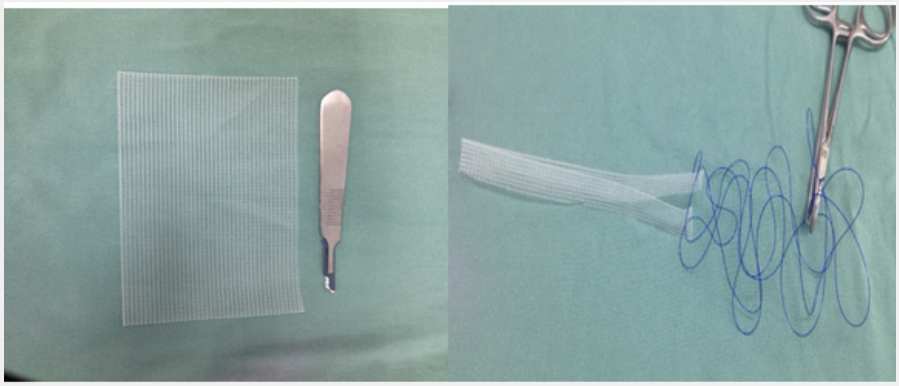


Figure 1: The polypropylene mesh used to prepare TOT tape and the handmade transobturator tape with the two PDS sutures.

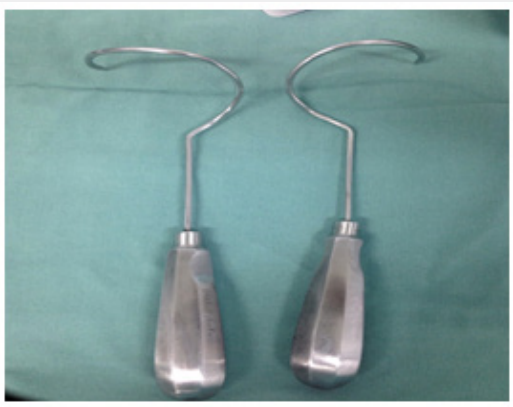
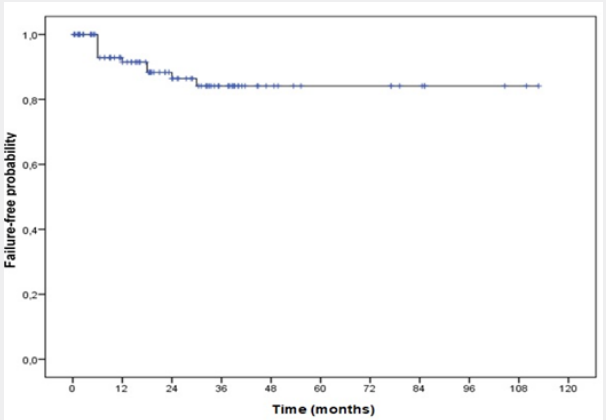


Figure 2: Reusable trocar used in the TOT procedure.



	1 year	2 years	3 years	5 years
Fail (%)	8.5%	13.6%	15.9%	15.9%

Figure 3: Failure-free probability according to follow-up time in the Kaplan-Meier curve.

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The TOT needle point entry is identified at the level of the clitoris, lateral to the inferior pubic rami. The tape is attached to the tip of the needle and it was removed using a reverse rotation motion pulling the tape out. The procedure was then repeated at the contralateral side. Care was taking to keep the tape flat at the mid-urethra. Tension was controlled by passing a clamp between the tape and the urethra. The excess tape left over the skin was cut, and the sling remained in the transobturator space with no tension or sutures. Uninterrupted absorbable Vicryl 3.0 sutures closed the anterior vaginal wall. In the first postoperative day, the Foley catheter was removed, and patients were oriented to voluntary micturition. Residual volumes was accessed by bladder catheterization if the complaint of incomplete emptying of the bladder was present and was considered normal when less than 100mL.

Result

The average follow-up was 24.3 months (percentiles 25-75: 11.3-39.1). The preoperative data are presented in Table 1. Urinary retention occurred in six patients (6.1%), and all were treated conservatively with intermittent bladder catheterization relieving the symptoms without intercurrences. Mesh extrusion was observed in four cases. The extrusion was spotted at the anterior vaginal wall. One case was identified in the first month of postoperative, two cases in the second year, and one case in the third year of follow-up. This complication was treated initially with local estrogen therapy, and as it was unsatisfactory, the patients were submitted to partial removal of the extruded sling. In those cases we observed no negative effects in the continence results - all remained without SUI. There were two cases of bladder perforation intraoperatively. One of them occurred during the correction of POP, the other during paraurethral dissection. Both bladder perforations were corrected at the same time, with the positioning of the mesh after the bladder suture. Other complications included groin pain (2%), vaginal discharge (1%), and discomfort involving the ability to feel the mesh subcutaneously in one case (1%). Of all the patients, 76 (76.8 %) were cured and 12 (12.1%) improved, while failure was observed in 11 patients (11%). Previous surgery for SUI and urodynamic tests showing Valsalva Leak Point Pressure (VLPP) <60cmH20 had statistical association with treatment failure. There was no significant difference in the outcome between patients with or without associated POP (all types) (p=0.86) or patients with associated cystocele (p=0.37).

It was possible to observe that surgery failure had increased over time, with 8.5% and 13.6% after the first and second years of observation, respectively. From the third year of follow-up, failure reached 15.9%, but remained stable, in this sample, until the fifth year (Figure 1 & Table 2).

Table 1: Preoperative data.

Variables	n=99
Mean age (years) ± SD	54.8 ± 9.6
Parity – md (P25 – P75)	3 (2 – 4)
Vaginal delivery – md (P25 – P75)	2 (2 – 4)
Comorbidity – n (%)	75 (77.3)
Hypertension	46 (47.4)
Psychiatric disorder	19 (19.6)
Dyslipidemia	14 (14.4)
Cardiovascular disease	10 (10.3)
Musculoskeletal disease	9 (9.3)
Thyroid disease	8 (8.2)
Other	9 (9.1)
BMI (kg/m^2) – md ± SD	28.5 ± 4.5
Smoking – n (%)	14 (15.7)
Premenopausal n (%)	33 (35.5)
Postmenopausal – n (%)	60 (64.5)
Previous surgery for UI – n (%)	3 (3.7)
Urodynamic– n (%)	
No exam	27 (28.1)
VLPP <60 cmH20	11 (11.5)
VLPP 60-90 cm H_20	27 (28.1)
VLPP >90 cm H_20	29 (30.2)

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No leakage of urine	2 (2.1)
Cystocele – n (%)	
Absent	15 (16.0)
Grade 1	42 (44.7)
Grade 2	26 (27.7)
Grade 3	11 (11.7)
Rectocele – n (%)	
Absent	37 (39.4)
Grade 1	26 (27.7)
Grade 2	23 (24.5)
Grade 3	8 (8.5)
Uterine prolapse n (%)	
Absent	66 (74.2)
Grade 1	13 (14.6)
Grade 2	5 (5.6)
Grade 3	4 (4.5)
Grade 4	1 (1.1)
Simultaneous POP repair – n (%)	56 (56.6)
Complications – n (%)	13 (13.1)
Mesh exposure	4 (4.0)
Urinary retention	6 (6.1)
Bladder perforation	2 (2.0)
Vaginal discharge	1 (1.0)
Groin pain	2 (2.0)
Felt subcutaneous suture	1 (1.0)

Md: Median, BMI: Body Mass Index, VLPP: Valsalva Leak Point Pressure

Table 2: Variables and their association with the outcome.

Variables	Cure (n=76)	Improve (n=12)	Fail (n=11)	p.
Mean age (years) – md ± SD	53.7 ± 9.4	56.2 ± 11.0	60.7 ± 7.0	0.062
Parity – md (P25 – P75)	3 (2 – 4)	2 (2 – 4.5)	4 (2.5 – 5.5)	0.281
Vaginal delivery – md (P25 – P75)	2 (2 – 4)	2 (0.5 – 2)	3 (1.5 – 5)	0.04
Comorbidity – n (%)	60 (81.1)	8 (66.7)	7 (63.6)	0.28
Hypertension	35 (47.3)	6 (50.0)	5 (45.5)	0.976
Cardiovascular disease / arrhythmia	9 (12.2)	1 (8.3)	0 (0.0)	0.452
Dyslipidemia	12 (16.2)	2 (16.7)	0 (0.0)	0.351
Diabetes Mellitus	6 (8.1)	0 (0.0)	0 (0.0)	0.37
Psychiatric disorder	13 (17.6)	3 (25.0)	3 (27.3)	0.661
Musculoskeletal disease	8 (10.8)	1 (8.3)	0 (0.0)	0.511
Repeated urinary tract infection	5 (6.8)	0 (0.0)	0 (0.0)	0.441
Thyroid disease	5 (6.8)	1 (8.3)	2 (18.2)	0.438
Gastrointestinal disorder	3 (4.1)	1 (8.3)	0 (0.0)	0.603
BMI (kg/m2) – md ± SD	29.0 ± 4.7	26.3 ± 2.4	27.9 ± 4.5	0.136
Smoking	12 (17.1)	0 (0.0)	2 (20.0)	0.382

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Premenopausal patients – n (%)	29 (40.3)	2 (18.2)	2 (20.0)	0.201
Postmenopausal patients – n (%)	43 (59.7)	9 (81.8)	8 (80.0)	0.201
Cervical conization – n (%)	2 (2.9)	2 (22.2)	0 (0.0)	0.026
Wertheim Meigs – n (%)	0 (0.0)	0 (0.0)	1 (11.1)	0.012
Previous surgery for SUI – n (%)	1 (1.5)	0 (0.0)	2 (25.0)	0.003
Urodynamic testing– n (%)				0.004
No exam	26 (35.1)	1 (9.1)	0 (0.0)	
VLPP <60 cm H_20	6 (8.1)	0 (0.0)	5 (45.5)	
VLPP 60-90 cm H_20	20 (27.0)	5 (45.5)	2 (18.2)	
VLPP >90 cm H_20	20 (27.0)	5 (45.5)	4 (36.4)	
No leakage of urine	2 (2.7)	0 (0.0)	0 (0.0)	
Cystocele – n (%)				0.377
Absent	10 (14.1)	1 (8.3)	4 (36.4)	
Grade 1	30 (42.3)	8 (66.7)	4 (36.4)	
Grade 2	22 (31.0)	2 (16.7)	2 (18.2)	
Grade 3	9 (12.7)	1 (8.3)	1 (9.1)	
Rectocele – n (%)				0.711
Absent	25 (35.2)	5 (41.7)	7 (63.6)	
Grade 1	21 (29.6)	3 (25.0)	2 (18.2)	
Grade 2	18 (25.4)	3 (25.0)	2 (18.2)	
Grade 3	7 (9.9)	1 (8.3)	0 (0.0)	
Uterine prolapse – n (%)				0.648
Absent	47 (69.1)	9 (90.0)	10 (90.9)	
Grade 1	12 (17.6)	1 (10.0)	0 (0.0)	
Grade 2	5 (7.4)	0 (0.0)	0 (0.0)	
Grade 3	3 (4.4)	0 (0.0)	1 (9.1)	
Grade 4	1 (1.5)	0 (0.0)	0 (0.0)	
Concomitant surgery – n (%)	47 (61.8)	6 (50.0)	3 (27.3)	0.086
Complications – n (%)	10 (13.2)	1 (8.3)	2 (18.2)	0.783
Mesh exposure	4 (5.3)	0 (0.0)	0 (0.0)	0.532
Urinary retention	5 (6.6)	1 (8.3)	0 (0.0)	0.652
Bladder perforation	1 (1.3)	0 (0.0)	1 (9.1)	0.2
Vaginal discharge	1 (1.3)	0 (0.0)	0 (0.0)	0.858
Groin pain	2 (2.6)	0 (0.0)	0 (0.0)	0.734
Felt subcutaneous suture	0 (0.0)	0 (0.0)	1 (9.1)	0,018

Md: Median, BMI: Body Mass Index, SUI: Stress Urinary Incontinence, VLPP: Valsalva Leak Point Pressure

Table 3: Cox Regression Analysis to evaluate factors independently associated with failure.

Variable	Hazard Ratio (HR)	IC 95%	P
Urodynamic – VLPP <60 cm H_20	5.03	1.47 – 17.2	0.01
Simultaneous POP repair	0.22	0.05 – 0.94	0.041
Mean age (years)	1.08	1.00 – 1.17	0.056

VLPP: Valsalva Leak Point Pressure

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The variables that presented a p<0.20 value in the multivariate analysis were inserted into a multivariate Cox regression model. The VLPP <60cmH20 remained associated with surgery failure, raising the probability by a factor of 5.03. Patients who underwent simultaneous POP repair showed a 78% decrease in failure probability. Age remained a borderline risk factor after adjustment (p=0.056), as presented in Table 3. The cost of our handmade mesh was about $61.5 USD. This is 6 times lower than the price of ready-to-use TOT sling (according to local prices).

Discussion

Despite the use of commercial slings being widely validated in the treatment of SUI, - cure rates reach 80-92% in 5 years of follow-up - there is a paucity of data in the literature regarding the long-term safety and efficacy of using modified (manufactured) meshes [13,14]. The advantages of this approach include the reduced material cost that allows the reproduction of the technique in public systems of health and in developing countries [15].

In this study we achieved a cure rate of 76.8% and an improvement rate of 12.1% in an average follow-up period of 2 years, with a failure rate of 11.1%. Our results corroborated other studies, as demonstrated by Onol et al. [16], whith 118 patients submitted to TOT with handmade polypropylene mesh, with or without POP repair, and achieved an 86.4% of cure and 9% of improvement for SUI. It is important to note that these authors included in their sample, obligatorily, patients with urinary leakage and urethral hypermobility present in physical examination, and urodynamic testing was conducted if there was severe associated POP or voiding symptoms, not only for diagnosing SUI. We observed in our sample that patients with these characteristics had their probability of achieving a cure augmented to 45%, in comparison to those that did not demonstrate urinary incontinence in the physical exam and those that had other indications for urodynamic testing. Additionally, mesh extrusion was observed in 14.8% of patients, all of whom underwent simultaneous POP repair. Our study showed positive correlation between the correction of POP and achieving a cure of SUI.

Elshemmy et al. [17] followed 63 patients for 5 years after transobturated sling with modified tape. Similar to our study, they included patients with urgency, UUI and intrinsic sphincter deficiency (ISD). In contrast with our study, however, urodynamic testing was performed preoperatively for all patients, and patients were excluded who had post-void residual urine >100ml, bladder capacity <300ml, impaired bladder compliance, neurological lesions, or urogenital prolapse more than grade 2 (according to the Baden-Walker classification). The authors found a 91% cure rate and 5% improvement of SUI, with 3% failure.

Ciftci et al. [18] compared the complications and success rates of handmade slings with commercial slings used in transobturated sling surgery after one year of follow-up. The handmade sling group presented 14.6% (seven cases) of mesh extrusion, all of which were identified in the first six months after surgery, with continence maintained in six cases after partial removal of the extruded sling. In comparison, the commercial sling group had 1.6% (one case) of this complication. Other authors have reported rates of vaginal mesh extrusion varying from 0-13.8% in transobturated sling [19,20]. In our study, mesh extrusion was identified in 4% of patients, being the most prevalent complication in our sample but not exceeding the rates already described for this complication in conventional surgeries.

The limitations of our study must be noted. One is the absence of a control group, allowing us to make comparisons only with other publications on transobturatory sling. Our study was conducted in a tertiary care teaching hospital and the surgeries were performed by different surgeons in training, in their fourth year of residency, always supervised by a mentor. However, one the strengths of this study is that it included a heterogeneous group of patients (with associated prolapse, UUI, previous surgery for SUI, IED), which is closely consistent with the reality of the public that searches for SUI treatment [21].

Conclusion

The handmade sling is a useful, safe and accessible alternative for treating SUI.

Further studies with a larger sample size and long-term follow-up

Author Contribution

GBV Piccin: project development, data collection, analysis and interpretation of data, manuscript writing, critical revision of the manuscript.

LFC Vieira: project development, critical revision of the manuscript.

RV Almeida: data collection

LP Palludo: data collection, manuscript writing.

P El Beitune: project development, critical revision of the manuscript.

MMBP Salcedo: project development, critical revision of the manuscript.

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