

Comparison of the outcomes of the sling technique using a commercial and hand-made polypropylene sling

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ABSTRACT

Purpose: To compare the outcomes and costs of stress urinary incontinence (SUI) surgery using a hand-made sling (Marlex®) versus a commercially available suburethral polypropylene sling (Advantage®).

Materials and Methods: Thirty-nine women with SUI due to bladder neck hypermobility and/or sphincter incompetence diagnosed by clinical examination and urodynamic studies were divided into two groups: group 1 (n = 19) consisted of patients from an academic center (Department of Urology, University Hospital of Federal University of Maranhão, and group 2 (n = 20) patients from private practice. The hand-made polypropylene suburethral sling was used in group 1 and the commercial sling in group 2. The patients were evaluated 30, 60 and 90 days after surgery.

Results: The mean duration of surgery was 43 min. in group 1 and 51 min. in group 2. No postoperative voiding difficulties were observed in group 1 (100%), as well as, in 94.7% of patients of group 2. A bladder catheter was not required in any of the patients of the two groups at the end of the study. The level of satisfaction was 100% in group 1, whereas, one patient of group 2 considered the surgery to be unsuccessful. Urodynamic studies showed low amplitude uninhibited contraction in 11.1% of patients of group 1 and 10.5% of group 2. No complications were observed in either group.

Conclusion: The hand-made polypropylene mesh (Marlex®) can be used for sling procedures, saving costs and yielding results similar to that obtained with commercial sling systems.

Key words: *surgical tape; urinary incontinence; suburethral sling; outcome; polypropylenes*

Int Braz J Urol. 2011; 37: 519-527

INTRODUCTION

Urinary incontinence is the involuntary loss of urine through the urethra causing physical and emotional distress in patients(1). In contrast, stress urinary incontinence (SUI) is the involuntary loss of urine through the urethra resulting from increased abdominal pressure and urethral occlusion mechanism dysfunction in the absence of detrusor muscle contraction (1).

Epidemiological studies suggest pregnancy and vaginal delivery as possible primary etiological factors of SUI. Alterations in pelvic support, perineal body and anal sphincter caused by vaginal delivery may contribute to the occurrence

of SUI (2). In most women, the pelvic musculature returns to normal within 2 months after delivery. However, in a small portion of women sequelae might remain that progress to prolapse and urinary incontinence (3). Although epidemiological data indicate a higher incidence of SUI among multiparous women (4,5), this disorder is observed in 16 to 31% of nulliparous women (6,7). Hormonal alterations resulting from aging, obesity, smoking, chronic cough, and constipation are associated with SUI (8).

SUI can be classified into three types according to leak-point pressure: type I is defined as urine loss at an abdominal pressure higher than 90 cm H₂O; in type II urine loss occurs at a pressure

of 90 to 60 cm H₂O as a result of urethral hypermobility, and in type II urine loss occurs at a pressure lower than 60 cm H₂O (9). The diagnosis of SUI is made clinically and anamnesis is the most important tool. The patient's history, including surgical, gynecological and obstetric history, should be obtained (10). The minimum parameters for the investigation of urinary incontinence recommended by the American Association of Urology consist of a detailed clinical history including micturition data and/or questionnaires about micturition habits, physical examination in the presence of a full bladder, micturition diaries, pad tests, and urodynamic study (11).

Behavioral alterations are recommended for the treatment of SUI. The cessation of smoking is advised since this habit causes respiratory diseases such as asthma, chronic obstructive pulmonary disease and chronic cough that have perineal repercussions (12). Weight control is necessary since obesity is a risk factor for the development of SUI, with overweight increasing the intra-abdominal pressure that influences the perineal musculature (13). Pharmacological treatment of SUI includes estrogens, alpha-adrenergic agonists and tricyclic antidepressants. Other, less frequently used drugs are alpha-adrenergic receptor antagonists and alpha2-adrenergic agonists (14).

Anatomical changes in the pelvic floor responsible for urinary incontinence in women should be corrected by surgical procedures that are aimed at the stabilization of the urethra. Intrinsic disorders of urethral sphincter mechanisms should be treated by interventions that promote urethral coaptation (1). Numerous surgical techniques have been developed for the correction of SUI, including conventional open surgeries and minimally invasive procedures such as periurethral injection therapy and procedures that use organic and synthetic materials to support the urethra, known as slings. The last procedure is currently the treatment of choice for the correction of SUI of any etiology.

Due to the efficiency of sling procedures, the present study proposes the use of a low-cost, hand-made polypropylene sling that could be used in the public health system offering similar results

to those obtained with commercial synthetic sling systems that are much more expensive in Brazil (15).

MATERIALS AND METHODS

From December 2007 and December 2009, a non-randomized study was conducted in Maranhão, Brazil; recruiting patients from the academic University Hospital (HU) of Federal University of Maranhão (UFMA), and from a local private urology practice.

A total of 39 women with urinary incontinence were included in the study. They were diagnosed according to the McGuire classification (9) (type I: urine loss at an abdominal pressure higher than 90 cm H₂O; type II: urine loss at a pressure of 90 to 60 cm H₂O; type III: urine loss at pressure less than 60 cm H₂O). Exclusion criteria included medical history of diabetes mellitus, major pelvic surgery accompanied by bladder denervation, previous radiotherapy, and malignant neoplasms of the bladder. Patients with active urinary infection and bladder stones diagnosed by urethrocystoscopy were treated and then included in the study.

Two groups were considered: group 1 consisted of 20 patients from the Urology Service of HU-UFMA, and group 2 included 19 patients from the private clinic. Group 1 was treated with a hand-made sling consisting of a Marlex® mesh measuring 1.5 cm in width and 30 cm in length. In group 2, the commercial Advantage™ Transvaginal Mid-Urethral Sling System (Boston Scientific Corporation, Maple Grove, MN) was used. This system was chosen because the fixation principle is similar to that of the Marlex® sling. In both cases, fixation of the prosthesis occurs by incorporation of the mesh into surrounding tissues through proliferation of fibrotic tissue that gives support to the suburethral sling. Group 2 had patients were recruited from a private practice due to the acquisition of the commercially available slings used in this study.

Before the surgical procedure, a complete history and physical examination, preoperative laboratory testing, urodynamic study, and urethrocystoscopy was filled out. Urodynamic analysis was performed according to the guidelines of the

International Continence Society using 0.9% saline at a temperature of 37°C, two Nelaton® 6F urethral catheters (one for fluid infusion and one for the measurement of bladder pressure) and a Nelaton 8F rectal catheter. The pressure producing stress urinary loss (PUL) was obtained after removal of the infusion catheter when the patient reported the first micturition desire. On this occasion, the patient was asked to increase abdominal pressure using a Valsalva maneuver. PUL was defined as the lowest abdominal pressure detected in the absence of detrusor contraction which was able to produce urinary loss (ICS, 1991). All patients were submitted to urethrocystoscopy and none of them presented bladder lithiasis or neoplastic alterations.

After hospital discharge, the patients were evaluated 30, 60 and 90 ± 2 days after the surgical procedure. Another form was filled out during these assessments and urodynamic analysis was performed on the last assessment (90 days after surgery). In this analysis, urinary residues less than 100 mL were defined as a normal result, indicating absence of significant urethral compression. Higher values were considered to indicate over-treatment and required reassessment.

All surgeries were performed by the same surgeon according to the technique described by Petros (16). Regional block was used for anesthesia and antibiotic prophylaxis (1 g cefazolin, intravenously) was administered 30 min before and up to 48 h after the end of surgery. The polypropylene sling used for urethra support consisted of a Marlex® mesh measuring 1.5 cm in width and 30 cm in length (Figure1). Using a special needle (Figure2), one end of the sling was passed through a vaginal incision in the direction of the abdominal wall, with the sling following a retropubic trajectory and exteriorizing through a 1 cm incision in the skin (Figure3). The procedure was repeated on the opposite side, forming a loop to support the middle third of the urethra. No additional stitches were used for fixation of the ends of the sling preventing hypermobility of the urethra. A Kelly clamp was placed between the urethra and sling to prevent unnecessary compression of the former (Figure 4). Urethrocystoscopy was performed dur-

ing each passage of the needle to rule out possible bladder injury which, if detected, was immediately corrected. The vaginal mucosa was closed with continuous 3.0 chromic catgut suture. The indwelling bladder catheter was maintained until the second postoperative day. The same surgical steps for the commercial sling system (Advantage®).

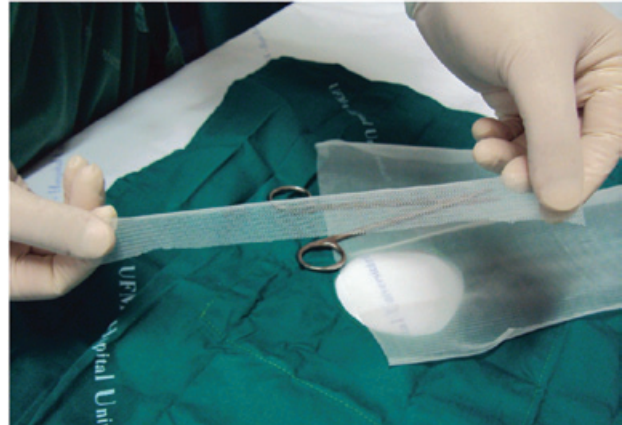


Figure 1 - Making the hand-made polypropylene sling for surgery.



Figure 2 - Stamey needles introduction.

The hand-made sling used in this study was fabricated from an original Marlex® mesh (30.5 x 30.5 cm), which costs R\$ 261.00 in Bra-

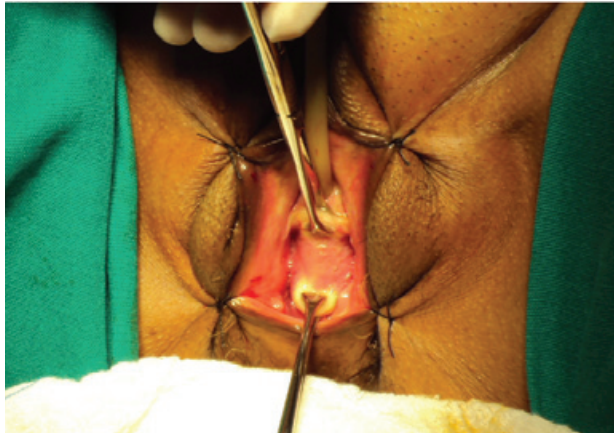


Figure 3 - Incision of mid urethra for introduction of sling.

zil according to electronic price quotation (<http://www2.ciashop.com.br/cpassos>). This mesh was divided into 20 segments of 1.5 x 30 cm, with one segment being used per surgery, corresponding to a cost per patient of approximately R\$ 13.05 (R\$ 261.00/20 segments). In contrast, the commercial sling system (Advantage®) costs R\$ 1.800.00 according to the Financial Sector of Covenants Box Health Care Emmployess of the Bank of Brazil (CASSI.).

The results are presented in tables. The Epi-Info program, version 3.3.2, was used for statistical analysis, adopting a level of significance of $p < 0.05$. The chi-square test was used for the calculation of significance in the univariate comparison of proportions.

The study was approved by the Ethics Committee of HU-UFMA (process 33104-0636/2005).

RESULTS

During the study period, 39 patients were submitted to surgical treatment of SUI, 20 in group 1 who received the hand-made sling and 19 in group 2 who received the commercial sling system.

With respect to age, patients aged 30 to 39 years ($n = 5$, 25%) and 50 to 59 years ($n = 5$, 25%) predominated in group 1. In contrast, in group 2 there was a predominance of patients aged 50 to 59 years ($n = 7$, 36.8%).

SUI was the only cause of urinary incontinence in 100% ($n = 20$) of cases of group 1 and in

84.2% ($n = 16$) of group 2. In group 2, only three (15.8%) patients presented with urgency in addition to SUI.

The mean duration of surgery was 43 min. in group 1 and 51 min. in group 2. The mean duration of hospitalization was 52.8 hr in group 1 and 49.14 hr in group 2.

Postoperative voiding difficulties were reported in three (15%) patients of group 1 during the first 30 days after the procedure, and one patient (5.3%) in group 2. At the end of follow-up, all patients of group 1 were able to void normally, and only one (5.3%) in group 2 continued to experience voiding difficulties, with no significant differences between groups.

A postoperative catheter was necessary in two (11.1%) patients in group 1 and in one (5.3%) patient in group 2 up to 30 days after surgery. None of the patients of either group required a catheter at the end of follow-up. The differences in the results observed between groups were not significant (Table-1).

Only two (11.1%) patients in group 1 did not have a normal urinary stream 30 days after surgery,



Figure 4 – Passage of hand-made polypropylene sling.

whereas a normal urinary stream was observed in all patients of the two groups on other assessments. The differences in the results observed between groups were not significant (Table-2).

The same number of patients in group 1 and group 2 ($n = 18$) did not report involuntary urine loss during the first 30 days after surgery. At 90 days of follow-up, none of the patients in group 1 presented

Table 1 - Length of time of indwelling bladder catheter after sling procedure for treatment of SUI.

Length of time of the bladder catheter - Postoperative day	Group 1 n (%)		Group 2 n (%)		p
	Yes	No	Yes	No	
30	2 (11.1)	18 (88.9)	1 (5.3)	18 (94.7)	0.9989
60	-	20 (100)	-	19 (100)	0.9994
90	-	20 (100)	-	19 (100)	0.994
Total	20 (100)		19 (100)		

Group 1: hand-made sling; Group 2: commercial sling system.

involuntary urine loss and only one (5.3%) in group 2. The differences in the results between groups were not significant (Table-3).

With respect to the degree of satisfaction with surgery, surgical failure was not observed in any of the patients of either group at the end of follow-up. At the end of the study, 18 (90%) patients of group 1 and 17 (89.4%) of group 2 were satisfied and considered themselves cured. Partial improvement (1 to 2 episodes of urine loss per day) at the end of follow-up was reported by two patients each in group 1 and group 2, with no significant differences between groups (Table-4).

Urodynamic study was performed on postoperative day 90 and revealed low amplitude uninhibited contractions in two (11.1%) patients in group 1 and two (10.5%) in group 2, with no significant differences between groups (Table-5). In both groups, patients with uninhibited bladder contractions of low

intensity did not reported loss of urine or change in urinary stream.

DISCUSSION

Sling surgery has proven to be efficient for treatment of SUI (15), the present study proposes a low-cost hand-made polypropylene sling that could be used routinely in the public health system with similar results obtained with commercial synthetic sling systems that are much more expensive.

In the present study, no significant difference in the variables analyzed were observed between the two groups treated with the hand-made (group 1) and commercial slings (group 2) over the 90-day follow-up. A higher number of patients in their sixth decade of life were observed in both groups, as described in other studies (17,18). This finding confirms the predominance of the disease in

Table 2 - Postoperative spontaneous void after sling surgery for the treatment of stress urinary incontinence.

Normal urinary stream - Postoperative day	Group 1 n (%)		Group 2 n (%)		p
	Yes	No	Yes	No	
30	18 (88.9)	2 (11.1)	19 (100)	-	0.9985
60	20 (100)	-	19 (100)	-	0.9994
90	20 (100)	-	19 (100)	-	0.9994
Total	20 (100)		19 (100)		

Group 1: hand-made sling; Group 2: commercial sling system.

Outcomes of the hand made sling

Table 3 - Postoperative urinary incontinence after sling surgery for the treatment of stress urinary incontinence.

Urine loss - Postoperative day	Group 1 n (%)		Group 2 n (%)		p
	Yes	No	Yes	No	
30	2 (11.1)	18 (88.9)	1 (5.3)	18 (94.7)	0.9989
60	1 (5.0)	19 (95.0)	1 (5.3)	18 (94.7)	0.9993
90	-	20 (100.0)	1 (5.3)	18 (94.7)	0.9995
Total	20 (100)		19 (100)		

Group 1: hand-made sling; Group 2: commercial sling system.

this age group. In the present study, similar to the hospitalization period, it was decided to leave the bladder catheter in place for 48h, as observed in 95% of the patients of both groups and in agreement with another Brazilian study (19).

In a recent study, eight of 128 patients submitted to sling surgery presented urinary retention and underwent clean intermittent catheterization until postoperative day 25, when spontaneous void returned, except for two patients who required urethrolisis (20). In the present study, only two (11.1%) patients in group 1 did not show a normal urinary stream during the first 30 days after surgery. However, all patients of the two groups presented a normal urinary stream on the subsequent assessments (60 and 90 days) and reported satisfactory micturition at the end of the study. In another series involving

21 patients submitted to sling surgery, the frequency of postoperative temporary voiding difficulties was 28.6% (21). In the present study, temporary voiding difficulties during the first 30 days after the procedure were observed in 15% of patients in group 1, but in only 5.3% of patients in group 2. At the end of follow-up, all patients of group 1 were able to void, whereas one patient of group 2 still experienced voiding difficulties. This finding suggests that voiding difficulty maybe a natural occurrence due to the surgical technique and is not related to the material used for the suburethral sling.

With respect to involuntary urine loss, none of the patients in group 1 experienced urine loss at the end of the observation period and only one (5.3%) patient in group 2 reported this symptom. In another study, 87% were completely dry

Table 4 - Postoperative satisfaction after sling surgery for the treatment of stress urinary incontinence.

Degree of satisfaction	Postoperative day					
	Group 1 n (%)			Group 2 n (%)		
	30	60	90	30	60	90
Cured	13 (65)	16 (80)	18 (90)	16 (84.1)	14 (73.6)	17 (89.4)
Partial improvement	6 (30)	4 (20)	2 (10)	1 (5.3)	4 (21)	2 (10.5)
Failure	1 (5)	-	-	2 (10.6)	1 (5.3)	-
Total	20 (100)			19 (100)		

Group 1: hand-made sling; Group 2: commercial sling system.

Table 5 - Presence of urodynamic abnormalities on postoperative day 90 after sling surgery for the treatment of stress urinary incontinence.

Urodynamic abnormalities	Group 1 n (%)	Group 2 n (%)	p
Yes	2 (11.1)	2 (10.5)	0.9991
No	18 (88.9)	17 (89.5)	
Total	20 (100)	19 (100)	

Group 1: hand-made sling; Group 2: commercial sling system.

and no longer experienced urine loss and 6.8% presented significant improvement, whereas surgical failure and persistent urine loss were observed in 5% (22). In another study including 45 patients that underwent sling surgery for the treatment of SUI, 74% of the patients experienced no urine loss, 11.2% presented one to two episodes a day, and 14.8% had three or more episodes a day (23).

With respect to the degree of satisfaction with the surgery, 18 (90%) patients of group 1 were satisfied and considered themselves cured and two (20%) reported improvement (1 to 2 episodes of urine loss per day). In group 2, 17 (89.4%) patients considered themselves cured and were satisfied and two (10.5%) reported improvement, with a reduction in the episodes of urine loss to 1-2 per day. In another Brazilian study, 29 of 30 patients submitted to surgery for the treatment of SUI using a hand-made polypropylene sling reported satisfaction with the surgery over a follow-up period of 15 months (24). Raz et al. (25), evaluating 26 patients submitted to vaginal sling surgery, observed excellent outcomes in 20 (77%) patients, very good outcomes in two (8%), improvement in one (4%), and failure in three (12%). These results demonstrate the efficacy of the technique, irrespective of the type of material used for fabrication of the sling.

In a recent study involving 80 patients surgically treated for SUI using a tension-free sling, only one patient developed a hyperactive bladder, accompanied by the loss of large volumes of urine (19). This patient required a bladder catheter for 9 days and the symptoms only improved after the introduction of anticholinergic medication. In

the present study, the urodynamic alterations observed on postoperative day 90 consisted of low amplitude uninhibited detrusor contractions in two (11.1%) patients in group 1 and two (10.5%) in group 2. This abnormality was not clinically significant and was tolerated by the patients, who did not require a bladder catheter. The symptoms disappeared after the introduction of anticholinergic medication. No complications were observed in either group and, therefore, no blood products transfusion was necessary.

Perforation of the bladder, which occurred in one patient in group 1 during passage of the needle, was identified by cystoscopy and procedure was continued. The patient had a good recovery and required a bladder catheter for 6 days. Bladder perforation is one of the most common complications of sling surgery. In a series of 20 patients submitted to sling surgery using a hand-made sling, bladder perforation was observed in two patients (18). During the follow-up there was no evidence of erosion of the urethra or vaginal mucosa in patients who had the hand-made polypropylene sling for surgery.

CONCLUSIONS

Despite the short postoperative follow-up (90 days) in the present study, investigations using the same material and a longer follow-up of 13 months (18), 15 months (24) and 23 months (17) reported similar cure rates of SUI or improvement of clinical symptoms (95%, 96% and 89%, respectively). These results demonstrate the long-term efficacy of a cost-effective hand-made polypropylene mesh sling for the treatment of SUI.

CONFLICT OF INTEREST

None declared.

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Submitted for publication:
June 16, 2010

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Accepted after revision:
November 19, 2010