

RETROPUBIC OR TRANSOBTURATOR SLINGS FOR TREATMENT OF STRESS URINARY INCONTINENCE

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ABSTRACT

OBJECTIVE. To compare the results of retropubic and transobturator slings for surgical treatment of female stress urinary incontinence (SUI).

METHODS. We randomized thirty patients with SUI, ten of whom underwent transobturator sling surgery and ten retropubic sling surgery. Patients were assessed before treatment and 1, 6 and 12 months after treatment on the basis of clinical history, physical examination, quality of life questionnaire (King's Health Questionnaire), pad test and urodynamic evaluation. The groups were homogenous prior to surgery.

RESULTS. One year after surgery, incontinence and quality of life parameters had improved significantly in both groups and there were no differences between them. There was a significant reduction in pad test weights in both groups. According to the urodynamic evaluation, 12 months after surgery cure rates were 84.2% for the transobturator group and 88.8% for the retropubic group. Subjective cure rates were 85% in the transobturator group and 88.8% in the retropubic group. No statistical difference was observed in complication rates.

CONCLUSION. Retropubic and transobturator slings were effective for treatment of women with SUI at 12-month follow-up. Both techniques had significant cure rates and improved quality of life with low complication rates.

KEYWORDS: Urinary incontinence, stress. Urogenital surgical procedures. Surgical procedures, minimally invasive.

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INTRODUCTION

Urinary incontinence is a common problem in the female population, affecting physical, emotional, psychological, social and sexual wellbeing, resulting in a major impact on women's quality of life.¹ It is estimated that 200 million people suffer from this condition and that there are 17 million cases in the United States, generating an annual expenditure of more than 26 billion dollars.² In Brazil, around 10% of patients presenting at gynecology clinics complain of this condition.

Stress urinary incontinence (SUI) is the most common cause of urine leakage, accounting for approximately 50% of incontinence in women.³ It is characterized by the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing.⁴

More than 100 different surgical techniques have been described throughout history. As understanding of the pathophysiology of SUI increased, more advanced techniques were

developed, including the recent minimally invasive techniques using tension-free tape. Approximately 85% of cases are cured, according to >5-year follow-up, and advantages include fewer incisions, less local anesthetic, shorter hospital stays and quicker patient recovery, up to the point that they can return to their daily activities.⁵

A number of synthetic materials have been developed and impressive reductions in surgical morbidity have been achieved. The use of synthetic meshes has reduced operating time and eliminated the possibility of morbidity at the autologous graft harvest site.⁶ The characteristics of different meshes differ in terms of their fibers, weave, porosity and flexibility. These properties affect the response of tissues and the capacity for incorporation into the host's tissues or for fighting infection. The synthetic material that results in the best tissue incorporation is monofilament macroporous polypropylene mesh.

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Although many different studies have observed high cure rates using the retropubic approach, perioperative complications have been described that include intestinal, vascular and bladder injuries.^{7,8,9} In an attempt to reduce these complications, Delorme et al.¹⁰ developed a procedure by which the sling is introduced via the obturator foramen, avoiding the tunnel through the retropubic space. Transmuscular insertion via the obturator muscles through a subcutaneous tunnel, providing anchorage and anatomic reinforcement for the urethropelvic ligament. The retropubic space is conserved and cystoscopy is unnecessary, reducing the duration and cost of the operation.

In view of the lack of certainty in terms of the results of surgery and the complications involved, we decided that it would be interesting to compare the retropubic and transobturator techniques. This study analysed and compared the results and associated complications of retropubic and transobturator Safyre sling surgery for the treatment of women with stress urinary incontinence.

METHODS

This study was conducted at the Urogynecology and Vaginal Surgery Clinic, part of the *Universidade Federal de São Paulo - Escola Paulista de Medicina's* Gynecology Department. Approval was granted by the Research Ethics Committee and all participants signed informed consent forms.

Thirty women were recruited, in accordance with the inclusion criteria of a diagnosis of stress urinary incontinence and clinical status appropriate for surgery.

Exclusion criteria were use of adrenergic, anticholinergic or serotonergic drugs, hormone therapy within the previous 6 months, prior pelvic radiotherapy or current chemotherapy or hormone therapy, uterine prolapse irrespective of clinical status or prolapse of the anterior or posterior vaginal walls at a clinical stage greater than II or mixed urinary incontinence.

Preoperative workup included patient history, general and gynecological physical examination, type I urine test and urine culture, urodynamic study including fluxometry, cystometry and flow-pressure study, pad test and quality of life questionnaire.

A Brazilian-made four channel Urosystem PL-2400 Polimed machine was used for the urodynamic studies. Cystometry was performed with the patient in a semi-seated position, by two-way urethral catheterization. The liquid used was distilled water at room temperature and the infusion velocity was 40ml/min. During the infusion phase, patients were requested to make a physical effort (coughing) after each 100 ml was infused in order to determine at what volume urine loss occurred. After 200 ml had been infused, patients performed the Valsalva maneuver in order to determine at what intravesical pressure urine leakage began. Maximum bladder capacity was defined as the urine volume at which an irresistible desire to urinate was felt. Soon after, still with bladder and rectum catheters in place, patients were asked to spontaneously urinate on a uroflow chair, fitted to a load cell and the urine flow curve and flow-pressure study were conducted. We thus collected the following data: maximum flow, total duration of micturation, mean flow, urine volume and a flow-pressure study comprising detrusor pressure at urethra opening and detrusor pressure at maximum flow. All of the terms used adhere to the International Continence Society's standardized definitions.⁴

A simplified version of the pad test was used to quantify urine loss. Patients were probed and the bladder fully emptied before 250 ml of distilled water was infused. Pads were weighed and then fitted and the patients were asked to perform the following maneuvers involving effort: coughing, jumping, crouching and contracting the abdominal muscles, ten times each. They were also asked to go up and down five steps, ten times, walk for 10 minutes and wash their hands in running water for 1 minute. The test took less than 20 minutes to perform. At the end of the test, the pad was weighed once more and differences in weight of more than 1 g were considered positive results.¹¹

The quality of life questionnaire used was the "King's Health Questionnaire", which comprises nine domains: general health perception, impact of incontinence, limitations to daily activities, physical limitations, social limitations, personal relationships, emotions, sleep and energy, measures of severity. Scores are calculated using a mathematical formula and range from 0 to 100. The lower the score, the better the patient's quality of life is.¹²

Patients were randomized into two groups, 20 in a transobturator group and ten in a retropubic group.

Surgery was conducted with intradural block anesthesia. An indwelling Foley 14 bladder catheter was fitted prior to the operation, and maintained until the day after the operation.

Patients were reassessed to test for cure on the basis of clinical complaints, the pad test, urodynamic study and quality of life questionnaire, administered 1, 6 and 12 months after the procedure.

Women who continued to suffer urinary incontinence postoperatively underwent sling readjustment in outpatients, under local anesthetic. For this technique the patient is placed in the lithotomy position, locoregional anesthesia is applied to the original suprapubic or thigh incision, on one side only. Once the surface layers have been opened, one of the ends is located and tractioned, the excess material is removed and the incision closed with single mononylon 4-0 sutures.

Intraoperative events and postoperative complications were recorded.

Statistics

Age and body mass index were compared using Student's *t* test for independent samples and obstetric history variables were compared using the Mann-Whitney test for independent samples. Associations between surgery and other qualitative variables were investigated using the Chi-square test or Fisher's exact test. Nonparametric tests were used for the results of surgery because the quantitative variables did not have a normal distribution.

The 1, 6 and 12-month assessments were compared within each surgery groups using the Friedman test and differences were identified using the Wilcoxon test with Bonferroni correction. The Mann-Whitney test was used to compare the groups at each assessment point. The chi-square test or Fisher's exact test were used to compare surgery groups in terms of complications.¹³

We adopted a significance level of 0.05 ($\alpha = 5\%$) and descriptive (*p*) levels below this limit were considered statistically significant.

RESULTS

The two groups were similar in terms of age, parity, number of normal and cesareans deliveries, hormone status, body mass index, prior surgery for stress urinary incontinence, hysterectomy and intrinsic sphincter defect (defined as leakage at pressures below 60 cmH₂O).

The quality of life scores calculated after administering the questionnaire are given in Table 1.

The two groups were similar in terms of general health perception, both preoperatively and postoperatively. A significant increase in general health perception scores was observed in the transobturator group, but at the 6 and 12-month follow-ups the improvement was no longer statistically significant. In the retropubic group, no statistically significant variation was detected after treatment (Table 1).

There was no difference between the two groups in the domains Impact of Incontinence, Limitations to Daily Activities, Physical Limitations, Personal Relationships, Emotions, Sleep and Energy and Measures of Severity during the period investigated, but there was a significant improvement in all factors after treatment (Table 1).

A significant difference was detected between the groups in the preoperative Social Limitations assessments, indicating that the groups were not homogenous at the study outset. There were significant improvements in both groups in all assessments after treatment (Table 1).

Table 2 lists the results of the pad test, before surgery and 1, 6 and 12 months after surgery. The weight of pads was significantly reduced in all postoperative tests in both groups and there was no difference when the groups were compared with each other.

There were no postoperative changes in urine volume, mean and maximum urine flow or detrusor pressure at maximum flow. The retropubic group exhibited significant postoperative increases in detrusor pressure opening at the 1 and 12-month follow-ups.

Cystometry did not detect significant variations between the groups before or after treatment in the parameters residual urine and bladder capacity at first urge to urinate. The two groups were comparable in the preoperative, 1-month and 6-month assessments. Maximum bladder capacity had reduced in both groups at 6 and 12 months, but there was no difference when one group was compared with the other.

In the transobturator group, three patients (15%) suffered urine loss during the urodynamic stress test 1 month after the surgery, although only one of them had a clinical complaint, and her sling was adjusted. After adjustment, at the 6-month follow-up, this patient continued to suffer clinical and urodynamic leakage. One of the patients who had had urodynamic leakage at 1 month did not suffer loss at the 6-month follow-up, but the other continued to exhibit urodynamic leakage and now also had a clinical complaint, so her sling was also adjusted. These two patients were still suffering urodynamic loss at the 12-month follow-up, although only one still had a clinical complaint (Table 3).

None of the patients in the retropubic group presented clinical or urodynamic urine loss 1 month after surgery. One patient suffered loss during the effort test at 6 and 12 months,

but refused sling adjustment because her complaint was mild.

In both groups, subjective and objective cure rates were 90%. One patient in each group failed to attend the 12-month urodynamic assessment, meaning that 16 out of 19 patients (84.21%) in the transobturator group, and eight out of nine patients (88.8%) in the retropubic group had been objectively cured.

Furthermore, we observed a 25% failure rate (two cases) among the eight patients with pressure at leakage below 60 cmH₂O who had been treated with transobturator Safyre procedures. There were no treatment failures among the four patients treated with retropubic Safyre procedures who had had pressure at leakage below 60 cmH₂O.

No significant differences were detected between the groups in terms of postoperative complications. All urinary tract infection cases were resolved by antibiotic therapy. One patient in each group developed urge incontinence and were treated with oxybutynin. There was one case of urine retention in the retropubic group, and the indwelling catheter was removed after 12 days, with a 50 ml residue, and at the 1, 6 and 12-month follow-ups, there were residual urine volumes of 100ml, zero and zero, respectively.

Three patients were uncomfortable and excess material had to be removed from the silicone for postoperative adjustment. These procedures were conducted under local anesthetic without incident.

One patient in the transobturator group suffered mild sporadic pain in the medial surface of the left thigh which improved with analgesics, but continued to be present at all follow-ups.

DISCUSSION

Few studies have compared the retropubic and transobturator approaches. Liapis et al.¹⁴ conducted a comparative study and concluded that the two routes are equally effective for surgical treatment of SUI, with cure rates of 90% and 89%, respectively. Mellier et al.¹⁵ conducted a similar study and observed cure rates of 90% for the retropubic approach and 95% for the transobturator approach. Similarly, Lee et al.¹⁶ reported a cure rate of 86.9% in both groups. In our study there was a 3.3% rate of bladder perforation in the retropubic group and there were no other perioperative complications. Improvement in quality of life was similar for both groups.

By using the transobturator approach the retropubic space is not violated, which reduces the risk of bladder, vascular or intestinal injury, and means that perioperative cystoscopy is unnecessary. De Leval et al.¹⁷ did not observe bladder or urethra injuries or vascular or neurological complications and stated that the transobturator approach is a safe procedure that does not require perioperative cystoscopy.

Palma et al.¹⁸ compared the efficacy of different Safyre surgical techniques, and did not detect any difference in terms of the cure rates, which were 92.1% using the suprapubic vaginal approach and 94% using the transobturator approach. However, the transobturator technique offered reduced time in the operating theatre and a lower rate of complications such as bladder perforation (2.3% and 0%, respectively) and postoperative urgency (20.6% and 10%, respectively). The sling became infected in 4.7% of the retropubic group and 1% of the transobturator group. None of the transobturator patients suffered from

Table 1 - Quality of life scores prior to surgery and after 1, 6 and 12 months

Domains	Pré-op	1 m	6 m	12 m	p
General Health Perception					
TOT	36.3±19.0	17.5±11.8	31.3±25.5	27.5±24.2	0.002
RP	47.5±21.9	22.5±18.4	30.0±23.0	30.0±19.7	0.059
p	0.22	0.46	0.96	0.58	
Impacto da incontinência					
TOT	96.7±10.3	3.3±10.3	5.0±16.3	8.3±23.9	<0.001
RP	90.0±16.1	0.0±0.0	3.3±10.5	3.3±10.5	<0.001
p	0.17	0.30	0.96	0.66	
Limitations to Daily Activities					
TOT	90.0±16.6	0.0±0.0	0.0±0.0	5.0±22.4	<0.001
RP	68.3±32.8	0.0±0.0	1.7±5.3	1.7±5.3	<0.001
p	0.06	-	0.15	0.64	
Physical Limitations					
TOT	94.2±13.5	0.0±0.0	0.8±3.7	5.0±22.4	<0.001
RP	78.3±27.3	0.0±0.0	1.7±5.3	1.7±5.3	<0.001
p	0.143	-	0.61	0.64	
Social Limitations					
TOT	68.3±21.7	0.0±0.0	0.0±0.0	3.9±17.4	<0.001
RP	42.2±27.3	0.0±0.0	1.1±3.5	1.1±3.5	<0.001
p	0.009	-	0.15	0.64	
Personal Relationships					
TOT	54.4±39.1	0.0±0.0	0.0±0.0	0.0±0.0	<0.001
RP	47.2±15.2	0.0±0.0	0.0±0.0	0.0±0.0	0.007
p	0.66	-	-	-	
Emotions					
TOT	63.9±36.7	0.0±0.0	0.0±0.0	5.0±23.4	<0.001
RP	65.6±36.8	0.0±0.0	0.0±0.0	0.0±0.0	<0.001
p	0.92	-	-	0.48	
Sleep and Energy					
TOT	42.5±41.3	0.0±0.0	0.0±0.0	5.0±22.4	<0.001
RP	30.0±37.5	0.0±0.0	0.0±0.0	0.0±0.0	0.002
p	0.39	-	-	0.48	
Measures of Severity					
TOT	75.0±14.8	0.8±2.6	1.7±5.1	6.3±19.3	<0.001
RP	63.3±28.4	4.2±5.9	5.8±13.1	5.0±13.1	<0.001
p	0.30	0.18	0.19	0.78	

Pre Op: preoperative assessment TOT: transobturator group RP: retropubic group

urine retention, which affected 3.1% of the retropubic patients. The sling was adjusted in 4.7% of the retropubic patients, (with a cure rate of 66.6%), and in 6% of transobturator patients (cure rate of 83.3%). There were no complications such as bleeding or vaginal or urethral perforation.

In this study we have conducted a prospective comparison of minimally invasive synthetic slings fitted via the retropubic or transobturator approach. Follow-up time was 12 months, in order to assess the results of surgery and postoperative complications.

The quality of life assessment showed that, in common with other authors, we achieved significant improvement.^{16,19}

In our patient sample, 6 months after surgery both subjective and objective cure rates were 90% in both groups. After 12 months, the subjective cure rate was 90% in the transobturator group and 88.8% in the retropubic group.

We observed that two (66.6%) of the three transobturator Safyre cases in which the 12-month urodynamic assessment indicated treatment failure had undergone prior surgery for urinary incontinence. In contrast, only one (6.25%) of the cases that achieved urodynamic cure had undergone prior surgery for urinary incontinence, indicating that this is an important risk factor for treatment failure. We were also able to observe treatment failures in the transobturator group where patients had body mass indexes greater than 31, which may indicate that this is a risk factor.

With relation to intrinsic sphincter deficiency (pressure below 60 cmH₂O at urine loss), we observed a 25% failure rate using the transobturator approach and 0% of failures in the retropubic group. Although this is a small sample, these data are similar to those reported from recent clinical trials. Rechberger et al. concluded that both approaches are effective for treatment of stress urinary incontinence, after an 18-month follow-up. Nevertheless, where patients had leakage at pressures below 60 cmH₂O, the retropubic technique was more effective.²⁸

There was no statistical difference in terms of postoperative complications. Other authors have published contrasting results, however, indicating that the rate of complications is lower using the transobturator technique.^{14,16,20}

Studies have reported incidence rates of bladder perforation ranging from 0.8% to 21% among patients treated using the retropubic technique.^{7,21,22} In contrast, few cases of bladder or urethra perforation are reported during transobturator surgery. Comparative studies only observed bladder perforation among patients in retropubic groups, with rates of 3% to 6.5%.^{14,16,20} In our study there were no cases of bladder perforation in either group.

Procedures employing a suburethral sling may have an obstructive effect, increasing urethral resistance and affecting urinary function. Some studies have described increased incidence of difficulty urinating after the retropubic approach, although these results are disputed. This possible advantage of the transobturator route is attributed to the horizontal positioning of the sling, which may result in lower incidence of urine retention and/or symptoms or urinary urgency.²³

In our patient sample there was just one case (10%) of urine retention in the retropubic group, which was resolved ten days after surgery. There was one retropubic case with urinary urgency and one case in each group of urge incontinence symptoms. There were no significant changes in maximum or mean urinary flow after surgery.

In our 12-month follow-up study no cases of vaginal of the sling were observed. Infectious complications have been observed after surgery using synthetic slings. Hammad et al.²⁴ described a 1.2% rate of vaginal erosion after retropubic TVT. Kuuva et al.²⁵ observed 0.8% of infection of the surgical wound. Rarer infectious complications that have also been observed include infected hematoma and necrotizing fasciitis.²⁶ Complications observed after transobturator surgery include inguinal and obturator abscesses and perineal cellulitis.^{19,27} There were no cases of postoperative infection in our sample.

Our results demonstrate that Safyre procedures, whether via the retropubic or transobturator approaches, are minimally invasive and are effective for the treatment of stress urinary incontinence. There was no statistical difference between the two approaches in terms of clinical or urodynamic results, quality of life assessment, pad test or number of complications. Notwithstanding, it is important to point out the need for studies with larger samples and longer follow-up, in order to determine the potential advantages of each technique and the differences

Table 2 – Pad test results prior to surgery and after 1, 6 and 12 months

Pad test	Pré-op	1 m	6 m	12 m	P
TOT	33.4±30.2	0.7±3.1	0.3±1.1	1.2±5.4	<0.001
RP	23.6±29.4	0.0±0.0	0.0±0.0	0.0±0.0	<0.001
p	0.48	0.30	0.48	-	

Pre Op: preoperative assessment TOT: transobturator group RP: retropubic group

Table 3 – Number of patients (%) suffering urine loss according to the urodynamic study results prior to surgery and after 1, 6 and 12 months

	Pré-op	1 m	6 m	12 m	p
Urine loss					
TOT	20 (100%)	3 (15%) 2 (10%)	3 (15%)	<0.001	
RP	10 (100%)	0 (0%)	1 (10%) 1 (10%)	<0.001	
p	-	0.53	1.0	1.0	

Pré-op: pré-operatório - TOT: grupo transobturatório - RP: grupo retropúbico

between them.

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