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Comparative study of polyvinylidene fluoride and polypropylene suburethral slings in the treatment of female stress urinary incontinence

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Abstract

Aims: Evaluate the effectiveness and safety of polyvinylidene fluoride (PVDF) transobturator suburethral slings/tapes (TOTs) in the treatment of stress urinary incontinence, and compare them to polypropylene (PP) slings.

Material and Methods: A retrospective cohort study was performed on women treated with a TOT procedure at Vall d'Hebron Hospital between February 2010 and May 2013. A PVDF sling was used in surgeries on 23 women. A comparison group was randomly selected among all women treated with a PP sling in a 1:4 ratio ($n = 92$). Failure incidence was analyzed by Kaplan–Meier survival functions and a multivariate Cox regression model.

Results: Both groups were similar in their initial characteristics. The median follow-up was 24.6 months in the PP group and 21.3 months in the PVDF group. The survival functions showed a higher incidence of failures in the PP group, primarily because of obstructive symptoms. However, the differences were not statistically significant (hazard ratio of failure of PP vs PVDF 4.31; 95% confidence interval 0.56–33.05). Complication rates did not differ between the two groups. More cases of voiding dysfunction were observed in the PP group.

Conclusions: Polyvinylidene fluoride suburethral tapes have been found to have an effectiveness and safety comparable to PP tapes.

Key words: midurethral sling, polypropylene, polyvinylidene fluoride, PVDF, stress urinary incontinence, suburethral sling.

Introduction

Currently, the first line surgical treatment for female stress urinary incontinence (SUI) is the use of tension-free suburethral tapes. Among them, transobturator (TOT) slings are the treatment of choice in many urogynecology units. Because of the high effectiveness of TOT slings, with a cure rate close to 85%, investigation and development efforts are aimed at decreasing the complications of the technique.[1] One line of development in this field during the last few years is a single-incision sling, which has obtained controversial results.[2,3]

Another approach to improve the outcomes of suburethral slings could be based on modifying the material used in the sling in order to decrease the complications directly related to the tape. Although many brands have developed their own slings, the synthetic material utilized in these tapes is mainly polypropylene (PP). However, the use of polyvinylidene fluoride (PVDF) in

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suburethral tapes was also approved in Europe. PVDF is a nonabsorbable fluoropolymer, introduced in 2002 for surgical mesh, with an excellent biocompatibility.[4–6] Its biomechanical properties include lower elongation and deformation capacities compared to PP.[7] These characteristics are the basis to hypothesize that PVDF slings could be associated with less mesh-related complications, such as erosions and urinary obstruction. Nonetheless, to the best of our knowledge, no studies comparing the clinical outcomes of both materials in suburethral slings exist.

The aim of the present study is to describe and compare the effectiveness and complication rates of PVDF and PP transobturator suburethral tapes in the treatment of female SUI.

Materials and Methods

A retrospective cohort study was performed to compare the outcomes of PP and PVDF suburethral slings for the treatment of SUI. Participants were selected among all women treated for SUI with a TOT sling procedure at Vall d'Hebron University Hospital between February 2010 and May 2013. Data was obtained by reviewing medical records and also during prospective follow-up. The hospital ethics committee approved the study.

Patients and definitions

Twenty-three women were treated with a PVDF suburethral sling during the above-mentioned period. The comparison group was randomly selected in a 1:4 ratio (n = 92), using the macro!RNDI for SPSS, among all women treated with a TOT made of PP during the same period (n = 457).[8] Patients with stress-predominant mixed urinary incontinence were also included. As this was an exploratory study, a previous sample size calculation was not conducted and the number of women who received surgery with a PVDF sling limited the number of patients included. However, the power of the study was estimated with the results.

Preoperative evaluation included a detailed physical examination, an interview following a questionnaire with signs and symptoms of lower urinary tract dysfunction based on the terminology recommended by the International Continence Society and a urinalysis and urine culture.[9] Urethral hypermobility was defined as a Q-tip test >30°. All women underwent a multichannel urodynamic study before surgery.

Procedure and follow-up

All of the slings used in the study are approved by our center and used in daily practice. The synthetic materials included in the study were: amid type-I polypropylene, with low elongation capacity, and PVDF, which is a macroporous mesh with a lower elongation capacity than PP.[7,10] All procedures were performed by four experienced urogynecological surgeons under spinal anesthesia, with the use of PVDF slings limited to two surgeons because the general experience with the use of PVDF slings is lesser than with PP. The tape used was the surgeon's preference. The tape was placed in a tension-free manner without the aid of a cough test. Surgery for pelvic organ prolapse (POP) correction was associated when needed.

Postoperative follow-up visits were scheduled at one, six and 12 months, and yearly thereafter. These included physical examination with a cough stress test (patients were invited to attend follow-up visits at least 2 hours after the last micturition), and an interview about signs and symptoms, use of urinary protections, micturition difficulties, pain in groins or thighs, dyspareunia and satisfaction with the procedure. Patient satisfaction was assessed with the question 'How satisfied are you with the result of surgery?' with possible responses of completely satisfied, moderately satisfied or dissatisfied. Postoperatively, the patients were regarded as cured if they had a negative cough stress test and were fully satisfied with results of the surgery (no leaks, no voiding dysfunction and no use of urinary protection). To be regarded as improved, the cough stress test had to be negative and the patient moderately satisfied with the results of surgery, with an increase in urinary frequency and/or sporadic urgency episodes. Patients were classified as failures in the presence of a positive cough test and/or dissatisfaction with surgery, including *de novo* or worsened urge-incontinence and/or voiding dysfunction associated with frequent urinary infections, and the use of the same urinary protections during daily activities as before surgery. Early-postoperative obstruction was defined as a post-void residual urine volume higher than 100 ml measured by transvaginal ultrasound or by urethral catheterization. *De novo* urgency was diagnosed clinically by the presence of bothersome overactive bladder symptoms that were not present before the procedure.

Statistical analysis

Data analysis was performed using SPSS version 18.0. Categorical variables were analyzed using the χ^2 test or

Fisher's exact test when indicated. Quantitative variables were compared with the Mann–Whitney U test because they did not follow a normal distribution. Kaplan–Meier survival functions analyzed the incidence of failure, which were compared with the log rank test. Multivariate Cox regression was used to calculate the hazard ratio (HR) of failure according to sling type, adjusting for potential confounding factors such as the presence of mixed urinary incontinence, the presence of urethral hypermobility and associated POP surgery. A two-tailed P value <0.05 was considered to indicate statistical significance and 95% confidence intervals (CI) were calculated.

Results

The preoperative characteristics of the patients are detailed in Table 1. No differences were found between the two groups with the exception of lower urethral closure pressures in the PVDF group.

Seventy-two women (63.2%) underwent concomitant surgery for POP (Table 1). During the surgery, three intraoperative complications were recorded: one bladder puncture and two vaginal perforations. All complications were identified during the needle passage, corrected at that time, and the suburethral sling was placed in all cases without further complications.

The median follow-up was 24.6 months in the PP group (interquartile range 12.6–39.5 months) and 21.3 in the PVDF group (interquartile range 12.3–31.0 months). A higher proportion of failures in the PP group was observed (Figure 1). The survival estimates showed that the likelihood of cure or improvement was 92.4%, 87.7% and 83.6% in the PP group and 95.7%, 95.7% and 95.7% in the PVDF group at six, 12 and 24 months of follow-up, respectively, although these differences were not statistically significant (P = 0.179). No differences in the incidence of failure were found (adjusted HR of failure of PP vs PVDF 4.31; 95% CI 0.56–33.05). The power of the study to find differences in the incidence of failure described was 73.5%. Two of the 15 failures observed in the PP group were because of obstructive micturition, nine because of severe urge-incontinence, three because of mixed incontinence and one because of persistent stress-only incontinence, while the failure described in the PVDF group was a result of persistent SUI.

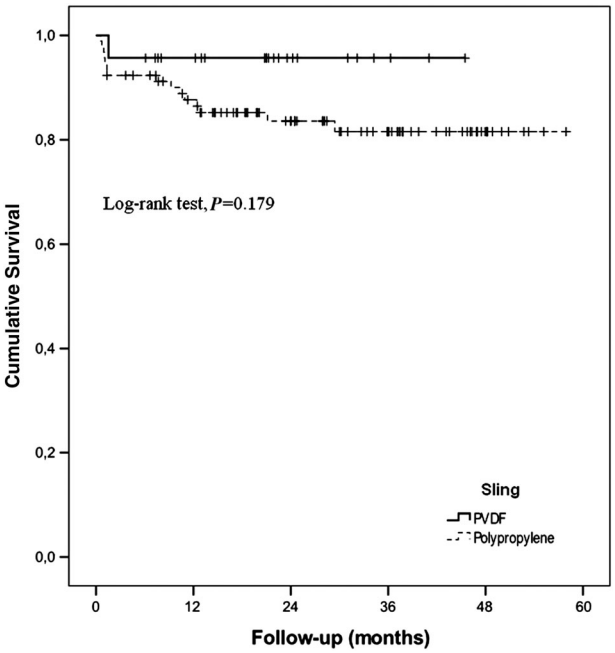

Figure 1 Kaplan-Meier survival functions for sling effectiveness. The steps indicate failures. PVDF, polyvinylidene fluoride.

Postoperative complications are summarized in Table 2. There were no differences between the two

Table 1 Initial characteristics

	Polypropylene	PVDF	*P*
Age (years)†	63.8 [39.3–80.5]	65.8 [41.1–85.0]	0.394
BMI†	29.7 [20.8–42.9]	30.1 [26.0–43.2]	0.507
Previous surgery‡	23 (25.3)	4 (17.4)	0.427
Associated POP‡	63 (68.5)	13 (56.5)	0.279
Previous UUI‡	32 (34.8)	10 (43.5)	0.439
Presence of DOA‡§	5 (15.6)	4 (40)	
Urethral hypermobility‡	72 (79.1)	15 (65.2)	0.267
MUCP†	49.0 [8–74]	45.0 [16–60]	0.018
Associated surgery‡	60 (65.9)	12 (52.2)	0.222

†Data expressed in median [range]; ‡data expressed in n(%); §percentage in relation to cases with UUI. BMI, body mass index; DOA, detrusor overactivity; MUCP, maximal urethral closure pressure; POP, pelvic organ prolapse; PVDF, polyvinylidene fluoride; UUI, urinary urge-incontinence.

Table 2 Complications

	Polypropylene	PVFD	*p*
Intraoperative	3 (3.3%)	0 (0%)	1
Bladder puncture	1	0	
Vaginal perforation	2	0	
Early postoperative	22 (23.9%)	3 (13.0%)	0.258
Cystitis†	2	0	
Temporary elevated PVRV	22	3	
Voiding difficulty requiring ISC	4	0	
Late postoperative	6 (6.5%)	0 (0%)	0.598
Repeated cystitis	1	0	
Urinary obstruction	4	0	
Transient groin pain	1	0	
Tape erosion	0	0	
***De novo* urgency**	13 (14.1%)	1 (4.3%)	0.295
Urethrolysis	7 (7.6%)	0 (0%)	0.342

†Positive urinary culture. ISC, intermittent self-catheterization; PVDF, polyvinylidene fluoride; PVRV, post-void residual urine volume.

groups; however, it was remarkable that a higher number of transient episodes of elevated post-void residuals occurred in the PP group during the early postoperative period. Those cases occurred more frequently in women with associated surgery for POP (75% of the cases), the episodes were self-limited and lasted between one and five days. Only four cases of urinary obstruction were more prolonged, lasting 10, 14, 17 and 28 days, respectively. These patients were all observed in the PP group and required temporary intermittent clean self-catheterization.

Sling division was required in seven women. The median time from TOT surgery to tape division was 17.1 months (range 6.9–47.1). In six cases it was performed because of severe urge-incontinence along with an obstructive pattern in a postsurgical urodynamic study that did not improve with anticholinergic treatment. In the remaining case it was performed because of persistent incomplete bladder emptying, associated with recurrent urinary infections. All of these cases occurred in the PP group, four (57.1%) in women who underwent concomitant POP surgery.

Discussion

Although the TOT complication rate is low, improvement of the material used in the slings would further decrease the rate.[1,11] PVDF is a synthetic material, widely used in mesh for abdominal wall hernias and in sutures for cardiovascular and orthopedic surgery, which has shown safety and biocompatibility. It exists in four different isomorphs (α, β, γ and δ), where the β-phase PVDF has the most significant piezoelectric properties. The relative proportion of the different isomorphs in a mesh could evoke different cellular responses. Nowadays, there is a good understanding of the parameters that influence the proportional rates of α- and β-phase PVDF during its manufacturing, making it possible to tailor the PVDF product to specific biomedical applications.[12,13] Because of its mechanical properties and enhanced biocompatibility, PVDF is presumed to be an excellent candidate for use in urogynecology.[14] The effectiveness and safety of PVDF for urogynecological indications has been shown; however, reports regarding its use in the treatment of SUI are scarce.[15,16] The present study determined that the effectiveness and safety of PVDF is similar to that of PP in the short and medium terms. However, the study is underpowered to find differences in the incidence of failures observed, and its power would be even lower in case that the real difference was smaller: the power would be of 57.5% to find a HR of 2, a difference that would be considered clinically relevant. In fact, survival analysis showed a trend of better outcomes with PVDF slings, despite the presence of some characteristics that would confer a worse surgical prognosis, such as a lower maximum urethral closure pressure or a higher prevalence of women with mixed urinary incontinence and detrusor overactivity, which were slightly more frequent in the PVDF group.

The complication rates observed in the study did not differ. However, a higher number of obstructive events were observed in the PP group, although these differences were not statistically significant. This observation could be justified for different reasons and among them, sling material would play a role. On the one hand, the

elastic properties of the tapes would be responsible for some early urinary obstructions because of the restoration to their initial shape after elongation during their insertion.[17] PVDF has been found to have a lower elongation and this could intervene in the lower number of immediate postoperative transient obstructions observed herein.[7] On the other hand, PVDF has shown excellent biocompatibility in different animal studies, resulting in lower inflammatory and foreign body reaction (FBR) than PP.[5,6] The level of FBR is directly associated with wound contraction and mesh shrinkage; therefore, PVDF would be associated with less mesh-related complications in the medium and long term, such as urinary obstructive symptoms, *de novo* urinary urge-incontinence and sling erosions.[6,14,17] Our findings seem to fit in with these hypotheses, although the present study could not confirm them.

In the present series, the PP group included a relatively high number of women who required sling revision; however, in our experience, in a high proportion of women with severe and refractory urge-incontinence and urinary obstruction, conditions dramatically improve after sling incision.[18] In fact, in the present series, six women (85.7%) were regarded as cured or improved one year after sling division.

In the present series, PVDF demonstrated similar effectiveness and safety as PP; however, the results of the study should be interpreted with caution. There are potential sources of bias, such as the retrospective nature of part of the data, the lack of randomization in the sling selection, and the comparative group could not be representative of all women treated with a TOT in our center. As PVDF procedures were limited to two surgeons, it could also be a potential source of bias, although this fact is unlikely because all surgeons were urogynecologists with experience in the TOT technique. PVDF seems to provide a good alternative to PP because, theoretically, PVDF would be associated with less mesh-related side effects. However, because of its design and results, the present study could not reach this conclusion. It is important to highlight that there is a potential field of improvement with the TOT procedure by determining the best material for the slings. The potential benefits of PDVF over PP used in suburethral slings should be further evaluated through randomized controlled trials with a long follow-up period.

Disclosure

No author has any potential conflict of interest.

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