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Polypropylene and polyvinylidene fluoride transobturator slings for the treatment of female stress urinary incontinence: 1-Year outcomes from a multicentre randomized trial

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Abstract

Aims: To compare the effectiveness and safety of polypropylene (PP) and polyvinylidene fluoride (PVDF) transobturator tapes (TOT) for the treatment of female stress urinary incontinence (SUI).

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Methods: This is a multicentre randomized trial. Women with SUI or stress-predominant mixed urinary incontinence and scheduled for a TOT procedure were randomized to PP or PVDF slings. The primary outcome was 1-year cure or improvement rate using composite criteria. Complications were also compared. Relationships with outcomes were analyzed using multivariable logistic regressions models.

Results: From April 2016 to January 2018 285 participants were randomized. PP and PVDF slings showed similar high cure or improvement rate (91.0% vs. 95.6%, $p = .138$). Improvement in validated questionnaires was also similar. PVDF slings were associated with a lower rate of de novo urgency incontinence (adjusted odds ratio = 0.35; 95% confidence interval = 0.15–0.80). We found no statistical differences in complications rates, although a higher incidence of long-term pain events were observed in the PP group. The study is underpowered to find differences in specific complications owing to the low number of events.

Conclusion: PP and PVDF TOTs are equally effective, although PVDF is associated with fewer cases of de novo urgency incontinence. Further studies are needed to give robust conclusions on safety profiles.

KEYWORDS

de novo urgency incontinence, midurethral sling, polypropylene, polyvinylidene fluoride, PVDF, sling complications, stress urinary incontinence, suburethral sling, suburethral tape, transobturator

1 | INTRODUCTION

One of the most common first line surgical treatments for female stress urinary incontinence (SUI) is currently the use of tension-free suburethral tapes. Both retropubic and transobturator routes have shown a similarly high effectiveness but with different complication profiles.^{1–5} Specifically, complication rates for transobturator tapes (TOT) ranged from 11% to 31%.⁶ It is well known that biomechanical and biocompatibility properties of the materials used in the slings are related to their success and complication rates.^{7–10} Therefore, some of the complications that could be related to the sling's material, such as de novo urgency incontinence (UUI), pain, sling extrusion and voiding dysfunction may be further decreased by improving this material.

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 suburethral tapes is also approved in Europe. PVDF is a nonabsorbable fluoropolymer introduced in 2002 for surgical meshes¹¹ with improved biocompatibility in animal studies.^{12,13} Some of its biomechanical properties are lower elongation and deformation capacities compared with PP.¹⁴ These characteristics are the basis to hypothesize that PVDF slings may be associated with less mesh-related complications.

In a previous descriptive clinical study we found similar effectiveness and complications with PP and PVDF slings, although more obstructive events were observed in the PP group.¹⁵ However, to date there are no clinical trials comparing those materials in suburethral slings. For that reason we designed this randomized controlled trial (RCT) to establish whether PP and PVDF TOTs are equally effective for treating female SUI. Secondly, safety profiles will be compared.

2 | MATERIALS AND METHODS

The present study was designed as a pragmatic, multi-centre RCT to compare the effectiveness of PP and PVDF TOTs for the treatment of female SUI. Eleven Spanish hospitals were initially included in the trial. The research protocol was approved by the Ethics Committee of the participating centers or explicitly accepted the approval of the coordinating center in the absence of an own ethics committee. The protocol was registered at the public registry ClinicalTrials.gov (NCT02886520).

Patients attending at the participant hospitals because of SUI or stress-predominant mixed urinary incontinence (MUI) were considered for participation in the study. Exclusion criteria were previous continence surgery with midurethral slings, the presence of MUI with predominant

urgency incontinence, intrinsic sphincter deficiency (defined as maximal urethral closure pressure of 20 cmH₂O or less or as Valsalva leak point pressure of 60 cmH₂O or less) when it was evaluable, the existence of neurogenic bladder, the incapacity to understand the information or to give their consent, and age less than 18 years. Women were regarded eligible if they met the inclusion and exclusion criteria. All women received a detailed explanation about the surgical procedure and the study, and written informed consent was obtained.

Preoperative evaluation included a detailed physical examination including a cough stress test (patients were invited to attend follow-up visits at least 2 h after the last micturition), an interview following a questionnaire with signs and symptoms of lower urinary tract dysfunction based on the terminology recommended by the International Continence Society,¹⁶ a urinalysis and urine culture. SUI was diagnosed clinically by the cough stress test in all cases. Pelvic organ prolapse (POP) was staged using the POP-Q system. Preoperative urodynamic study before surgery was optional according to each center's protocol. Participants also completed preoperatively the Sandvik's incontinence severity index validated for Spanish language and that categorizes incontinence into four groups (a fifth group was defined for zero punctuation that means no-incontinence)¹⁷ and the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF).

A block-randomization procedure, stratified by center, was carried out using a random number generator program. Allocation was performed in a 1:1 ratio. Randomization sequence was concealed in a centralized electronic website designed specifically for this study (<http://www.ribk.com/C3PO/>). Group assignment was performed before surgeries once participants agreed with the study. Commercial kits of Amid Type-I PP-TOTs used were those that each center used in their daily practice. The second material studied in TOTs was PVDF (DynaMesh-SIS direct soft; FEG Textiltechnik). All the procedures were performed by experienced surgeons with experience of both types of sling material. Patients were not blinded for the procedure. TOT procedures were done following the standard technique¹⁸ and according to the instructions of the different brands, including the insertion routes. The tapes were placed tension-free without the aid of a cough test. PP and PVDF slings were left under the midurethra in the same manner, leaving a small distance between tape and urethra by placing a scissor or a forceps between them. Surgery for POP correction was associated when needed.

Postoperative follow-up visits were scheduled at 1, 6 (optional), and 12 months. These included physical examination with a cough stress test in the same conditions

than in the preoperative evaluation and an interview about symptoms of incontinence, use of urinary protection, micturition difficulties, pain in groins or thighs and dyspareunia. Patient satisfaction was assessed with the patient global impression of improvement (PGI-I) questionnaire¹⁹ one year after surgery. Women also completed the Sandvik and ICIQ-SF questionnaires at this follow-up point.

The primary outcome was the cure or improvement rate one year after surgery, classified following a composite objective and subjective criteria. Patients were regarded as cured if they had no stress leaks, the stress test was negative and they were fully satisfied with the operation (Sandvik and ICIQ-SF scores = 0, PGI-I = 1–2). To be regarded as improved, the cough stress test had to be negative and the patient moderately satisfied with the result of surgery due to sporadic stress leaks or to an increase in urinary frequency with or without sporadic UII episodes (Sandvik and ICIQ-SF > 0, PGI-I = 2–3). Patients were classified as failures in the presence of a positive cough test and/or dissatisfaction with the surgery, including de novo UII and/or voiding dysfunction associated with frequent urinary infections and the use of the same urinary protection during daily activities as before the surgery (PGI-I ≥ 4). Intraoperative and postoperative complications were also recorded. Early postoperative complications were defined as those that occurred within the first month after surgery; late postoperative complications were those that were present greater than 1 month after surgery. De novo urgency was diagnosed clinically by the presence of new onset bothersome overactive bladder symptoms or by worsening of previous ones. Elevated post-void residual volume was defined as a urine residual of greater than 100 ml measured by introital ultrasound or by urethral catheterization.

Sample size calculation was based on the results of our preliminary study with both materials¹⁵ and also according to clinical relevance criterion. It was estimated that 282 patients were needed to provide 80% power to detect a 10% difference in success rate with an assumed cure rate of 95% for the reference procedure and a two-sided α -error of 0.05.

Statistical analysis was conducted by a third party not involved in the study. Normal distribution for continuous variables was assessed using the Shapiro–Wilk test. Quantitative variables were compared using the unpaired Student's *t* test and with the Mann–Whitney *U* test for those variables that did not follow a normal distribution. Categorical variables were analyzed using the χ^2 test or Fisher's exact test when indicated. Outcomes analyses were performed on an intention-to-treat basis. A second per-protocol analysis for the primary outcome was projected. Univariate analyses were performed with each

baseline variable by means of logistic regression. Multivariate logistic regression models were constructed forcing them to keep the sling material and using a forward process based on the improvement of the likelihood and the Akaike's criterion of the model with a $p < .10$ to decide to include a new variable. Sensitivity for the primary outcome was evaluated using a shrinkage coefficient to calibrate the model. One prespecified subgroup analysis was planned on women with detrussor underactivity. Changes in quantitative variables within-procedures were analyzed by means of the Student's paired t test and differences in the changes between-procedures were compared with the unpaired t test. A two-tailed $p < .05$ was considered to indicate statistical significance for the analyses cited hereinbefore and 95% confidence intervals (CIs) were calculated. Analyses were conducted with the software Stata version 15.1 (StataCorp) and SPSS version 18.0 (IBM).

3 | RESULTS

Between April 2016 and January 2018 a total of 307 patients were assessed for eligibility. One of the 11 participating centers withdrew from the study before including any participant. Patients' recruitment was stopped once the estimated sample size was reached. Of them, 285 patients underwent randomization during the study period, but one withdrew her consent to the study after having been randomized. Finally, 284 women were suitable for the analysis, 140 in the PP group and 144 in the PVDF one (Figure 1). Preoperative characteristics of both groups were similar and are detailed in Table 1. In the PP group the TOT was inserted via the outside-in route in 123 women, whereas in the remaining 16 patients the inside-out route was used. All women in the PVDF group underwent the TOT through the outside-in approach. At the time of the surgery 73 women (25.4%)

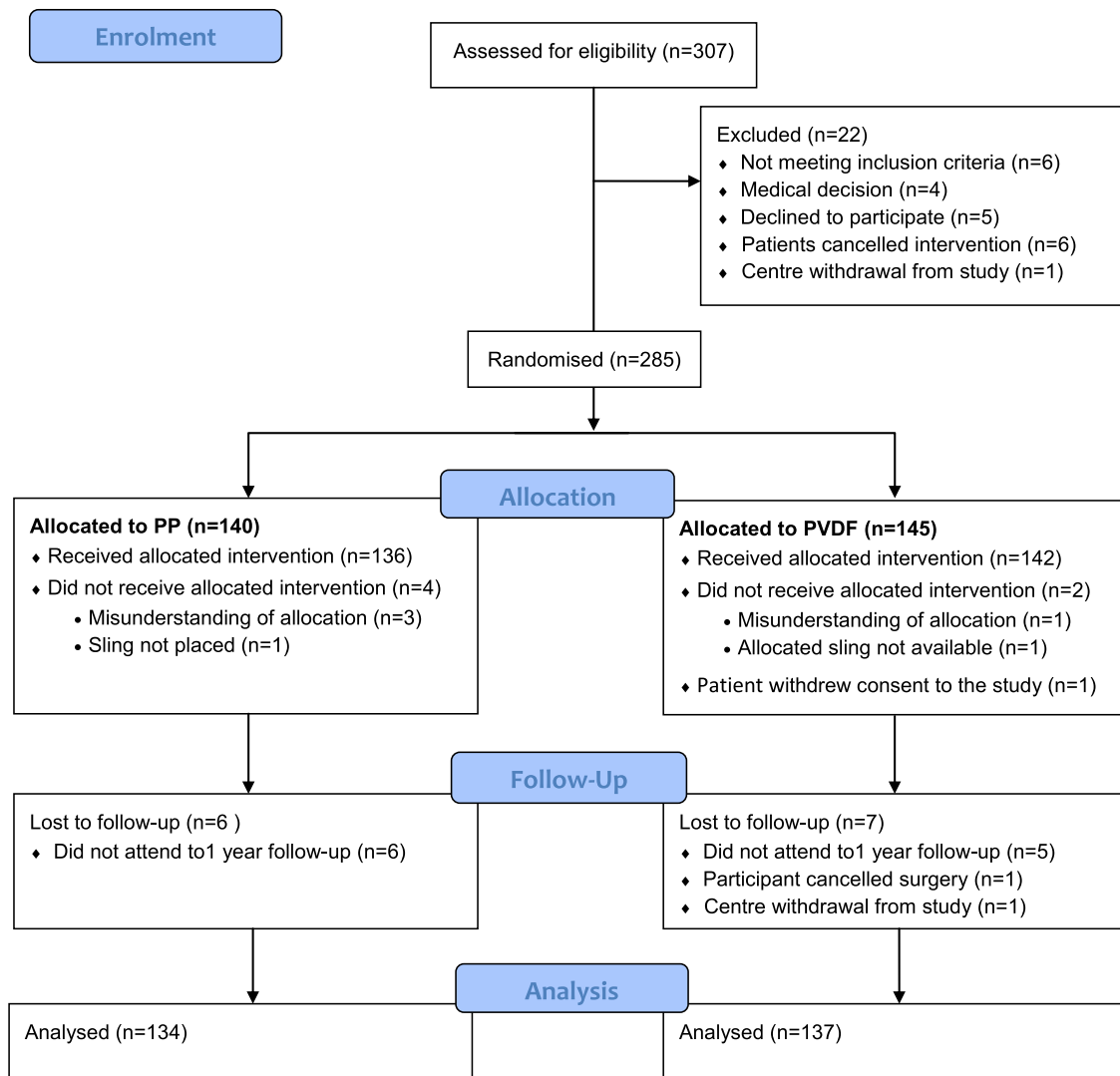


FIGURE 1 CONSORT flow diagram of the study. PP, polypropylene; PVDF, polyvinylidene fluoride

TABLE 1 Baseline characteristics

	PP	PVDF	<i>p</i> ^a
Age (years) ^b	55.3 (48.2–67.0)	58.9 (50.1–68.1)	.133
BMI ^b	28.3 (25.6–31.9)	27.8 (24.9–32.1)	.683
Parity ^b	2 (2–3)	2 (2–3)	.607
Vaginal deliveries ^b	2 (2–3)	2 (2–3)	.548
Menopause ^c	88 (62.9)	94 (65.3)	.671
Smoking habit ^c			.417
Nonsmoker	98 (71.5)	92 (65.3)	
Former smoker	18 (13.1)	19 (13.5)	
Current smoker	21 (15.3)	30 (21.3)	
Urethral hypermobility ^c	112 (80.6)	107 (77.0)	.463
Sandvik score ^b	8 (8–12)	8 (8–12)	.399
ICIQ-SF ^b	16 (14–18)	16 (14–18)	.332
Previous UUI ^c	61 (44.2)	51 (36.9)	.430
Associated POP ^c	55 (39.3)	52 (36.4)	.612
Associated surgery ^c	34 (24.5)	39 (27.3)	.590
Anterior repair	12	12	
Manchester procedure	0	1	
Vaginal hysterectomy	5	8	
Vaginal hysterectomy + anterior and/or posterior repair	13	13	
Posterior repair	0	3	
Colpocleisis	1	2	
Other surgeries	3	0	

Abbreviations: BMI, body mass index; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; PP, polypropylene; POP, pelvic organ prolapse; PVDF, polyvinylidene fluoride; UUI, urinary urge-incontinence.

^a*p* Value comparing groups characteristic.

^bData expressed in median (interquartile range).

^cData expressed in *n* (%).

underwent concomitant surgery for POP. During the 1-year follow-up period, 13 women (4.58%) were lost to follow-up.

3.1 | Primary outcome

On the intention-to-treat analysis the cure/improvement rate was similar with both sling materials: PP 91% (122/134) versus PVDF 95.6% (131/137, *p* = .138). In the univariate analysis the presence of urge-incontinence

before surgery was the only variable associated with a failure of the procedure (odds ratio [OR] = 3.21, 95% CI = 1.10–9.32). Concomitant POP surgery was not associated to failure (*p* = .785). Among failures (*n* = 18), 5 women (27.8%) underwent concomitant POP surgery while 13 (72.2%) did not. However, in the final multivariate analysis the sling material was the only variable included in the final model obtaining the same results (PVDF OR = 0.47, 95% CI = 0.17–1.28). The failures observed in the PP group were because of persistent SUI in three cases, MUI in four cases, severe de novo urge incontinence in four cases and voiding dysfunction in one case. In the PVDF group 2 cases failed because of persistent SUI and four cases because of MUI. Both the ICIQ-SF and Sandvik scores improved after surgery with PP and PVDF slings. Subjective improvement, assessed with these questionnaires and the PGI-I, was similar in both groups (Table 2). Calibrated model leads to a shrinkage coefficient of 0.098 and therefore no correction of the coefficients has been finally performed.

We conducted a per-protocol analysis including 130 women in the PP group and 135 in the PVDF group. Results were materially unchanged, with an OR of failure in the PVDF group of 0.46 (95% CI = 0.17–1.26).

The subgroup analyses on patients with suspected detrussor underactivity included only 33 women. The observed results were similar to those on the whole study population, with an OR of failure in the PVDF group of 0.25 (95% CI = 0.02–3.10).

3.2 | Complications

Complications are detailed in Table 3. Seven women (5.1%) experienced an intraoperative complication in the PP group and four (2.8%) in the PVDF group. The sling material was not associated with intraoperative complications on the multivariate model (PVDF OR = 1.10, 95% CI = 0.97–1.25) as any other variable either.

Early postoperative complications were observed in 25 women in the PP group (18.1%) and 22 in the PVDF one (15.5%). In the multivariate analysis only the associated surgery to the TOT procedure was related to these complications (OR = 2.58, 95% CI = 1.26–5.28). Eight women (5.71%) in the PP group experienced voiding dysfunction with elevated post-void residual volumes, one of them requiring sling loosening in the first days after surgery. In the PVDF group elevated post-void residual volumes were present in 10 women (6.94%). One case of very early sling vaginal exposure was present in each group.

Late postoperative complications were recorded in 14 women (10.4%) in the PP group and 10 in the PVDF

TABLE 2 Questionnaires scores

	Preoperative		Postoperative		p Within group		p Between groups
	PP	PVDF	PP	PVDF	PP	PVDF	
ICIQ-SF ^a	16 (14–18)	16 (14–18)	0 (0–6)	0 (0–5)	.000	.000	.149
Sandvik ^a	8 (8–12)	8 (8–12)	0 (0–3.75)	0 (0–3)	.000	.000	.173
No UI	4 (2.9%)	4 (2.8%)	72 (54.5%)	76 (55.9%)			
Slight	3 (2.2%)	1 (0.7%)	20 (15.2%)	24 (17.6%)			
Moderate	26 (19.0%)	23 (16.3%)	32 (24.2%)	32 (23.5%)			
Severe	64 (46.7%)	66 (46.8%)	7 (5.3%)	3 (2.2%)			
Very severe	40 (29.2%)	47 (33.3%)	1 (0.8%)	1 (0.8%)			
PGI-I ^a			1 (1–2)	1 (1–2)			.757
Very much/much better			115 (89.1%)	122 (91.7%)			
Little better			7 (5.4%)	6 (4.5%)			
No change or worse			7 (5.4%)	5 (3.8%)			

Abbreviations: ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; PGI-I, patient global impression of improvement; PP, polypropylene; PVDF, polyvinylidene fluoride; UI, urinary incontinence.

^aData expressed in median (interquartile range).

TABLE 3 Complications

	PP	PVDF	p ^a
Intraoperative	7 (5.1%)	4 (2.8%)	.356
Bleeding	1 (0.7%)	1 (0.7%)	
Vaginal perforation	4 (2.9%)	2 (1.4%)	
Other	2 (1.4%)	1 (0.7%)	
Early postoperative	25 (18.1%)	22 (15.5%)	.452
Temporary elevated PVR	8 (5.8%)	10 (7.0%)	
Cystitis ^b	2 (1.4%)	3 (2.1%)	
Suburethral hematoma	2 (1.4%)	1 (0.7%)	
Obturator/hypogastric pain	6 (4.3%)	4 (2.8%)	
Vaginal exposition	1 (0.7%)	1 (0.7%)	
Other	8 (5.8%)	4 (2.8%)	
Late postoperative	14 (10.4%)	10 (7.2%)	.313
Repeated cystitis ^b	2 (1.5%)	5 (3.6%)	
Voiding dysfunction	1 (0.7%)	1 (0.7%)	
Tape extrusion	3 (2.2%)	2 (1.5%)	
Obturator/hypogastric pain	7 (5.2%)	2 (1.5%)	
Dyspareunia	4 (3.0%)	1 (0.7%)	
Sling division	3 (2.2%)	0 (0%)	.121
De novo urgency	22 (16.4%)	10 (7.3%)	.012

Abbreviations: PP, polypropylene; PVDF, polyvinylidene fluoride; PVR, post-void residual urine volume.

^aAdjusted *p* value according to final multivariable models.

^bPositive urinary culture.

group (7.2%). Neither overall late complication rate (PVDF OR = 0.64, 95% CI = 0.27–1.52) nor any specific late complication was associated with sling material. Finally, we find a lower rate of de novo UUI in the PVDF group with an adjusted OR = 0.35 (95% CI = 0.15–0.80; Table 3). Associated POP was not related to de novo UUI (*p* = .456). Among women who suffered de novo UUI, 6 (27.3%) underwent associated POP surgery whereas 16 women (72.7%) did not in the PP group (*p* = .753). In the PVDF group four women (40.0%) underwent associated POP surgery and six (60.0%) did not (*p* = .458). Sling division was needed in three patients in the PP group (in 2 because of voiding dysfunction and in 1 because of vaginal extrusion) while none in the PVDF group, however this difference was not significant (*p* = .121).

4 | DISCUSSION

There are no previous clinical trials comparing the effectiveness of PP and PVDF in midurethral slings for treating female SUI. The present study finds similar effectiveness of both materials under the specified criteria. The observed overall high success rates at 1 year are in accordance with the results obtained in a previous observational study.¹⁵ However, no data are available on long-term outcomes comparing these materials.

Safety however, is also a major issue for surgical procedures. Safety of PVDF meshes in urogynecology has been reported previously.^{15,20,21} In the present trial, we

observed a higher incidence of de novo UUI in the PP group. This finding was also observed in our previous descriptive study,¹⁵ and could be explained in part by the lower elongation and better biocompatibility of PVDF than PP described in experimental studies.^{12–14} The amount of foreign body reaction and the consequent mesh contraction^{13,22} could explain some cases of de novo UUI. In addition, the overall rates of de novo UUI are similar to those described previously.^{15,23} On the contrary, we have not found the differences in obstructive events observed previously,¹⁵ nor in other complications. However, a higher number of adverse events that could be associated with the material used were observed in the PP group, such as long-term pain, dyspareunia and the need for sling division. Although the present study was designed to compare the effectiveness of the techniques, it is underpowered to find differences in specific complications due to the low number of events.

This clinical trial compares these materials obtaining robust data on their effectiveness as TOT slings. The objective assessment based on the cough stress test was limited because it was not performed with a specified bladder volume, but the effect of this limitation was reduced by using a composite outcome based on both objective and subjective criteria. Another limitation of the present study is that as it was designed to compare the effectiveness of the slings, it has not shown enough power to find differences in complications with low incidence. In addition, some complications may appear over time and would require a longer follow-up to be observed. Therefore, we could not give conclusive results on the differences in the adverse events. We wish to highlight that improving the properties of materials used in urogynecology to enhance their safety while maintaining their efficacy is an important area of research. In this regard, PVDF seems to be a good alternative to PP obtaining similar high cure rates with fewer adverse events, such as de novo UUI. Despite the fact that PVDF has shown promising results in this study, there is a larger experience worldwide with PP slings and therefore the present results should be taken with caution. Other studies by different groups are desirable to corroborate or to refute our clinical findings.

5 | CONCLUSION

We observed a similar high effectiveness with PP and PVDF TOTs for the treatment of female SUI. PVDF slings seem to be related with less mesh related adverse events, such as de novo UUI and pain symptoms, however these observations should be confirmed in future studies and on long-term follow-up.

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CONFLICT OF INTERESTS

JL Poza has received a speaker honorarium from Astellas Pharma outside the submitted work. The remaining authors declare that they have no conflict of interests.

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