UROGYNECOLOGY

Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up

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OBJECTIVE: The aim of this study was to explore the nature and rate of surgical intervention after transvaginal Prolift mesh repair for pelvic organ prolapse.

STUDY DESIGN: This was a retrospective study of all patients who underwent Prolift mesh repair between January 2005 and January 2009. Patient data were obtained from medical records, and patients were telephoned to check if they had surgery in other hospitals.

RESULTS: A total of 600 consecutive patients were identified. Of these, 524 patients (87.3%) were included in the study, with a median follow-up duration of 38 months (range, 15–63). Global reoperation rate was 11.6%. Indications of intervention were surgery for urinary incontinence (6.9%), mesh-related complications (3.6%), or prolapse recurrence (3%).

CONCLUSION: The global reoperation rate after transvaginal Prolift mesh repair was 11.6%, with urinary incontinence surgery being the most common indication. Rates of mesh complications and prolapse recurrence are relatively low in an experienced team.

Key words: complications, pelvic organ prolapse, polypropylene mesh, reoperation, transvaginal mesh, vaginal surgery

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Mesh kits are increasingly being used in surgery for pelvic organ prolapse (POP) because traditional procedures using weak native tissue have important rates of failure, with reintervention in almost 30% of patients.[1] Vaginal approach, using mesh reinforcement to improve anatomical results, is an attractive option for management of POP,[2] as a minimally invasive form of surgery.

The French Transvaginal Mesh (TVM) group has developed a standardized procedure using the transobturator and the transgluteal route through sacrospinous ligament route for anterior, middle, and posterior compartment prolapse.[3,4] As a new procedure, data about safety and effectiveness are important to judge its value. Many studies reported low operative morbidity for this technique but their follow-up duration was rather short[4-8] and with only 1 prospective study reporting rather encouraging medium-term results.[9] Several randomized controlled trials have compared traditional repairs with the use of vaginal mesh kits.[10-14] These studies suggest better anatomic success rates, particularly in anterior vaginal wall repairs, but with a higher rate of mesh-related complications, requiring management such as mesh erosion.[15,16] Little work has been carried out on surgical intervention after transvaginal mesh repair.[16,17] The aim of this study was to analyze the nature and rate of reoperation after Prolift mesh repair for POP in a large cohort of patients.

Materials and Methods

This was a retrospective cohort study of all patients who underwent transvaginal Prolift mesh repair for POP between January 2005 and January 2009. Indications for surgery were symptomatic and significant prolapse, POP-Q stage II or more. All patients were managed at the

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Preoperative consultation included history and physical examination, including cough stress test to detect stress urinary incontinence (SUI) or occult urinary incontinence if the urine leakage was only revealed after prolapse reduction. All patients underwent staging of POP according to a simplified version of the International Continence Society (ICS) POP-Q staging system, as described by Swift et al.[18] Urodynamic evaluation was performed only when symptoms suggested concomitant SUI.

The surgical technique was the standardized transvaginal mesh procedure, previously described by the TVM group.[3] The anterior mesh is inserted between the bladder and the vagina and secured bilaterally by 2 arms passing through the obturator foramen, at the level of the arcus tendineus fasciae pelvis. The posterior mesh is inserted between the rectum and vagina and is secured bilaterally by 1 arm passing through the ischiorectal fossa and sacrospinous ligament. The synthetic prosthesis is a precut nonabsorbable monofilament polypropylene mesh (Prolift Pelvic Floor Repair System; Ethicon Women's Health and Urology, Somerville, NJ). The type of Prolift procedure (isolated anterior, posterior, or total Prolift) was based on the type and stage of prolapse (POP-Q stage II or more), taking note of the patient's complaint(s). Pre- or postoperative local estrogens were not routinely prescribed. A concomitant procedure was performed if necessary, including vaginal hysterectomy or traditional repairs such as sacrospinous fixation or colporrhaphy. Cystoscopy was not routinely used intraoperatively. In all patients with preexisting or occult SUI, concomitant tension-free vaginal tape-obturator (TVT-O) sling insertion was carried out alongside Prolift mesh repair, according to the technique described by de Leval.[19]

The study protocol was approved by the institutional review board of the French College of Obstetricians and Gynecologists (#CEROG-2011-GYN-02-01). In this single center retrospective cohort study, patient data were obtained from electronic hospital medical records. Data collection was made by 1 author (S.I.) and checked for accuracy by the first author (L.dL.). All patients were available for a follow-up gynecologic examination at 2 months after surgery and they were telephoned by a single physician (L.dL.) to check if they had surgery in other hospitals to avoid underestimation of reoperation rates. The following information was collected: age, medical, surgical, gynecologic and obstetric history, stage of POP and compartment involved, type of Prolift, concomitant surgery, intraoperative complications, and indication as well as nature of reoperation. Complications requiring surgical intervention were graded according to Dindo classification. This surgical-complication grading system is based on the invasiveness of a procedure, which represents an objective outcome for the evaluation of this study. Severe adverse events, Dindo grade III are reported for this study.[20]

Statistical analysis was performed in collaboration with the Biostatistic department (CHRU, Lille, France). Data were analysed using SAS software (SAS Institute, Cary, NC). Results were expressed as means, standard deviations for continuous variables, fitting normal distribution, resorting to the median, and range for continuous data that did not fit a normal distribution and as frequencies and percentages for categorical variables. Comparative analyses were obtained using the χ^2 test for categorical data resorting to Fisher exact test when expected frequencies dictated. For numerical variables, we used the unpaired Student *t* test when the size of the groups was greater than 30, resorting to the Mann-Whitney test for smaller groups. A P value $< .05$ was considered statistically significant. Kaplan-Meier analysis curves were used to illustrate the rate of reoperation after transvaginal Prolift mesh repair over time.

RESULTS

Six hundred consecutive patients were eligible for this study and all electronic medical records were available. Attempts were made to contact all the patients by phone; 524 patients (87.3%) were available for phone interview and agreed to be included in the study. The 76 patients (12.7%) excluded from the study included 68 patients who were lost to follow-up (11.33%) and 8 patients who died (1.33%) during the follow-up period.

A total of 524 patients have been included in the study and the global rate of reoperation was 11.6% (n = 61). The median follow-up of this retrospective study was 38 months (range, 15–63 months). Of the 61 patients requiring surgical intervention, 58 patients (95.1%) were managed in our institution and 3 patients (4.9%) had surgery in other hospitals. In the group of patients not included, 7 of 76 patients (9.2%) had intervention in our institution. All medical records were available for these patients. There was no significant difference in subsequent intervention rate in our hospital between the 2 groups ($P = .5322$).

Patient characteristics are summarized in Table 1. Among the 524 patients included in the study, 111 patients (21.2%) had a history of hysterectomy, 98 patients (18.7%) underwent prior prolapse repair, and 69 patients (13.2%) had a previous surgery for SUI. Most of the mesh repairs (78.6%) were performed by senior surgeons (J-P.L., M.C.) with extensive experience in pelvic reconstructive surgery. Residents performed the rest of the procedures, under supervision (21.4%). Concomitant hysterectomy was performed for 44 patients (8.4%). Surgery for SUI, in the form of transobturator tape (TVT-O) sling insertion, was carried out in 178 patients (34%). Preoperative stages of prolapse are reported in Table 1. An isolated anterior Prolift mesh was inserted in 48 patients (9.15%), an isolated posterior Prolift mesh in 103 patients (19.65%) and an anterior and posterior Prolift in 373 patients (71.2%).

Intraoperative complications included 3 bladder perforations (0.7%), which occurred during the dissection of the paravesical fossa. All were confirmed by methylene blue test and directly repaired with vicryl suture, followed by mesh insertion. One rectal injury (0.2%) occurred in a primary insertion during the initial dissection of the rectum from the posterior vaginal wall. This injury occurred during an iso-

lated posterior mesh repair, was directly repaired and the surgeon decided to abandon the procedure.

Postoperative reoperation indications and rates are reported in Table 2. In this retrospective study, the global rate of surgical intervention after Prolift mesh repair was 11.6% (n = 61). The most frequent indication was related to urinary incontinence (6.9%). Nineteen patients (3.6%) presented with mesh-related complications, with a global rate of reoperation for Prolift mesh exposure of 2.5%. Sixteen patients (3%) underwent repeat surgery for prolapse recurrence.

Three patients (0.6%) had postoperative severe blood loss, over 400 mL, which required laparotomy in 2 cases for uterine bleeding or paravesical hematoma and laparoscopy for paravesical hematoma in the third. All 3 required admission to the intensive care unit for observation afterward (Table 2).

A total of 19 patients (3.6%) required surgical intervention for mesh-related complication (Table 2) and the most frequent complication was mesh exposure, which happened in 14 cases (2.7%). Thirteen patients (2.5%) required partial mesh excision from the anterior vaginal wall in 5 cases (1.2%) and the posterior vaginal wall in 8 cases (1.7%). The median time to intervention for mesh exposition was 13 months (Figure). One patient (0.2%) presented with mesh infection after a total Prolift mesh repair with concomitant hysterectomy. This infection occurred in the early postoperative period and needed wide surgical excision of the mesh 14 days after insertion. This patient required laparoscopic sacrocolpopexy for vaginal vault prolapse 19 months later. Two patients (0.4%) presented with severe symptomatic mesh retraction, combined with exposure in 1 case. Both were treated by a wide mesh excision. Two patients (0.4%) required wide mesh excision for rectal compression causing significant constipation and dyschesia. Finally, 2 patients (0.4%) needed surgery for symptomatic vaginal synechia.

Among the 524 patients who underwent a Prolift mesh repair, 16 patients (3%) underwent repeat surgery for prolapse recurrence, with a median duration since Prolift mesh insertion of 23 months (Table 2 and Figure). After an isolated anterior Prolift repair, 4 of 48 patients (8.3%) had indirect recurrence in the form of posterior vaginal wall prolapse in 3 cases and uterine prolapse in 1 case. All were treated by a posterior Prolift mesh repair. Among the 103 patients who had isolated posterior Prolift repair, 4 patients (3.9%) needed further surgery. Two patients underwent vaginal hysterectomy for uterine prolapse and 2 pa-

TABLE 1
Patient and surgical characteristics

Characteristic	n = 524
Age, y (mean ± SD)	64 (10.1)
Parity, n (mean ± SD)	3 (1.5)
Previous surgeries,[a] n (%)	
Previous hysterectomy	111 (21.2)
Previous prolapse surgery	98 (18.7)
Previous continence surgery	69 (13.2)
Surgeon	
Senior	412 (78.6)
Resident	112 (21.4)
Concomitant surgery,[a] n (%)	
Traditional prolapse repair (sacrospinous fixation, anterior colporrhaphy)	3 (0.6)
Hysterectomy	44 (8.4)
Surgery for SUI	178 (34)
POP-Q stage n (%)	
Cystocele	
Stage 0-I	92 (17.55)
Stage II	70 (13.35)
Stage III-IV	362 (69.1)
Uterine/vaginal vault prolapse	
Stage 0-I	119 (22.7)
Stage II	166 (31.7)
Stage III-IV	239 (45.6)
Rectocele	
Stage 0-I	147 (28.05)
Stage II	206 (39.3)
Stage III-IV	171 (32.65)
Type of Prolift	
Anterior only	48 (9.15)
Posterior only	103 (19.65)
Anterior and posterior	373 (71.2)
Anterior and posterior with uterine preservation	286 (54.6)
Anterior and posterior with concomitant hysterectomy	22 (4.2)
Total (previous hysterectomy)	65 (12.4)

POP-Q, pelvic organ prolapse questionnaire; *SD*, standard deviation; *SUI*, stress urinary incontinence.

[a] Multiple answers possible.

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TABLE 2
Postoperative reoperation indications, rates, presentation time and management[a]

Complication	n (%)	Presentation time, mo, median (range)	Management
Surgery for hemorrhage	3 (0.6)	0	
Paravesical hematoma	2/421 (0.5)	0	Hemostasis by laparotomy (1/2) or laparoscopy (1/2)
Uterine artery bleeding	1/44 (2.3)	0	Laparotomy for hemostasis
Mesh-related complication	19 (3.6)	15 (0.5–49)	
Mesh exposure	13/524 (2.5)	13 (1–49)	Partial mesh excision
Anterior	5/421 (1.2)	17 (1–49)	Partial mesh excision
Posterior	8/476 (1.7)	8 (4–23)	Partial mesh excision
Mesh infection	1/524 (0.2)	0.5	Total mesh excision
Severe symptomatic mesh retraction	2/524 (0.4)	14 (11–16)	Large mesh excision
Rectal compression	2/476 (0.4)	18 (12–24)	Large mesh excision
Symptomatic synechia	2/524 (0.4)	25 (11–38)	Division of vaginal adhesions
Prolapse recurrence	16 (3)	23 (3.2–61)	
After anterior Prolift	4/48 (8.3)	21 (12–43)	
Rectocele	3/48 (6.2)	23 (12–43)	Posterior Prolift
Uterine prolapse	1/48 (2.1)	14	Posterior Prolift
After posterior Prolift	4/103 (3.9)	23 (3–41)	
Cystocele	2/103 (1.95)	31 (21–41)	Anterior Prolift
Uterine prolapse	2/103 (1.95)	15 (3–26)	VH
After anterior and posterior Prolift	8/373 (2.1)	25 (5–61)	
Uterine prolapse	7/373 (1.9)	28 (5–61)	Laparoscopic sacrocolpopexy (3/7); VH and sacrospinous fixation (3/7); VH (1/7)
Enterocele[b]	1/373 (0.2)	7	Laparoscopic sacrocolpopexy
Urinary continence	36 (6.9)	13 (0.25–60)	
TVT-O mesh exposure	3/178 (1.7)	8 (3–14)	Partial TVT-O mesh excision
Occult SUI	23/277 (8.3)	16 (1–60)	Suburethral tape
Persistent SUI	7/178 (3.9)	5 (2–9)	Second TVT-O (2/7); TVT-O tightening (3/7); TVT (1/7); artificial urinary sphincter (1/7)
Recurrent SUI	2/69 (2.9)	23 (3–43)	Suburethral tape
Voiding dysfunction	1/178 (0.6)	0.25	TVT-O readjustment
Other	2 (0.4)	27 (16–38)	
Postmenopausal bleeding	2/369 (0.5)	27 (16–38)	
Total	61/524 (11.6)		

Persistent SUI: failure after concomitant TVT-O for SUI during the Prolift mesh repair. Recurrent SUI: recurrence of SUI after the Prolift mesh repair in patients with prior incontinence surgery.
SUI, stress urinary incontinence; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator; *VH*, vaginal hysterectomy.

[a] Multiple answers possible; [b] Recurrence after the removal of a Total Prolift mesh infection.

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tients had anterior Prolift mesh repair for anterior vaginal wall prolapse. After combined anterior and posterior prolapse mesh repair, 7 of 373 patients (1.9%) had uterine prolapse develop (3 had laparoscopic sacrocolpopexy, 3 had vaginal hysterectomy and sacrospinous fixation, and 1 had vaginal hysterectomy). Another patient, already mentioned in the mesh-related complication paragraph, presented with apical prolapse after the removal of a total Prolift mesh for infection. This patient was managed with laparoscopic sacrocolpopexy. For all patients, follow-up examination revealed excellent anatomic results.

The most frequent indication for surgical intervention after Prolift mesh repair was related to urinary incontinence (Table 2). Thirty-six patients (6.9%) complained of urinary problems, with a median presentation time of 13 months after Prolift mesh repair (Figure). SUI was the most frequent urinary symptom. Of the 277 patients who did not have urinary incontinence before Prolift mesh repair, 23 patients (8.3%) underwent a suburethral sling insertion. Two of the 69 patients (2.9%) who had incontinence surgery before Prolift mesh repair required a secondary retropubic or TVT-O sling insertion for recurrent SUI. Among the 178 patients who underwent

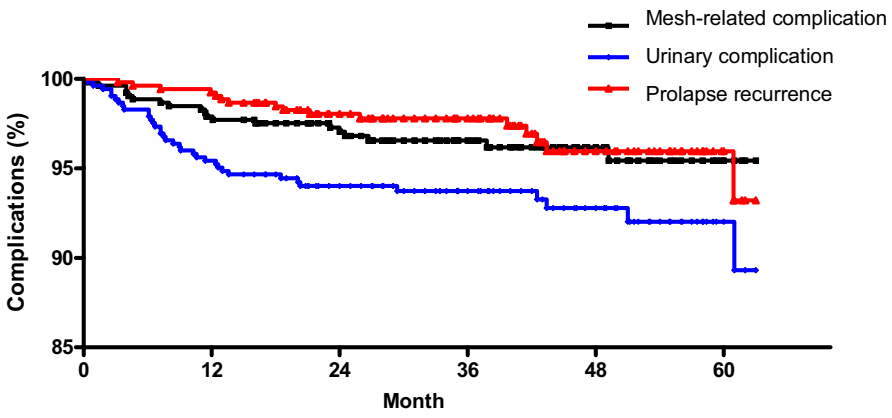
concomitant surgery for incontinence by TVT-O sling insertion, 7 patients (3.9%) experienced persistent SUI. These failures were managed by tightening the preimplanted tape sling in 3 cases,[21] secondary TVT-O sling insertion in 2 cases, tension-free vaginal tape (TVT) sling insertion in 1 case, and an artificial urinary sphincter in 1 case. One patient (0.6%) presented with early postoperative voiding dysfonction after TVT-O sling insertion requiring a readjustment of the sling at day 5. Finally, 3 patients (1.7%) presented with suburethral mesh exposure managed by partial excision of the tape. One of these 3 patients required new suburethral sling insertion surgery for recurrence of SUI.

Among the 369 patients with uterine conservation during the procedure, 2 patients (0.5%) presented with postmenopausal bleeding, which was managed by laparoscopic total hysterectomy. Histologic analysis revealed benign lesions in both cases.

In the population of patients deceased during the follow-up, 7 died because of unrelated causes and 1 patient died of an endometrial cancer 3 years after the prolapse surgery. Preoperatively, this patient had a negative Papanicolaou test-smear and no endometrial thickening was noted on pelvic ultrasound examination.

Statistically, there is no significant correlation between global reoperation rate and the following variables: age, parity, year of surgery, previous hysterectomy, previous continence and/or prolapse surgery, type of Prolift mesh repair, surgeon experience, concomitant hysterectomy, or stage of POP. Regarding the type of postoperative complications, an early cystocele stage (stage II) was found to be a significant predictor of mesh-related complications ($P = .037$). In addition, patients requiring surgical intervention for prolapse recurrence were significantly younger (mean age 53.5 years, SD = 9.63) as compared with patients who did not require additional surgery (mean age 64 years, SD = 10.07) ($P = .017$). These patients were also more likely to have severe uterine prolapse, 5.64% with stage III-IV prolapse, compared with 46.1% with stage III-IV among women who did not undergo surgery for recurrence ($P = .017$). No factors were associated with urinary continence complications.

FIGURE
Time to reoperation after transvaginal Prolift mesh repair



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COMMENT

The introduction of transvaginal mesh repair expanded the surgical options available for surgical management of POP. This followed the success and wide use of minimally invasive tapes for SUI surgery. Nonetheless, when compared with more established procedures such as sacrocolpopexy, there is a need for evidence on safety and long-term efficacy of the transvaginal mesh procedure.[22,23]

In the current study, the global surgical intervention rate after transvaginal Prolift mesh repair was 11.6%, with a median follow-up of 38 months (range, 15–63). The incidence of perioperative complications was 1.4%, including 0.8% of visceral injury and 0.6% of vascular injury. These results are consistent with most published reports on Prolift mesh repair in which the rates of visceral or vascular injuries are ranged from 0 to 6.6%.[4,6-9,24-30]

The mesh exposure rate was 2.7% and 13 of 14 patients (2.5%) required reoperation. Most of these exposures presented within the first year after surgery (Table 2). This percentage is low when compared with other large cohort studies in which the rate varied from 3.2% to 17%.[2,4,7-10,24,28] Nonetheless, it is comparable to the 3.4% reported rate after sacrococolpopexy in the review of Nygaard et al.[23] There was no significant correlation between mesh-related complication and concomitant hysterectomy ($P = .667$). This might reflect the lower rate of concomitant hysterectomy (8.4% compared with 59.2%) and avoidance of inverted T incisions, previously identified as significant risk factors of mesh exposure.[24] In addition, mesh placement underneath the full thickness of the vaginal wall may have reduced the damage to tissue vascularization. Both of these potential factors await further evaluation. Mesh retractions were classified according to the most severe presenting symptom. It can be a cause of pelvic pain or functional digestive disorder, but the treatment is wide mesh excision, as for mesh exposure. These mesh-related complications are serious and need to be identified and treated adequately in referral centers by experienced surgeons.

The rate of surgical intervention for prolapse recurrence is 3%, which matches the 2.3% to 4% reported in studies that provided a minimum 1-year follow-up (Table 2).[8,9,27,28,30] However, in a systematic review of apical vaginal prolapse repair, Diwadkar et al[16] reported a rate of reoperation for prolapse recurrence of 1.3% (range, 0–16). This is lower than the 3% reported in this study but the follow-up duration was shorter (mean 17 ± 13.8 months). In our study, the median time of surgical intervention for prolapse recurrence was 23 months, which may suggest that the rate of recurrence increases

with longer follow-up (Figure). Eight patients developed indirect recurrence, more often after isolated anterior (4/48, 8.3%) than isolated posterior Prolift mesh repair (4/103, 3.9%) ($P = .055$). These results are consistent with the study of Withagen et al[30] and the theory of DeLancey[31,32] and Lowder et al[33] who demonstrated that anterior repair restores level II support, whereas posterior repair provides level I support, which is associated with lower risks of subsequent recurrence of POP. However, in a recent study comparing posterior mesh repair vs sacrospinous ligament fixation, Lopes et al[34] observed the same anatomic results in both groups. Actually, there is still limited evidence to recommend posterior transvaginal mesh repair for the treatment of posterior or apical prolapse.[2,16,34] After combined anterior and posterior prolapse mesh repair, 8 of 373 patients (2.1%) had recurrence develop requiring reoperation; 7 for uterine prolapse and 1 for enterocele. These patients were significantly younger ($P = .017$) compared with patients who did not require additional surgery. The quality of the pelvic floor connective tissues may play a role in the development of prolapse recurrence in this group of patients.[35,36] These patients were also more likely to have worse degrees of uterine prolapse ($P = .017$), which again reflects poor tissue strength. Recurrence in the apical compartment was more frequent in patients with uterine prolapse than vaginal vault prolapse. This necessitates looking at the value of securing the mesh into the uterus with a nonabsorbable suture, when performing Prolift mesh repair without concomitant hysterectomy in patients who did not have prior hysterectomy.

Urinary problems were the most frequent indications for surgical intervention after Prolift mesh repair (Table 2). Even with a notable number of patients having previous continence surgery, 23 of the 277 patients (8.3%) who were continent before Prolift mesh repair subsequently underwent a suburethral sling insertion for SUI. These findings show that occult SUI can be a major indication for reoperation. The rate encountered in this series is higher than in previous reports, where it ranged from 2% to 4.5%.[4,7,8,29] Nonetheless, the follow-up in these studies was much shorter, with the median not exceeding 1 year. It is possible that longer follow-up in these reports may reveal higher rates, matching those encountered in this series. The median duration to suburethral tape insertion in this series was 16 months, which suggests that occult SUI can manifest after 1 year.

The introduction of a new technique brings about new complications that need to be highlighted and recognized for best management. The purpose of this study was to evaluate reoperation rates as well as severe complications of this type of surgery, Dindo grade III.[20] This represents an objective outcome, which can be easily assessed in a retrospective study.

The findings of this study should be considered within its limitations and strengths. Although this study was not a randomized controlled trial and was limited to a single center, it reports a large cohort of patients with the longest median follow-up duration. Reoperation rates only represent complications treated surgically and do not reflect the overall morbidity of the technique. The retrospective nature of the study precluded comparison of subjective aspects like symptoms and degree of bother, quality of life, and sexual function. The large number of patients (12,7%) lost to follow-up may represent another bias in this study. However, there were no significant differences between the patients included and the patients excluded from the study, with only 3 patients who chose to be operated in another hospital during the follow-up period.

Moreover, complications can be underestimated because some patients can present with an adverse event and choose not to undergo a surgery. This must be kept in mind when interpreting results. A further potential bias of this report is that most of the procedures are conducted by surgeons with considerable experience in pelvic reconstructive surgery using mesh kits. This element may explain the lower rates of complications when compared with other studies with smaller numbers. Nonetheless, possessing such experience is essential before embarking on such techniques, and the findings of this study should underline this important message.

In conclusion, the global surgical intervention rate after transvaginal Prolift mesh repair in our study was 11.6%. The most frequent indication was related to urinary incontinence. Rates of complications because of the use of mesh kits or prolapse recurrence were low, bearing in mind the experience of the team in pelvic floor reconstruction and mesh surgery. The 3 years median follow-up results show that this procedure is safe and effective in the medium term. Further follow-up will provide long-term outcome and randomized controlled trials are needed to evaluate the place of this technique in pelvic reconstructive surgery. ■

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