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-