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Safety of Vaginal Mesh Surgery Versus Laparoscopic Mesh Sacropexy for Cystocele Repair: Results of the Prosthetic Pelvic Floor Repair Randomized Controlled Trial

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Abstract

Background: Laparoscopic mesh sacropexy (LS) or transvaginal mesh repair (TVM) are surgical techniques used to treat cystoceles. Health authorities have highlighted the need for comparative studies to evaluate the safety of surgeries with meshes.
Objective: To compare the rate of complications, and functional and anatomical outcomes between LS and TVM.
Design, setting, and participants: Multicenter randomized controlled trial from October 2012 to April 2014 in 11 French public hospitals. Women with cystocele stage ≥2 (pelvic organ prolapse quantification), aged 45–75 yr, without previous prolapse surgery.
Intervention: Synthetic nonabsorbable mesh placed in the vesicovaginal space, sutured to the promontory (LS) or maintained by arms through pelvic ligaments (TVM).
Outcome measurements and statistical analysis: Rate of surgical complications ≥grade II according to the modified Clavien–Dindo classification at 1 yr. Secondary outcomes were reintervention rate, and functional and anatomical results.
Results and limitations: A total of 130 women were randomized in LS and 132 in TVM; five women withdrew before intervention, leaving 129 in LS and 128 in TVM. The rate of complications ≥grade II was lower after LS than after TVM, but did not meet statistical significance (17% vs 26%, treatment difference 8.6% [95% confidence interval, CI −1.5 to 18]; $p = 0.088$). The rate of complications of grade III or higher was nonetheless significantly lower after LS (LS = 0.8%, TVM = 9.4%, treatment difference 8.6% [95% CI 3.4%; 15%]; $p = 0.001$). LS was converted to TVM in 6.3%. The total reoperation rate was lower after LS but did not meet statistical significance (LS = 4.7%, TVM = 10.9%, treatment difference 6.3% [95% CI −0.4 to 13.3]; $p = 0.060$). There was no difference in symptoms, quality of life, improvement, composite

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definition of success, anatomical results rates between groups except for the vaginal apex and length, and dyspareunia (in favor of LS).
Conclusions: LS is a valuable option for primary repair of cystocele in sexually active patients. LS is safer than TVM, but may not be feasible in all cases. Both techniques offer same functional outcomes, success rates, and anatomical outcomes, but sexual function is better preserved by LS.
Patient summary: Our study demonstrates that laparoscopic sacropexy (LS) is a valuable option for primary repair of cystocele. LS offers equivalent success rates to vaginal mesh procedures, but is safer with a lower rate of complications and reoperations, and sexual function is better preserved.

1. Introduction

Cystocele is a disabling and frequent pelvic condition most commonly treated by transvaginal repair with native tissue repair (colpectomy with colporraphy) [1]. The past 2 decades have seen the development of cystocele treatment with a transvaginal polypropylene mesh (transvaginal mesh repair [TVM]) [2]. The abdominal approach (sacral colpohysteropexy, hereafter sacropexy) has also become a surgical standard for primary cystocele repair in several European countries. Laparoscopic sacropexy (LS) has supplanted the open abdominal route because it offers the same anatomical results with lower morbidity rates [3,4].

Both LS and TVM are performed as routine care for the treatment of cystocele [1], and TVM may have some advantages over LS in terms of ease of performance and reduced operative and recovery time [5,6]. Nonetheless, reports of complications have led several health authorities to issue warnings and restriction about vaginal mesh use [7]. On the contrary, serious adverse events also occur with the use of mesh during sacropexy [8]. We therefore conducted a multicenter randomized controlled trial (RCT PROSPERE: Prosthetic Pelvic Floor Repair) to compare LS and TVM for cystocele repair, and to evaluate their risk–benefit ratio with safety and complications as the principal outcomes.

2. Patients and methods

From October 2012 through April 2014, patients aged 45–75 yr with a primary prolapse of the anterior vaginal wall of stage 2 or higher (pelvic organ prolapse quantification [POP-Q] classification [9]) were invited to participate in the study by their surgeon in 11 French public hospitals. Exclusion criteria were previous surgical POP repair, impossibility or contraindication to either route, pelvic organ cancer, contraindication to the use of mesh, inability to read French, lack of social insurance, pregnancy, or wish for future pregnancy.

Prior to start of the study, key technical points for both procedures were standardized across centers by a Delphi process. Both procedures aimed to place the anterior mesh deep within the vesicovaginal space, just above the bladder neck. For TVM, the mesh should be suspended with four arms. Apical support was mandatory (via the mesh or an additional procedure). For LS, the mesh was anchored to the prevertebral ligament in front of the sacral promontory with nonabsorbable sutures. The decision about placement of a posterior mesh was left to the operator's judgment. Hysterectomy was not to be performed systematically (shared medical decision with the patient; details in the Supplementary material, Surgical techniques). All participating centers were referral centers for the treatment of POP and had experience with LS and TVM (>30 procedures per year for both approaches). Within each center, eligibility of a given surgeon to practice one or other of the two approaches was based on the usual criteria of >30 procedures performed prior to the beginning of this study. Follow-up visits were scheduled at 6 wk, 6 mo, and 12 mo after surgery (Supplementary material, Follow-up and assessment of complications).

Eligible participants were randomly assigned at a 1:1 ratio to LS or TVM. The randomization process was performed centrally online using a password-protected database, with balanced blocks of four patients, stratified by center and by sexual activity (yes/no). The random number list was generated before the beginning of the study by an independent statistician researcher using computer-generated random numbers (SAS Proc Plan). Randomization was performed by the investigator after obtaining informed consent from the patient, and after clinical assessment and questionnaires. Allocation was revealed only when baseline data for a patient were provided. Patients were informed of their treatment assignment a few days before surgery.

The primary outcome was the rate of complications of grade II or higher in the modified Clavien–Dindo (mCD) classification [10]. Three independent assessors, blinded to the surgical arm, were appointed to grade the complications. Each complication was extracted from the database and revised to remove all characteristics related to the approach, so that the assessors were completely blinded to the surgical arm. Before the gradation began, a consensus on grading based on the literature [11–13] was provided and achieved with the experts in order to give assistance for cases difficult to grade with the mCD, and to minimize the interobserver disagreement. After training on 20 cases with consensus feedback, the assessors were sent the complication reports in random order. Each assessor has to decide first whether a given case of complication was attributable to the study and then to grade it according to the mCD. Each assessor made decisions independently, with no knowledge of the others' grades. The grade was considered validated when the three assessors gave the same answers. For discordant cases, assessors had to achieve a consensus by telephone conference. The authors of the manuscript were not involved in the grading process and did not participate in these conferences. We also analyzed grade III–IV complications and their consequences, as they were considered relevant from the clinical point of view because they included only clinically important complications such as reoperations [10].

Secondary outcomes were pre- and postoperative events, including reoperation for pelvic floor dysfunction (ie, stress urinary incontinence or pelvic organ prolapse recurrence), functional and anatomical outcomes, and composite criteria of success [14]. Functional outcomes were assessed using validated questionnaires in French (PFDI-20, ICIQ-UI SF, PFIQ7, ODS, EQ-5D, PGI-I, FSFI, and PISQ-IR).

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