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Original Article

# Perioperative morbi-mortality after pelvic organ prolapse surgery in a large French national database from gynecologist surgeons

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ABSTRACT

*Objective:* To assess morbidity and mortality following pelvic organ prolapse surgery in France, irrespective of the surgical technique, using a broad national database.
Materials and methods: This descriptive multicenter retrospective study was conducted using a database populated via an application run by a professional association.
*Results:* 286 gynecologists contributed data to the database. Of the 4322 surgeries analyzed, an abdominal approach was used in 975 of cases (22.5%), a vaginal approach in 3277 (75.9%), and a combined approach in 68 (1.6%). After one year, abdominal surgery was associated with higher rates of de novo urinary incontinence, constipation, and intestinal obstruction, whereas vaginal surgery was associated with higher rates of urinary retention, hematoma, de novo chronic pain, and vaginal mesh extrusion. There was no significant difference between the groups in the incidence of severe complications. After one year, vaginal mesh-augmented cystocele repair was associated with higher rates of de novo urinary incontinence, de novo chronic pain, and reoperation than native tissue repair. Mesh repair was also associated with higher rates of severe complications at one year.
*Conclusion:* After pelvic organ prolapse surgery, the perioperative morbidity and mortality associated with transabdominal and transvaginal approaches are similar. However, transvaginal mesh repair is associated with greater perioperative morbidity than transvaginal native tissue repair.


## Brief summary

Morbidity is common after both abdominal and vaginal surgeries for genital prolapse. Transvaginal mesh repair is associated with greater morbidity than transvaginal native tissue repair.

## Introduction

Pelvic organ prolapse (POP) is a common disorder among women, although its prevalence is difficult to study [1]. Its estimated prevalence is between 2.9% and 11.4% when based on self-report questionnaires, and between 31.8% and 97.7% when detected through physical examination using the Baden-Walker or POPQ system [2].

Surgery to correct POP accounts for a substantial proportion of public health spending [3], with an estimated 20.2% of the female population undergoing surgery for POP or urinary incontinence by the age of 85 years in the Netherlands [4] and 20% in the United States [5]. In France, 50 469 POP surgeries were performed in 2012 [3].

Surgical treatment for POP significantly improves patients' quality of life and reduces POP-related symptoms [6]. Several surgical techniques have been described for POP repair and two approaches are used: abdominal or vaginal. Since the 2000s, the use of nonabsorbable synthetic mesh has reduced the risk of POP recurrence in comparison with native tissue repair [7]. However, the use of these meshes with the vaginal approach exposes women to the risk of a number of complications that can require

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reoperation [8] and compromise functional outcomes. The International Urogynecological Association (IUGA) and the International Continence Society (ICS) have in fact developed a classification of complications directly related to the use of mesh in pelvic floor surgery [9]. A report by the US Food and Drug Administration (FDA) in 2011 [10] alerted patients and health professionals to the complications of transvaginal placement of these meshes. A review by the Cochrane Library on the surgical treatment of POP concluded that there was insufficient evidence for superior success rates with vaginal mesh surgery, and alerted practitioners and patients to the complications associated with meshes [11].

In France, there is currently no registry of morbidity and mortality associated with POP surgery. Gynerisq is a professional association created in September 2007 at the instigation of the French national college of obstetricians and gynecologists (CNGOF) and the French national union of obstetricians and gynecologists (SYNGOF), and accredited by the French National Authority for Health (HAS). Gynerisq is responsible for organizing risk management in obstetrics and gynecology. Its risk management activities are based on practitioner-reported adverse events. A website on POP surgery, which can be accessed via the Gynerisq website, was launched in May 2010. It was initially created for office-based surgeons and was subsequently extended to include public-sector practitioners based in general hospitals and university hospitals. Surgeons were invited to enter all the POP surgeries they performed and to record any intraoperative, early postoperative and one-year postoperative complications. A registry was thus created from all the POP surgeries performed and reported by participants over a 30-month period, from May 2010 to November 2012.

The aim of this study was to evaluate the intraoperative, early postoperative, and one-year postoperative complications of POP surgeries performed over the 30-month period during which the registry set up by the association Gynerisq was active, in both public- and private-sector French hospitals that undertake urogynecological surgery, including all surgical techniques and to compare the complication rates of the various types of surgery performed, through subgroup analyses.

## Materials and methods

### *Methodology*

This was a retrospective, multicenter descriptive study using data from a database populated via an application run by the professional association Gynerisq. The website was accessible to all hospital-based and office-based gynecologists performing POP surgery. Insurance bonuses were offered to encourage reporting by office-based surgeons.

Nimes University Hospital Institutional review board approval was obtained (IRB n°15/10-01) and methods were performed in accordance with the relevant guidelines and regulations. Patients were informed orally and were able to refuse their participation in the study.

### *Data collection*

The database analyzed in this study contained all the surgeries performed and reported on the website during a 30-month period from May 2010 to November 2012. Each surgeon had to enter the following personal and professional information: their place of work, year of birth, number of years of experience since qualifying, and the number of POP surgeries performed per year. Once these data had been collected, each surgeon was assigned an ID number to use when entering each new patient in the registry, obviating the need to enter this information again.

For each intervention, anonymized data were collected about the patient: the first two letters of their surname and forename, date of birth, history (cesarean sections, hysterectomy, or surgery for stress urinary incontinence or POP), and comorbidities (diabetes, obesity, cardiovascular disease, or anticoagulation). Details about each intervention were also collected: its code (using the French CCAM classification); the surgical approach; the type of procedure performed; whether mesh was used and its type; whether concomitant hysterectomy, concomitant surgery for stress urinary incontinence, or a concomitant vulvoperineal procedure was performed; the type of anesthesia used; and the length of the hospital stay, and any prolongation of hospitalization and its duration.

When complications occurred, participants were asked to record their type and grade, using the Clavien-Dindo classification [12]. This classification is not specific for POP surgery but is the most widely used in publications evaluating the morbidity associated with surgical interventions. Table 1 lists all the intraoperative, early postoperative and one-year postoperative complications collected, classified by their Clavien-Dindo grade. Severe postoperative complications are those graded IIIa or higher in the Clavien-Dindo classification.

In order to provide data on complications one year after the date of surgery, the gynecologists must have had a follow-up consultation with the patient in person or by telephone and to have then logged in to the website. Gynerisq sent a reminder email to surgeons who had not provided these follow-up data.

The database was cleaned up to eliminate duplicate entries, surgeries on which too many data were missing, and surgeries that had not been performed during the specified period.

**Table 1**
Complications collected, classified by their Clavien-Dindo grade.

| CLAVIEN-DINDO GRADE | COMPLICATION |
|---|---|
| Grade I | Significant blood loss >300 mL but not requiring transfusion |
| | Hematoma not requiring surgical revision |
| | Abscess treated by nursing care or bedside drainage |
| | Chronic pain |
| | Dyspareunia |
| | Painful mesh contraction |
| Grade II | Lower urinary tract infection or pyelonephritis |
| | Urinary retention |
| | Transfusion |
| | Phlebothrombosis |
| | Vaginal mesh exposition treated medically |
| | Obstructed defecation |
| | Stress urinary incontinence |
| | Overactive bladder |
| | Voiding dysfunction |
| Grade IIIa | Vaginal mesh exposition treated under LA |
| | Surgical revision under LA |
| Grade IIIb | Urinary tract injury |
| | Gastrointestinal tract injury |
| | Vascular injury |
| | Trocar injury |
| | Abscess requiring surgical drainage |
| | Intestinal obstruction |
| | Visceral extrusion |
| | Fistula |
| | Vaginal mesh exposition treated under GA |
| | Surgical revision under GA |
| Grade IVa | Discitis |
| Grade IVb | Pulmonary embolism |
| | Cardiovascular or respiratory complications |
| | Neurological complications |
| | Admitted into intensive care |
| Grade V | Death |

LA: local anesthesia; GA: general anesthesia.

*Statistical analysis*

Qualitative variables were expressed as a percentage and 95% confidence interval, and compared using the chi-square test or Fisher's exact test when the conditions for applying the chi-square test were not met.

Quantitative variables were expressed as a mean and standard deviation (SD), and compared using Student's t-test.

Results were considered statistically significant when the *p* value was less than 0.05.

Mutlivariate analysis was performed by using logistic regression. For model building, we applied a « change in estimate » criterion, which involves looking at the unadjusted OR compared with the adjusted OR for each single variable, separately. If the unadjusted and adjusted values differed by more 10% (ie. OR adjusted / Or unadjusted is either >1.1 or <0.9), the variable was included in the model.

## Results

The Gynerisq registry database contained 4820 POP surgeries performed by 317 gynecologists. After eliminating surgeries that had not been performed during the period the registry was active, as well as duplicates, and surgeries that were unusable due to too many missing data, there remained 4322 surgeries, performed by 286 gynecologists. The results of our analysis of these surgeries are presented below.

*Description of the surgeons*

All of the recorded characteristics of the surgeons who participated in the study are shown in Table 2.

**Table 2**
Characteristics of the gynecologists who participated in the registry (n = 286).

| | |
|---|---|
| Sector | |
| • Private clinic-based | n = 250 (87.4%) |
| • Public hospital-based | n = 36 (12.6%) |
| Sex | |
| • Male | n = 251 (87.8%) |
| • Female | n = 35 (12.2%) |
| Age | Mean: 54.3 years (SD 8.7) |
| • 31–40 years | n = 31 (10.8%) |
| • 41–50 years | n = 56 (19.6%) |
| • 51–60 years | n = 123 (43%) |
| • 61–70 years | n = 75 (26.2%) |
| • 71–80 years | n = 1 (0.4%) |
| Years of experience since qualifying | Mean: 19.4 years (SD 8.9) |
| • 1–10 years | n = 57 (20.1%) |
| • 11–20 years | n = 93 (32.7%) |
| • 21–30 years | n = 106 (37.3%) |
| • 31–40 years | n = 28 (9.9%) |
| Number of POP surgeries performed per year | |
| • Fewer than 25 | n = 124 (43.5%) |
| • Between 25 and 50 | n = 100 (35.1%) |
| • Between 50 and 75 | n = 36 (12.6%) |
| • Between 75 and 100 | n = 18 (6.3%) |
| • More than 100 | n = 7 (2.5%) |
| Number of POP surgeries entered in the registry | |
| • Office-based gynecologists | Mean 12.6 (SD 16) |
| • Hospital-based gynecologists | Mean 33.7 (SD 41.4) |

SD: standard deviation; POP: pelvic organ prolapse.

*Description of the surgeries*

Of the 4322 analyzable surgeries in the registry, 3109 (71.9%) were performed by office-based gynecologists and 1213 (28.1%) by hospital-based gynecologists. An exclusively abdominal approach was used in 975 of the 4322 surgeries recorded (22.5%), an exclusively vaginal approach in 3277 of cases (75.9%), and a combined approach in 68 cases (1.6%). Combined method consisted mainly of the association of perineal colporrhaphy and sacrocolpopexy.

Tables 3 and 4 show all of the recorded characteristics of the exclusively transabdominal and transvaginal surgeries, respectively.

*Description of the patients*

The mean age of the patients in the registry was 66.5 years (SD 31.8). Compared with patients who underwent transvaginal surgery, those who underwent transabdominal surgery were significantly younger and less likely to have comorbid conditions (Table 5).

Among the patients who underwent cystocele repair, those treated with transvaginal mesh were more likely to have a history of hysterectomy, surgery for stress urinary incontinence, or POP surgery than those treated by plication of the anterior vaginal wall. The comparison of the patient characteristics for these two types of surgery is shown in Table 6.

*Comparison of complications: abdominal surgery versus vaginal surgery*

A total of 1609 data on 4277 interventions were collected in early postoperative period and at one year (Table 7). In the vaginal surgery group, 60% were lost to follow-up at 1 year, versus 69% in the abdominal surgery group.

There was no statistically significant difference between the groups in the incidence of intraoperative injury to neighboring organs, i.e. the bladder and gastrointestinal tract. Significant intraoperative blood loss was more frequent in the vaginal surgery group, although the difference was not statistically significant. As regards intraoperative complications specific to laparoscopy and trocar placement, abdominal wall bleeding was observed in 0.4% of cases, but no gastrointestinal or vascular injuries were reported.

There was no statistically significant difference between the two groups in terms of severe early postoperative complications (Clavien-Dindo grade IIIa or higher). Compared with abdominal surgery, vaginal surgery was associated with a statistically significant increased incidence of hematoma, urinary tract infections, and urinary retention. Surgical treatment of stress urinary incontinence is a major risk factor for postoperative urinary retention and could have been a confounding factor. However, analysis of POP surgeries involving concomitant surgery for stress urinary incontinence found that the incidence of urinary retention was 5.6% for vaginal surgery versus 2.7% for abdominal surgery.

Intestinal obstruction and obstructed defecation were significantly more frequent after abdominal surgery than after vaginal surgery. Mesh extrusion rates after placement of at least one mesh

**Table 3**
Characteristics of the POP surgeries performed via an exclusively abdominal approach (n = 975).

| | |
|---|---|
| Mode of suspension | |
| Sacral | n = 968 (99.3%) |
| Lateral (Kapandji's technique) | n = 7 (0.7%) |
| Approach | |
| Laparoscopic | n = 745 (77%) |
| Robotic | n = 75 (7.7%) |
| Open abdominal | n = 139 (14.4%) |
| Conversion to open abdominal | n = 9 (0.9%) |
| Conversion to vaginal | n = 2 (0.2%) |
| Posterior mesh | **n = 898 (92.3%)** |
| Fixation to levator ani | n = 729 (81.2%) |
| Fixation to posterior vaginal wall | n = 458 (51%) |
| Fixation to uterosacral ligaments | n = 407 (45.3%) |
| Fixation to uterine isthmus or vaginal vault | n = 259 (28.8%) |
| Rectopexy | n = 159 (17.7%) |
| Material used | |
| Polypropylene | n = 613 (63%) |
| Polyester | n = 338 (34.7%) |
| Individual sutures | n = 12 (1.2%) |
| Unspecified | n = 10 (1%) |
| Sacral promontory fixation | |
| Sutures | n = 884 (90.9%) |
| Tackers | n = 47 (4.8%) |
| Unspecified | n = 39 (4.0%) |
| Concomitant hysterectomy | **n = 364 (37.4%)** |
| Subtotal | n = 355 (97.5%) |
| Total | n = 5 (1.4%) |
| Unspecified | n = 4 (1.1%) |
| Concomitant urinary incontinence procedure | **n = 260 (26.7%)** |
| -Burch | n = 69 (26.5%) |
| -Midurethral sling | n = 185 (71.2%) |
| • Retropubic | • n = 10 (3.8%) |
| • Transobturator | • n = 153 (58.8%) |
| • Mini-sling | • n = 22 (8.5%) |
| Unspecified | n = 6 (2.3%) |

**Table 4**
Characteristics of the POP surgeries performed via an exclusively vaginal approach (n = 3277).

| | |
|---|---|
| ANTERIOR COMPARTMENT | **n = 2764 (84.3%)** |
| Anterior wall plication | n = 1388 (48.4%) |
| Anterior wall mesh | n = 1340 (48.5%) |
| • Nonabsorbable synthetic | • n = 1240 (92.5%) |
| • Absorbable | • n = 100 (7.5%) |
| • 2 fixation arms | • n = 300 (24.2%) |
| TO | n = 185 (61.7%) |
| SSL | n = 75 (25%) |
| ATFP | n = 26 (8.7%) |
| TM | n = 11 (3.7%) |
| • 4 fixation arms | • n = 933 (75.2%) |
| TO | n = 611 (65.5%) |
| TO + SSL | n = 107 (11.5%) |
| TO + TM | n = 20 (2.1%) |
| TO + ATFP | n = 88 (9.4%) |
| TM | n = 4 (0.4%) |
| ATFP | n = 5 (0.5%) |
| SSL | n = 13 (1.4%) |
| SSL + TM | n = 30 (3.2%) |
| SSL + ATFP | n = 49 (5.3%) |
| • Unspecified | • n = 7 (0.6%) |
| • Concomitant anterior colpectomy | • n = 267 (19.9%) |
| • No anterior colpectomy | • n = 1073 (80.1%) |
| Colpectomy alone | n = 79 (2.9%) |
| Intervention unspecified | n = 7 (0.3%) |
| APICAL COMPARTMENT | **n = 1985 (60.6%)** |
| -Sacrospinous fixation | n = 697 (35.0%) |
| • Unilateral | • n = 500 (71.7%) |
| • Bilateral | • n = 177 (25.4%) |
| • Unspecified | • n = 20 (2.9%) |
| • Anterior | • n = 134 (19.2%) |
| • Posterior | • n = 487 (69.9%) |
| • Unspecified | • n = 76 (10.9%) |
| Hysteropexy to the sacrospinous ligament | n = 516 (25.9%) |
| Uterosacral ligament suspension | n = 329 (16.6%) |
| Mesh | n = 434 (21.8%) |
| • SSL fixation | • n = 408 (94.4%) |
| • TM fixation | • n = 21 (4.9%) |
| • Fixation unspecified | • n = 3 (0.7%) |
| Intervention unspecified | n = 13 (0.6%) |
| POSTERIOR COMPARTMENT | **n = 2396 (73.1%)** |
| Enterocele repair | n = 376 (15.7%) |
| Rectocele repair | n = 1578 (65.9%) |
| • Posterior wall plication | • n = 1022 (64.8%) |
| • Posterior wall mesh | • n = 525 (33.3%) |
| SSL fixation | n = 422 (80.4%) |
| TM fixation | n = 25 (4.8%) |
| Fixation unspecified | n = 78 (14.9%) |
| • Posterior colpectomy alone | • n = 20 (1.3%) |
| • Intervention unspecified | • n = 11 (0.7%) |
| Levator myorrhaphy | n = 1102 (46%) |
| Perineorrhaphy | n = 1488 (62.1%) |
| Sphincteroplasty | n = 16 (0.7%) |
| Concomitant hysterectomy | **n = 1683 (51.3%)** |
| With an anterior compartment procedure | n = 1554 (56.2%) |
| • With anterior wall plication | • n = 1008 (75.3%) |

were significantly higher in the vaginal surgery group than in the abdominal surgery group, during both the early postoperative period and one year after surgery. At one year, the rate of severe postoperative complications was higher in the abdominal surgery group, but the difference was not statistically significant. De novo urinary incontinence, de novo constipation, and de novo chronic pain were significantly more frequent in the abdominal surgery group. Decompensation of an untreated compartment was reported more frequently in the abdominal surgery group than in the vaginal surgery group. Four patients had died in the vaginal surgery group one year after surgery, one from neoplastic disease, one from myocardial infarction, one from respiratory decompensation in a context of chronic respiratory disease, and in one case the cause was unknown.

For all complications, intra-operatively, early postoperatively and one year after surgery, a bivariate analysis for each of the potential confounding factors (age, comorbidities such as obesity, diabetes and cardiac pathology, previous cesarean section, previous hysterectomy, previous prolapse surgey) was performed by logistic regression for age. The decision to include the variable in the logistic model was based on a change in the relative risk of complications by type of surgery (vaginal or abdominal), by more than 10% when adjusting for each of the factors relative to the gross relative risk. Finally, none of the factors met the criteria of confounding factors except age. Only age was integrated into the final logistic regression model. No difference was observed in the overall complication rates whatever the follow-up after surgery after adjustment on age. The raw and adjusted ORs are included in Table 7.

| | |
|---|---|
| • With anterior wall mesh | • n = 484 (36.1%) |
| • With anterior colpectomy alone | • n = 62 (78.5%) |
| With an apical compartment procedure | n = 1130 (56.9%) |
| • With a Richter procedure | • n = 679 (97.4%) |
| • With mesh | • n = 172 (39.6%) |
| • With uterosacral ligament repair | • n = 270 (82.1%) |
| -With a posterior compartment procedure | n=1359 (56.7%) |
| • With posterior wall plication | • n = 542 (53.0%) |
| • With posterior wall mesh | • n = 201 (38.3%) |
| Colpocleisis | **n = 94 (2.9%)** |
| Concomitant stress urinary incontinence surgery | **n = 891 (27.2%)** |
| Retropubic sling | n = 111 (12.5) |
| Transobturator sling | n = 733 (82.3%) |
| Mini-sling | n = 40 (4.5%) |
| Unspecified | n = 7 (0.8%) |
| Type of anesthesia | |
| General | n = 2220 (67.7%) |
| Regional | n = 985 (30%) |
| Unspecified | n = 73 (2.2%) |

TO: transobturator; SSL: sacrospinous ligament; ATFP: arcus tendineus fascia pelvis; TM: transmuscular.

*Comparison of complications: native tissue versus mesh for vaginal cystocele repair*

All the intraoperative, early postoperative, and 1-year postoperative complications are shown in Table 8. The proportion of patients lost to follow-up was 57% in the mesh group and 60% in the native tissue group.

Intraoperative bladder injury, pelvic vein injury, and blood loss were more frequent in the mesh surgery group, but the differences were not statistically significant. De novo urinary incontinence was more frequent in the early postoperative period and one year after surgery in the mesh repair group than in the native-tissue repair group. The reoperation rate was significantly higher in the mesh group both in the early postoperative period and one year after surgery. Some of the reoperations were due to mesh extrusions, which were reported at a rate of 3.1% one year after surgery. The rates of severe complications (Clavien-Dindo grade IIIa or higher) in the early postoperative period and one year after surgery were significantly higher in the mesh group than in the native-tissue repair group.

## Discussion

*Description of the surgeries*

In the Gynerisq database, 87.4% of the surgeries were performed by office-based gynecologists and 12.6% by hospital-based gynecologists. During the same period, a greater percentage of POP surgeries in the French national database of hospital activity, PMSI, were performed by office-based gynecologists too: 60.2% (24 538 surgeries) versus 39.8% (16 200 surgeries) by hospital-based gynecologists. The most frequent POP procedure codes in the PMSI database were JKDC001 (laparoscopic sacral colpopexy/hysteropexy) and JLDA002 (transvaginal vaginal vault suspension), a pattern also found in the Gynerisq database. The Gynerisq database was more representative of national practice for surgery performed by office-based gynecologists and for transvaginal surgery.

An abdominal approach was used in 22.5% of the surgeries described in the Gynerisq database. In a descriptive study by Haya et al. [3] of POP and incontinence surgeries performed in member countries of the OECD (Organisation for Economic Co-operation and Development) in 2012, abdominal sacrocolpopexy accounted for 32.9% of POP surgeries in France. The difference between these data and those in the Gynerisq database may be due in part to the fact that the latter only included surgeries performed by gynecologists and excluded those performed by urologists, who predominantly use sacrocolpopexy to treat POP. In Haya's study, over 70% of sacrocolpopexies were performed in France by laparoscopy, which is close to the 77.2% found in the Gynerisq database. The most frequently employed mesh material was polypropylene, consistent with guidelines on the use of mesh in POP surgery [8]. When transabdominal POP surgery was combined with a procedure for stress urinary incontinence, Burch colposuspension was used in 26.5% of cases in the Gynerisq database and a midurethral sling in 71.2% of cases. In Haya's study [3], France was the OECD country with the lowest use of midurethral sling procedures to treat female urinary incontinence (63.6%). However, among the transvaginal surgeries in the Gynerisq registry, stress urinary incontinence was always treated with a sling.

Among the transvaginal surgeries, anterior mesh was used in half of the cystocele repairs. Such a high proportion of mesh placement is very rare in the literature. For example, a US study [13] described how the use of mesh has declined since the FDA's notifications, with vaginal mesh procedures accounting for 27% of POP surgeries in 2008 and fewer than 2% by the end of 2011. In another US study [14], although the number of mesh surgeries increased from 1461 to 2114 between 2008 and 2011, the proportion of mesh surgeries in 2011 (28.8%) were still well below that observed in the Gynerisq database. It is likely that the rate of vaginal mesh use in France has also declined since 2012.

Finally, concomitant hysterectomy was performed in 36.1% of anterior compartment mesh repairs, 39.6% of surgeries involving apical sling placement, and 38.3% of posterior compartment mesh repairs. These figures are rather high in light of the recommendation in the international guidelines [11] to avoid concomitant hysterectomy with mesh placement, due to the increased risk of vaginal mesh erosion [15].

**Table 5**
Comparison of the baseline characteristics of patients who underwent vaginal versus abdominal surgery.

| Characteristics | Vaginal surgery (n=3277) | Abdominal surgery (n=975) | *p* |
|---|---|---|---|
| Age | 68.0 (SD 11.1) | 60.3 (SD 10.1) | <**0.0001** |
| Comorbidities | | | |
| Obesity | 11.6% (95% CI: 10.5–12.7) | 5.8% (95% CI: 4.3–7.2) | <**0.0001** |
| Diabetes | 5.4% (95% CI: 4.7–6.2) | 2.7% (95% CI: 1.7–2.7) | **0.005** |
| Anticoagulation therapy | 4.8% (95% CI: 4.1–5.6) | 1.3% (95% CI: 0.6–2.1) | <**0.0001** |
| Cardiovascular disease | 20.7% (95% CI: 19.3–22.1) | 8.7% (95% CI: 7.0–10.5) | <**0.0001** |
| Surgical history | | | |
| Cesarean section | 2.5% (95% CI: 2.0–3.0) | 4.6% (95% CI: 3.3–5.9) | **0.007** |
| Hysterectomy | 15% (95% CI: 13.8–16.2) | 10.5% (95% CI: 8.6–12.4) | **0.004** |
| SUI surgery | 6.9% (95% CI: 6.0–7.7) | 6.3% (95% CI: 4.7–6.8) | 0.5 |
| POP surgery | 10.9% (95% CI: 10.9–13.1) | 9.2% (95% CI: 7.4–11.1) | 0.13 |

SD: standard deviation; 95% CI: 95% confidence interval; SUI: stress urinary incontinence: POP: pelvic organ prolapse.

**Table 6**
Comparison of the baseline characteristics of patients treated for cystocele with mesh versus native-tissue surgery.

| Characteristics | Mesh (n = 1341) | Native tissue (n = 1338) | *p* |
|---|---|---|---|
| Age | 70 (SD 54) | 68.5 (SD 11) | 0.33 |
| Comorbidities | | | |
| Obesity | 12.1% (95% CI: 10.3–13.8) | 10.6% (95% CI: 9.0–12.3) | 0.22 |
| Diabetes | 4.9% (95% CI: 3.8–6.1) | 5.8% (95% CI: 4.5–7.0) | 0.3 |
| Anticoagulation therapy | 5.1% (95% CI: 4.0– 6.3) | 4.6% (95% CI: 3.4–5.7) | 0.55 |
| Cardiovascular disease | 20.7% (95% CI: 18.6–22.9) | 21.2% (95% CI: 19.0–23.3) | 0.75 |
| Surgical history | | | |
| Cesarean section | 2.3% (95% CI: 1.5–3.1) | 2.7% (95% CI: 1.8–3.6) | 0.5 |
| Hysterectomy | 14.8% (95% CI: 12.9–16.7) | 9.3% (95% CI: 7.8–10.9) | <**0.0001** |
| SUI surgery | 6.8% (95% CI: 5.4–8.1) | 4.4% (95% CI: 3.3–5.5) | **0.007** |
| POP surgery | 10.7% (95% CI: 9.1–12.4) | 6.6% (95% CI: 5.2–7.9) | **0.0002** |

SD: standard deviation; 95% CI: 95% confidence interval; SUI: stress urinary incontinence: POP: pelvic organ prolapse.

*Comparison of complications associated with vaginal versus abdominal surgery*

Our study found no differences in the rates of intraoperative injuries between vaginal and abdominal surgery. Severe postoperative complications (≥Clavien-Dindo grade III) occurred at similar rates with both types of surgery in the early postoperative period. One year after surgery, severe complications were more frequent in the abdominal surgery group, although the difference was not statistically significant. It should also be borne in mind that 60% of patients were lost to follow-up for vaginal surgery and 69% for abdominal surgery.

A significant association was found between vaginal surgery and both postoperative urinary tract infection and postoperative urinary retention. This finding was difficult to interpret because some of the operations included in this analysis involved a concomitant procedure for stress urinary incontinence surgery, which considerably increases the incidence of urinary retention [16]. On analysis of the subgroup of POP surgeries that involved concomitant surgery for stress urinary incontinence, the rate of urinary retention was significantly higher in the vaginal surgery group. However, another potential confounding factor was the older age of the patients who underwent vaginal surgery, since age is another known risk factor for postoperative urinary retention [17]. In contrast, abdominal surgery was associated with a significantly higher rate of de novo urinary incontinence and a higher reoperation rate for urinary incontinence (5%), a finding that is consistent with the literature [18].

The rate of intestinal obstruction in the abdominal surgery group was low (1.2%) and comparable with rates reported in the literature [19] (1%), but significantly higher than in the vaginal surgery group. This difference was evidently related to the surgical approach. This higher rate of intestinal obstruction may explain in part the higher rate of admissions to intensive care in the abdominal surgery group observed in our study.

Abdominal surgery was associated with a higher risk of decompensation of an untreated compartment at one year, although there was no difference in recurrence rates between the two groups. However, as the analysis of this registry was not intended to evaluate the efficacy of treatment, no conclusions can be drawn on this finding.

In two clinical trials comparing abdominal sacral colpopexy versus vaginal sacrospinous fixation, the abdominal approach was associated with fewer recurrences of vault prolapse, and fewer cases of de novo urinary incontinence and de novo dyspareunia [20,21]. In contrast, the vaginal approach was associated with shorter operating times, lower cost, and earlier return to activities of daily living. Another clinical trial [22] compared laparoscopic sacrocolpopexy versus vaginal mesh surgery to treat apical compartment prolapse and found that laparoscopic sacrocolpopexy was associated with longer operating times but less intraoperative blood loss, shorter hospital stays, and earlier resumption of activities of daily living. After two years of follow-up, anatomic outcomes were better in the sacrocolpopexy group, with a higher reoperation rate in the vaginal mesh surgery group (22% versus 5%). However, there was no evaluation of complications of urinary, gastrointestinal or sexual function, or of chronic pain. The risk of mesh erosion was similar in the vaginal and abdominal approach groups. A recent US cohort study [23] compared the efficacy and complications of laparoscopic sacral hysteropexy versus vaginal mesh hysteropexy to treat uterine prolapse and found no significant difference in complications. Vaginal mesh extrusion was more frequent in this study with vaginal surgery but the difference was not statistically significant (6.6% versus 2.7%, p = 0.4).

An International Federation of Gynecology and Obstetrics (FIGO) report published in 2015 [24] established laparoscopic sacrocolpopexy as the standard treatment for apical compartment prolapse. The literature therefore suggests that sacrocolpopexy is the first-choice technique for apical prolapse repair, but for anterior compartment prolapse the situation is much less clear. The aim of the French multicenter study PROSPERE [25] is to compare sacrocolpopexy versus vaginal mesh surgery in cystocele repair. The primary endpoint is the incidence of complications ≥ Clavien-Dindo grade II. The results of this study have not yet been published but should help establish the best surgical strategy for cystocele.

The rate of vaginal mesh extrusion in our study was significantly higher in the vaginal mesh group than in the abdominal surgery group during both the early postoperative period and one year after surgery. This is related to the surgical approach itself, difficulties with vaginal wound healing, and the risk of infection. Although the use of mesh in abdominal surgery is the gold standard currently, its use in vaginal surgery remains controversial. A 2007 report by the French National Authority for Health (HAS) and a Cochrane review [11] both support this view and call for controlled prospective studies to compare the efficacy and complication rates of transvaginal mesh repair versus transvaginal native-tissue repair.

*Comparison of the complications of transvaginal mesh surgery versus transvaginal native-tissue surgery*

In our study, transvaginal mesh surgery was associated with a higher rate of severe postoperative complications than transvaginal native-tissue surgery in the early postoperative period and one year after surgery; with loss to follow-up rates of 57% for mesh surgery and 60% for native-tissue repair in the treatment of cystocele.

Many articles have compared the complication rates of vaginal native-tissue versus mesh repair. As mentioned above, the 2016 Cochrane review [11] concluded that vaginal surgery was associated with a higher rate of dyspareunia than abdominal

**Table 7**
Comparison of the intraoperative, early postoperative and one-year postoperative complications of abdominal versus vaginal surgery.

| Complications | Vaginal surgery (n = 3277) | Abdominal surgery (n = 975) | *p* (chi-square) OR (95%CI) |
|---|---|---|---|
| | INTRAOPERATIVE | | |
| Bladder injury | n = 40 (1.2%) | n = 16 (1.6%) | 0.3 |
| Colo-rectal injury | n = 11 (0.3%) | n = 2 (0.2%) | 0.7 |
| Vascular injury | n = 6 (0.2%) | n = 3 (0.3%) | 0.4 |
| Blood loss >300 mL | n = 22 (0.7%) | n = 3 (0.3%) | 0.2 |
| **Overall** | **n = 79 (2.4%)** | **n = 24 (2.5%)** | **OR 1.0 (0.6–1.6) p = 0.95** |
| | | | **Adj OR 0.9 (0.6–1.5) p = 0.77** |
| | EARLY POSTOPERATIVE | | |
| Hematoma | n = 75 (2.3%) | n = 13 (1.3%) | **0.05** |
| Abscess | n = 10 (0.3%) | n = 3 (0.3%) | 0.98 |
| Urinary tract infection/pyelonephritis | n = 133 (4.1%) | n = 23 (2.4%) | **0.01** |
| Urinary retention | n = 125 (3.8%) | n = 11 (1.1%) | **0.00003** |
| With concomitant SUI surgery | 891 SUI procedures n=50 (5.6%) | 260 SUI procedures n = 7 (2.7%) | **0.05** |
| Bowel obstruction | n = 2 (0.1%) | n = 12 (1.2%) | **0.000001** |
| Mesh contraction | n = 4 (0.1%) | n = 0 (0%) | 0.6 |
| Vaginal mesh exposition | n = 47 (1.4%) | n = 6 (0.6%) | **0.04** |
| Surgery with at least one mesh | 1490 meshes n = 47 (3.2%) | 954 meshes n = 6 (0.6%) | **0.000006** |
| Visceral extrusion | n = 1 (0.03%) | n = 1 (0.1%) | 0.4 |
| Chronic pain | n = 40 (1.2%) | n = 16 (1.6%) | 0.3 |
| Dyspareunia | n = 16 (0.5%) | n = 1 (0.1%) | 0.1 |
| Fistula | n = 3 (0.1%) | n = 0 (0%) | 0.98 |
| De novo urinary incontinence | n = 59 (1.8%) | n = 20 (2.1%) | 0.5 |
| Obstructed defecation | n = 24 (0.7%) | n = 24 (2.5%) | **0.000003** |
| Thromboembolic complications | n = 2 (0.06%) | n = 1 (0.1%) | 0.5 |
| Respiratory complications | n = 1 (0.03%) | n = 0 (0%) | 0.98 |
| Cardiovascular complications | n = 6 (0.2%) | n = 0 (0%) | 0.3 |
| Neurological (CNS) complications | n = 6 (0.2%) | n = 1 (0.1%) | 0.98 |
| Blood transfusion | n = 13 (0.4%) | n = 0 (0%) | **0.05** |
| Inpatient days | 4.43 days (SD 1.7) | 4.42 days (SD 6.2) | 0.98 |
| Prolongation of hospitalization | n = 236 (7.2%) | n = 45 (4.6%) | **0.004** |
| -Medical reason | n = 163 (69.1%) | n = 38 (84.4%) | **0.04** |
| -Other reason | n = 66 (28.0%) | n = 7 (15.6%) | 0.08 |
| Rehospitalization | n = 111 (3.4%) | n = 24 (2.5%) | 0.2 |
| Reoperation | n = 91 (2.8%) | n = 22 (2.3%) | 0.6 |
| Admitted into intensive care | n = 4 (0.1%) | n = 5 (0.5%) | **0.01** |
| Death | n = 0 (0%) | n = 1 (0.1%) | 0.2 |
| **Severe complications (≥Clavien-Dindo grade IIIa)** | **n = 95 (2.9%)** | **n = 28 (2.9%)** | **1** |
| **Overall** | **n = 574 (17.5%)** | **n = 153 (15.7%)** | **OR 0.9 (0.7-1.1) p = 0.19** |
| | | | **Adj OR 0.8 (0.7-1.0) p = 0.10** |
| | ONE YEAR POST-SURGERY | | |
| | n = 1309 (response rate 40%) | n = 300 (response rate 31%) | |
| De novo urinary incontinence | n = 92 (7.0%) | n = 33 (11%) | **0.02** |
| De novo overactive bladder | n = 66 (5.0%) | n = 16 (5.3%) | 0.8 |
| De novo voiding dysfunction | n = 45 (3.4%) | n = 10 (3.3%) | 0.9 |
| Ureteral lesion | n = 1 (0.08%) | n = 1 (0.3%) | 0.3 |
| Ureterovaginal fistula | n = 1 (0.08%) | n = 0 (0%) | 0.6 |
| De novo constipation | n = 32 (2.4%) | n = 16 (5.3%) | **0.007** |
| Bowel obstruction | n = 1 (0.08%) | n = 2 (0.7%) | **0.03** |
| De novo chronic pain | n = 27 (2.1%) | n = 15 (5.0%) | **0.005** |
| De novo dyspareunia | n = 53 (4.0%) | n = 8 (2.7%) | 0.3 |
| Vaginal mesh exposition | n = 22 (1.7%) | n = 1 (0.3%) | 0.07 |
| Surgery with at least one mesh | 635 meshes n = 22 (3.5%) | 300 meshes n = 1 (0.3%) | **0.003** |
| POP recurrence | n = 51 (3.9%) | n = 12 (4.0%) | 0.9 |
| Surgical correction of POP recurrence | n = 13 (1.0%) | n = 4 (1.2%) | 0.8 |
| Decompensation of an untreated compartment | n = 14 (1.0%) | n = 8 (2.7%) | **0.04** |
| Surgical treatment of de novo urinary incontinence | n = 36 (2.8%) | n = 15 (5.0%) | **0.02** |
| Rehospitalization | n = 72 (5.5%) | n = 26 (8.7%) | **0.04** |
| Reoperation under LA | n = 11 (0.8%) | n = 1 (0.3%) | 0.4 |
| Reoperation under GA | n = 68 (5.2%) | n = 23 (7.7%) | 0.09 |
| Admitted into intensive care | n=0 (0%) | n = 0 (0%) | 1 |
| Death | n = 4 (0.3%) | n = 0 (0%) | 0.3 |
| **Severe complications (≥Clavien-Dindo grade IIIa)** | **n = 83 (6.3%)** | **n = 24 (8.0%)** | **0.3** |
| **Overall** | **n = 339 (25.9%)** | **n = 92 (30.7%)** | **OR 1.3 (0.96-1.7) p= 0.10** |
| | | | **Adj OR 1.2 (0.9-1.5) p = 0.29** |

SUI: stress urinary incontinence; POP: pelvic organ prolapse; CNS: central nervous system; LA: local anesthesia; GA: general anesthesia; Adj OR: OR adjusted on age.

surgery, although this was not the case in our study. However, this review did not report a difference in postoperative dyspareunia rates between the two types of vaginal surgery. Mesh surgery was associated with a lower rate of recurrence but also with certain complications: longer operating times, more blood loss, increased risk of decompensation of another compartment, more de novo urinary incontinence, and more reoperations for mesh erosions. Similarly, in a randomized trial to compare anterior mesh repair with anterior colporrhaphy, Altman [26] reported longer operative times after mesh surgery as well as higher rates of hemorrhage and

**Table 8**
Comparison of the complications of vaginal cystocele repair using mesh versus native tissue.

| Complications | Mesh repair (n = 1341) | Native-tissue repair (n = 1338) | *p* (chi-square) |
|---|---|---|---|
| | INTRAOPERATIVE | | |
| Bladder injury | n = 22 (1.6%) | n = 16 (1.2%) | 0.4 |
| Vascular injury | n = 5 (0.4%) | n = 2 (0.1%) | 0.5 |
| Blood loss >300 mL | n = 12 (0.9%) | n = 8 (0.6%) | 0.4 |
| | EARLY POSTOPERATIVE | | |
| Hematoma | n = 33 (2.5%) | n = 30 (2.2%) | 0.6 |
| Abscess | n = 4 (0.3%) | n = 6 (0.4%) | 0.5 |
| Urinary tract infection or pyelonephritis | n = 64 (4.8%) | n = 52 (3.9%) | 0.3 |
| Urinary retention | n = 56 (4.2%) | n = 57 (4.3%) | 0.9 |
| Mesh contraction | n = 4 (0.3%) | n = 0 (0%) | 0.1 |
| Vaginal mesh exposition | n = 45 (3.4%) | n = 0 (0%) | **<0.0000001** |
| Chronic pain | n = 23 (1.7%) | n = 9 (0.7%) | **0.02** |
| Dyspareunia | n = 6 (0.4%) | n = 7 (0.5%) | 0.7 |
| Bladder fistula | n = 0 (0%) | n = 2 (0.1%) | 0.2 |
| De novo urinary incontinence | n = 34 (2.5%) | n = 17 (1.3%) | **0.02** |
| Thromboembolic complications | n = 2 (0.1%) | n = 0 (0%) | 0.5 |
| Reoperation | n = 49 (3.7%) | n = 30 (2.2%) | **0.02** |
| Prolongation of hospitalization | n = 112 (7.0%) | n = 94 (8.4%) | 0.2 |
| Admitted into intensive care | n = 3 (0.2%) | n = 1 (0.07%) | 0.6 |
| Death | n = 0 (0%) | n = 0 (0%) | 1 |
| Severe complications (≥Clavien-Dindo grade IIIa) | n = 52 (3.9%) | n = 31 (2.3%) | **0.02** |
| | ONE YEAR POST-SURGERY | | |
| | n = 575 (response rate 43%) | n = 542 (response rate 40%) | |
| De novo urinary incontinence | n = 51 (8.9%) | n = 28 (5.2%) | **0.02** |
| De novo overactive bladder | n = 17 (3.0%) | n = 36 (6.6%) | **0.005** |
| De novo voiding dysfunction | n = 18 (3.1%) | n = 10 (1.8%) | 0.2 |
| Ureteral lesion | n = 0 (0%) | n = 1 (0.2%) | 0.5 |
| Ureterovaginal fistula | n = 0 (0%) | n = 1 (0.2%) | 0.5 |
| De novo constipation | n = 15 (2.6%) | n = 12 (2.2%) | 0.7 |
| Gastrointestinal obstruction | n = 0 (0%) | n = 1 (0.2%) | 0.5 |
| De novo chronic pain | n = 16 (2.8%) | n = 5 (0.9%) | **0.02** |
| De novo dyspareunia | n = 26 (4.5%) | n = 15 (2.8%) | 0.1 |
| Vaginal mesh exposition | n = 18 (3.1%) | n = 0 (0%) | **0.000007** |
| POP recurrence | n = 21 (3.7%) | n = 18 (3.3%) | 0.7 |
| Surgical correction of POP recurrence | n = 7 (1.2%) | n = 2 (0.4%) | 0.2 |
| Decompensation of an untreated compartment | n = 5 (0.9%) | n = 6 (1.1%) | 0.7 |
| Surgical treatment of de novo SUI | n = 23 (4.0%) | n = 9 (1.7%) | **0.02** |
| Reoperation under LA | n = 6 (1.0%) | n = 3 (0.6%) | 0.5 |
| Reoperation under GA | n = 43 (7.5%) | n = 17 (3.1%) | **0.001** |
| Rehospitalization | n = 43 (7.5%) | n = 18 (3.3%) | **0.002** |
| Death | n = 0 (0%) | n = 3 (0.6%) | 0.1 |
| Severe complications (≥Clavien-Dindo grade IIIa) | n = 49 (8.5%) | n = 23 (4.2%) | **0.004** |

SUI: stress urinary incontinence; POP: pelvic organ prolapse; LA: local anesthesia; GA: general anesthesia.

de novo urinary incontinence. The reoperation rate for mesh exposure in Altman's trial was 3.2%. A recent US study [14] in over 20 000 patients who had undergone transvaginal POP surgery found that the only complications more frequently associated with mesh surgery were reoperation within the first year (hazard ratio [HR] 1.47; 95% CI 1.21–1.79) and urinary retention within 90 days after surgery (risk ratio [RR] 1.33; 95% CI 1.18–1.51). According to other authors [27–29], the only difference in complications between the two types of surgery was vaginal mesh extrusion following mesh surgery.

A Cochrane review published in February 2016 compared transvaginal mesh versus native-tissue repair. In this review, mesh surgery was associated with improved anatomic results, fewer POP-related symptoms, and lower rates of repeat surgery for POP recurrence. In terms of urinary tract complications, mesh surgery was associated with a higher risk of de novo urinary incontinence (RR 1.39; 95% CI 1.06–1.82), although this did not translate into an increase in incontinence surgery, and a higher risk of intra-operative bladder injury (RR 3.92; 95% CI 1.62–9.50). No difference in the frequency of overactive bladder or dyspareunia was observed between the groups. Analysis of a composite endpoint comprising reoperation for POP recurrence, stress urinary incontinence or mesh exposure showed that mesh surgery was associated with a higher reoperation rate.

The strengths of our study are that it provides a representative overview of POP surgery and analyzed a large number of interventions, enabling us to demonstrate differences in the incidence of rare complications between several types of surgery and to therefore compare them.

The main limitation of our study was the high loss to follow-up rate at one year (about 60%). In addition, collecting data from individual surgeons meant that some data on the interventions entered were missing, and some surgeons reported only a proportion of the surgeries they actually performed. Another limitation was that complications were reported by the surgeons themselves. This could be partly due to reporting bias, since those surgeons with severe or many complications would be more prone not to report their cases compared to those with minor or few complications. The retrospective design of the study was also a limitation because the patients were not uniformly followed up. Finally, the characteristics of the patients differed according to the type of surgery they underwent.

## Conclusion

The Gynerisq database contains a representative sample of POP surgeries performed in France by gynecologists. An unusual feature of this registry was the high proportion of cystocele repair

surgeries in which mesh was used. The large number of patients included in the registry enabled us to demonstrate the existence of differences in postoperative complications and to analyze the morbidity associated with the main types of POP surgery performed. Every surgical technique exposes patients to the risk of complications, although transvaginal mesh repair was associated with greater perioperative morbidity than transvaginal native tissue repair. Knowledge of the postoperative morbidity associated with the various types of POP surgery is essential to help surgeons choose the surgical strategy best suited to each patient.

## AUTHORSHIP CONTRIBUTIONS

**I Le Teuff:** Data analysis, Manuscript writing
**M Labaki:** Data collection
P Fabbro-Peray: Data analysis
**P Debodinance:** Project development, Data collection
**B Jacquetin:** Project development, Data collection
**J Marty:** Project development, Data collection
**V Letouzey:** Data collection
**G Eglin:** Project development, Data collection
**R de Tayrac:** Project development, Data collection, Data analysis, Manuscript writing

## Conflict of interest statement

P Debodinance: Consultant for Boston Scientific and Coloplast
V Letouzey: Consultant for Boston Scientific and Cook
R de Tayrac: Consultant for Boston Scientific and Coloplast, Congress invitation by Astellas.
No Conflict of Interest for ILT, ML, PFP, JM, GE and BJ

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