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ORIGINAL ARTICLE

Complications and reoperation after pelvic organ prolapse, impact of hysterectomy, surgical approach and surgeon experience

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Abstract

Introduction and hypothesis The surgical treatment of pelvic organ prolapse (POP) is associated with specific complications. Our primary objective was to assess the recurrence requiring reoperation after prolapse surgery, and our secondary objectives were to assess the early complications and secondary surgery for urinary incontinence.

Methods Retrospective study of a population-based cohort of all hospital or outpatient stays including POP surgery from 2008 to 2014, using the French nationwide discharge summary database. We calculated the rates of hospital readmission following surgery as well as the rates of reoperation for recurrent prolapse and subsequent procedures performed for urinary incontinence.

Results A total of 310,938 patients had undergone surgery for POP. Two hundred fourteen (0.07%) patients died, and 0.45% were admitted to an intensive care unit; 4.4% of the patients underwent surgery for the recurrence of prolapse. Concomitant hysterectomy in the first surgery was associated with a significantly lower risk of POP surgery recurrence: (hazard ratio (HR) [95% confidence interval (CI)] = 0.51 [0.49; 0.53]). A total of 1386 (2.5%) patients were readmitted to the hospital for early (30-day) complications of prolapse surgery. The most frequent reasons for early readmission were local infection (32.8%), hemorrhage (21.4%) and pain (17.2%). Risk factors for complications were obesity, hospitals with low levels of activity and associated incontinence surgery; 4.6% of the patients required secondary surgery for urinary incontinence; obesity was a risk factor (HR [95% CI] = 1.12 [1.01; 1.24]), and the vaginal route was a protective factor (odds ratio = 1.86 for laparoscopy, 1.44 for laparotomy and 1.25 for multiple approaches).

Conclusions POP surgery is associated with low rates of complication and recurrence. Complications occurred most commonly following combined surgeries for both prolapse and incontinence and in hospitals with low surgical volumes. Concomitant hysterectomy appears to be protective for the need for additional prolapse surgery, and the vaginal route leads to a lower frequency of secondary surgery for urinary incontinence.

Keywords Prolapse surgery · Complication · Urinary incontinence · Hysterectomy

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Abbreviations

aHR	Adjusted hazard ratio
CCAM	Classification Commune Des Actes Médicaux
CI	Confidence interval
HR	Hazard ratio
ICD-10	International Classification of Diseases, 10th edition
POP	Pelvic organ prolapse
SD	Standard deviation
SUI	Stress urinary incontinence
UI	Urinary incontinence

Introduction

Pelvic organ prolapse (POP) is a common type of pelvic disorder in women; it occurs in almost 50% of parous women, and one in ten of these cases may need surgical treatment [1, 2]. Prolapse is not life-threatening, and so prolapse surgery has a functional objective; as such, the associated risks and benefits must be accurately evaluated.

Patients undergoing POP surgery are at risk of early or late complications, which can cause major functional disorders that require readmission to hospital and (in some cases) further surgery [3]. The overall complication rate varies markedly from one study to another (3.4% [4] to 40% [5]). A number of risk factors for complications have been identified: previous prolapse surgery, obesity, menopause, tobacco consumption, concomitant hysterectomy, certain surgical operations, inexperienced surgeon and the concomitant correction of several prolapses [3, 5–7].

Most studies have focused on a specific surgical technique, and few have provided a comprehensive overview of complications of prolapse surgery (i.e., after various surgical technique and at various follow-up times after surgery) [1, 2, 5].

The objective of the present study was to evaluate the incidence of and risk factors for mid- and long-term recurrences of prolapse requiring further surgery and, second, early complications of POP surgery requiring readmission to hospitalization and secondary surgery for urinary incontinence (UI).

Materials and methods

We analyzed the French national discharge summary database (*Programme de Médicalisation des Systèmes d'Information*) [8], and a unique anonymous identifier enables linking the different inpatient stays of a given patient, across the country and in different healthcare settings. This database is exhaustive and contains all the discharge summaries from all non-profit and for-profit acute care hospitals in France (discharge summaries are the basis of hospital funding). Each summary contains administrative and demographic data (the patient's age, gender, admission date, etc.), the primary and secondary diagnoses (coded according to the International Classification of Diseases; 10th Edition [9]) and diagnostic and medical procedures [coded using the French *Classification Commune des Actes Médicaux* (CCAM)] classification [10].

We performed a retrospective study of a population-based cohort by selecting all the inpatient stays that included POP surgery between 2008 and 2014 The surgical procedures included anterior colpoperineorrhaphy (cystocele surgery), posterior colpoperineorrhaphy (rectocele surgery), Richter's sacrospinous ligament fixation (with or without Douglas resection), Lefort colpocleisis, laparoscopic or open sacrocolpopexy (with or without hysterectomy), and laparoscopic or open rectopexy (we cannot individualize mesh surgeries because of some common CCAM codes between mesh or non-mesh surgeries). In some cases, several of these interventions were combined. The corresponding CCAM codes for these procedures are listed in the Supplementary Material. Men and patients under the age of 18 were excluded.

We used diagnostic and procedural codes to group patients into clinically intelligible groups. The patients were followed up for as much as 7 years after the initial prolapse surgery; hospital readmissions (including those to other institutions) were analyzed, and complication and reoperation rates were calculated.

We used the vaginal approach as the reference for calculating the hazard ratios (HRs) because it was the most common surgical approach route in our study, it has been well characterized since the advent of prolapse surgery, and it is relevant for comparison with all the other approaches.

Descriptive statistics were calculated for the variables of interest. Continuous variables were quoted as the mean ± standard deviation (SD). Non-normally distributed data were described as the median [interquartile range]. The 95% confidence interval (CI) was calculated using the central limit theorem. Categorical variables were quoted as the frequency (percentage). The 95% CI was calculated using the binomial distribution method. The chi-squared test or Fisher's exact test was used to compare categorical variables. The Welch two-sample t-test and an analysis of variance were used to compare means. Readmissions and reoperations were studied as censored variables. Cox models were used to search for risk factors among all the available variables. Hazard ratios were reported with their 95% CI. Regarding hospital readmission within 30 days of the initial prolapse surgery, the event was analyzed as a binary variable, a logistic regression was used to search for risk factors, and odds ratios were reported with their 95% CI.

All tests were two-sided, and the threshold for statistical significance was set to $p < 0.05$. All p values $< 10^{-10}$ are reported here as "$p = 0$."

There were no missing data.

This observational study consisted of a secondary use of nationwide anonymous data. It was performed within the frame of a specific French national regulation. A

Table 1 Description of the population

	n	% or ± SD
Age (mean, in years)	62.7	± 13.5
Length of hospital stay (mean, in days)	5.9	± 3.3
Type of hospitalization		
Inpatient stay/conventional hospitalization	304,001	97.8
Ambulatory care	6937	2.2
Mortality	214	0.1
Critical care/intensive care units	1386	0.5
Approach in the initial prolapse surgery		
Vaginal	170,610	54.9
Laparoscopy	75,430	24.3
Laparotomy	35,942	11.6
Anal	17,493	5.6
Multiple	11,463	3.7
Concomitant hysterectomy	121,318	39.0
Laparoscopy		3.0
Laparotomy		8.0
Vaginal		27.0
Associated surgery for SUI*	91,523	29.4
Comorbidities		
Obesity	13,175	4.2
Respiratory failure	7927	2.6
Cardiac failure	16,899	5.4
Diabetes	15,236	4.9

**SUI* stress urinary incontinence

national authorization was therefore obtained from the CNIL, and no IRB advice was necessary.

Results

The database comprised 181,971,138 inpatient stays between 1 January 2008 and 31 December 2014. Of these, 310,938 (0.17%) corresponded to POP surgery.

As shown in Table 1, the mean ± SD age of the patients having undergone POP surgery was 62.7 years, and 97.8% of the hospitalizations were inpatient stays (i.e., conventional hospitalization). The prevalences of chronic conditions were as follows observed: 5.4% for cardiovascular disease, 4.9% for diabetes, 4.2% for obesity and 2.6% for respiratory insufficiency. Regarding the surgical approach, a vaginal approach was used in 54.9% of the patients, whereas 24.3% had undergone laparoscopic surgery, 11.6% had undergone laparotomy, and an anal approach was used in 5.6%. Two or more approaches were used with 3.7% of the patients. Overall, 39.0% of the patients had undergone hysterectomy at the same time as prolapse surgery.

POP surgery was associated with concomitant urinary incontinence surgery in 29.4% of cases.

Immediate postoperative complications included the need for intensive care in 1386 patients (0.45%); additionally 214 patients died during the initial hospital admission for surgery (0.07%).

Regarding the rate of recurrence of prolapse requiring additional surgery, we observed a rate of 0.10% (2.02% at 1 year after the initial surgery and 5.8% at 5 years) (Fig. 1). Compared with the vaginal approach, laparoscopic and laparotomic approaches protected against the recurrence of prolapse (Table 2). Concomitant hysterectomy (aHR = 0.51) and the year of surgery (aHR = 0.98) were also found to protect against recurrence (Table 2). A hospital's annual prolapse surgical volume was not significant regarding recurrence rates (number of acts of prolapse surgery per year per hospital).

Regarding early complications, 2.5% of the patients were readmitted to hospital within 30 days of prolapse surgery (Table 3). The most frequent causes of readmission hospitalization were local infection (31%), hemorrhage (20.3%), pain (16.3%) and postoperative care (urinary cathether, wound local care, sutures, pads, oversight) (15.8%).

Factors associated with hospital readmission for early complications are listed in Table 4. On one hand, a high

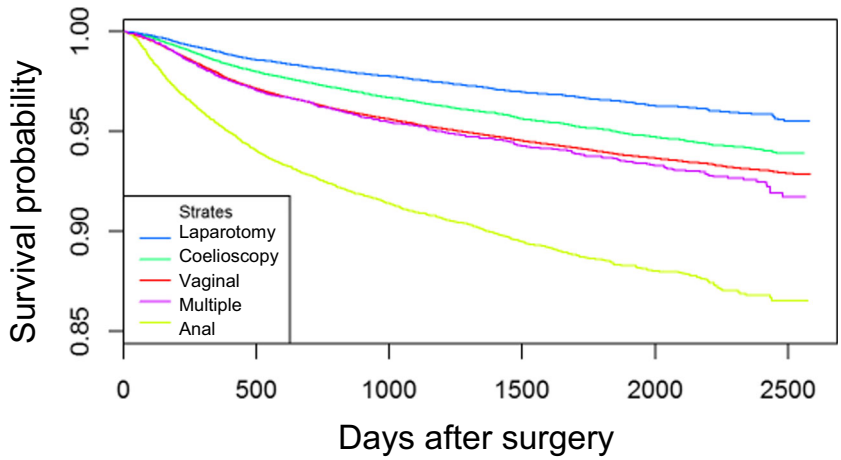

Fig. 1 Hospital readmission for the recurrence of pelvic organ prolapse, as a function of the surgical approach ($n = 13{,}600$)

Table 2 Risk factors for the recurrence of prolapse ($n = 13,600$)

	aHR	95% CI
Initial surgical approach		
Vaginal	1	
Laparoscopy	0.62	[0.59; 0.65]
Laparotomy	0.63	[0.59; 0.67]
Anal and perineal	1.50	[1.42; 1.60]
Two or more approaches	0.94	[0.87; 1.03]
Concomitant hysterectomy	0.51	[0.49; 0.53]
Year of initial prolapse surgery	0.98	[0.97; 0.99]

aHR: adjusted hazard ratio in a Cox regression with the factors in the table, together with diabetes, chronic heart failure or chronic respiratory insufficiency, which were not significant

CI confidence interval

surgical volume (defined as > 50 operations per year per establishment) appeared to be a protective factor (compared with < 20 operations per year) as was ambulatory care and older age at the time of surgery. On the other hand, concomitant surgery for UI (adjusted HR (aHR) [95% CI] = 1.09 [1.04; 1.15]) and obesity (aHR 1.14 [1.03; 1.26]) were risk factors of complication, along with a greater length of hospital stay.

When we focused on the rate of UI surgery after the initial prolapse surgery, we observed that this event occurred in 2.25% of patients at 6 months, in 3.56% at 1 year and in 6.04% at 5 years. There were 10,964 reoperations for de novo UI (SUI) (5.0%) (Table 5). Again, concomitant hysterectomy appeared to be a protective factor (aHR [95% CI] = 0.76 [0.73; 0.80]) (Table 5). In contrast, laparoscopy (aHR [95% CI] 1.82 [1.74; 1.91]), laparotomy (aHR [95% CI] = 1.44 [1.31; 1.58]) and multiple approaches in prolapse surgery (aHR 1.25 [1.13; 1.38], relative to the vaginal route, age (for a 10-year increment) and obesity, were risk factors for secondary surgery for UI (Table 5 and Fig 2).

Table 3 Types of complication at 30 days post-surgery

	n	%
Infection	15,647	31.0
Hemorrhage	10,126	20.3
Pain	8156	16.3
Postoperative care[a]	7916	15.8
Urinary retention	4183	8.4
Hematoma	4127	8.3
Mesh-related complications	4005	8.0
Complications[b]	133	0.3

[a] Urinary care, suture, dressings, etc.

[b] Bladder, rectal or vascular injury and per- or postoperative systemic complications (heart failure, anemia, etc.)

Table 4 Risk factors for early complications

	aHR	95% CI
Hospital activity (procedures per year per hospital)		
1 to 19	1	
20 to 49	0.92	[0.84; 1.01]
50 to 99	0.84	[0.77; 0.92]
≥ 100	0.88	[0.81; 0.96]
Type of stay		
Ambulatory care	0.75	[0.62; 0.90]
Length of hospital stay (days)	1.03	[1.03; 1.04]
Year of surgery (for a 1-year increment)	1.03	[1.02; 1.04]
Concomitant surgery for urinary incontinence	1.09	[1.04; 1.15]
Age (for a 10-year increment)	0.94	[0.92;0.95]
Obesity	1.14	[1.03; 1.26]

aHR: adjusted hazard ratio in a Cox regression with the factors in the table together with diabetes, chronic heart failure or chronic respiratory insufficiency, which were not significant

CI confidence interval

Discussion

Surgery for the recurrence of prolapse concerned 4.4% of the women (from 0.1% at 1 month to 5.8% at 5 years). Concomitant hysterectomy during the initial surgery was associated with a significantly lower risk of prolapse recurrence needing secondary prolapse surgery (aHR [95% CI] = 0.51 [0.49; 0.53]).

We observed a total of 7802 (2.5%) hospitalizations for complications within the first month post-surgery. The most

Table 5 Risk factors for secondary surgery for urinary incontinence

	aHR	95% CI
Initial surgical approach		
Vaginal	1	
Laparoscopy	1.82	[1.74; 1.91]
Laparotomy	1.44	[1.31; 1.58]
Anal and perineal	0.89	[0.75; 1.07]
Two or more approaches	1.25	[1.13; 1.38]
Concomitant hysterectomy	0.76	[0.73; 0.80]
Principal diagnosis: urinary incontinence	2.54	[1.82; 3.55]
Age (for a 10-year increment)	1.03	[1.01; 1.04]
Obesity	1.12	[1.01; 1.24]

aHR: adjusted hazard ratio in a Cox regression with the factors in the table, together with diabetes, chronic heart failure or chronic respiratory insufficiency, which were not significant

CI confidence interval

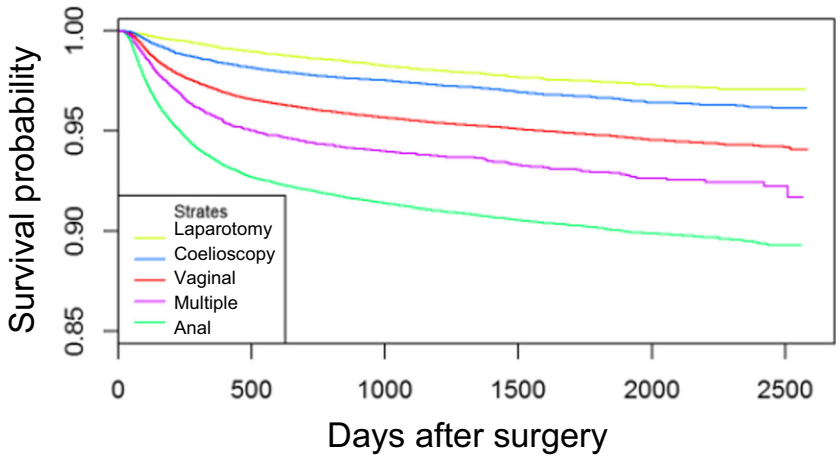

Fig. 2 Hospital readmission for urinary incontinence surgery, as a function of the surgical approach ($n = 10{,}964$)

frequent complications were operative wound infections (32.8%), hemorrhage (21.4%) and pain (17.2%). The main risk factors for complications were obesity, concomitant surgery for UI and hospitals with a low level of activity.

There were 14,226 secondary operations (4.6%) for UI correction after the first surgery for genital prolapse (whether de novo or persistent), and obesity was a risk factor for this (aHR [95% CI] = 1.12 [1.01; 1.24]). The vaginal route for prolapse correction was a protective factor from secondary urinary incontinence correction (aHR [95% CI] = 1.86 for laparoscopy, 1.44 for laparotomy, 1.25 for multiple routes).

The reoperation rate for prolapse recurrence was 5.8% at 5 years; this is lower than the values in the literature, although the latter specifically concerned the abdominal route or the vaginal route. For example, Lucot et al. reported that the global reoperation rate ranged from 7.8% although the numbers of patients were small [11]. The rates vary markedly from one study to another (from 10% to 30%) [12, 13], suggesting that the effectiveness of the surgical treatment of prolapse and the surgeon's habits depend on the country or the region. As has been suggested in several previous studies with low numbers of patients, we sought to include many patients so that the recurrence rate would be representative. We found that the main risk factors for recurrence were general comorbidities, such as obesity, diabetes, and chronic cardiac or respiratory disease. These general data should focus the surgeon's attention on high-morbidity patients when the surgical treatment of prolapse is being considered. In line with the literature data, the main protective factor was an abdominal approach (laparoscopy or laparotomy).

The frequency of concomitant hysterectomy in our study (39%) (laparoscopy 3%, laparotomy 8%, vaginal route 27%) was lower than the value of 50% reported a few years ago [14]. Concomitant hysterectomy also appears to be associated with a lower rate of readmission for prolapse recurrence. The literature data in this respect are contradictory; most studies have found that hysterectomy was not a protective factor but was contrarily a risk factor for complications [5, 15, 16]. However, even though the influence of hysterectomy is subject to debate, a protective effect has been found in several studies that focused specifically on surgical procedures for pelvic organ prolapse. Hysterectomy was associated with a lower reoperation rate for all prolapse compartments, with an OR ranging from 0.50 to 0.76 [14, 17]. Other studies obtained the same result but were focused on specific surgical techniques [18, 19]. Moreover, hysterectomy was not a risk factor for early complications in our study.

We found that the vaginal route was associated with less frequent secondary surgery for de novo UI (with aHRs of 1.82 and 1.44 for laparoscopic and laparotomic surgery, respectively) but more frequent recurrence of prolapse (HR = 0.62 and 0.63 for laparoscopic and laparotomic surgery, respectively). This is in line with earlier studies showing that sacrocolpopexy (abdominal surgery) led to more secondary operations for UI [20], which was symptomatic in up to 54% of women and required surgery in 16% [21]. In contrast, UI was symptomatic in 28% to 32% of women operated on via the vaginal route [22, 23], and only a small proportion (5.3%) required surgery for UI [22]. This result should be used with precautions because we do not know the proportion of mesh or native tissue repair.

Ambulatory care appears to be a protective factor for early complications (aHR [95% CI] = 0.75 [0.62; 0.90]). Confusion bias could have been induced by the fact that ambulatory patients were selected for their low morbidity and straightforward surgical procedures; accordingly, we adjusted our analysis for comorbidities such as diabetes and chronic organ failure. Moreover, a high level of hospital activity (number of procedures per year > 50 and > 100) was a protective factor. This was probably because the risk of complication is associated with surgeon experience. However, this risk factor is rarely mentioned in the literature and is not always significantly associated with the risk of complications. Achtari et al. did observe a significant association but had only studied mesh surgery; our finding is therefore novel because we studied all types of prolapse surgery [5, 24].

The rate of surgery for SUI (whether persistent or de novo) was 6.0% after 5 years of follow-up. In the literature, the rate

of de novo SUI is around 10 to 12% for women with no symptoms of SUI prior to the initial prolapse surgery [1, 19, 20, 25]. As mentioned above, use of the vaginal route in the initial surgery was associated with a lower incidence of secondary or persistent SUI (relative to laparoscopy or laparotomy) but a higher frequency of prolapse recurrences.

In the present study, the main risk factor for SUI after prolapse surgery was obesity, confirming results of other recent studies [26].

Another strength of our study is that we analyzed a large cohort of patients so that the data were representative of all types of POP surgery, we assessed the majority of the different surgical routes and techniques, the duration of follow-up was relatively long, and we collected a lot of data about the patients' characteristics, the surgery and post-surgery events. The study also had limitations. Notably, these databases were not created for research so we were unable for example to collect specific data on mesh surgery because the CCAM codes do not distinguish between mesh and non-mesh operations. We had no information on parity and type of delivery, which are known to be risks factors of POP.

In conclusion, the results of the present study showed concomitant hysterectomy protects against prolapse recurrence and is not associated with a greater risk of early complications. A high level of hospital activity (procedures per year) was a protective factor for complications. Second, the early complication rate after functional prolapse surgery is low but non-negligible. Lastly, use of the vaginal route may be protective against surgery for SUI.

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Authors contribution S Mairesse: Manuscript writing.
S Bartolo: Protocol development, Manuscript editing.
G Giraudet: Manuscript editing.
M Cosson: Protocol development, Manuscript editing.
E Chazard: Protocol development, Data management, Data analysis.

Compliance with ethical standards

Conflicts of Interest None.

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