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ORIGINAL ARTICLE

Incidence and risk factors for reoperation of surgically treated pelvic organ prolapse

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Abstract
Introduction and hypothesis The objective of our study was to estimate the incidence and to identify the risk factors for reoperation of surgically treated pelvic organ prolapse (POP).
Methods We conducted a nested case–control study among 1,811 women who underwent POP surgery from January 1988 to June 2007. Cases (n=102) were women who required reoperation for POP following the first intervention through December 2008. Controls (n=226) were women randomly selected from the same cohort who did not require reoperation.
Results The incidence of POP reoperation was 5.1 per 1,000 women-years. The cumulative incidence was 5.6%. Risk factors included preoperative prolapse in more than two vaginal compartments (adjusted OR 5.2; 95% CI 2.8–9.7), history of surgery for POP and/or urinary incontinence (adjusted OR 3.2; 95% CI 1.5–7.1), and sexual activity (adjusted OR 2.0; 95% CI 1.0–3.7).
Conclusions The risk of POP reoperation is relatively low and is associated with preexisting weakness of pelvic tissues.

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Keywords Nested case–control study · Pelvic organ prolapse · Incidence · Risk factors · Reoperation

Abbreviations

POP	Pelvic organ prolapse
OR	Odds ratio
CI	Confidence interval
BMI	Body mass index
HT	Hormonal replacement therapy

Introduction

Surgery for pelvic organ prolapse (POP) and urinary incontinence is common. The lifetime risk of undergoing a first procedure was estimated to be between 11% and 19% [1–3]. The prevalence of reoperation reported in some studies is high (43–56%) but likely overestimated as these studies included genital prolapse after Burch colposuspension [4, 5]. Prevalence of reoperation for POP or urinary incontinence was 29.2% in a community-based population [1]. Therefore, in an attempt to improve outcomes and based on this high risk of recurrence, surgeons increasingly use prosthetic materials for the treatment of POP to limit the risk of recurrence. The use of mesh is nevertheless associated with a non-negligible risk of complications such as vaginal erosions, granulomas, dyspareunia, vesicovaginal fistulas, and increase in overactive bladder symptoms, thereby potentially reducing the quality of life of women [6–8]. Recent studies reported lower rates (between 1.5% and 13%) of reoperation for surgically treated POP and urinary incontinence [9–11]. In another recent study, the risk of POP recurrence after reconstructive pelvic surgery without using prosthetic material was 10% [12].

Very little is known on the factors associated with surgical failure. Data arise from a few studies with few identified risk factors. Younger age, high BMI, and advanced preoperative prolapse (grade III–IV) were associated with an increased risk of reoperation in some studies [9, 12, 13]. However, these results were contradicted by other studies in which these associations were not observed [2, 10]. History of surgery for POP and/or urinary incontinence at the time of primary surgery was associated with an increased risk of reoperation in two studies [10, 14].

Based on our clinical experience, we hypothesized that the risk of reoperation would be lower than some of the above-mentioned estimates [1, 4, 5]. The purpose of this study was to estimate the incidence and identify the risk factors for POP reoperation after previous POP reconstructive surgery.

Materials and methods

We performed a case–control study nested within a cohort. This study was approved by the Institutional Ethics Committee of the Geneva University Hospitals (protocol number 07-242R). We identified, by using a computerized medical record database, all women (N=1,811) who underwent POP surgery in the Department of Obstetrics and Gynecology, Geneva University Hospitals, from January 1988 to June 2007. This is a teaching hospital where all women had their operation performed either by a supervised resident in gynecological surgery or by an experienced gynecological surgeon (consultant, professor). Cases (n=102) were women of this cohort who required reoperation for recurrent POP following the first intervention through December 2008 in our institution. Because our hospital is the only public institution in the canton of Geneva and women needing a reoperation cannot be treated either outside the canton or in private institutions, we believe that most cases were identified using this strategy. Controls (n=226) were patients, randomly selected from the same cohort, who did not require reoperation for POP during the same period. We selected all cases and drew a sample of controls (two controls per case) from the hospital database which includes all women who had POP surgery. We calculated that a sample size of 309 women with 103 cases and 206 controls had a power of 80% with a two-tailed alpha of 0.05 to demonstrate statistical significance of odds ratios of 2 in a plausible range of probability of exposure to a risk factor. We selected a few more controls to reach the desired number in case of unavailable medical charts.

Cases and controls for whom medical records were not available were excluded from the analysis (n=2). To avoid bias in the evaluation of risk factors, data were collected in the medical charts blinded to the study group. The medical charts were photocopied and stripped of a patient's identity. The part concerning the first intervention was separated from that of the second in cases. One of the authors (CJ) reviewed all the medical charts related to the first intervention (328 surgically treated pelvic organ prolapse) and another one (PD) reviewed the charts related to the second intervention (102 reoperations for recurrent prolapse). Variables extracted from the charts included age, weight, height, parity, number of vaginal deliveries, previous cesareans, menopausal status, hormonal replacement therapy, smoking, constipation, chronic obstructive pulmonary disease, cardio-vascular disease, and history of surgery for genital prolapse or urinary incontinence performed outside our institution or outside the study period. All women had a standardized preoperative prolapse assessment, using the Baden–Walker classification, which was the classification system used in our institution during the study period [15]. The grade of cystocele, uterine or vaginal vault prolapse, rectocele, and enterocele, as well as the grade of urinary stress incontinence, were identified. In the analysis, we discussed pelvic organ prolapse in terms of segments of the vaginal wall rather than the organ that lies behind, as described by Bump et al. [16]. We considered three major vaginal compartments: the anterior vaginal wall, the posterior vaginal wall, and the superior vagina comprising the cervix or the vaginal vault. We considered prolapse of the posterior fornix (pouch of Douglas) as a fourth vaginal segment in a woman who still had a cervix [16]. The date and indication for POP surgery were collected, as well as the route of POP surgery (abdominal, vaginal, or laparoscopic) and the use of prosthetic material. The surgical techniques used in our institution for abdominal and vaginal POP reconstruction were those described by Hirsch et al. [17]. Most of the procedures were conventional vaginal POP repairs without mesh, which were the techniques performed in our institution from 1988 to 2003. Laparoscopic POP reconstruction techniques were the ones developed by Dubuisson et al. and included the use of mesh from 2003 onwards [18]. Concomitant procedures such as urinary incontinence repair or hysterectomy were also identified. Post-operative complications such as fever or vault abscess were systematically searched.

Cases and controls were compared for the predictor variables mentioned above. Differences in proportions were tested with chi-square test or Fisher exact test. Differences in continuous variables were tested using t-test. We performed a univariable analysis to compute the odds ratios (ORs) for each predictor. Variables found to be statistically associated with the outcome or clinically important were then entered in logistic regression models to compute adjusted odds ratios. A P-value less than 0.05 was considered as statistically significant and 95% confidence intervals (CIs) were reported. The annual incidence of

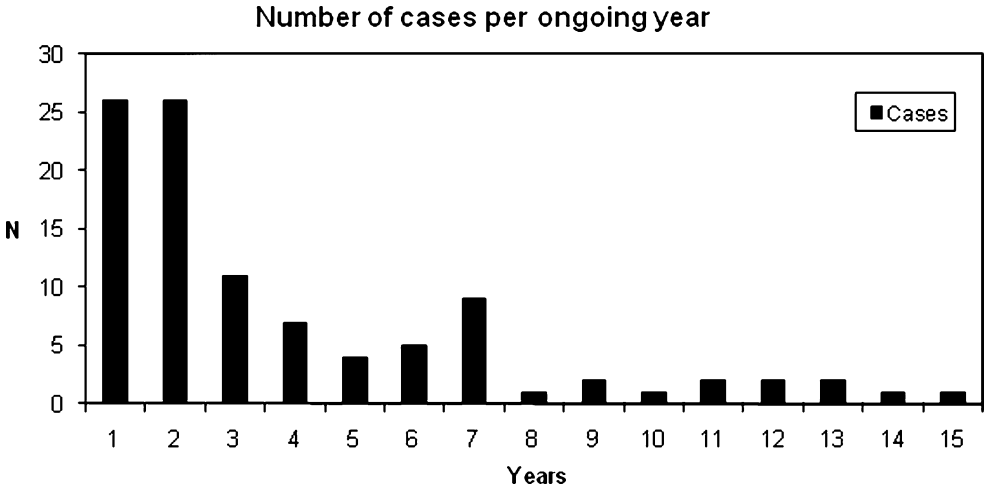

Fig. 1 Number of cases of reoperation per ongoing year

reoperation was computed taking into account the fact that only a sample of the potential controls was included. We multiplied the number of person-years at risk of controls by the sampling fraction (226/1,811). Data were managed and analyzed with Epi-Info 6 (Centers of Disease Control and Prevention, Atlanta, GA, USA) and SPSS 15.0 statistical software (SPSS Inc., Chicago, IL, USA).

Results

Between January 1988 and June 2007, 1,811 consecutive POP surgeries were performed in our institution. The incidence of POP reoperation was 5.1 per 1,000 women-years. Between January 1988 and December 2008, 102 women of this cohort were reoperated for subsequent POP, a cumulative incidence of 5.6%. The mean interval between operations was 3.4 years (range, 2 months to 15.8 years) in the case group and the mean duration of follow-up was 11.4 years (range, 1.8 to 22.0 years) in controls. Only two women in the case group and none in the control group was

Table 1 Characteristics of the study population at first POP intervention

	Cases (n=100)	Controls (n=226)	P
Age (year), mean (SD)	58.5 (12.2)	62.3 (13.5)	0.02
Height (cm) mean (SD)	159.7 (6.9)	159.1 (6.4)	0.45
Weight (kg) mean (SD)	66.7 (11.4)	67.0 (11.6)	0.85
BMI (kg/m^2) mean (SD)	26.2 (4.4)	26.4 (4.7)	0.70
Menopause n (%)[a]	65 (65.0)	172 (76.0)	0.14
HT, n (%)[a]	20 (20.0)	44 (19.5)	1.00
Diabetes, n (%)[a]	7 (7.0)	19 (8.4)	0.83
Asthma or COPD, n (%)[a]	1 (1.0)	5 (2.2)	0.67
Smoking>5 cigarettes/day, n (%)[b]	13 (13.0)	27 (11.9)	0.72
Cardio-vascular disease, n (%)	3 (3.0)	18 (8.0)	0.05[b]
Constipation, n (%)[c]	33 (33.0)	57 (25.2)	0.22
Sexual activity, n (%)[c]	67 (67.0)	106 (46.9)	0.001

P values are calculated with the Fisher exact test for proportions and with the t-test for means unless specified

BMI body mass index, *HT* hormonal replacement therapy, *COPD* chronic obstructive pulmonary disease

[a] There was one missing value in the case group

[b] There were three missing values in the case group

[c] There were respectively 10 and 11 missing values in the case group and 30 and 29 in the controls, with similar percentages for the two groups, for constipation and sexual activity

Table 2 Description of preoperative POP at first intervention

	Cases (n=100)	Controls (n=226)
POP Grade 1 and 2	31 (31.0)	81 (35.8)
POP Grade 3 and 4	69 (69.0)	145 (64.2)
Cystocele		
None	3 (3.0)	36 (15.9)
Grade 1 and 2	52 (52.0)	84 (37.2)
Grade 3 and 4	45 (45.0)	106 (46.9)
Uterine prolapse		
None	24 (24.0)	92 (40.7)
Grade 1 and 2	59 (59.0)	89 (39.4)
Grade 3 and 4	17 (17.0)	45 (19.9)
Vaginal vault prolapse		
None	93 (93.0)	209 (92.5)
Grade 1 and 2	3 (3.0)	12 (5.3)
Grade 3 and 4	4 (4.0)	5 (2.2)
Rectocele		
None	31 (31.0)	116 (51.3)
Grade 1 and 2	56 (56.0)	90 (39.8)
Grade 3 and 4	13 (13.0)	20 (8.9)
Enterocele		
None	94 (94.0)	218 (96.5)
Grade 1 and 2	3 (3.0)	5 (2.2)
Grade 3 and 4	3 (3.0)	3 (1.3)

Data are presented as n (%)

Table 3 Description of preoperative POP according to the number of prolapsed vaginal segments (anterior and posterior vaginal wall, superior vagina, and posterior fornix) of any grade at first intervention

Number of vaginal wall segments protruding	Cases (n=100)	Controls (n=226)
One segment	7 (7.0)	72 (31.9)
Two segments	35 (35.0)	78 (34.5)
Three segments	54 (54.0)	73 (32.3)
Four segments	4 (4.0)	3 (1.3)

Data are presented as n (%)

excluded from the analysis because records were not available or risk factors were missing This left 100 cases and 226 controls for the analysis. The number of cases per ongoing year is shown in Fig. 1. Half of the cases were reoperated within 2 years (Fig. 1).

The mean age was different, while the mean body mass index (BMI) was similar between groups (Table 1). The distribution of preoperative POP characteristics at first intervention is described in Table 2. Table 3 describes the distribution of preoperative POP at first intervention according to the number of prolapsed vaginal wall segment of any grade.

In univariable analysis, risk factors included age≤ 70 years (odds ratio (OR) 1.9; 95% confidence interval (CI) 1.1–3.5; P=0.024), sexual activity (OR 2.6; 95% CI 1.5–4.6; P=0.01), and history of surgery for POP and/or urinary incontinence (OR 2.7; 95% CI 1.3–5.5; P=0.007). Multiparity, vaginal deliveries, constipation, pulmonary disease, and previous hysterectomy were not associated with a higher risk of reoperation (Tables 1 and 4). The stage of POP assigned according to the most severe portion of the prolapse did not differ between groups. Preoperative POP≥ stage 3 was present in 69.0% of cases and 64.2% of controls (OR 1.2; 95% CI 0.8–2.1; P=0.45) (Table 2). However, the number of prolapsed vaginal segments of any grade involved in the pelvic floor defect differed between groups, and the presence of POP in more than two vaginal segments in the same patient was a significant risk factor (OR 2.7; 95% CI 1.7–4.4; P<0.001) (Table 3). Regarding the access, most of the patients were operated through a vaginal approach. There was no difference according to the type of surgical approach (vaginal, abdominal, and laparoscopic) (Table 5). The absence of posterior repair at initial surgery increased the risk of reoperation (OR 1.7; 95% CI 1.0–2.8; P=0.04). Concomitant urinary incontinence repair (OR 1.3; 95% CI 0.7–2.1; P=0.39) or hysterectomy (OR 1.2; 95% CI 0.7–2.1; P=0.44) did not increase the risk of reoperation. Vaginal approach was a protective factor, although not statistically significant (OR 0.5; 95% CI 0.3–1.0; P=0.06). The use of mesh was not a protective factor (OR 1.4; 95% CI 0.6–3.1; P=0.51). The weight of the uterus, in case of hysterectomy, and post-operative complications were similar in both groups (Table 5).

In multivariable analysis, when all statistically significant variables were taken into account, age≤70 years was no longer a risk factor. Sexual activity remained a risk factor (adjusted OR 2.0; 95% CI 1.0–3.7; P=0.022) independently of age. The most important risk factors in a multivariable analysis were the presence of POP in more than two vaginal segments (adjusted OR 5.2; 95% CI 2.8–9.7; P<0.001), history of surgery for POP and/or urinary incontinence (adjusted OR 3.02; 95% CI 1.4–6.3; P=0.003), and the absence of posterior repair at initial surgery (OR 2.9; 95 CI 2.8–9.7; P<0.001) (Table 6).

Table 4 Risk factors for POP reoperation: obstetric history and previous pelvic surgery

	Cases (n=100)	Controls (n=226)	Unadjusted OR (95% CI)	P
Parity				
Nulliparous	5 (5.0)	8 (3.5)	Reference	
Multiparous	95 (95.0)	218 (96.5)	0.7 (0.2–2.2)	0.55
Vaginal delivery				
None	5 (5.0)	10 (4.4)	Reference	
One or more	95 (95.0)	216 (95.6)	0.9 (0.3–2.6)	0.78
Cesarean section				
None	96 (96.0)	219 (96.9)	Reference	
One or more	4 (4.0)	7 (3.1)	1.3 (0.4–4.6)	0.74
Previous POP or incontinence surgery				
None	82 (82.0)	209 (92.5)	Reference	
One or more	18 (18.0)	17 (7.5)	2.7 (1.3–5.5)	0.007
Previous hysterectomy[a]	9 (9.0)	34 (15.0)	0.6 (0.2–1.3)	0.16
None	90 (90.0)	192 (85.0)	Reference	

P values are calculated with the Fisher exact test. Data are presented as n (%)

OR odds ratios, *CI* confidence interval, *POP* pelvic organ prolapse

[a] The percentages do not add to 100 because there was one missing value in the case group

Table 5 Risk factors for POP reoperation: primary operation

	Cases (n=100)	Controls (n=226)	Unadjusted OR (CI 95%)	P
Abdominal approach[a]	5 (5.0)	9 (4.0)	1.3 (0.4–3.9)	0.77
Vaginal approach[a]	83 (83.0)	205 (90.7)	0.5 (0.3–1.00)	0.06
Laparoscopic approach[a]	16 (16.0)	23 (10.2)	1.7 (0.9–3.3)	0.14
Use of mesh	10 (10.0)	17 (7.5)	1.4 (0.6–3.1)	0.51
Types of prolapse intervention				
Anterior colporraphy	77 (77.0)	185 (81.9)	0.7 (0.4–1.3)	0.36
Posterior colporraphy	40 (40.0)	119 (52.7)	0.6 (0.4–1.0)	0.04
Vault suspension	13 (13.0)	22 (9.7)	1.4 (0.7–1.9)	0.44
Enterocele repair	4 (4.0)	7 (3.1)	1.3 (0.4–4.6)	0.74
Culdoplasty	17 (17.0)	11 (4.9)	4.0 (1.8–8.9)	0.01
Urinary incontinence repair				
None	66 (66.0)	161 (71.2)	Reference	
Slingplasty	22 (22.0)	49 (21.7)	1.0 (0.6–1.8)	1.0
Colposuspension	12 (12.0)	16 (7.1)	1.8 (0.8–3.9)	0.20
Any	34 (34.0)	65 (28.8)	1.3 (0.7–2.1)	0.39
Associated hysterectomy[b]				
None	29 (29.0)	76 (33.6)	Reference	
Subtotal	2 (2.8)	0	NA	
Total	69 (69.0)	150 (66.4)	1.2 (0.7–2.1)	0.48
Any	71 (71.0)	150 (66.4)	1.2 (0.7–2.1)	0.44
Mean weight of uterus in grams (SD)	87.8 (66.9)	91.7 (160.9)		0.87
Post-operative complications				
None	95 (95.0)	217 (96.0)	Reference	
Fever>38°C	4 (4.0)	7 (3.1)		
Vaginal vault abscess	2 (2.0)	1 (0.4)		
Hematoma	2 (2.0)	3 (1.3)		
Any[c]	5 (5.0)	9 (4.0)	1.3 (0.4–3.9)	0.77

Data are presented as n (%) except for the weight of the uterus. P values are calculated with the Fisher exact test for proportions and with the t-test for means unless specified

[a] The numbers do not add up to 326 because some patients had combined approaches (abdominal and vaginal in nine and laparoscopic and vaginal in six)

[b] One missing information in the control group

[c] The numbers do not add up to 100 because some patients combined fever with hematoma or abscess

Discussion

Our study suggests that the risk of reoperation after POP surgery is relatively low and associated with variables indicating preexisting weakness of pelvic floor tissues. History of surgery for POP and/or urinary incontinence and an increasing number of prolapsed segments of the lower reproductive tract before reconstructive pelvic surgery are the main risk factors for reoperation.

We systematically searched MEDLINE (search terms: "reoperation for surgically treated/managed pelvic organ prolapse, recurrent pelvic organ prolapse, follow-up studies", all languages, from 1966 to 2010) and found few studies reporting the incidence of reoperation for recurrent POP. Most authors measured the combined risk of reoperation for surgically treated prolapse and urinary incontinence, thus overestimating the rate for POP reoperation alone. The risk of reoperation for POP or urinary incontinence of 29.2% frequently quoted as a reference in further studies results to a retrospective cohort study of 384 women [1]. The same cohort was followed prospectively and the cumulative incidence of reoperation for POP and urinary incontinence at 5 and 10 years was 13% and 17%, respectively [10, 14]. The risk of reoperation for POP alone, during a 5-year follow-up, was much lower (1.5%) in another study. The risk was probably underestimated as a low percentage of women (58.8%) agreed to the 5-year follow-up [9]. In a large cohort comprising 2,099 women,

Table 6 Risk factors for prolapse reoperation: multivariable analysis. Odds ratios and 95% confidence intervals were adjusted for the other factors in the model

	Adjusted OR (95% CI)	*P*
Age≤70 years	1.3 (0.6–2.6)	0.49
Sexual activity	2.0 (1.0–3.7)	0.04
Premenopause	1.4 (0.8–2.5)	0.29
Absence of posterior repair	2.9 (1.5–5.5)	0.001
Previous POP and incontinence surgery	3.2 (1.5–7.1)	0.003
POP in more than two vaginal compartments	5.2 (2.8–9.7)	<0.001

P values are calculated with the chi-square test unless specified. Each OR and 95% CI is adjusted for all other covariates listed in this table

the majority of repeat procedures did not involve the same compartment as the initial operation, and the overall cumulative rate of reoperation following surgery for POP was 11.8 at 11 years, which is closer to our cumulative incidence of 5.6% [11]. Similarly, a recent study based on the Western Australian Data Linkage System identified 51,137 women who underwent surgery for POP between 1981 and 2005. Surgery was a first-time procedure in 44,728 women (87.5%); thereby, the remaining 6,409 (12.5%) should be a repeated procedure [3]. The incidence is influenced by access to medical care and financial considerations, rending comparisons between different populations difficult. The difference with higher rates might be partly explained by operations performed outside our university clinic and not included in our cohort, resulting in an underestimation of the real incidence. However, that number is probably low as our clinic is the only public institution in the canton of Geneva. Women followed in public hospitals in Switzerland rarely go to private clinics due to their lack of private health insurance coverage, and Swiss health insurances only exceptionally accept that a patient be operated in another canton or country. Surgically treated prolapse represents the severe end of the spectrum of POP. The anatomical recurrence rate in our cohort is probably higher; but, in most cases, women are asymptomatic and do not require surgery. In a cohort of 389 women who underwent POP vaginal repair, recurrence (stage 2 or more) was observed in 58% of the women after only 1 year [13]. However, only 9.7% had prolapse protruding beyond the hymen. In another study, anatomical failure (vaginal wall prolapse stage 2 or more) was 31.3%, but only 7.4%, which is close to our risk of reoperation of 5.6%, had POP-related symptoms[9].

Little is known about the risk factors that prevent or promote recurrence and consecutive reoperation. Similar to other authors, we found that POP severity, expressed as the most distal preoperative POP stage, did not increase the risk of reoperation, neither did advancing age, BMI, and vaginal deliveries [14, 19]. However, an important finding of our study was that the number of prolapsed vaginal wall segments and the absence of complete repair at initial surgery increased the risk of reoperation. Severity of prolapse should take into account not only the stage of the most distal end but also the number of compartments involved. The absence of posterior repair at initial surgery was associated with an increased risk of reoperation and suggests that it might be worthwhile to repair any posterior vaginal prolapse, even asymptomatic, at the time of primary surgery.

We found that the history of surgery for POP and/or urinary incontinence, before the primary pelvic floor reconstruction, increased the risk of reoperation, suggesting the presence of preexisting weakness of pelvic floor tissues, as shown in previous reports [10]. It is nowadays widely accepted that underlying connective abnormalities, as well as hereditary factors, predispose to POP, and our study shows that they also predispose to POP recurrence [20–23].

Our study suggested that sexual activity significantly increased the risk for pelvic floor reoperation following primary surgical management. Women who are sexually active may actively seek POP surgery, explaining the higher risk of reoperation in this population, independently from age as shown by the multivariable model. There may be an association with other variables influencing the decision to operate, such as the physical condition of the patient. However, we have no other variable to confirm this hypothesis. We may also hypothesize that mechanical factors associated with sexual activity increase the risk of subsequent genital prolapse. We found a similar association in a previous report [24].

During most of the study period (1988–2003), concerning more than 80% of our patients, women were operated with conventional vaginal prolapse surgery, without the use of any prosthetic material. Based on previous reports, we would expect a high rate of reoperation, which is not the case. Our study supports the idea that conventional vaginal surgery is effective to treat POP. The number of abdominal and laparoscopic POP repair was too small in our cohort to draw any conclusion. The use of mesh was not associated with a lower risk of reoperation, but the number, too, was small. The learning curve associated with the use of vaginal or laparoscopic mesh could explain the lack of benefit observed as it was our initial experience. However, the benefit of prosthetic material on the risk of POP recurrence still remains to be proven, as shown in a recent randomized controlled trial [25].

The limitations of our study included those typical of studies relying on information collected in medical records. Despite similar efforts to trace the medical charts, two

medical records were not available in the case group. The unavailable records might have been due to changing names as in Switzerland individuals do not have a unique identifier.

The strength of this study was the availability of a continuously updated computerized register, which allowed us to identify cases and controls in the same large cohort with a long follow-up. Another strength was the preoperative standardized assessment of the genital prolapse according to the Baden–Walker classification. The assessment of prolapse was more precise than in studies using questionnaires.

Based on our data and recent studies, we believe the risk of reoperation for recurrence after POP reconstructive surgery to be between 6% and 12% rather than 30% as previously described. The risk of recurrence being associated with the number of prolapsed vaginal compartments, it might be important to repair all segments at index surgery.

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Conflicts of interest None.

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