

Risk of fistula formation and long-term health effects after a benign hysterectomy complicated by organ injury: A population-based register study

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Funding information

This work was supported by grants from the Center for Clinical Research Dalarna (CKF UU 507631), the Swedish Research Council (project number 2012-00087), and the Uppsala-Örebro Regional Research Council (RFR310821). The funders had no involvement in the collection, analysis, and interpretation of the data or on the decision to submit the article for publication.

Abstract

Introduction: There is a paucity of data on the impact of organ injury on long-term outcomes after a hysterectomy for benign indications. The aim of this study was to investigate fistula formation and patient-reported long-term health outcomes after organ injury at the time of a hysterectomy.

Material and methods: This was a population-based study of 22 538 women undergoing a hysterectomy between 2000 and 2014 in Sweden. Their medical history, characteristics of their surgery, and patient-reported outcomes were retrieved from Swedish national health and quality registers. Predictors for fistula formation were investigated with logistic regression and are presented as odds ratios with a 95% CI.

Results: Fistulas were reported in 7% of women with organ injuries, compared with 0.4% of those without organ injuries (adjusted odds ratio 15.29 [9.81-23.85]). Laparotomy and postoperative infection were associated with postoperative fistulas. Most of the women reported having better health 1 year after the hysterectomy, but 7% of those with organ injuries and 24% of those with fistulas reported deteriorated health, compared with 2% of women without injuries.

Conclusions: Organ injury at the time of hysterectomy is associated with the development of fistulas involving the female genital tract and increases the proportion of women reporting deteriorated health 1 year after surgery.

1 | INTRODUCTION

Although the rate of benign hysterectomies has declined globally over the last few decades,¹⁻³ hysterectomies remain a common major gynecological surgical procedure performed worldwide in women due to symptomatic conditions. In Sweden approximately 8000 hysterectomies are performed annually, according to national inpatient and outpatient registers.⁴ Patient-reported symptoms before a hysterectomy include bleeding disorders, pelvic pain and strain, and prolapse symptoms.^{2,3,5} Rates and indications of hysterectomies differ with the women's age and context. Endometriosis is a common indication at a younger age, leiomyoma at middle age, and uterine prolapse in women older than 55 years.³ Previous reports indicate that most women undergoing

a hysterectomy report improved health and are satisfied with the procedure, but women with preoperative depression or pelvic pain are less satisfied.^{6,7}

Intra-abdominal adhesions contribute to longer operating times, an increased risk of surgical complications such as organ injury, hemorrhage, and conversion from laparoscopic surgery to laparotomy at pelvic surgery.⁸⁻¹⁰ An iatrogenic organ injury may result in prolonged sick leave, re-operation, organ dysfunction, persistent pelvic pain, and fistula formation.¹¹ Pelvic organ fistulas have been reported in one of 788 women following a hysterectomy.¹² Lower urinary tract injury at pelvic surgery is regarded as one of the major predisposing factors for fistula formation,¹³ but the attributable proportion of organ injury has been hard to estimate. In low-income contexts, obstetric injuries are still the most common cause of fistula formation,

either caused by prolonged labor or the complications of a cesarean section.¹⁴

We previously reported that a previous cesarean section, bowel surgery, and endometriosis were the risk factors for organ injury and severe postoperative complications at time of a benign hysterectomy.¹⁵ However, it remains unclear to what extent these bladder, bowel, and ureter lesions contribute to fistula formation and affect women's health in the long term. The aims of this study were to assess the effect of organ injury on fistula formation and describe patient-reported outcomes after a benign hysterectomy complicated by organ injury or fistula formation.

2 | MATERIAL AND METHODS

This is a longitudinal, population-based register study of 25 354 women undergoing benign hysterectomies during 2000–2014 at 46 different gynecological units in Sweden. During this time 1 30 036 hysterectomies were performed in Sweden⁴(Figure 1). The study population and variables in the dataset have been described in a previous publication.¹⁵ Here, a brief summary with complementary information of patient-reported measures is provided. Data were

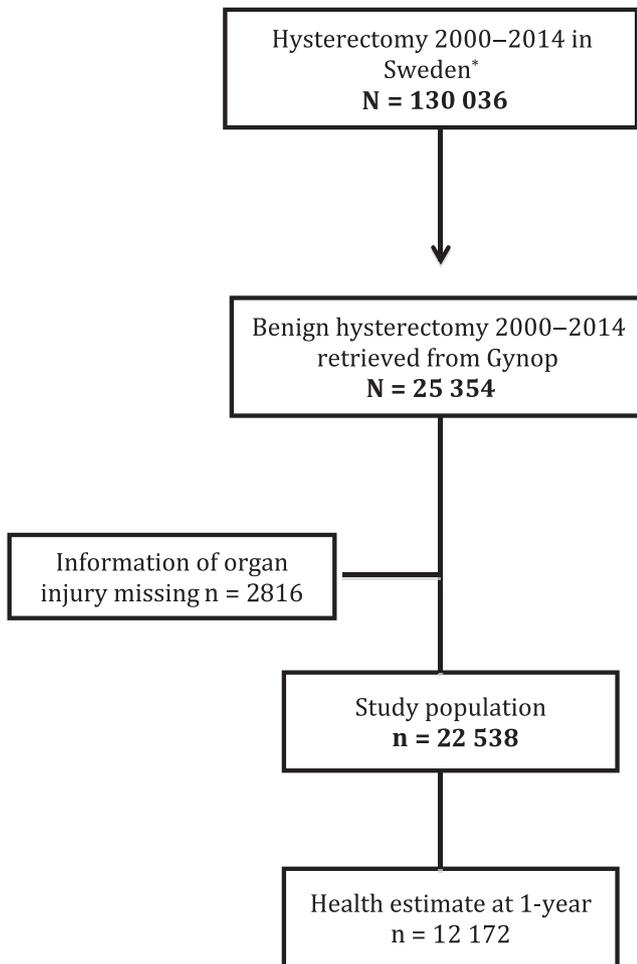


FIGURE 1 Flowchart of study population

Key message

Organ injury at hysterectomy is an important risk factor for the formation of fistulas involving the female genital tract and is associated with a longer recovery time and a poor long-term health estimate.

acquired from a Swedish National Quality Register of Gynecological Surgery (<https://www.gynop.org>) containing prospectively collected data through checkboxes with multiple choices and complementary text.⁵ The Swedish National Quality Register of Gynecological Surgery includes patient questionnaires collected preoperatively at 8 weeks and 1 year after surgery, respectively. The patients' questionnaires have previously been evaluated and are considered reliable and well tolerated by patients.¹⁶ The preoperative measurements included the patients' characteristics; age (years), body mass index (BMI, kg/m²), American Society of Anesthesiologists' class (divided into classes 1–2 and 3–4), and smoking, classified as yes or no, regardless of quantities. Preoperatively, patient-reported pain as the primary or secondary indication of surgery was regarded as the presence of preoperative pelvic pain. Symptoms of urinary retention were dichotomized into yes (1–3 times/month to daily) and no (never or almost never). Route of hysterectomy was categorized as abdominal (including subtotal and total), laparoscopic (total, subtotal, robotic, and vaginal assisted), and vaginal hysterectomy, all with or without concomitant adnexal surgery. Adhesions and endometriosis in the surgical field were reported by the surgeon and defined as yes or no, regardless of density and location. Uterine weight (g), blood loss (mL), blood transfusion (yes/no), > 24 hours' stay at the intensive care unit, and re-operation were all reported by the physician at discharge and length of hospital stay (days) was calculated. At 8 weeks after surgery the presence of postoperative infection and hematoma (deep or superficial and non-specified) were recorded. Information on inflammatory bowel disease and previous abdominal surgery, including cesarean section, was retrieved from national registers; the Swedish Patient Register and the Swedish Medical Birth Register.^{17,18}

2.1 | Exposure

Organ injuries included mild and severe bladder injuries, vascular, bowel, and ureter injuries identified by the surgeon preoperatively or detected during hospital stay, and for ureter injuries also within 8 weeks postoperatively. Data were complete for 22 538 women (89%), who formed the study population (Figure 1). Ureter injury was categorized as early detection (before discharge from the hospital) and late detection (within 8 weeks after surgery).

2.2 | Outcomes

Fistulas (n = 117) involving the female genital tract following a hysterectomy were reported by the physician to the Swedish National

Quality Register of Gynecological Surgery through the 8 week or 1 year questionnaire (n = 76), or were identified in the Swedish Patient Register by diagnosis code N82 (n = 76), according to the 10th revision of the International Classification of Diseases.¹⁹ In total, 35 cases were encountered in both registers.

Patient-reported outcome measures at 8 weeks included time to return to active daily life (days) and ending sick leave (days) after surgery. A general health assessment after 1 year was reported on

a 5-grade scale (much better, better, equal, worse, and much worse) compared with before surgery. This question was gradually introduced into in 2007 and included for all centers in the questionnaire from 2010 and was categorized into better (much better, better), equal and worse (worse, much worse). Deteriorated health corresponded with the answer worse or much worse. Furthermore, pelvic pain, urinary and bowel retention symptoms (never or almost never, 1-3 times/month, 1-3 times/wk-daily) were also assessed after 1 year.

TABLE 1 Characteristics of patients, surgery, and postoperative course according to organ injury (n = 495) at hysterectomy (N = 22 538)

	Missing n	%	Organ injury ^a		No organ injury, n		P-value ^b
			n	%		%	
Patient							
Age mean ± SD	—		47.27 ± 7.57	N/A	47.60 ± 7.75	N/A	0.354
BMI (kg/m ²) mean ± SD	2413	10.7	26.30 ± 4.84	N/A	26.36 ± 4.62	N/A	0.802
ASA class 3-4	420	1.9	13	2.7	269	1.2	0.006
Smoker	1830	9.1	82	18.6	3877	19.1	0.777
Previous CS	—	—	151	30.5	4369	19.8	<0.001
Previous bowel/pelvic surgery	—	—	253	51.1	9954	45.2	0.008
Endometriosis	—	—	55	11.1	1812	8.2	0.021
Inflammatory bowel disease	—	—	9	1.8	214	1.0	0.060
Preoperative pelvic pain	—	—	215	43.4	8724	39.6	0.083
Urinary retention symptoms	5740	25.5	77	20.9	3287	20.0	0.663
Surgery							
Route of hysterectomy	15	0.1					0.003
Abdominal			346	69.9	13 780	62.6	
Laparoscopic			39	7.9	1918	8.7	
Vaginal			110	22.2	6330	28.7	
Adhesions	—	—	184	37.2	4844	22.0	<0.001
Uterine weight (g) mean ± SD	1674	7.4	341 ± 530	N/A	323 ± 370	N/A	0.474
Blood loss (mL) mean ± SD	347	1.5	505 ± 738	N/A	231 ± 279	N/A	<0.001
Blood transfusion	274	1.2	86	18.0	1242	5.7	<0.001
Intensive care unit	1995	8.9	4	0.9	21	0.1	<0.001
Reoperation	13	0.1	151	31.3	387	1.8	<0.001
Time to discharge (d) mean ± SD	82	0.4	3.9 ± 4.0	N/A	2.5 ± 8.9	N/A	<0.001
8 wk							
Postoperative infection	604	2.7	173	39.9	3057	14.2	<0.001
Readmission	1321	5.9	45	10.8	703	3.4	<0.001
1-year							
Nerve pain/lesion	—	—	37	7.5	657	3.0	<0.001
Fistula	—	—	36	7.3	81	0.4	<0.001

BMI, body mass index; ASA, American Society of Anesthesiologists; SD, standard deviation; N/A, not applicable.

^aBladder (n = 275), vascular (n = 38) and bowel injury (n = 86) detected preoperatively or before discharge. Ureter injuries (n = 136) within 8 weeks. More than one organ can be affected.

^bStudent's t test, Pearson's chi-squared test.

2.3 | Statistical analyses

The characteristic of the patients, surgery, and postoperative characteristics according to organ injury are presented as absolute and relative frequencies, means \pm standard deviation and medians with interquartile range, depending on the order and distribution of the variable. Comparisons between groups were assessed by Pearson's chi-squared test, Student's *t* test and the Mann-Whitney *U* test, as applicable. A two-sided *P*-value <0.05 was considered statistically significant. Preoperative and postoperative determinants for fistula formation were investigated, with logistic regressions of potential predictors presented as crude odds ratios with a 95% CI. Multiple logistic regression

was performed to evaluate the impact of organ injury with the following covariates: a history of previous cesarean section, inflammatory bowel disease, presence of endometriosis, route of hysterectomy, with vaginal approach set to the reference group, blood loss ≥ 500 mL at surgery and postoperative infection, and presented as adjusted odds ratios with a 95% CI. A characterization of loss to follow up at the 1-year questionnaire was performed with tests of differences.

2.4 | Ethical approval

The Regional Ethical Board at Uppsala approved the study on 7 December 2014 (No. 2014/488).

Exposure	Pelvic organ fistula (n = 117)			
	n	Rate (%)	Crude OR (95% CI)	aOR (95% CI) ^a
Age (y), mean \pm SD	47.20 \pm 7.59	N/A	0.99 (0.97-1.02)	—
BMI (kg/m ²), mean \pm SD	26.12 \pm 3.68	N/A	0.99 (0.97-1.02)	—
ASA class 3-4	2	0.7	1.36 (0.34-5.53)	—
Smoker	18	0.5	0.91 (0.54-1.51)	—
Previous CS	40	0.9	2.08 (1.42-3.05)	1.33 (0.88-2.02)
Previous bowel surgery	57	0.6	1.15 (0.80-1.65)	—
Endometriosis	17	0.9	1.89 (1.13-3.17)	1.58 (0.92-2.72)
Inflammatory bowel disease	4	1.8	3.59 (1.31-9.18)	2.52 (0.86-7.39)
Organ injury	36	7.3	21.27 (14.21-31.83)	15.29 (9.81-23.85)
Bladder	23	8.4	21.75 (13.55-34.90)	
Ureter	15	11.0	27.06 (15.29-47.88)	
Bowel	2	2.3	4.66 (1.13-19.18)	
Route of hysterectomy				
Abdominal	93	0.7	2.84 (1.64-4.90)	2.20 (1.22-3.96)
Laparoscopic	9	0.5	1.98 (0.87-4.53)	1.75 (0.74-4.14)
Vaginal	15	0.2	1.0 (ref)	1.0 (ref)
Adhesions	45	0.9	2.19 (1.51-3.18)	—
Uterine weight (g), mean \pm SD	323 \pm 299	N/A	1.00 (1.00-1.00)	—
Blood loss ≥ 500 mL	26	0.9	2.06 (1.33-3.19)	1.05 (0.65-1.72)
Postoperative hematoma	8	0.8	1.56 (0.76-3.21)	—
Postoperative infection	55	1.7	5.57 (3.84-8.07)	3.68 (2.48-5.47)

TABLE 2 Risk factors of fistula formation (n = 117) according to characteristics of patients and surgery (N = 21 588)

aOR, adjusted odds ratio; ASA, American Society of Anesthesiologists; BMI, body mass index, CS, cesarean section; N/A, not applicable.

^aExplanatory variables in the model adjusted for cesarean section, endometriosis, inflammatory bowel disease, organ injury, route of hysterectomy, blood loss, and postoperative infection. Adhesions were excluded from the model to avoid any collinearity with organ injury.

TABLE 3 Patient-reported outcomes after hysterectomy according to organ injury

	Organ injury	%	No organ injury	%	P-value ^a
8 weeks					
Time to active daily life (d), median (IQR)	10 (5-15)	N/A	6 (3-10)	N/A	<0.001
Sick leave (d), median (IQR)	36 (29-46)	N/A	31 (25-39)	N/A	<0.001
1 y					
Health assessment					<0.001
Better	214	86	10 877	91	
Equal	16	7	778	7	
Worse	18	7	269	2	
Pelvic pain	79	22	2681	16	0.001
Urinary retention					0.004
Never-almost never	267	80	13 660	86	
1-3 times/month	24	7	703	4	
1-3 times/wk-daily	44	13	1 540	10	
Bowel retention					0.019
Never-almost never	236	71	12 089	76	
1-3 times/month	57	17	1 926	12	
1-3 times/wk-daily	39	12	1 948	12	

Missing values for: active daily life (12%), sick leave (31%), health assessment (46%), pelvic pain (22%), urinary (28%) and bowel retention (28%).

IQR, interquartile range; N/A, not applicable.

^aMann-Whitney U test, Pearson's chi-squared test.

3 | RESULTS

The characteristics of patients, surgery, and postoperative characteristics according to organ injury detected preoperatively and postoperatively are displayed in Table 1. Patients with an organ injury had a medical history of previous cesarean section, bowel/pelvic surgery more often, and the presence of endometriosis or adhesions were recorded more frequently in this group. For the entire study population, preoperatively reported pelvic pain and urinary retention symptoms were common and most hysterectomies were abdominal. Increased blood loss, blood transfusion, admission to an intensive care unit, repeated surgery, postoperative infection, and longer hospital stay were more frequent among women with organ injuries than those with no organ injury. Fistulas involving the female genital tract were reported in 7% of women with an organ injury compared with 0.4% of women without an organ injury. In the 76 of 117 fistulas registered in the Swedish Patient Register the median time to diagnose was 65 days after surgery (interquartile range 30-353). A main risk factor for a fistula was organ injury (adjusted odds ratios 15.29 [9.81-23.85], Table 2). Fistulas were reported in 8.4% of women with a bladder injury compared with 0.4% in those with no organ injury. Stratified by mild or severe bladder injury, there was no difference in the prevalence of fistula formation (8.3% vs 8.4%, $P = 0.982$). Altogether 11% were diagnosed with a fistula following ureter injury. There was no difference in fistula formation if

the ureter injury was reported before discharge or at the 8-week follow-up questionnaire (9% vs 13%, $P = 0.447$). Laparotomy and postoperative infection were associated with postoperative fistulas (Table 2).

Patient-reported outcome measures at 8 weeks and 1 year for women with organ injuries compared with no organ injury preoperatively or postoperatively and for women with fistulas compared with no fistula postoperatively are presented in tables 3 and 4 respectively.

For women with organ injuries and fistulas, it took a longer time to active daily life and ending sick leave at the 8-weeks' questionnaire than those without. Health assessment at 1 year was reported by 54% women in total, but from 2007 the response rate was 66%. Non-responders were slightly younger, were more often smokers, and more often underwent an abdominal hysterectomy, but there was no difference in respect to organ injury or fistulas compared with responders (Supporting Information Table S1). Most women reported better health at 1 year, while 7% of women with organ injuries and 24% of women with fistulas reported deteriorated health, compared with 2% of women without injuries. Postoperative urinary retention symptoms were more common in women with an organ injury and fistula formation than in those without. Women with an organ injury experienced bowel retention symptoms more often than women without an organ injury but there was no difference between women with or without a fistula.

	Fistula		No fistula		P-value ^a
	n	%	n	%	
8 weeks					
Time to active daily life (d), median (IQR)	8 (5-20)	N/A	6 (3-11)	N/A	<0.001
Sick leave (d), median (IQR)	34 (28-54)	N/A	31 (25-40)	N/A	0.002
1-year					
Health estimate					<0.001
Better	34	63	11 057	91	
Equal	7	13	787	7	
Worse	13	24	274	2	
Pelvic pain	23	26	2737	16	0.006
Urinary retention					0.004
Never-almost never	63	74	13 864	86	
1-3 times/month	5	6	722	4	
1-3 times/wk-daily	17	20	1567	10	
Bowel retention					0.518
Never-almost never	61	74	12 264	76	
1-3 times/month	8	10	1975	12	
1-3 times/wk-daily	13	16	1974	12	

Missing values for: active daily life (12%), Sick leave (31%), health assessment (46%), pelvic pain (22%), urinary (28%) and bowel retention (28%).

IQR, interquartile range; N/A, not applicable.

^aMann-Whitney *U* test, Pearson's chi-squared test.

4 | DISCUSSION

Organ injury at a benign hysterectomy was an important risk factor for the formation of fistulas involving the female genital tract and was associated with a longer recovery time and poor health self-assessment following a hysterectomy.

The proportion of fistulas involving the female genital tract following a hysterectomy was 0.5% in this study population, which is higher than the 0.12% reported by Hilton and Cromwell investigating 286 053 benign hysterectomies in respect of fistula formation within 1 year after surgery.¹² In a Swedish cohort, 0.2% women (469 out of 182 641) underwent fistula surgery after a hysterectomy.²⁰ In our cohort, information about fistulas was retrieved from both the Swedish National Quality Register of Gynecological Surgery as well as from the diagnostic Swedish Patient Register, possibly increasing the detection rate. Only 76 of 117 fistulas in the study population were registered in the Swedish Patient Register and if this study had reported only from this national patient register the incidence would have been 0.3%, corresponding with previously published studies. Thus, there may be an underestimation of the number of fistulas after a hysterectomy. Although the median time to diagnose was 65 days after surgery, 41 of 76 fistulas in the Swedish Patient Register were not reported in the National Quality Register, reflecting the risk of missing data in the 1 year follow-up in the Swedish National Quality Register but also indicating a discrepancy between the different

TABLE 4 Patient-reported outcomes after hysterectomy according to fistula formation

registers. In 1998 Härkki-Sirén analyzed 142 urinary tract injuries after hysterectomies. In this population, bladder injuries occurred in 0.08% and most bladder injuries were discovered after fistula formation.¹¹ Having had a previous cesarean section is an important risk factor for bladder injury at hysterectomy, regardless of route,^{9,21,22} and is often considered to heal without complications if appropriately detected. We found that urinary tract injuries, not restricted to ureter injuries but also bladder lesions, were strongly associated with subsequent fistulas. The rate of fistula did not differ if the physician considered the bladder injury mild or severe or if the ureter injury was detected before discharge or within 8 weeks. This stresses the importance of injuries to the urinary tract and their impact on fistula formation regardless of the time of detection and whether the injury affects the bladder or ureters.

The impact of age on fistula formation is varied. Forsgren et al. noted an increased risk of complications when hysterectomies were performed on women who were older, while Hilton and Cromwell found the contrary to be the case. In our study, neither age, BMI, American Society of Anesthesiologists' class nor smoking influenced the risk of fistula formation. In concordance with previous studies, risk factors of a fistula were an abdominal hysterectomy (with vaginal route as reference) and postoperative infection. However, the causative direction of postoperative infection in fistula formation should be interpreted with caution, as undetected or persistent fistulas may lead to infection,¹³ and the association with the abdominal

route may reflect selection bias. The association between a previous cesarean section, endometriosis, and inflammatory bowel disease and fistula formation did not remain after adjusting for organ injury and other predictors.

Our results are in agreement with previous reports on patient-reported outcomes of a hysterectomy, concluding that most women are satisfied following surgery.⁶ Pelvic pain, as the primary indication of hysterectomy, has previously been reported in 7%–10% of hysterectomies,^{2,23} and is associated with dissatisfaction after a hysterectomy.^{6,7} In our study population, the presence of pelvic pain based on self-reported symptoms prior to surgery was reported to a high extent (40%) and did not correlate with deteriorated health postoperatively. Preoperatively, one of five women reported voiding difficulties from 1–3 times/month to daily. At 1 year follow-up, urinary and bowel retention symptoms once a month to daily were more common in women exposed to organ injury but the differences were small and may be confounded by other patient and surgery characteristics. Smorgick et al. investigated the occurrence of urinary retention as a short-term outcome after a laparoscopic hysterectomy and found it was twice as common after robotic surgery than after traditional laparoscopic surgery, whereas a previous cesarean section, endometriosis, and adhesions did not influence the prevalence of urinary retention.²⁴ The impact of fistula formation on women's lower health assessment after 1 year is important and warrants a close follow up of these women. Although a detected fistula is expected to be operated on and healed, thus posing less impact on a health assessment once it has been corrected, our results imply that these women are at much higher risk of a poor health assessment 1 year after primary surgery. This may also be due to other concomitant factors with fistula formation, such as comorbidities.

This study is, to our knowledge, the first longitudinal study giving risk estimates of fistula formation and patient-reported health assessments after a hysterectomy is complicated by an organ injury. Information of fistulas was retrieved from two independent sources, both considered reliable,^{5,16,25} but the discrepancy of case findings indicates a need for a further evaluation of the registers. In the Swedish National Quality Register of Gynecological Surgery there were guidelines to the surgeon on how to describe the nature and degree of complications, but this was not standardized, incurring the possibility of misclassification. Recently the Clavien-Dindo classification²⁶ was incorporated in the register, which potentially reduces the risk of subjective assessment in future studies. Time to diagnosis was not calculated, and definite conclusions about the effect of delayed detection of an organ injury on fistula formation could not be determined, as information of the time at which the organ injury was detected was not available through the Swedish National Quality Register of Gynecological Surgery. Information on whether other types of surgery were performed before the diagnosis of fistulas was not available; however, median time to diagnosis was 65 days after the hysterectomy. Data on patient-reported health assessments after surgery were collected from 2007, yielding a response rate

of two-thirds, which may be considered fair, but selection bias and a varied response rate between hospitals may still be a problem in the generalizability of the results.

5 | CONCLUSION

Organ injury at the time of hysterectomy is associated with development of fistulas involving the female genital tract and increases the proportion of deteriorated health 1 year after surgery. Different locations, degrees, and time to the detection of urinary tract injuries seemed to play a minor role in fistula formation but need to be evaluated further. The discrepancy of case findings in national registers is intriguing and calls for a further audit validation of the registers.

CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

How to cite this article: Hesselman S, Bergman L, Högberg U, Jonsson M. Risk of fistula formation and long-term health effects after a benign hysterectomy complicated by organ injury: A population-based register study. *Acta Obstet Gynecol Scand*. 2018;97:1463–1470. <https://doi.org/10.1111/aogs.13450>