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Effects of hysterectomy on pelvic floor function and sexual function-A prospective cohort study

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Abstract

Introduction: Hysterectomy is one of the most common major surgical procedures in women. The effects of hysterectomy on pelvic floor and sexual function are uncertain. Our objective was to investigate the effects of hysterectomy for benign indications on pelvic floor and sexual function and to compare different modes of surgery. Material and methods: We performed a prospective clinical cohort study. In all, 260 women scheduled for hysterectomy answered validated questionnaires (Pelvic Floor Impact Questionnaire, Pelvic Floor Distress Inventory and Female Sexual Function Index). Participants were followed 6 months and 1 year after surgery. Data were analyzed using nonparametric statistics and mixed effect models.

Results: Women with subtotal hysterectomy, vaginal hysterectomy, laparoscopic assisted vaginal hysterectomy, and previous prolapse/incontinence surgery were excluded from further analysis, leaving the remaining cohort to 242 patients. The response rate at 6 months and 1 year follow-up was 180/242 (74.3%) and 169/242 (69.8%), respectively. There was an improvement of pelvic floor function at both follow-ups; mean score of Pelvic Floor Impact Questionnaire at baseline was 42.5 (51.7), at 6 months 19.9 (42.2) and at 1 year 23.7 (50.3) (p < 0.001). The mean score of Pelvic Floor Distress Inventory at baseline was 69.6 (51.1), at 6 months 49 (43.2) and at 1 year 49 (43.2) (p < 0.001). There was an improvement of sexual function after 6 months (mean score of Female Sexual Function Index at baseline 17.9 [SD 11.7] and at 6 months 21.0 [SD 11.7]) (p < 0.001). There was no difference in pelvic floor or sexual function when comparing surgical techniques.

Conclusions: Robotic assisted laparoscopic hysterectomy, laparoscopic hysterectomy and abdominal hysterectomy improve pelvic floor function to the same extent at 6 months and 1 year after surgery. There was an overall improvement of sexual function 6 months after hysterectomy, but this did not persist after 1 year.

Abbreviations: CI. confidence interval: CRAD-8. Colorectal-Anal Distress Inventory: CRAIO-7. Colorectal-Anal Impact Ouestionnaire: FSFI, Female Sexual Function Index: LAVH. laparoscopic assisted vaginal hysterectomy; OR, odds ratio; PFDI-20, Pelvic Floor Distress Inventory; PFIQ-7, pelvic floor impact questionnaire; POPDI-6, Pelvic Organ Prolapse Distress Inventory; POPIQ-7, Pelvic Organ Prolapse Impact Questionnaire; RTLH, robotic assisted total laparoscopic hysterectomy; SD, standard deviation; TAH, total abdominal hysterectomy; TLH, total laparoscopic hysterectomy; UDI-6, Urinary Distress Inventory; UIQ-7, Urinary Impact Questionnaire; VH, vaginal hysterectomy.

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KEYWORDS

abdominal hysterectomy, female sexual function, laparoscopic hysterectomy, minimally invasive surgery, pelvic floor function, robotic assisted laparoscopic hysterectomy

1 | INTRODUCTION

Since the millennium there has been a shift in surgical technique of hysterectomy worldwide.¹ Developments in surgery have led to more minimally invasive options such as robotic assisted laparoscopic hysterectomy (RTLH) and laparoscopic hysterectomy (TLH), with a declining number of abdominal (TAH) and vaginal hysterectomies (VH) being performed.^{2,3} The prevalence of pelvic floor dysfunction is bothersome among the female population; the rate of one or more pelvic floor disorders was 25.0% in US women.⁴ The effect of hysterectomy on pelvic floor dysfunction has been discussed and whether the mode of hysterectomy affects pelvic floor function is uncertain. Nevertheless, according to several cohort studies, hysterectomy is a risk factor for pelvic organ prolapse and urinary incontinence.⁴⁻⁶

There have been conflicting reports about the impact of hysterectomy on female sexual function, partly due to the use of different parameters and definition of sexual function.⁷ There is at present no consensus how minimally invasive hysterectomy techniques effect female sexual function.⁸ Radosa et al.⁹ compared TLH, VH and subtotal laparoscopic hysterectomy and demonstrated that female sexual function was improved regardless of surgical technique. There are a considerable number of studies suggesting unchanged or even improved sexual function after hysterectomy.^{10,11} The aim of this prospective clinical cohort study is to investigate the effects of hysterectomy for benign indication on pelvic floor function and sexual function, as well as compare certain modes of surgery.

2 | MATERIAL AND METHODS

Patients scheduled for elective hysterectomy for benign indications at the Department of Obstetrics and Gynecology, Danderyd Hospital, Stockholm, Sweden, from January 2016 until September 2018 were asked to participate. Exclusion criteria were inability to speak, understand and write Swedish, pelvic organ prolapse as an indication for surgery, obstetric hysterectomy, and genital tract malignancy. Selection of surgical approach was made according to the preference of the surgeon and patient. During the period January 2016 until September 2018, a total of 417 women went through a hysterectomy at our clinic. Of these, 260 fulfilled the inclusion criteria, agreed to participate, and gave oral and written consent. Participants filled in a basic questionnaire on their height/weight, their obstetric history, family history of prolapse (mother, grandmother or sister) and potential smoking habits. Along with this they filled in three validated questionnaires: Pelvic Floor Impact Questionnaire (PFIQ-7), Pelvic Floor Distress Inventory (PFDI-20) and Female Sexual Function Index (FSFI) before hysterectomy, 6 months and 1 year postoperatively. They were approached by

Key message

The effects of benign hysterectomy on pelvic floor and sexual function were examined in a prospective clinical cohort study. An overall improvement of pelvic floor function was seen at 1 year independent of mode of surgery. Sexual function remained unchanged.

mail and reminded on two occasions. PFIQ-7 is used to assess life impact in women with pelvic floor disorders and consists of questions from the Urinary Impact Questionnaire (UIQ-7), the Pelvic Organ Prolapse Impact Questionnaire (POPIQ-7) and the Colorectal-Anal Impact Questionnaire (CRAIQ-7). PFDI-20 is a symptom inventory and a measure of the degree of bother and distress caused by pelvic floor symptoms. Questions are taken from the Pelvic Organ Prolapse Distress Inventory (POPDI-6), Colorectal-Anal Distress Inventory (CRAD-8) and Urinary Distress Inventory (UDI-6). The PFIQ-7 and PFDI-20 subscales are scored from 0 to 100 with an overall summery score of 0–300, higher scores indicating higher frequency of symptoms.

FSFI is a validated multidimensional self-reporting questionnaire. It contains 19 items evaluating sexual desire, arousal, lubrication, orgasm, satisfaction and pain. Scores are summaries from the six domains after being multiplied by a predefined domain factor. Missing data values are replaced by the average value of questions with non-missing values in the domain. The FSFI question 18 was missing in delivered data. Higher values indicate better sexual function. Sexually active was defined as not reporting zero on any of the FSFI scores at baseline. All questionnaires demonstrated high validity¹² and the Swedish short forms showed acceptable validity and reliability.^{13,14} We registered the following data in a database: surgical parameters, age, parity, vaginal delivery, body mass index, family history of prolapse, smoking habits, menopause status, the use of menopausal hormone therapy, previous prolapse or incontinence surgery and medical history.

Baseline characteristics were described as mean (standard deviation [SD]) and median (range) for continuous variables, absolute and relative frequencies for categorical variables. Results were presented with 95% confidence intervals (CI).

A *p*-value <0.05 was considered significant. Test for difference in baseline characteristics was performed using Kruskal-Wallis test and Chi-square test. For each questionnaire (PFIQ-7, PFDI-20 and FSFI) individual domain scores and full scale (overall) score were derived according to a computational formula. Mixed effect models were fitted to test for changes in questionnaire scores across follow-up. Each model included occasion (baseline, 6 months, 12 months) and operation type (RTLH, TLH, TAH) as fixed effects and a random

intercept for patients. All statistical analyses were performed using R version 3.6.2 (https://www.R-project.org/). A sample size calculation determined that a minimum of 60 patients would be sufficient to determine a 20% postoperative change in symptoms of pelvic function, with α < 0.05 and β = 0.80.

2.1 | Ethics statement

The study was approved by the regional ethics committee (Regionala Etikprovningsnamnden Stockholm), with reference number 2015/131–31 on April 16, 2015.

3 | RESULTS

The original cohort consisted of 260 women. After reading the patients' answers in the basic questionnaires and studying the surgical reports, women who had previous pelvic organ prolapse surgery, previous incontinence surgery or subtotal hysterectomy were excluded. Women who had VH and LAVH were also excluded from the analysis because of the low number during the study period. To optimize the analyses on pelvic floor and sexual function, the cohort was reduced to 242 patients, as shown in Figure 1. Patients were followed with identical guestionnaires at a mean of 7.1 (SD 1.7) months and 13.4 months (SD 1.8) after hysterectomy. Overall response rates were 180/242 (74.3%) and 169/242 (69.8%), respectively. Response rate at 1 year for each mode of hysterectomy was: RTLH 53/73 (72.6%), TLH 51/71 (71.8%) and TAH 65/98 (66.3%). Patient characteristics and descriptive data at baseline are presented in Table 1. The predominant indications for hysterectomy were uterine fibroids (with or without menometrorrhagia) (58.0%), cervical dysplasia (14.6%), endometrial hyperplasia (9.6%) and menometrorrhagia (8.4%). The participants in the TAH cohort had a significantly higher amount of bleeding at surgery (492.9 ml, SD 296.2) and the mean uterus weight was higher (962.4 g, SD 596.2) (p < 0.001). Women in the TLH cohort were more frequently postmenopausal compared with TAH and RTLH (Table 1). Sexually active (n = 162) and sexually inactive (n = 80) women at baseline were compared; the sexually active women were significantly younger (48.4 years, SD 7.6; p < 0.05) and were more often premenopausal (87%; p < 0.05). There were no other significant differences in baseline preoperative characteristics. Basic characteristics of non-responders and responders were compared, and the non-responders had higher mean body mass index (BMI) (26.6 and 25.0, respectively) (p < 0.05) and they were younger at hysterectomy (46.6 and 50.1 years, respectively; p < 0.05).

3.1 | Improvement of pelvic floor function after hysterectomy

There was a significant decrease of pelvic floor symptoms, urinary symptoms and bowel symptoms affecting activities, relationships

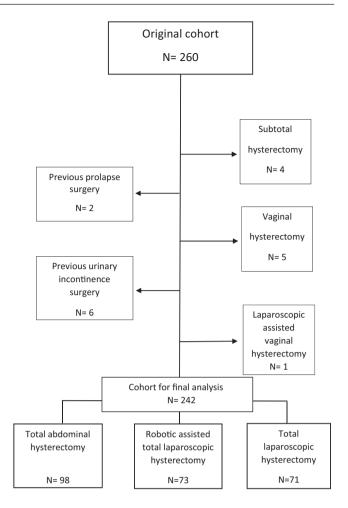


FIGURE 1 Flow chart showing the original cohort of 260 women and the cohort of 242 women remaining for analysis of Pelvic Floor Impact Questionnaire, Pelvic Floor Distress Inventory and Female Sexual Function Index after excluding subtotal hysterectomy, previous incontinence or prolapse surgery, vaginal hysterectomy and laparoscopic assisted vaginal hysterectomy.

and feelings in the study population at the 6-month follow-up as well as at the 1-year follow-up: PFIQ-7 mean score at baseline 42.5 (51.7) to 19.9 (42.2) at 6 months, p < 0.001, and to 23.7 (50.3) at 1 year, p < 0.001 (Figure 2). The improvement was seen in all three domains of PFIQ-7: the UIQ-7 describing symptoms or conditions related to bladder or urinary function (mean score at baseline 16.0 [20.7] to 7.6 [14.5] at 6 months, *p* < 0.001, and to 10.4 [18.9] at 1 year, p < 0.001), the CRAIQ-7 describing symptoms or conditions related to bowel or rectum function (mean score at baseline 11.0 [18.9] to 5.8 [15.9] at 6 months, *p* < 0.001, and to 7.0 [18.1] at 1 year, p < 0.001) and the POPIQ-7 describing conditions related to vaginal or pelvic symptoms (mean score at baseline 16.1 [24.0] to 6.5 [16.6] at 6 months, p < 0.001, and to 6.5 [17.7] at 1 year, p < 0.001) (Figure 2). The degree of bother and distress caused by pelvic floor symptoms significantly decreased in the study population at both follow-ups (mean score PFDI-20 at baseline 69.6 [51.1] to 49 [43.2] at 6 months, p<0.001, and to 51.0 [48.3] at 1 year, p < 0.001) (Figure 2). Over time, patients reported fewer pelvic floor symptoms, such as pressure in the lower abdomen,

TABLE 1 Basic characteristics of study population at baseline by surgical technique

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	All n = 242	Total abdominal hysterectomy (TAH) n = 98 (40%)	Robotic assisted total laparoscopic hysterectomy (RTLH) n = 73 (30%)	Total laparoscopic hysterectomy (TLH) n = 71 (29%)
Mean age at surgery years (SD)	49.9 (9.6)	49.8 (7.9)	48.0 (9.4)	51.9 (11.5)
Mean BMI, kg/m ² (SD)	26.4 (4.9)	26.2 (4.8)	25.5 (4.4)	27.5 (5.6)
Mean vaginal delivery (SD)	1.5 (1.2)	1.5 (1.2)	1.5 (1.2)	1.5 (1.3)
Heredity of prolapse (%) ^a	38 (16.4)	10(11)	17(23.6)	11 (15.9)
Smoking (%)	33 (13.6)	10 (10.2)	11 (15.1)	12 (16.9)
Bleeding at surgery, mL (SD)	238.3 (290.7)	492.9 (296.2)*	56.5(85.7)	75.1 (99.5)
Weight of uterus, g (SD)	513.8 (532.8)	962.4 (596.2)*	243.0 (161.4)	203.6 (147.1)
BSOE (%)	46 (19.0)	14 (14.3)	12 (16.4)	20 (28.2)
Bilateral salpingectomy (%)	180 (74.4)	74 (75.5)	59 (80.8)	47 (66.2)
Postmenopausal (%)	43 (17.8)	14 (14.3)	10 (13.7)	19 (27.1)**
Menopausal hormone therapy (%)	11 (4.5)	5 (5.1)	1 (1.4)	5 (7.0)

Note: BMI = body mass index (= weight²/length).

^aHeredity question asked in questionnaire. BSOE = bilateral salpingo-oophorectomy. Figures are numbers of patients (%). SD = standard deviation. *p <0.001 compared with robotic assisted total laparoscopic hysterectomy (RTLH) and total laparoscopic hysterectomy (TLH).; **p <0.05 compared with robotic assisted total laparoscopic hysterectomy (RTLH) and total laparoscopic hysterectomy (TLH).

heaviness, a bulge falling out, bladder emptying problems and manual defecation (mean score POPDI-6 at baseline 22.8 [18.6] to 13.7 [14.3] at 6 months, *p* < 0.001 and to 13.9 [17.1] at 1 year, p < 0.001). The study participants described less urinary distress, less frequent urination, stress incontinence or urge incontinence, small leakages, bladder emptying difficulties or pain (mean score UDI-6 at baseline 28.2 [22.4] to 21.4 [19.5] at 6 months, *p* < 0.001, and to 21.5 [21.1] at 1 year, p < 0.001). There was a significant difference in symptoms from the bowel at 6 months (CRAD-8 mean score baseline 18.5 [19.1] to 14.7 [16.7], *p* = 0.014) but not after 1 year, 15.6 (17.9), p = 0.154 (Figure 2). Over time there were no significant differences in pelvic floor symptoms between the RTLH cohort, TLH cohort and the TAH cohort (Figure 3). A test for association between test occasion, uterus weight and operation type on different questionnaire scores showed an association between score change and uterus weight (p < 0.05), demonstrating that women with heavier uteruses at the time of surgery experienced a greater reduction in PFIQ-7 and PFDI-20 scores over time. However, there were no differences depending on operation type.

3.2 | Sexual function

The mean score of FSFI at baseline was 17.9 (SD 11.7). More than half of the women reported an FSFI score <26 at all follow-ups (baseline 150/242 [64.4%], 6 months 91/169 [53.8%] and 1 year 96/156 [61.5%]). There was a significant improvement of sexual function in the study population 6 months after hysterectomy (mean score of FSFI 17.9 [SD 11.7] at baseline and 21.0 [SD 11.7]) at 6 months (p < 0.001) (Figure 4). The improvement after 6 months was seen in the following domains of female sexuality: desire, arousal, lubrication, orgasm and satisfaction, but not in the pain domain. At the 1-year follow-up, the improvement was non-significant (mean score 19.1 [SD 11.7]) (Figure 4). A subgroup analysis of participants who were sexually active at the time of hysterectomy (162/242 [66.9%]) was performed. The mean FSFI scores were higher in this group; however, there was a significant decline in sexual function after 1 year: mean FSFI score at baseline 25.2 (SD 6.6), at 6 months 25.3 (SD 9.2) and at 1 year 23.6 (SD 9.1) (p < 0.05) (Figure 4). The decline in sexual function after 1 year was seen in three of the domains of female sexuality; arousal, lubrication and orgasm. A test for association between test occasion, uterus weight and operation type on different FSFI scores showed no significant differences in change of scores based on the operation type or on uterus weight.

4 | DISCUSSION

In this cohort of 242 women there was an overall reduction of urinary, bladder and pelvic floor symptoms after hysterectomy for benign indications at 6 months and 1 year independent of mode of surgery (RTLH, TLH, TAH). The severity of pelvic floor symptoms reported (mean score of PFIQ-7) was reduced by approximately 50% at 6 months and 40% at 1 year. The degree of bother and distress caused by pelvic floor symptoms (mean score of PFDI-20) was reduced by approximately 30% at both follow-ups. The reduction of symptoms was independent of mode of hysterectomy.

There was a low sexual function in our cohort of women. Improvement was seen at 6 months following hysterectomy but it was non-significant after 1 year. When analyzing only the women reporting to be sexually active before hysterectomy, there was a slight decline in sexual function over time. However, the effect of hysterectomy on sexual function must be interpreted with caution

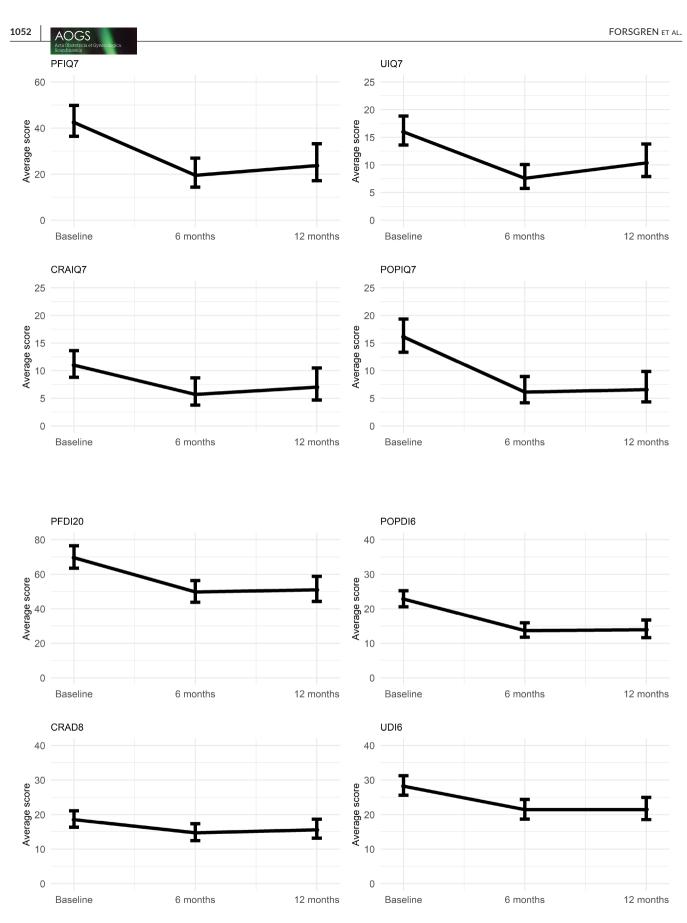
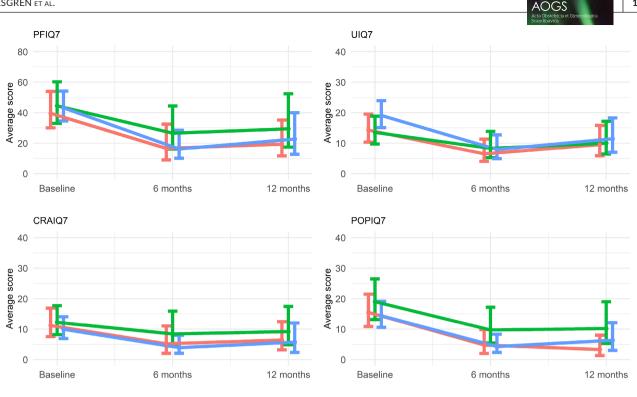
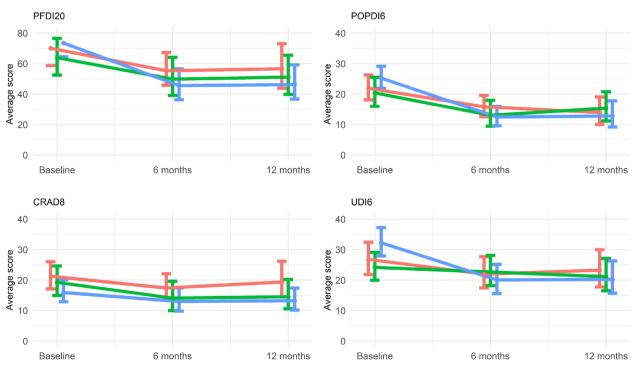


FIGURE 2 Mean score of Pelvic Floor Impact Questionnaire-7 (PFIQ-7), Urinary Impact Questionnaire (UIQ-7), Colorectal-Anal Impact Questionnaire (CRAIQ-7), Pelvic Organ Prolapse Impact Questionnaire (POPIQ-7), Pelvic Floor Distress Inventory (PFDI-20), Pelvic Organ Prolapse Distress Inventory (POPDI-6), Colorectal-Anal Distress Inventory (CRAD-8) and Urinary Distress Inventory (UDI-6) at baseline, 6 months and 12 months follow-up (mean score with 95% confidence interval).







Operation type 🗯 Robotic 🖛 Laparoscopic 🖛 Abdominal

FIGURE 3 Mean score of Pelvic Floor Impact Questionnaire-7 (PFIQ-7), Urinary Impact Questionnaire (UIQ-7), Colorectal-Anal Impact Questionnaire (CRAIQ-7), Pelvic Organ Prolapse Impact Questionnaire (POPIQ-7), Pelvic Floor Distress Inventory (PFDI-20), Pelvic Organ Prolapse Distress Inventory (POPDI-6), Colorectal-Anal Distress Inventory (CRAD-8) and Urinary Distress Inventory (UDI-6) at baseline, 6 months and 12 months follow-up (mean score with 95% confidence interval). Operation type: Robotic = robotic assisted total laparoscopic hysterectomy; Laparoscopic = total laparoscopic hysterectomy; Abdominal = abdominal hysterectomy.

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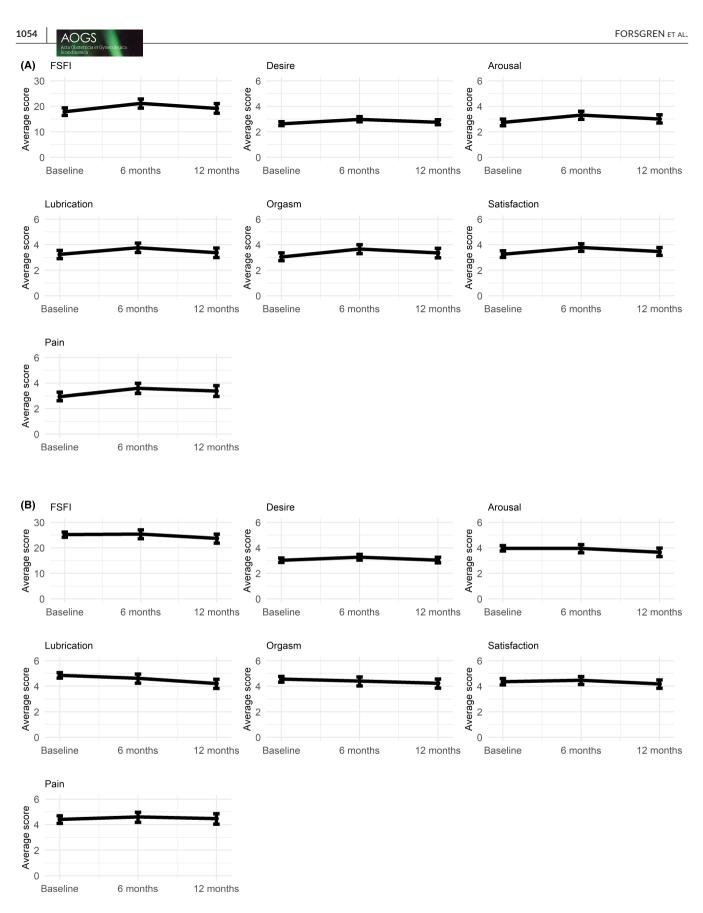


FIGURE 4 (A) Female Sexual Function Index (FSFI) score and domains in all women (n = 242) at baseline (before hysterectomy) at 6 months and 12 months follow-up (median score with 95% confidence interval). (B) Female Sexual Function Index (FSFI) score and domains in sexually active women (n = 162) at baseline (before hysterectomy) at 6 months and 12 months follow-up (median score with 95% confidence interval).

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considering the low sexual activity in the entire cohort and missing values in the follow-up.

In this real-life clinical study, we found an overall improvement of pelvic floor function after hysterectomy. Most clinical studies, both observational and randomized,¹⁵ with short-term or median time follow-up after hysterectomy¹⁶ show a recuperation of pelvic floor symptoms even though long-term follow-up has shown an increased risk for pelvic organ dysfunction.⁴⁻⁶ In a recent study by Karjalainen et al.¹⁷ a reduction of 24 points in the PFDI-20 score or a reduction of 11 points in the POPDI-6 score, can be used to indicate a clinically relevant improvement within a group. In addition, postoperative scores ≤60 for PFDI-20 and ≤17 for POPDI-6 can be used as a cutoff, below which patients are likely to have reached an acceptable symptom state after surgery. We observed a mean reduction of 19.8 points in the PFDI-20 score and a mean reduction of 9.1 points in POPDI-6 scores, 6 months after hysterectomy. The postoperative scores at 6 months were 49.8 (mean) for PFDI-20 and 13.7 (mean) for POPDI-6, clearly falling below Karjalainen's proposed cutoff, indicating a clinically meaningful improvement after surgery and further supporting our overall conclusion that pelvic floor function improves significantly after hysterectomy.

Women who underwent hysterectomy with a heavier uterus had lower PFIQ-7 and PFDI-20 scores over time. This is in accordance with Bohlin et al. who found that remission of urinary incontinence was more common after hysterectomy in women with a large uterus.¹⁸ However, pelvic floor function after hysterectomy is multifactorial, with important factors such as multiple vaginal deliveries and obesity playing substantial roles.¹⁸ Minimally invasive surgery has been proven to be superior in many aspects¹⁹ but the minimally invasive surgical approach in this cohort (RTLH and TLH) showed no difference concerning pelvic floor function. The TLH cohort had a higher proportion of postmenopausal women (27.8%), probably related to the surgeons' choice to perform TLH in women with low uterine weight.

A FSFI mean score of <26 indicates female sexual disorder according to Wiegel et al.²⁰ and more than half of the cohort reported an FSFI score <26 at all follow-ups. There are possible explanations for this. In our cohort, 48 women (18.5%) were classified as postmenopausal and, according to some studies, FSFI might not be an accurate instrument when applied to postmenopausal women.²¹ Women with gynecological disorders such as uterine fibroids causing bleeding, pain and pelvic discomfort are also more likely to suffer from sexual dysfunction.²² There was a slight decline in sexual function over time in the sexually active cohort. Whether this reflects the surgical impact of disrupting blood circulation and nerve supply to the pelvis and thus consequently affecting the lubricationswelling process²³ as well as sensibility, remains to be studied. Ercan et al,²⁴ found that total hysterectomy shortened vaginal length and compromised sexual function regardless of surgical technique. In contrast, De La Cruz et al.²⁵ demonstrated that vaginal length decreased after VH compared with RTLH, but there were no differences between the groups regarding sexual function.

For women to make an informed decision on whether or not to have a hysterectomy and when considering the mode of hysterectomy, information on immediate outcomes of surgery as well as long-term effects are important. In a recent Danish study, the odds ratio for major complications after abdominal hysterectomy was 1.66 (1.52–1.81) compared with minimally invasive hysterectomy²⁶ and VH, RTLH as well as TLH have proven patient benefits over the abdominal approach.¹⁹ Whether the minimally invasive methods of hysterectomy are superior to abdominal hysterectomy considering pelvic floor function and sexual function has not been determined and, in our study, we found no significant differences between the modes of hysterectomy. It is encouraging that pelvic floor function was improved after 1 year and that sexual function was unchanged or only slightly declined over time in the sexually active group. A multicenter randomized controlled study comparing the different routes of hysterectomy with short-term as well as long-term follow-up would be appropriate to follow-up our results.

One strength of the present study is the high response rate among all subjects. The study is in a real-life clinical setting reflecting surgical approach to hysterectomy in an academic affiliated district general hospital and is therefore relevant to patients in many hospitals. Other advantages of the study include the combined use of medical records for general health, obstetric history and surgical parameters, and self-reported validated questionnaires.

A limitation is that our study is restricted to subjective symptom assessment and does not include objective measurements. On the other hand, by definition, clinically important pelvic organ prolapse only occurs when a woman has symptoms associated with changes in pelvic anatomy.²⁷ In this prospective study, patients served as their own controls, and we recognize that a simultaneous non-hysterectomy cohort would have added information. A possible selection bias might be introduced, since the surgical approach for hysterectomy was chosen based on the preference of the surgeon and patient. Additionally, the study was underpowered when considering the low sexual activity in this group of women, missing values in the FSFI follow-up and the low number of VH and LAVH during the study period.

5 | CONCLUSION

Women going through TLH, RTLH or AH experience an overall improvement of pelvic floor function after 6 months and after 1 year independent of surgical mode. There was an improvement of female sexual function at 6 months following hysterectomy, but it was nonsignificant after 1 year. In the group of women sexually active at baseline, there was a minor decline of sexual function. The longevity of these results is uncertain, and our study participants will subsequently be surveyed 3 years after surgery. Findings of the present study may help in guiding and managing patients with benign gynecological disease facing hysterectomy.

AUTHOR CONTRIBUTION

CF and UJ: study design, project development, data collection, data analysis, manuscript writing. MA: data collection, data analysis, manuscript writing.



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CONFLICT OF INTERESTS

Catharina Forsgren and Ulrika Johannesson received a clinical research grant from Intuitive Surgical. Martina Amato reports no conflicts of interest.

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