GYNECOLOGY

Pelvic organ prolapse surgery and quality of life—a nationwide cohort study

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BACKGROUND: Patient satisfaction and health-related quality of life are nowadays considered as the most important outcomes of pelvic organ prolapse treatment, and large, prospective clinical studies reporting the patient-reported surgical outcomes are needed.

OBJECTIVE: To evaluate the effect of female pelvic organ prolapse surgery on health-related quality of life and patient satisfaction and to determine predictors of outcome.

STUDY DESIGN: This prospective nationwide cohort study consisted of 3515 women undergoing surgery for pelvic organ prolapse in 2015. The outcomes were measured by validated health-related quality of life instruments (generic 15D, Pelvic Floor Distress Inventory-20, and Patient Global Impression of Improvement) at 6 months and 2 years postoperatively. The baseline predictors of outcomes were studied with logistic regression analysis.

RESULTS: In total, 2528 (72%) women were eligible for analysis at 6 months and 2351 (67%) at 2 years. The mean change in the total 15D score suggested a clinically important improvement at 6 months but not at 2 years. However, an improvement in sexual activity, discomfort and symptoms, and excretion was observed during both follow-up assessments. Altogether, 77% and 72% of the participants reported a clinically significant improvement in Pelvic Floor Distress Inventory-20 at the 6-month and 2-year follow-ups, respectively. A total of 84% were satisfied with the outcome and 90% reported an improvement in comparison with the preoperative state with Patient Global Impression of Improvement-I. The strongest predictive factors for a favorable outcome were advanced apical prolapse (adjusted odds ratio, 2.06; 95% confidence interval, 1.58—2.70) and vaginal bulge (1.90, 1.30—2.80). Smoking was associated with an unfavorable outcome as measured by Patient Global Index of Improvement-I (1.69, 1.02—2.81).

CONCLUSION: Pelvic organ prolapse surgery improved health-related quality of life in 7 of 10 patients over a 2-year follow-up period, and patient satisfaction was high. Apical prolapse beyond the hymen and vaginal bulge were the most consistent predictors for improvement. Our results suggest that patients should be encouraged to stop smoking to avoid an unfavorable outcome.

Key words: HRQoL, Patient Global Impression of Improvement, patient-reported outcome measure, patient satisfaction, Pelvic Floor Distress Inventory, pelvic organ prolapse, pelvic reconstructive surgery, PFDI-20, PGI-I, POP, quality of life, surgery, urogynecology, 15D

Pelvic organ prolapse (POP) is a common health issue; up to 50% of parous women have some degree of POP on examination.[1] Although most cases of POP are asymptomatic, more than 1 in 10 women require surgical treatment for POP during their lifetime.[2] The most frequently reported symptom of POP is the presence of vaginal bulge that can be seen or felt; urinary symptoms including voiding dysfunction, incontinence, urgency, and frequency and bowel symptoms like outlet obstruction and fecal incontinence are also common.[3,4] These symptoms greatly affect women's body image and may affect personal, social, and sexual activities, which can result in some women stopping these activities.[5,6] Furthermore, approximately one-third of postmenopausal women with symptomatic POP are reported to suffer from symptoms of depression.[7]

The primary goal of POP treatment is to reduce symptoms and improve health-related quality of life (HRQoL).[8] However, outcomes of randomized controlled trials on HRQoL have been inconsistent.[1,9] Most studies have focused on the anatomical outcomes of selected surgical methods in vaginal compartment prolapse.[10,11] Therefore, more evidence on the clinical and real-world impact of POP surgery on HRQoL is needed from representative, prospective studies with validated instruments.

We explored the effectiveness of POP surgery in terms of HRQoL in a nationwide prospective cohort study with validated HRQoL instruments 6 months and 2 years after surgery. Second, we evaluated patient satisfaction and predictive factors for both favorable and unfavorable outcomes of surgery.

Materials and Methods

Study design

This national, prospective multicenter longitudinal cohort study was organized and funded by the Finnish Society for Gynecological Surgery. All Finnish hospitals performing POP surgery were invited to join the study and, altogether, 41 of 45 hospitals participated. The inclusion criteria were age >18 years and the ability to communicate in written and oral Finnish or Swedish. The study population (n=3515 patients, 3535 operations) covered 83% of all women operated on for POP in 2015 in Finland. Altogether, 81% of the patients were treated by native tissue repair, 12% by transvaginal mesh, and 7% by abdominal mesh (sacrocolpopexy), of which 91% were laparoscopic. The surgical

Cite this article as: Mattsson NK, Karjalainen P, Tolppanen A-M. Pelvic organ prolapse surgery and quality of life—a nationwide cohort study. Am J Obstet Gynecol 2020

0002-9378/$36.00

https://doi.org/10.1016/j.ajog.2019.11.1285

AJOG at a Glance

Why was this study conducted?

The effect of pelvic organ prolapse surgery on the quality of life remains unclear. The predictive factors accounting for the differences in the changes in the health status are not well understood.

Key findings

The generic health-related quality of life among women with prolapse was worse than that of the age-standardized population; it improved after surgery. During the 2-year follow-up, 90% patients perceived their condition to be improved and 72% reported significant improvement in condition-specific quality of life. Apical prolapse beyond the hymen and vaginal bulge were the most consistent improvement predictors. Smoking was associated with unfavorable surgery outcomes.

What does this add to what is known?

Surgical treatment for pelvic organ prolapse improves health-related quality of life; patient satisfaction after surgery is high.

method was determined by the individual surgeon's preference based on clinical judgment. The study protocol, methods of surgery, and patient characteristics have been described previously.[12]

Ethical approval

The Research Ethics Committee of the Northern Savo Hospital District approved the study on May 20, 2014 (reference number: 5//2014). The study protocol was approved by the Finnish Ministry of Social Affairs and Health and institutional approval of each participating hospital. It was also included in the ClinicalTrials.gov protocol registration system (NCT02716506). The ethical standards for human experimentation established by the Declaration of Helsinki of 1964, revised in 2013, were followed.[13] Written informed consent was obtained from each patient.

Evaluation of HRQoL

The preoperative questionnaires were administered in electronic or printed form. We asked the patients to assess their worst pelvic distress symptom (awareness of a bulge, urinary or defecatory symptoms, pain, or other symptoms). The severity of symptoms was evaluated by a disease-specific Pelvic Floor Distress Inventory questionnaire (PFDI-20), which has been validated in several languages including Finnish.[14] PFDI-20 includes 6 questions about the inconvenience of the prolapse (Pelvic Organ Prolapse Distress Inventory, POPDI-6), 8 questions regarding difficulties in defecation (Colorectal-Anal Distress Inventory, CRADI-8), and 6 questions regarding difficulties in urination (Urinary Distress Inventory, UDI-6).[1] Each subscale ranged from 0 to 100, and the maximum total score is 300; greater scores are indicative of more bothersome symptoms. We evaluated the generic HRQoL using the validated 15-dimensional instrument (15D), which covers social, physical, and emotional health.[15] The health status description of this instrument includes the following 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech (communication), excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity. The respondents have 5 levels to choose in each dimension that describe best her status of health at present. The index score ranged from 0 to 1 (1=healthy, 0=death) and is calculated from the health status descriptive system using a set of population-based preference or utility weights. The 15D instrument has been shown to be valid for assessing patients who underwent pelvic reconstructive surgery.[16]

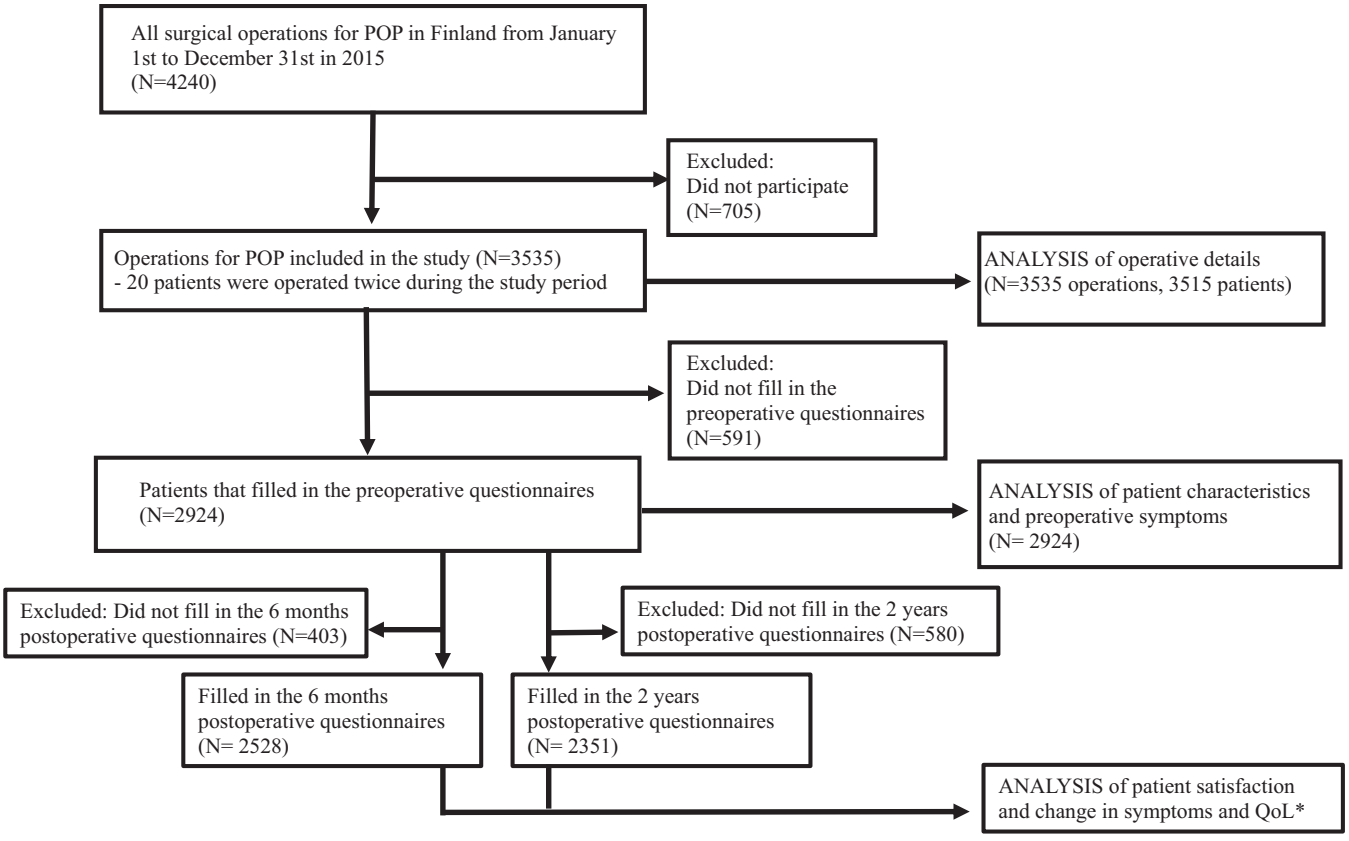
Patient follow-up

The 2931 patients who answered the preoperative questionnaire received a follow-up questionnaire at 6 months and 2 years after the primary operation. Changes in the scores were calculated for all those who answered the postoperative questionnaire at either 6 months (n=2528) or 2 years (n=2351). A threshold value for clinically important improvement in the PFDI-20 total score was set at a decrease of at least 23 points.[17] For the 15D total score, 0.035 indicated much better and 0.015 for slightly better health state.[18] These threshold values apply to the change or difference in the total 15D score only, not to changes in the dimension level values. In addition, we administered a patient global impression of improvement (PGI-I), a single-item question that asks persons to rate their improvement after treatment on a 7-point Likert scale. PGI-I is a validated instrument for assessing the outcome of surgery in several surgical fields, including incontinence surgery and prolapse surgery.[19] Patient satisfaction was assessed on a 7-point scale (highly satisfied — satisfied — fairly satisfied — not satisfied nor unsatisfied — fairly unsatisfied — unsatisfied — very unsatisfied). We asked patients whether they would recommend the operation to a close friend suffering from POP symptoms and to report any complications or surgical treatments after the primary operation.

Statistical analysis

Patient characteristics and surgical details were analyzed in the whole study population, including between those who responded to the 2-year follow-up and those who dropped out. The statistical significance was set at $P<.05$. The differences in categorical variables between the respondents and drop-outs were tested with the χ^2 test. Q-Q-plots were used to assess the distribution of continuous variables, and the Levene test was used to assess the equality of variances in the different groups (respondents and non-respondents). For variables with a skewed distribution, the Kruskal—Wallis test was used. A paired sample t test was used to test the statistical significance of differences in the means of outcome variables at

FIGURE 1
Flow diagram of study enrollment and analysis of the study participants



*Analysis of change ofPFDI-20 scores was performed for 2522 patients at six months and 2337 at two years after the operation and of 15D index 2440 at six months and 2275 patients at two years.

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different points of time (eg, 6-month and baseline values). Statistical significance of differences in the means of the 15D score and dimension level values between the study cohort and an age-standardized sample of the Finnish general female population was tested with an independent samples *t* test. The population data came from the National Health 2011 Health Examination Survey.[20]

We used binary logistic regression to identify the predictors for favorable and unfavorable outcome of surgery. A favorable outcome of surgery at 2 years after the primary operation was defined separately for the different instruments as follows: PFDI-20, total score diminished more than 45 points compared with baseline; PGI-I, patients considered their condition to be much better or very much better than before the operation (PGI-I scale 1 or 2); 15D, total 15D score improved by 0.035 or more compared to baseline. Correspondingly, we defined an unfavorable outcome as no clinical improvement or worse situation than before the operation: PFDI-20, total symptom score diminished less than 23 points; PGI-I, patients considered their condition to be same or worse than before the operation (PGI-I scale 4−7); 15D, the change in the total 15D score was ˂0.015 compared with baseline. These threshold scores were based on previous studies defining the minimal important change of QoL instruments.[8,17,18]

We adjusted the results for age, body mass index, smoking, parity, sexual activity, degree of prolapse, and type of hospital. There were no indications for collinearity between the factors included in the model (all correlation coefficients <0.4). All statistical analyses were performed with SPSS 25.0 (IBM Corp, Armonk, NY).

Results

Patient characteristics

The study flow is shown in Figure 1 and patient characteristics in Appendix 1. The patients who did not return the questionnaire were younger than those who participated in the 2-year follow-up (mean age: 63.3 vs 64.4 years, *P*=.004). Those who were treated with mesh surgery were more likely to return the follow-up questionnaire than those who underwent native tissue repair (73.6% in the transvaginal mesh and 73.0% in the abdominal mesh group vs 65.4% in the native tissue repair group, *P*<.001). Smoking was less common

TABLE 1
Symptom scores from the PFDI-20 at baseline and at the 6-month and 2-year follow-up

	Score	Change of score from baseline	
PFDI scale	Mean (95% CI)	Mean (95% CI)	%
POPDI-6			
Baseline	40.8 (40.0–41.6)		
6 mo	10.9 (10.2–11.5)	−29.6 (28.7–30.4)	−72.5
2 y	13.2 (12.5–13.9)	−27.6 (26.7–28.5)	−67.6
UDI-6			
Baseline	32.4 (31.5–33.3)		
6 mo	16.7 (15.9–17.4)	−15.4 (14.6–16.1)	−47.5
2 y	18.6 (17.8–19.4)	−13.8 (12.9–14.7)	−42.6
CRADI-8			
Baseline	26.0 (25.1–26.8)		
6 mo	15.2 (14.5–15.8)	−11.0 (10.3–11.6)	−42.3
2 y	17.0 (16.3–17.8)	−8.9 (8.2–9.7)	−34.2
Total			
Baseline	99.2 (97.1–101.3)		
6 mo	42.7 (41.0–44.4)	−55.5 (53.7–57.3)	−55.9
2 y	48.8 (46.9–50.7)	−50.4 (48.4–52.4)	−50.8

CI, confidence interval; *CRADI-8*, Colorectal-Anal Distress Inventory with 8 questions concerning difficulties of defecation; *PFDI-20*, Pelvic Floor Distress Inventory; *POPDI-6*, Pelvic Organ Prolapse Distress Inventory with 6 questions about the inconvenience of the prolapse; *UDI-6*, Urinary Distress Inventory with 6 questions about difficulties in urination.

Greater scores indicate greater symptom distress.

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among the respondents (7.9% among respondents vs 11.9% among nonrespondents, $P=.001$). There was no difference in the symptom scores or generic HRQoL between the respondents and nonrespondents.

During the 2-year follow-up, 165 of 2351 patients (7.0%) reported that they underwent repeated surgery for recurrent POP. Data on whether recurrence occurred in the same or different vaginal compartment as the previous correction or on the use of conservative management for recurrent prolapse were not available. Awareness of a bulge was reported at baseline by 2574 of 2774 (93%) patients and assessment of the worst symptom was as follows: awareness of a bulge (1083; 63%), urinary symptoms (468; 16%), defecatory symptoms (297; 10%), feeling of pressure (200; 7%), and pelvic pain (60; 2%).

PFDI-20

The PFDI-20 scores are shown in Table 1. A significant reduction in the total mean PFDI-20 scores was observed at the 6-month follow-up and the difference remained at the 2-year follow-up. At 2 years, 433 of 2300 (18.8%) patients reported a bothersome bulge symptom. A total of 1756 (76.3%) patients that answered the 2-year questionnaire met the criteria of having no symptomatic bulge and no reoperation for prolapse.

Generic HRQoL

Changes in generic HRQoL are shown in Figure 2. The baseline 15D score of the patients was significantly lower than that of the age-standardized female population (mean [standard deviation] 0.889 [0.082] vs 0.904 [0.030], $P<.001$). The difference was also marginally clinically important. At 6 months, a clinical improvement in the 15D score was observed (+0.019, 95% confidence interval [CI], 0.017−0.012), resulting in a mean score of 0.908 (95% CI, 0.905−0.912). At the 2-year follow-up, the total score had decreased close to baseline level (mean 0.898, 95% CI, 0.894−0.902). A marked improvement was observed throughout the study period in sexual activity, discomfort and symptoms, and excretion. There was no difference in the mean change in symptom scores or generic HRQoL scores between those 165 women who were reoperated for recurrent prolapse during the 2-year follow-up period compared with the women who did not undergo repeated surgery (mean for PFDI-20 −45.39 vs −49.72, $P=.255$ and for 15D +0.0112 vs +0.0065, $P=.362$).

Patient global impression of improvement

Response to the surgical treatment measured by the PGI-I is shown in Figure 3. At 2 years, 90.1% of the patients considered their condition better and 4.8% considered it worse than before the operation. Altogether, 1935 (84.4%) patients answered that they were satisfied with the result of the operation at 2 years. The most common reason for dissatisfaction was the recurrence of prolapse (n=227) and 40 patients were dissatisfied because of a complication. Those who were reoperated during the 2-year follow-up period reported significantly worse outcome in PGI-I, but still 80.0% considered their condition to be better than that before the primary operation (vs 90.7% among those who were not reoperated, $P<.001$). At the 2-year follow-up, 2127 (93.8%) of the patients recommended the operation to a close friend experiencing POP.

Predictive factors for surgical outcome

The predictive factors for a favorable surgical outcome are shown in Table 2. Apical prolapse beyond the hymen was the most consistent predictor for a favorable outcome, measured by all 3 instruments, with risk ratios (RRs) ranging from 1.27 to 2.06. The same factors that predicted a favorable

FIGURE 2
Generic HRQoL measured using the 15D

Measurements were at baseline, 6 months, and 2 years after the operation. After each dimension, the changes in the 6-month- and 2-year-follow-up are listed in parentheses.

15D, 15-dimensional generic quality of life instrument; *HRQoL*, health-related quality of life

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outcome of surgery, especially advanced apical prolapse, had inverse associations with an unfavorable outcome of surgery (RR, 0.48−0.78) (Appendix 2). Sexual activity was also a preventive factor of an unfavorable outcome of surgery as evaluated by the 15D (RR, 0.70; 95% CI, 0.57−0.85, $P<.001$). The need of reoperation for recurrent prolapse during the follow-up period did not affect the favorable outcome, as measured by PFDI-20 and 15D. The retrospective assessment using PGI-I showed that the reoperation rate during the 2-year follow-up period was a predictive factor for unfavorable outcomes. Reoperation also doubled the risk of unfavorable outcomes, as measured by PFDI-20. Current smoking status was associated with an unfavorable outcome as evaluated by PGI-I (RR, 1.69; 95% CI, 1.02−2.81, $P=.042$).

Comment

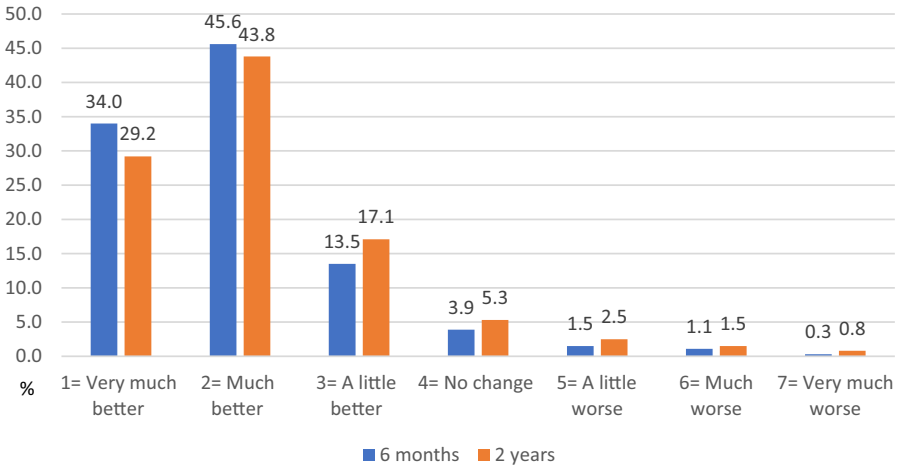
Principal findings

This large nationwide cohort study provides evidence that the surgical treatment of POP effectively improves the associated symptoms and HRQoL. At 2 years after the operation, 90.0% of patients perceived their condition to be improved. Altogether, 72% of patients reported a clinically significant improvement in condition-specific QoL compared with the preoperative situation. Consequently, the patient satisfaction was high.

Results of the study in the context of other observations

Surgical intervention of prolapse can improve the overall QoL in women with POP according to a systematic review.[21] In this review of 5 randomized controlled trials (RCTs), the mean change in the PFDI-20 score for surgical treatment was 74.03 (66.3−81.6). Due to different methods and outcome-measure reporting, comparing the results between this study and the RCT results is challenging, as these

FIGURE 3
PGI-I at 6 months and 2 years after the operation



PGI-I, Patient Global Impression of Improvement.

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randomized studies have evaluated the outcomes of a selected vaginal compartment repair with selected surgical methods.[11,21,22] Furthermore, as RCTs are designed to evaluate the efficacy of an intervention, they have lower heterogeneity, and due to exclusion and inclusion criteria (such as certain degree of prolapse in a specific compartment), the patients often have greater potential for improvement than in a more heterogeneous, real-world sample; therefore, the benefits observed in RCTs often are diluted. In reality, prolapse often involves multiple vaginal compartments and the surgical method is chosen based on clinical judgment. In our study, 46% of operations covered more than 1 vaginal compartment. This was also observed in a recent retrospective cohort study of nearly 100,000 women, in which 56% of women underwent multicompartment repairs.[23] The improvement in the PFDI-20 in our study was smaller than that reported in RCTs (55.5 at 6 months and 50.4 at 2 years after the operation). However, our results are in line with a cohort study of patients with POP undergoing apical mesh surgery with a 5-year follow-up,[24] where the mean decrease in the PFDI-20 score was 56.9 and 78.8% of participants achieved a minimally important change, compared with 72.2% observed in our study. Still, when comparing the study results, it is important to acknowledge that certain surgical methods have their own characteristics.

Our study also shows that POP reduces generic HRQoL. The average 15D score at baseline, as well as its changes over the follow-up period, are comparable with a previous Nordic study on apical prolapse mesh surgery.[16] Similar to previous studies, we showed a marked improvement in prolapse-related 15D dimensions (sexual activity, excretion, and discomfort and symptoms) at 6 months. These improvements were sustained during the 2-year follow-up. In addition, we found that sexually active women were less likely to have an unfavorable outcome of surgery as evaluated by the 15D. This is in line with a previous study showing that surgical treatment improves QoL, sexual function, and body image among women suffering from POP.[25]

Consistent with improvements in these patient-reported instruments, the patient satisfaction was high: 84.4% were satisfied with surgery and 93.8% would recommend the treatment to a close friend. In a previous prospective POP database study, 72.5% were satisfied with surgery and 89.7% would recommend the treatment to a friend.[26] However, in that study, 1 in 4 women requested additional therapy in the first year after POP repair and 8.2% were treated surgically for recurrent POP or incontinence. In the present study, the most frequent cause for dissatisfaction was recurrence of the prolapse and pelvic floor symptoms. In randomized studies, mesh augmentation has shown to decrease the probability of a recurrent prolapse but is associated with greater complication and reoperation rates.[11,27] In the present study, women undergoing transvaginal mesh surgery were more likely to have a favorable outcome, as measured by PGI-I. However, before drawing conclusions on the surgery methods, it is important to acknowledge that unmeasured confounding factors between surgical groups may remain despite adjustments, and the recurrence of prolapse and mesh associated complications may occur years after the surgery.[11]

The strongest predictive factors for a favorable outcome of surgery were advanced apical prolapse beyond the hymen and vaginal bulge. We found that smoking was associated with an increased the risk of unfavorable outcomes of surgery, as measured by PGI-I. In contrast, no association between smoking and increased symptoms measured by PFDI-20 was found. This may be partly explained by other health-related disadvantages of smoking. However, smoking decreases blood flow and wound healing and thus may hinder recovery from the surgery, which has been shown previously in plastic reconstructive surgery.[28] Smoking also has been shown to be a significant risk factor for mesh erosion in POP surgery.[29] These observations support the previous recommendations that when planning surgical treatment, smoking cessation should be encouraged.[28]

Strengths and limitations

To our knowledge, this is the largest prospective cohort study of prolapse surgery and QoL that has been published. The strength of this study is that we evaluated the outcome of surgery using several validated patient-reported

TABLE 2
Associations of patient characteristics and favorable surgery outcome[a] measured with the PFDI-20, PGI-I, and 15D

Characteristic	PFDI-20 aOR[b] (95% CI)	PGI-I aOR (95% CI)	15D aOR (95% CI)
Age (per year)	1.00 (0.99–1.01)	1.00 (0.98–1.01)	0.98 (0.97–1.00)
BMI (per 1 kg/m^2)	1.02 (1.00–1.04)	0.98 (0.96–1.01)	0.99 (0.97–1.01)
Parity (vs nulliparous)	1.04 (0.98–1.11)	1.06 (0.98–1.14)	1.05 (0.98–1.12)
Current smoking (vs nonsmokers)	0.92 (0.66–1.28)	0.71 (0.49–1.01)	1.15 (0.81–1.63)
Sexual activity (vs sexual inactive)	1.08 (0.89–1.32)	1.17 0.94–1.47)	1.15 (0.81–1.63)
Previous POP surgery (vs no previous surgery)			
Same compartment	0.93 (0.66–1.29)	0.74 (0.52–1.07)	0.97 (0.68–1.41)
Different compartment	1.31 (1.04–1.66)	1.10 (0.84–1.44)	0.85 (0.67–1.09)
Degree of prolapse (vs prolapse in hymen or above it)			
Anterior prolapse beyond hymen	0.95 (0.78–1.17)	1.33 (1.08–1.64)	1.19 (0.99–1.43)
Posterior prolapse beyond hymen	1.09 (0.88–1.36)	1.01 (0.72–1.42)	1.06 (0.78–1.45)
Apical prolapse beyond hymen	1.71 (1.38–2.12)	2.06 (1.58–2.70)	1.27 (1.01–1.59)
Any compartment beyond hymen	1.18 (0.95–1.48)	1.56 (1.23–1.97)	1.00 (0.79–1.28)
Bothersome bulge[c] (vs no bothersome bulge feeling)	2.04 (1.39–3.01)	1.90 (1.30–2.80)	1.19 (0.78–1.81)
Method of surgery			
Native tissue repair	1.00 reference	1.00 reference	1.00 reference
Transvaginal mesh	1.31 (1.00–1.71)	1.54 (1.11–2.15)	0.95 (0.71–1.29)
Abdominal mesh (vs native tissue repair)	1.36 (0.98–1.88)	1.19 (0.81–1.74)	1.02 (0.71–1.45)
Reoperation (vs no reoperation during follow-up)	0.85 (0.60–1.22)	0.46 (0.32–0.67)	1.14 (0.78–1.67)
Hospital type			
Tertiary	1.00 reference	1.00 reference	1.00 reference
Secondary	0.96 (0.78–1.18)	1.51 (0.91–1.45)	0.96 (0.76–1.20)
Primary	1.02 (0.80–1.30)	1.30 (0.98–1.72)	0.93 (0.71–1.21)
Private	0.78 (0.34–1.82)	1.55 (0.56–4.27)	0.61 (0.22–1.67)

15D, 15-dimensional generic quality of life instrument; *aOR*, adjusted odds ratio; *BMI*, body mass index; *CI*, confidence interval; *PFDI-20*, Pelvic Floor Distress Inventory-20; *PGI-I*, Patient Global Impression of Improvement; *POP*, pelvic organ prolapse.

[a] Definition of favorable outcome: PFDI-20: Total PFDI-20 scores diminished more than 45 points. n=1164 (49.8%). PGI-I: Patients felt their condition to be much improved or very much more improved than before the operation (PGI-I index 1 or 2). n=1693 (73.0%). 15D: Total 15D score improved 0.035 or more. n= 697 (30.6%); [b] aOR adjusted with age, BMI, parity, smoking, sexual activity, degree of prolapse, method of surgery, and hospital type; [c] Definition of bothersome bulge: answer "yes, bothers somewhat/moderately/quite a bit" for PFDI-20 question number 3 ("usually have a bulge or something falling out that you can see or feel in your vaginal area?").

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instruments in addition to patient satisfaction. To improve the generalizability of our results, we included all surgical pelvic reconstructive surgery methods in all vaginal compartments. There were large differences in the surgical approaches for both native tissue and mesh augmentation surgeries. This may be considered a limitation; however, it does reflect the real-life clinical setting. Furthermore, anatomical success rates were not assessed. We do not consider this as a major limitation because the absence of vaginal bulge symptoms postoperatively significantly correlate with the patient's assessment of overall improvement, whereas anatomical success alone does not.[8] A limitation regarding the assessment of cure after prolapse surgery was that we did not ask the patients whether they had undergone any conservative treatment, such as pessaries or physiotherapy, after the surgery. In future follow-up studies, we plan to include this information. Retreated women were included in the original analyses, as we wanted to describe the effectiveness of POP surgery among all women undergoing surgery, including those who require retreatment to provide more realistic information on the effect of POP surgery on the HRQoL. Despite the need for reoperation, these women also reported significant improvement in the HRQoL measures. The participation rate was high, but as often happens in cohort studies, the loss to follow-up may not be entirely random. However, the baseline characteristics of the respondents at 2 years was a good representation of the whole study population. So far, our study only

includes outcomes up to 2 years after surgery, but follow-up is currently ongoing.

Conclusion and clinical implications

In conclusion, our results show that surgical treatment of POP effectively improves HRQoL, resulting in high patient satisfaction. Our large cohort with a high response rate offers a holistic picture of one nation's practice and patient-reported outcomes of POP surgery. These results could be used in patient counseling on whether to undergo surgical treatment for POP. ■

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Received Sept. 4, 2019; revised Nov. 26, 2019; accepted Nov. 27, 2019.

H.S. is the developer of the 15D and obtains royalties from its electronic versions. The other authors report no conflict of interest.

The study was funded by Finnish Society for Gynecological Surgery and supported by grants from the Emil Aaltonen's foundation, the Finnish Cultural Foundation, Häme Regional Fund and the Ministry of Health and Social Welfare in Finland via Medical Research Funds of Kanta-Häme Central Hospital.

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SUPPLEMENTAL TABLE 1

Patient characteristics at baseline: Comparison of baseline characteristics made between respondents and nonrespondents for 2-year follow-up

Patient baseline characteristic	All patients	Data available, n (%)	Patients that answered the 2-year follow-up	Data available, n (%)	*P* value[a]
Age at operation, y, mean±SD	64.0±10.7	3512 (100)	64.4±10.1	2350 (66.9)	<.001
BMI, kg/m^2, mean±SD	26.9±4.1	2825 (80.4)	26.8±4.0	2281 (64.9)	.186
Current smokers, n (%)	252 (8.7)	2913 (82.9)	184 (7.9)	2342 (66.6)	.001
Parity, mean±SD	2.55±1.4	2924 (83.2)	2.58±0.1	2310 (65.7)	.227
Sexually active, n (%)	1054 (39.1)	2698 (76.7)	866 (39.7)	2179 (62.0)	.072
Previous POP surgery, n (%)	872 (24.8)		603 (25.6)		.185
Same compartment n, (%)	604 (17.2)		423 (18.0)		
Different compartment, n (%)	268 (7.6)		180 (7.7)		
Prolapse beyond the hymen					
Anterior vaginal wall, (POPQ Aa or Ba >0), n (%)	1731 (50.6)	3420 (97.3)	1143 (50.2)	2277 (64.8)	.616
Posterior vaginal wall, (POPQ Ap or Bp >0), n (%)	985 (28.1)	3409 (97.0)	636 (28.1)	2262 (64.4)	.106
Apex of the vagina, (POPQ C>0), n (%)	843 (25.9)	3374 (96.0)	545 (24.3)	2244 (63.8)	.224
At least 2 of these >0, n (%)	2717 (79.0)	3441 (98.0)	1802 (66.7)	2288 (65.1)	.691
PFDI-20 baseline scores, mean (95% CI)	99.2 (97.1-101.3)	2903 (82.6)	98.7 (96.7-100.8)	2346 (66.7)	.466
15D baseline scores, mean (95% CI)	0.889 (0.886-0.892)	2865 (81.5)	0.891 (0.889-0.894)	2310 (65.7)	.187
Method of surgery		3515 (100)		2351 (66.9)	<.001
Native tissue repair, n (%)	2855 (80.8)		1863 (79.2)		
Transvaginal mesh	429 (12.2)		310 (13.2)		
Abdominal mesh	251 (7.1)		178 (7.6)		
Hospital type		3515 (100)		2351 (66.9)	.153
Tertiary, n (%)	946 (32.5)		750 (31.9)		
Secondary, n (%)	1303 (44.7)		1060 (45.1)		
Primary, n (%)	627 (21.5)		504 (21.4)		
Private, n (%)	37 (1.3)		28 (1.2)		

15D, 15-Dimensional generic quality of life instrument; *BMI*, body mass index; *CI*, confidence interval; *POP*, pelvic organ prolapse; *POPQ*, Pelvic Organ Prolapse Quantification system; *PFDI-20*, Pelvic Floor Distress Inventory; *SD*, standard deviation.

[a] *P* value is counted for the difference of baseline characteristics between participants who answered the questionnaire at 2 years' follow-up and drop-outs.

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SUPPLEMENTAL TABLE 2

Regression analysis for unfavorable outcome[a] of surgery and patient baseline characteristics: adjusted with age, BMI, parity, smoking, sexual activity, degree of prolapse, method of surgery, and hospital type

Characteristic	PFDI-20 aOR (95% CI)	PGI-I aOR (95% CI)	15D aOR (95% CI)
Age	1.01 (1.00–1.02)	1.03 (1.01–1.05)	1.02 (1.01–1.03)
BMI	1.00 (0.97–1.02)	1.01 (0.97–1.05)	1.01 (1.00–1.03)
Parity	0.94 (0.87–1.02)	0.94 (0.83–1.06)	0.97 (0.91–1.03)
Current smoking	1.03 (0.71–1.49)	1.69 (1.02–2.81)	1.20 (0.86–1.68)
Sexual activity	0.99 (0.79–1.24)	0.90 (0.64–1.26)	1.47 (1.20–1.80)
Prior POP surgery			
Same compartment	1.32 (0.92–1.89)	1.33 (0.96–1.83)	1.32 (0.93–1.86)
Different compartment	1.00 (0.72–1.38)	1.21 (0.97–1.51)	1.20 (0.89–1.62)
Degree of prolapse			
Anterior prolapse beyond hymen	0.75 (0.61–0.92)	0.64 (0.46–0.87)	0.94 (0.78–1.32)
Posterior prolapse beyond hymen	1.17 (0.90–1.39)	1.01 (0.72–1.42)	0.94 (0.77–1.15)
Apical prolapse beyond hymen	0.54 (0.41–0.70)	0.48 (0.31–0.74)	0.78 (0.63–0.96)
Any compartment beyond hymen	0.71 (0.58–0.90)	0.52 (0.37–0.73)	1.10 (0.88–1.38)
Bothersome bulge	0.40 (0.28–0.57)	0.46 (0.28–0.77)	0.89 (0.62–1.29)
Method of surgery			
Native tissue repair	1.00 reference	1.00 reference	1.00 reference
Transvaginal mesh	0.86 (0.63–1.18)	0.79 (0.49–1.27)	1.07 (0.77–1.50)
Abdominal mesh	0.94 (0.65–1.36)	0.62 (0.32–1.21)	1.12 (0.75–1.68)
Reoperation during follow-up	1.94 (1.20–3.15)	2.71 (1.69–4.34)	0.78 (0.51–1.17)
Hospital type			
Tertiary	1.00 reference	1.00 reference	1.00 reference
Secondary	0.91 (0.72–1.14)	0.82 (0.58–1.15)	0.62 (0.25–1.53)
Primary	0.82 (0.62–1.08)	0.77 (0.50–1.17)	0.51 (0.21–1.28)
Private	1.30 (0.54–3.14)	1.20 (0.34–4.23)	0.55 (0.22–1.36)

15D, 15-Dimensional generic quality of life instrument; *aOR*, adjusted odds ratio; *BMI*, body mass index; PFDI-20, Pelvic Floor Distress Inventory; *PGI-I*, Patient Global Impression of Improvement; *POP*, pelvic organ prolapse.

[a] Definition of unfavorable outcome: PFDI-20: Total PFDI-20 scores decreased less than 23 points, N=649. PGI-I: Patients felt their condition to be the same or worse than before the operation (PGI-I scale 4–7), N=232. 15D: Total 15D score increased less than 0.015, N=1286.

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