

# Patient reported outcome measures in women undergoing surgery for urinary incontinence and pelvic organ prolapse in Denmark, 2006–2011

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## Abstract

**Introduction and hypothesis** The aim of this study was to evaluate the impact of urogynecological surgery on quality of life based on patient reported outcome measures (PROMs).

**Methods** Data were retrieved from the Danish Urogynaecological Database. Inclusion criteria were Danish women undergoing surgery for urinary incontinence (UI) or pelvic organ prolapse (POP) from 2006 to 2011. Using frequency of symptoms and a visual analogue scale (VAS) both pre- and postoperatively, their severity of symptoms and quality of life were measured by questionnaires.

**Results** During the study period, 20,629 urogynecological procedures were performed. The questionnaires on severity of symptoms and the VAS had been completed both pre- and postoperatively for approximately one third of women undergoing surgery. For UI surgery, 83 % had improved

symptoms, 13 % were unchanged, and 4 % had worse symptoms postoperatively. For POP surgery, 80, 17, and 3 % were improved, unchanged, and worsened, respectively. The postoperative bother of symptoms and interference in everyday life evaluated by VAS were significantly reduced for both UI [preoperative median VAS score 9, postoperative median score 1 ( $p < 0.001$ )] and POP [8 preoperatively and 0 postoperatively ( $p < 0.001$ )].

**Conclusions** Based on PROMs, surgery for UI and POP is effective in alleviating symptoms associated with UI or POP, and it can improve quality of life in symptomatic women. Pre- and postoperative questionnaires are useful tools in assessing symptomatic outcome measures after surgery.

**Keywords** Patient reported outcome measures · Pelvic organ prolapse · Quality of life · Questionnaire · Urinary incontinence · Visual analogue scale

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## Abbreviations

UI	Urinary incontinence
POP	Pelvic organ prolapse
VAS	Visual analogue scale
DugaBase	Danish National Urogynaecological Database
PROMs	Patient reported outcome measures
ASA	American Society of Anesthesiologists classification
BMI	Body mass index

## Introduction

The Danish Urogynaecological Database (DugaBase) was established in 2006 to provide systematic data on urinary incontinence (UI) and pelvic organ prolapse (POP) surgery in Denmark. The registry is used to monitor, ensure, and

improve the quality of urogynecological surgery and is funded by the five national regions running the Danish national health services.

UI and POP are prevalent disorders in women, with an estimated one fifth of women in the USA experiencing symptoms of UI or POP [1] and with the prevalence increasing with age [2, 3]. Only one study has examined the prevalence of UI in Denmark (estimated prevalence 16 %) [4], and no Danish data exist on the prevalence of POP. Neither UI nor POP are life-threatening disorders, but both are important health concerns affecting daily life in various ways and can highly impair quality of life, including sexual function [5–7]. For both disorders, surgery remains a dominant treatment option [8], with an estimated lifetime risk of surgery at 11 % [9, 10]. Approximately 5,000 surgical procedures are performed for UI or POP in Denmark annually [11].

Assessment of the outcome of surgery is needed to evaluate whether an operation is feasible, safe, and effective [12]. Outcome measurements can be objective (e.g., cough stress test, pad test, urodynamic evaluation, and anatomical restoration) and subjective (e.g., patient satisfaction and quality of life). Physicians underestimate the extent to which patients are affected by their symptoms by 25–37 % [13], which suggests that outcomes after treatment should include subjective measures. The importance of the patient's perspective on disease impact has been increasingly recognized leading to the development of patient reported outcome measures (PROMs) [14] as well as routine measurement of quality of life [15]. As objective measures are poor representatives of PROMs, validated subjective instruments are highly recommended for addressing the management of urogynecological symptoms [16]. Such questionnaires have been translated into Danish and are included in the DugaBase.

The aim of this study was to assess the change in symptoms and quality of life after UI or POP surgery measured by PROMs in the nationwide DugaBase.

## Materials and methods

### Study population and study period

This study was based on self-administered patient questionnaires completed both pre- and postoperatively by women undergoing surgery for UI and POP in Denmark from April 2006 to December 2011. Only those who completed the questionnaires both pre- and postoperatively were included in the main analyses.

Definitions conform to the international joint report on the terminology for female pelvic floor dysfunction unless otherwise stated [17].

### Data collection

Data collection for the DugaBase began in April 2006 and includes women 18 years of age or older residing in Denmark who undergo surgical procedures for UI and POP (a complete list of codes can be obtained from the corresponding author). The hospital departments and private hospital/clinics use a Web-based national input module to report all data reported directly to the DugaBase. The DugaBase contains information on:

1. Referral.
2. A self-administered patient questionnaire including questions based on the validated International Consultation on Incontinence Questionnaire (ICIQ) on symptoms and disease-specific quality of life (ICIQ-UI and ICIQ-VS) [18, 19], which have been translated into Danish (but not validated in Danish). The questionnaire is completed prior to the first preoperative doctor's examination.
3. A questionnaire completed by the gynecologist including a preoperative examination prior to surgery with baseline information on patient characteristics, e.g., parity, prior urogynecological surgery, height, and weight.
4. Information about the surgical procedures.
5. Follow-up data consisting of the same self-administered questionnaire used before surgery to allow assessment of improvement as well as possible complications and a questionnaire administered by the gynecologist or a nurse.

The follow-up part is usually completed within 3–6 months of surgery. Administration of the follow-up part varies amongst the participating departments. Some use a telephone interview conducted by a nurse to complete the questionnaire, while others post an identical version as a self-administered patient questionnaire. Only a subset of departments routinely offer follow-up visits after surgery. As regards UI surgery, the women were asked: "How often do you leak urine?" with the following response categories (symptom score): 0 = never, 1 = about once a week or less often, 2 = two or three times per week, 3 = about once a day, 4 = several times a day, and 5 = all the time. Quality of life was assessed by "Overall, how much does leaking urine interfere with your everyday life?" on a visual analogue scale (VAS) from 0 to 10—as a surrogate outcome of patient satisfaction and success following surgery—0 being the lowest and 10 the highest.

For POP surgery, the women were asked: "Are you aware of a lump or bulge coming down in your vagina?" with the following response categories: 0 = never, 1 = occasionally, 2 = sometimes, 3 = most of the time, and 4 = always. Quality of life was assessed by "How much does this bother you?" on a VAS scale from 0 to 10.

Patient characteristics were retrieved from the DugaBase and included age, body mass index (BMI), American

Society of Anesthesiologists (ASA) classification, smoking, alcohol consumption, previous hysterectomy, and previous UI or POP surgery.

The completeness of the DugaBase has increased from 13 % in 2006 to 91 % in 2011 [11], using the Danish National Patient Register as reference [20]. The quality of the main variables in the DugaBase has recently been examined and they had high validity (agreement compared to medical records 90–100 %) [21].

#### Statistical analysis

Initially, both symptom score and VAS were stratified by UI and POP procedures and calendar year. Because no results yielded any substantial differences between the calendar years these were merged for the entire study period (2006–2011).

At the individual level, a clinically relevant improvement of symptoms was defined as a reduction of one or more on the ordinal scale of symptom scores. When symptom scores were equal, this was recorded as unchanged, and when increased by one or more, as a worsening of symptoms.

Patient characteristics were analyzed within three categories: (1) improved, (2) unchanged, and (3) worsened symptom score. The chi-square test was used to compare categorical variables and one-way analysis of variance (ANOVA) to compare continuous variables.

The VAS scores were reported as medians with 25th–75th percentiles. Comparisons of median VAS scores pre- and postoperatively were analyzed by the Kruskal-Wallis test. The figures for symptom score illustrate the difference in symptom score at the individual level.

In subanalyses we compared baseline characteristics prior to surgery between included women and women who had not completed both pre- and postoperative patient questionnaires. Thus, we compared the preoperative questionnaire on symptom score and VAS score between included women and women who had only completed the preoperative questionnaire as well as the postoperative symptom score and VAS score between included women and women who had only completed the postoperative questionnaire. A *p* value of less than 0.05 was considered significant.

Post hoc power analyses: For UI, we determined a power of 100 % from our results based on 1,697 women included with a mean VAS score of 8.2 preoperatively (SD 2.8) and a mean VAS postoperatively of 2.3 (SD 2.5), alpha 0.05; for POP, a power of 100 % based on 4,288 women with a mean VAS score of 7.1 preoperatively (SD 2.8) and a mean VAS of 1.2 (SD 2.5) postoperatively. Data analyses were performed using Stata version 12.1 (StataCorp, College Station, TX, USA).

#### Approvals

The DugaBase has been approved by the Danish authorities to monitor the health professional services in this disease area (Danish National Board of Health j. no. 7-201-03-11/1/KIKR). This study has been approved by the Danish Data Protection Agency (no. 2009-41-3564). This is a register-based study; therefore, informed consent from the women should not be retrieved according to Danish law.

#### Results

Between April 2006 and December 2011, 20,629 procedures were registered of which 5,612 were UI procedures and 15,204 were POP procedures; 187 of these were procedures with UI and POP procedures performed concomitantly. For UI surgery, a total of 3,600 (64 %) had completed the patient questionnaire for symptom score preoperatively, and of these 1,778 (49 %) had completed the same questionnaire during follow-up. Similarly, a total of 3,562 (63 %) had completed the patient questionnaire for VAS preoperatively, and 1,697 (48 %) of these had completed this questionnaire postoperatively. For POP surgery, the equivalent numbers were 10,144 (67 %) with preoperative completed questionnaire for symptom score and 4,652 (46 %) of these completed the questionnaire during the follow-up and 10,066 (66 %) filled in the VAS score preoperatively of which 4,288 (43 %) completed the questionnaire for VAS during follow-up.

#### Surgery for UI

The distribution of changes in symptom scores is shown in Table 1. After surgery, 83 % of the women had improved scores, 13 % had unchanged scores, and 4 % had worsened symptom scores. Age, BMI, ASA and previous surgery (hysterectomy, UI, POP) differed significantly between the three symptom categories (Table 1). Smoking and alcohol consumption did not differ significantly between the categories.

The results for symptom scores are shown in Fig. 1. The majority of women were in the group with preoperative symptoms of UI “several times a day” (=4). 84 % within this group had improved symptom score, including 39 % who improved to “Never” (=0) postoperatively.

The changes in VAS score are illustrated in box plots (Fig. 2). For UI surgery, the VAS score median was 9 (25th–75th percentiles 7–10) preoperatively and 1 (0–4) postoperatively ( $p < 0.001$ ).

#### Surgery for POP

The distribution of changes in symptom scores is shown in Table 2. After surgery, 80 % of the women had improved

**Table 1** Baseline patient characteristics prior to surgery according to improved, unchanged, or worsened symptom score after UI surgery, Denmark 2006–2011

	Symptom score after UI surgery							<i>p</i>
	Total	Improved		Unchanged		Worsened		
	<i>n</i> <sup>a</sup>	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)	
Number	1,778	1,484	(83)	224	(13)	70	(4)	
Age, years, mean (SD)	1,778	53.7	(12.6)	59.4	(14.2)	57.9	(15.2)	<0.001
Age group, years	1,778							<0.001
18–39		180	(12.1)	17	(7.6)	6	(8.6)	
40–69		1,124	(75.8)	147	(65.6)	47	(67.1)	
70–		180	(12.1)	60	(26.8)	17	(24.3)	
BMI, kg/m <sup>2</sup> , mean (SD)	1,645	26.4	(4.6)	27.6	(5.4)	28.2	(5.8)	<0.001
ASA	1,580							<0.001
1–2		1,245	(93.7)	161	(84.7)	53	(86.9)	
3–6		84	(6.3)	29	(15.3)	8	(13.1)	
Smoking	1,557							0.852
Yes		295	(22.5)	45	(24.1)	12	(21.1)	
No		1,018	(77.5)	142	(75.9)	45	(78.9)	
Alcohol units per week, mean (SD)	1,412	2.9	(3.8)	3.4	(4.4)	3.6	(6.9)	0.259
Previous hysterectomy	1,721							<0.001
Yes		277	(19.2)	65	(32.3)	13	(19.7)	
No		1,166	(80.8)	136	(67.7)	53	(80.3)	
Previous UI surgery	1,721							<0.001
Yes		89	(6.2)	30	(14.4)	15	(22.1)	
No		1,356	(93.8)	178	(85.6)	53	(77.9)	
Previous POP surgery	1,704							0.047
Yes		164	(11.4)	35	(17.1)	10	(15.9)	
No		1,272	(88.6)	170	(82.9)	53	(84.1)	

POP pelvic organ prolapse, UI urinary incontinence, BMI body mass index, ASA American Society of Anesthesiologists classification

<sup>a</sup>Total *n*<1,778 in some variables because of missing data

scores, 17 % had unchanged scores, and 3 % had worsened symptom scores. Age differed significantly between the three symptom categories (Table 2). BMI, ASA, smoking, alcohol consumption, and previous surgery (hysterectomy, UI, POP) did not differ significantly between the categories.

The results for symptom scores are shown in Fig. 3. The majority of women were in the group with preoperative symptoms of POP “always” (=4); 90 % within this group had improved symptom scores, including 78 % who improved to “never” (=0) postoperatively.

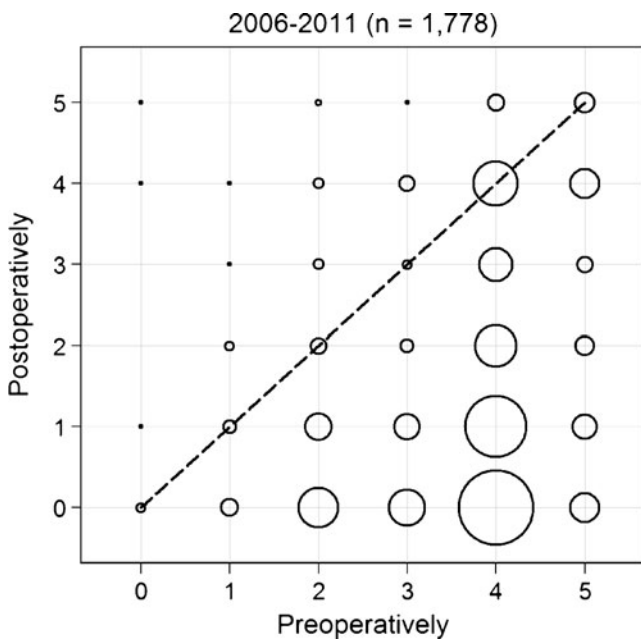
The changes in VAS score are illustrated in box plots (Fig. 4). For POP surgery, the VAS score median was 8 (25th–75th percentiles: 5–10) preoperatively and 0 (0–1) postoperatively ( $p<0.001$ ).

#### Subanalyses

For UI, there were no differences found in baseline characteristics prior to surgery between included women and

women who had not completed both the pre- and postoperative questionnaires. The preoperative VAS score did not differ between included women and women who had only completed the preoperative questionnaire. The only difference was encountered for the postoperative symptom-free score (40.8 % of patients with both questionnaires completed and 47.4 % of patients with only postoperative questionnaire completed,  $p=0.002$ ).

For POP, minor differences were seen in baseline patient characteristics prior to surgery for mean age (61.5 vs 62.2 years,  $p=0.001$ ), alcohol units per week (3.2 vs 2.9,  $p<0.001$ ), ASA (ASA 1–2 89.5 vs 92.4 %; ASA 3–6 10.5 vs 7.6 %,  $p<0.001$ ), and prior POP surgery (21.5 vs 19.6 %,  $p=0.014$ ). Minor differences were seen for the preoperative symptom-free score (11.0 % of included women vs 7.4 % of women with only the preoperative questionnaire completed,  $p<0.001$ ), preoperative VAS score 10 (26.2 vs 29.3 %,  $p<0.001$ ), and postoperative symptom-free score (80.1 vs 76.5 %,  $p=0.026$ ).



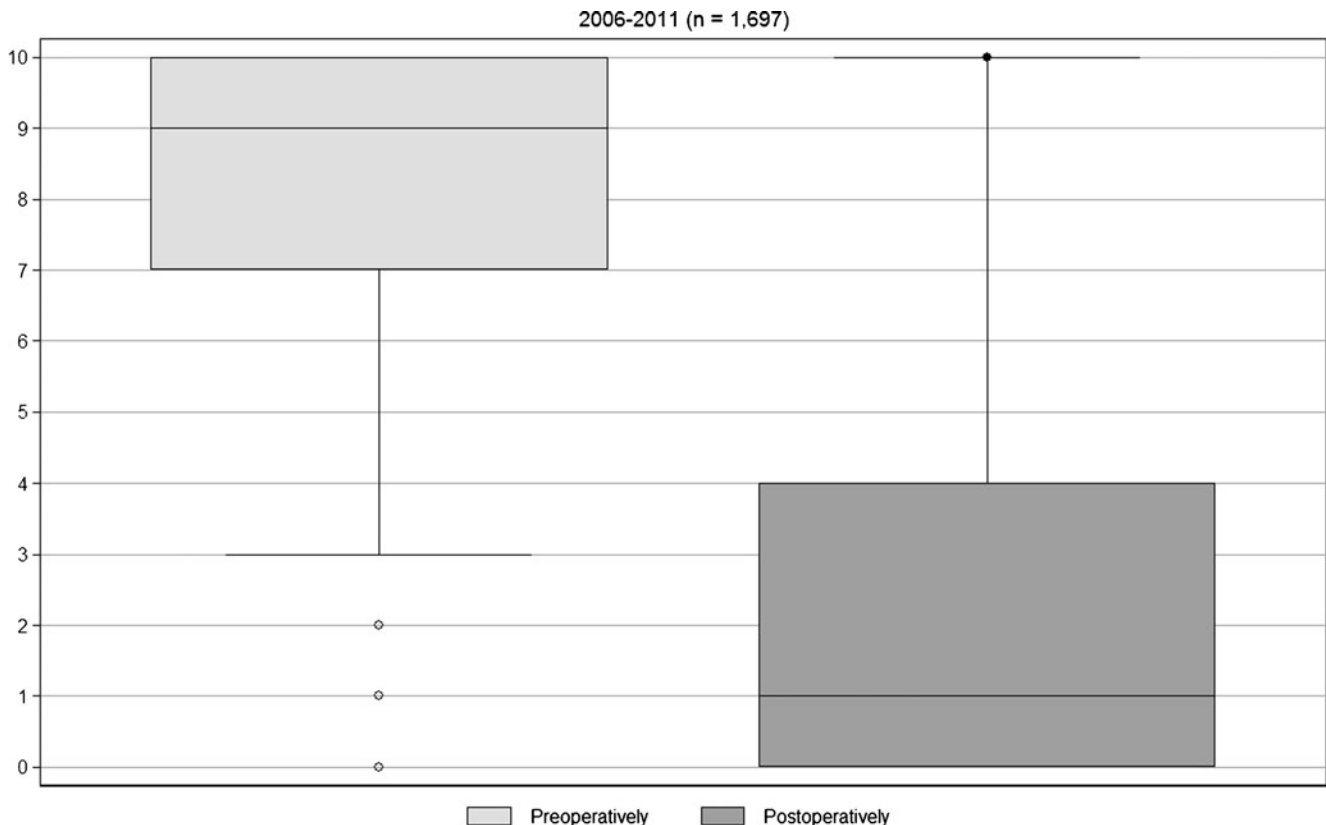
**Fig. 1** Symptom score “How often do you leak urine?” for UI surgery pre- and postoperatively ( $n=1,778$ ). The area of the circles is directly proportional to the number of the observations represented in the circle. The diagonal lines illustrate no change in symptoms after surgery. The observations below the diagonal line illustrate improved symptom score and above illustrate worse symptom score after surgery

**Discussion**

Overall, this study indicates reassuring improvement in women after surgery for UI and POP assessed by PROMs. For UI, 83, 13, and 4 % reported improved, unchanged, or worsened postoperative symptom scores, respectively. For 50 % of the women with UI surgery, the VAS scores were 9–10 preoperatively and reduced to 0–1 postoperatively. For POP, 80, 17, and 3 % reported improved, unchanged, or worsened postoperative symptom scores, respectively, and the VAS scores for 50 % of the women were reduced from 8–10 to 0–1 postoperatively.

This is the first study of PROMs on this topic based on a national population. The strengths of this study were data from a national database on UI and POP surgery with access to PROMs to evaluate the change of symptoms associated with UI and POP and change in quality of life after surgery.

However, our study also had limitations. Information on symptom score and VAS score were not available for all women recorded in the DugaBase. Though comparisons between patients with both questionnaires completed and patients without both questionnaires completed revealed mainly minor and immaterial differences, we cannot rule out some selection bias at baseline or during follow-up.



**Fig. 2** VAS score for UI surgery pre- and postoperatively ( $n=1,697$ ) in box plots. The bottom and top of the boxes are the 25th and 75th percentiles, and the line near the middle of the boxes is the median

**Table 2** Baseline patient characteristics prior to surgery according to improved, unchanged, or worsened symptom score after POP surgery, Denmark 2006–2011

	Symptom score after POP surgery							<i>p</i>
	Total	Improved		Unchanged		Worsened		
	<i>n</i> <sup>a</sup>	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)	
Number	4,652	3,725	(80)	806	(17)	121	(3)	
Age, years, mean (SD)	4,652	62.2	(11.8)	58.8	(14.1)	57.4	(12.9)	<0.001
Age group, years	4,652							<0.001
18–39		175	(4.7)	87	(10.8)	12	(9.9)	
40–69		2,532	(68.0)	523	(64.9)	83	(68.6)	
70–		1,018	(27.3)	83	(24.3)	26	(21.5)	
BMI, kg/m <sup>2</sup> , mean (SD)	4,377	26.0	(4.0)	26.1	(4.3)	26.4	(4.2)	0.41
ASA	4,200							0.096
1–2		3,036	(89.9)	620	(87.3)	102	(91.9)	
3–6		343	(10.1)	90	(12.7)	9	(8.1)	
Smoking	4,218							0.976
Yes		491	(14.5)	108	(14.8)	16	(14.7)	
No		2,890	(85.5)	620	(85.2)	93	(85.3)	
Alcohol units per week, mean (SD)	3,798	3.2	(4.3)	3.1	(4.1)	2.7	(4.5)	0.492
Previous hysterectomy	4,577							0.713
Yes		818	(22.2)	178	(22.6)	30	(25.3)	
No		2,858	(77.8)	609	(77.4)	89	(77.7)	
Previous UI surgery	4,530							0.612
Yes		167	(4.6)	41	(5.2)	7	(6.0)	
No		3,463	(95.4)	742	(94.8)	110	(94.0)	
Previous POP surgery	4,557							0.339
Yes		799	(21.9)	157	(20.0)	22	(18.3)	
No		2,851	(78.1)	630	(80.0)	98	(81.7)	

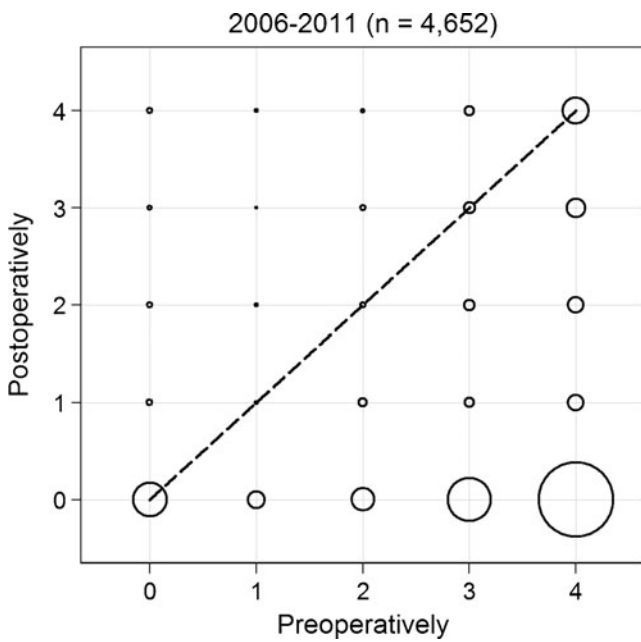
POP pelvic organ prolapse, UI urinary incontinence, BMI body mass index, ASA American Society of Anesthesiologists classification

<sup>a</sup>Total *n*<4,652 in some variables because of missing data

However, we believe the calculated differences are so small that their clinical relevance is negligible, and selection bias does not seem to be a major problem. Avoiding selection bias related to lack of compliance to the follow-up is probably a more important issue than selection bias related to low participation at baseline [22]. Another aspect was the timing of administration of the pre- and postoperative patient questionnaires. All preoperative questionnaires were administered to the women to be completed prior to the first doctor's examination. Regarding the postoperative questionnaires, the timing was not standardized, but the vast majority was completed within 3–6 months after the surgery. Furthermore, completed patient questionnaires of frequency of symptoms and VAS score were used as an expression of patient satisfaction. Other questionnaires on patient satisfaction (e.g., Patient Global Impression of Improvement) have been developed, and such data are planned to be implemented in the DugaBase.

Concomitant surgery for POP and UI is neither frequently nor routinely performed in Scandinavia, where it is customary to employ a conservative approach of addressing the predominant problem of either POP or UI in sequential surgery [23]. Therefore, a low number of concomitant surgeries were found in our study. This is in contrast to reports from other parts of the world, where many surgeons routinely or with low threshold insert slings in women undergoing vaginal prolapse surgery with overt or occult concomitant stress UI [24, 25].

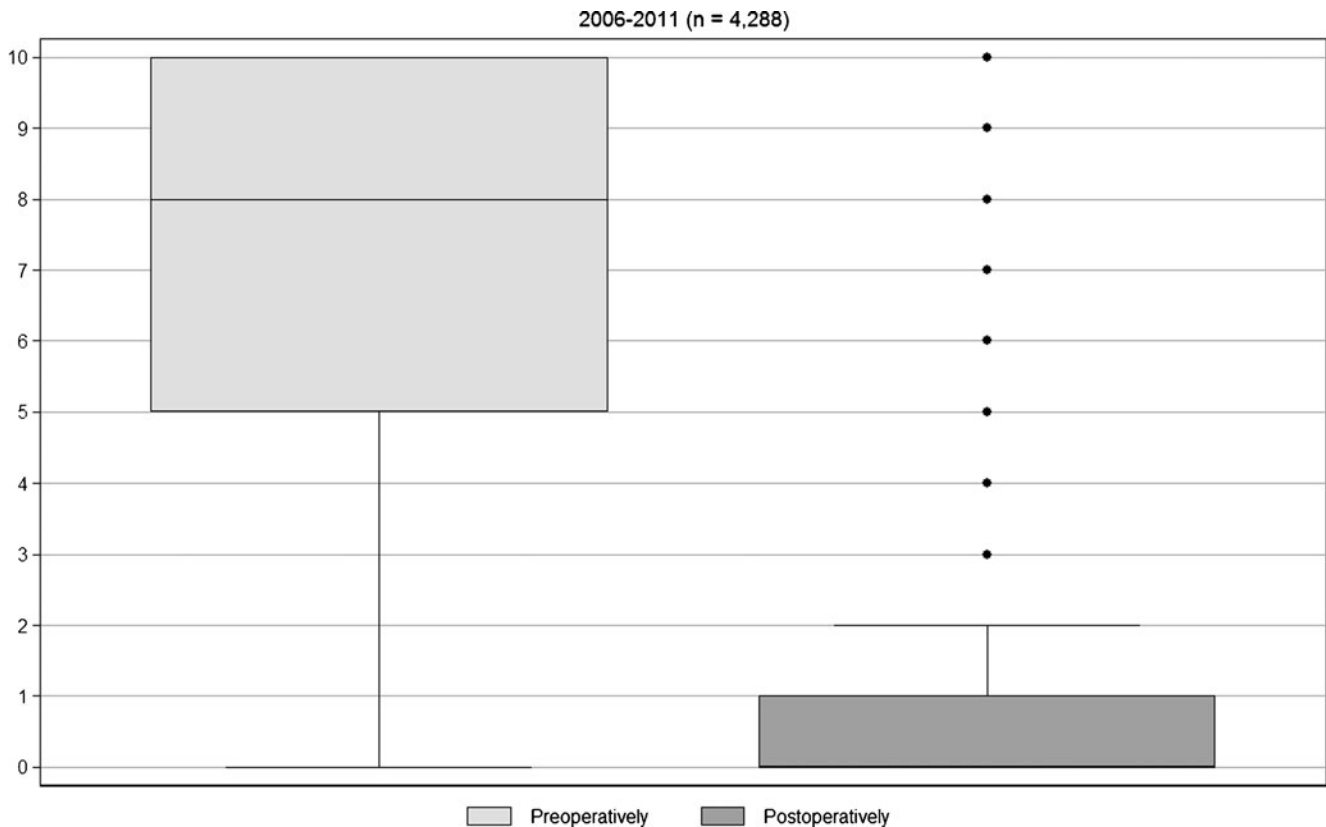
There is no recommended gold standard for postoperative follow-up regimens. In Denmark there is inconsistency in the mode of follow-up: in some departments a nurse conducts a telephone interview, some have mail questionnaires, and some have routine follow-up visits. The mode of follow-up is not registered and therefore cannot be taken into account when evaluating the data.



**Fig. 3** Symptom score “Are you aware of a lump or bulge coming down in your vagina?” for POP surgery pre- and postoperatively ( $n=4,652$ ). The area of the circles is directly proportional to the number of the observations represented in the circle. The diagonal lines illustrate no change in symptoms after surgery. The observations below the diagonal line illustrate improved symptom score and above illustrate worse symptom score after surgery

In the beginning of the DugaBase’s existence the patient completeness was low. This could lead to “healthy patient bias” if only the successful treatments were reported to the DugaBase. However, the pattern of change in symptoms and improvement of quality of life was very consistent across calendar years, even with the increasing patient completeness, which argues against a potential healthy patient bias. The low completeness was mainly for certain departments, while others had a high completeness from the very beginning. This along with the assumption of geography being less important especially since hospital services are free of charge in Denmark [26] argues against selection bias.

We further found that the women with UI who reported improved symptom scores were generally younger than those who had unchanged or worsened scores. Conversely, the women with POP who reported improvements were older than those who had unchanged or worsened scores. Furthermore, UI patients with improved symptom score had lower BMI, lower ASA, and less often previous surgery than the unchanged or worsened groups; no differences were found for POP. For women with UI, this finding is consistent with other published studies that seem to indicate that age, BMI, and previous surgery are independent predictors of a less successful outcome of surgery [27–29], presumably due to factors such as an age-related deterioration in urethral function and



**Fig. 4** VAS score for POP surgery pre- and postoperatively ( $n=4,288$ ) in box plots. The bottom and top of the boxes are the 25th and 75th percentile, and the line near the middle of the boxes is the median

an increased load on the urethral closure apparatus with increased body weight. For women with POP, the reverse relation of outcome to age was found. This could be due to decreased activities of daily life and sexual activity, explaining a lesser bother of POP.

Measurements of symptom severity and changes in quality of life in women with UI or POP are essential in the evaluation and treatment of these women [30]. It has been suggested that it is difficult to evaluate the success of urogynecological procedures due to lack of consensus and comparability of outcome measures [31].

In conclusion, our study suggests that surgery for UI and POP is effective in alleviating disease-related symptoms as well as improving quality of life, and PROMs using validated, internationally accepted questionnaires are useful in evaluating surgical success.

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**Conflicts of interest** None.

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