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Quality of life after Uphold™ Vaginal Support System surgery for apical pelvic organ prolapse—A prospective multicenter study

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ABSTRACT

Objective: To study the effects on quality of life in women operated for apical pelvic organ prolapse using the Vaginal Uphold™ System.
Study design: In this prospective cohort study, women (n = 207) with symptomatic apical prolapse, with or without cystocele, were operated using the Uphold™ Vaginal Support System. Follow-up for quality of life was performed at 12 months after surgery, and assessed by the PFDI-20, and PFIQ-7, and sexual function by the PISQ-12. We used odds ratios (ORs) with 95% confidence intervals (CIs) for outcome association analyses using logistic regression.
Results: At one-year follow-up majority of women experienced an overall postoperative improvement in quality of life ($p < 0.001$). One year after surgery Uphold™ operation alone increased the risk for prolapse related bother as compared to Uphold™ combined with anterior colporraphy (POP-IQ-7; OR 2.1; 95% CI 1.01–4.3). The frequency of dyspareunia decreased postoperatively ($p = 0.004$), however, after one-year, overall sexual function deteriorated significantly ($p < 0.001$). The worsening in sexual function scores was mainly attributed to the partner related domain, whereas the behavioral-emotive and physical domains showed no significant changes.
Conclusion: Apical prolapse repair using Uphold™ improved quality of life among our patients but worsened overall sexual function postoperatively.

Introduction

Although the restoration of vaginal topography often results in improvements in pelvic organ prolapse symptoms the incongruence between objective and subjective outcomes in pelvic organ prolapse surgery is well established [1–3]. As a consequence, the focus of pelvic organ prolapse surgery has pivoted towards patients centered outcomes and quality of life measures, [4–6] rather than simply measuring pelvic anatomy outcomes of surgery.

In women after pelvic organ prolapse surgery quality of life measures may entail a variety of domains of which the effects on sexual function has received perhaps the most attention [7]. Nonetheless, it remains unclear how, and to what extent, sexual dysfunction relates to pelvic reconstructive surgery. Some studies suggest that sexual dysfunction is a common sequela after mesh augmented reconstructive surgery [8,9], others suggest that surgery has no effect [10–12], or even improve sexual function domains [13,14]. Ambiguous results have also been shown for other quality of life domains in relation pelvic organ prolapse surgery.

We have previously reported on the safety and efficacy outcomes and subjective relief of condition specific symptoms after using the Uphold™ Vaginal Support System [15]. In the present study we assessed quality of life and sexual function outcomes following Uphold™ surgery in a prospective cohort of women with apical prolapse and with or without concurrent cystocele.

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Materials and methods

We performed a multicenter, prospective, open label, single cohort study throughout 24 clinics in Sweden, Denmark, Norway and Finland. A total of 207 patients with primary or secondary apical prolapse ≥stage 2 (point C/D), with or without anterior vaginal wall prolapse > or equal to −1 (point Ba >−1), according to POP-Q staging [16], underwent surgery using the Uphold™ Lite Vaginal Support System (Boston Scientific). All patients underwent a pre-trial standardized surgical procedure using the Uphold™ Lite system and all gynecologic surgeons participating in the trial had supervised hands-on operating room training before initiation of the study. The surgical procedure has been described elsewhere [17]. Briefly a small incision was used, leaving approximately 2 cm undisturbed at the vaginal apex. The Capio® Suture Capturing Device was used to connect the mesh to the sacrospinosus ligament and suspending the apex. If decided by the operator, anterior vaginal wall prolapse was corrected concomitantly by traditional colporraphia anterior, but there was not any stage of prolapse when this was mandatory. The peri- and postoperative morbidity and complications associated with the procedure were reported by Altman et al. [15]. Follow-up visits were performed at two months and one year after surgery. Five women did not attend any follow-up and thus, the final cohort was 202 women.

There were no restrictions on body mass index, menopausal status, or previous surgery. Other pelvic disorders for which surgery was indicated (including stress incontinence, cervix elongation and posterior prolapse), as well as, previous or current pelvic organ cancer, severe rheumatic disease, insulin treated diabetes mellitus, connective tissue disorder, and current systemic steroid treatment were regarded as exclusion criteria's.

Vaginal topography and quantification of pelvic organ prolapse was assessed at baseline, as well as, after two months and one year postoperatively during a gynecological exam in the lithotomy position using the POP-Q system [16]. Stage <2 of the apical compartment was considered an optimal anatomical outcome after surgery.

Quality of life outcomes were assessed using the Pelvic Floor Distress Inventory 20 (PFDI-20), Pelvic Floor Impact Questionnaire- short form 7 (PFIQ-7), Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) at baseline and one year follow-up. The main results of PFDI-20 are reported before [15], but these data were included here when analyzing the possible risk factors for subjective operation failure. The PFIQ-7 provides a comprehensive condition specific assessment of the effect of pelvic floor distress on quality of life during the last three months. The questionnaire includes seven questions and three scales: Urinary Impact Questionnaire (UIQ-7), Colorectal-Anal Impact Questionnaire (CRAIQ-7), and Pelvic Organ Prolapse Impact Questionnaire (POPIQ-7). The scale score is obtained by the mean value of all the answered questions and multiplying them to obtain scale score from 0 (least impact) to 100 (greatest impact). In the summary higher points indicates more distress. The PISQ consists of 12 questions, which measures the impact of pelvic organ prolapse on the patient's sexual life during the last six months. The responses are graded on a 5-point Likert scale from "never" to "always". The questionnaire can be divided to three subscales, behavior-emotional, physical, and partner related. Higher points indicate better sexual satisfaction and the maximum score is 48.

Data on the quality of life questionnaires are presented as means ± SD. Comparison between baseline and one-year outcomes were analyzed by the Wilcoxon –Matched-Paired-Signed-Rank test. As possible risk factors for unsuccessful outcomes (i.e. POP-Q stage ≥2 in point C or an adverse effects on quality of life instruments) we evaluated a number of variables in a multivariate logistic regression analysis including: previous hysterectomy, previous pelvic organ prolapse surgery, age >65 years, BMI ≥25, multiparity (≥3 deliveries), chronic diseases (cardiovascular diseases, asthma, thyroidea dysfunction, non-insulin treated diabetes, fibromyalgia, rheumatism), and concomitant anterior vaginal wall repair. Results from the risk analysis are presented as odds ratios (ORs) with 95% confidence intervals (CIs). A p-value < 0.05 was considered significant for all analyses. All statistics were performed with IBM SPSS Statistics, version 22.

The study was approved by the appropriate research ethics committees in the participating countries and the study was registered at www.clinicaltrials.gov (NCT01823055). The study protocol was vetted by the mesh manufacturing company prior to providing an investigator initiated study grant but the company had no further influence over execution of the study, analyses and interpretation of the data, or drafting the manuscript. Furthermore, the company provided funding for two investigator meetings held before and after completion of the trial.

Results

Baseline characteristics of the patients included in the study are presented in Table 1. In total 88% of the women were postmenopausal (183) and 38% (79 women) had a history of previous hysterectomy. Mean age at surgery was 66.3 (SD ±9.2) years, mean body mass index (BMI) was 25.3 (SD ±4.6) and median parity was 2 (range 0–5).

The PFIQ-7 questionnaire was filled adequately by 197 women at baseline, and after one year by 183 women. Of these women 179 filled the questionnaires adequately both at baseline and at one year. One hundred-sixteen (64.8%) women had lower score points one year postoperatively indicating an improved quality of life, 19 (10.6%) women reported no change, and 44 (24.6%) women showed worsening in quality of life. Detailed outcome of PFIQ-7 questionnaire is presented in Table 2. Pelvic organ prolapse and urinary symptoms caused equal distress before the operation. The total score points showed an overall improved quality of life at one-year follow-up ($p < 0.001$) (Table 2). Both pelvic organ prolapse and urinary problems improved significantly after one year ($p < 0.001$), whereas in the colorectal-anal scale no statistically significant change was detected (Table 2).

Table 1
Baseline characteristics and the operation information.

Age y, mean ± SD (range)	66.3 ± 9.2 (34–92)
Weight	70.1 ± 9.4
BMI mean ± SD (range)	25.3 ± 4.6 (19.6–35.3)
Parity median (range)	2 (0–5)
Multiparous (≥3 deliveries) N (%)	78 (38)
Menopause N (%)	183 (88)
Smokers N (%)	11 (5)
Somatic diseases N (%)	
No diseases	68 (33)
Cardiovascular diseases	81 (39)
Thyroid dysfunction	21 (10)
Asthma	12 (6)
Diabetes	4 (2)
Fibromyalgia + rheumatism	6 (3)
Other	4 (2)
Previous surgeries N (%)	
Hysterectomy	79 (38)
Subjects with previous pelvic floor surgery	88 (43)
Hysterectomy or incontinence + colporraphia anterior	39 (19)
Operating time min (mean ± SD)	54.6 ± 18.8
Bleeding ml, mean ± SD (range)	78 ± 122 (0–1000)
Hospital stay days median (range)	2 (0–7)