Original Article

Morbidity of a Single Incision Transvaginal Mesh to Correct Apical Prolapse

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ABSTRACT

Study Objective: To determine complications and related reintervention rates associated with use of the Uphold Vaginal Support System (Boston Scientific, Boston, MA) for symptomatic vaginal apical prolapse.

Design: A multicenter retrospective study.

Setting: Two teaching hospitals.

Patients: Fifty-nine women with symptomatic vaginal apical prolapse.

Intervention: Vaginal apical prolapse surgery using the Uphold Mesh Kit system with or without other concomitant procedures.

Measurements and Main Results: A chart review was performed, including the following parameters: perioperative and postoperative complications, repeat surgery, and recurrence rate. A total of 59 patients met the criteria for inclusion in the study. Bladder perforation occurred perioperatively in 1 patient. Postoperative voiding difficulties were observed in 16 patients (27.1%), including 9 women (15.2%) who left the hospital with an indwelling catheter in place. There were 5 cases (8.5%) of transient groin pain, all of which resolved spontaneously. One patient developed a vaginal hematoma. Nine women (15%) required reoperation, including 4 (6.7%) because of recurrent prolapse and 1 (2%) for pelvic pain considered related to the mesh. Three patients (5%) required release of a midurethral sling (MUS) that had been placed concomitantly with the Uphold system. Two patients (3%) required a MUS for de novo stress incontinence.

Conclusion: Use of the Uphold Vaginal Support System for symptomatic vaginal apical prolapse was associated with a significant risk of obstructed micturition. In our study population, 15% required repeat surgery, mainly for recurrent pelvic organ prolapse and de novo stress urinary incontinence. No surgical-related complication resulted in long-term morbidity.

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The surgical management of women with pelvic organ prolapse (POP) remains a significant challenge, as demonstrated by the 17% to 20% risk of reoperation for recurrence [1]. Surgical approaches can be vaginal, laparoscopic, or open. The choice of procedure depends heavily on the surgeon’s training and experience, resulting in significant practice variation. There is evidence that compared with native tissue repair, vaginal mesh procedures result in better anatomic and subjective outcomes of the anterior vaginal wall, but this is not reflected in lower reoperation rates [2–4].

Since the notification published by the US Food and Drug Administration in 2011, the use of vaginal mesh has decreased significantly, and the opinion is widespread among both physicians and patients that vaginal mesh surgery has an unfavorable balance between benefits and risks [5]. However, this does not reflect the ongoing improvements in vaginal mesh surgery with respect to both the construct itself and the delivery technique.

In the field of urogynecology, it is acknowledged that optimal suspension of the apex is a key to successful
prolapse repair. Laparoscopic sacrocolpopexy has been suggested as the technique with the most favorable outcomes, but the learning curve is extensive, and the duration of the procedure is long [6]. Consequently, vaginal sacrospinous fixation is the most commonly performed vaginal apical suspension, even though it results in horizontal overcorrection of the vaginal axis. The latter is associated with an increased risk of postoperative anterior vaginal wall prolapse, and the mobility of the apex is sometimes limited after surgery. This limited mobility is due to fixation to the sacrospinous ligament (SSL), which may be one of the main reasons for the relatively high risk of postoperative dyspareunia.

Developed to provide a better technique for apical suspension, the Uphold Vaginal Support System (Boston Scientific, Boston, MA) allows for a vaginal approach with less backward deviation of the vaginal axis compared with suture-based SSL fixation, which may reduce the risk of postoperative cystocele. Several studies have reported on the efficacy of the Uphold system, but data on the morbidity associated with this procedure are limited. In our opinion, morbidity includes not only surgery-related complications, but also follow-up surgery for recurrent pelvic organ prolapse (POP) and stress urinary incontinence.

In the present retrospective study, we aimed to evaluate the risk of complications and follow-up surgery related to use of the Uphold system for vaginal surgical correction of apical prolapse. Because randomized controlled trials have known biases in patient recruitment and sample populations, resulting in limited generalizability, we evaluated a retrospective cohort representing actual clinical data.

Methods

We performed a retrospective chart review at 2 teaching hospitals in Cape Town, South Africa: Chrisitan Barnard Memorial Hospital and Groote Schuur Hospital. All patients who underwent surgery using the Uphold system in one of these hospitals between 2012 and 2017 were included in this study.

Indications for Uphold

The indications for an Uphold mesh included women undergoing primary prolapse surgery with either point C of greater than stage 1 or point Aa and/or Ba of greater than stage 1. A patient underwent surgery only if prolapse symptoms were bothersome and conservative therapy had failed. For patients with additional posterior compartment POP-Q stage 2 or greater, laparoscopic sacrocolpopexy was offered. The Uphold mesh was also offered to women with recurrent POP-Q stage 1 anterior vaginal wall prolapse and very bothersome prolapse symptoms.

Indication for Concomitant Procedures

A cough stress test was routinely performed with or without reduction of the prolapse in all patients during intake. A midurethral sling (MUS) was inserted in patients with demonstrable stress incontinence (with or without prolapse reduction) or a history of stress incontinence. Concomitant perineorrhaphy was performed if the urogenital hiatus was >5 cm. In cases of posterior vaginal wall prolapse with POP-Q point Bp at −2 cm or beyond, a combination of posterior colporrhaphy was also performed. The catheter and vaginal pack were removed on the day after surgery.

Surgical Technique

The Uphold mesh is applied exclusively in the anterior compartment using a single midline incision. The patient is catheterized, and a 20-mL solution of normal saline plus bupivacaine 1% plus 1:200,000 adrenaline is injected into the anterior vaginal wall. A deep midline incision is made extending 3 cm from the meatus toward either the vaginal vault or the cervix. This is followed by a full-thickness dissection extending paravaginally to the ischial spine. Digital dissection is then used to further extend the dissection and clear approximately 2 to 3 cm of the SSL on both sides. In women who have undergone previous hysterectomy, the vaginal vault is exposed in the midline, and in women with an intact cervix, the anterior aspect is cleared of overlying fascia. The Uphold mesh kit consists of a small central body measuring 5 × 6 cm with 2 mesh apical arms that are fixed to the SSL on each side using the Capio SLIM suture capturing device included in the kit. It is essential that these arms be placed at least 2 cm from the ischial spine, to avoid the pudendal nerve. The apex of the mesh is attached to the cervix or vaginal vault using 2 PDS 0 sutures. This is followed by a bladder fascial plication using PDS 3/0. Then the distal part of the mesh is sutured to the bladder neck with 2 Vicryl 2/0 sutures 1 cm right and left of the midline. Vicryl 2/0 is used to close the vaginal incision. A vaginal pack and catheter are left in situ and removed the following morning. Cystoscopy was performed in all cases.

Eligible patients were identified using a comprehensive computerized surgical database and online patient record-keeping systems. The clinical notes, theatre notes, and follow-up notes of each patient were reviewed. Information on the main outcome variables, perioperative and postoperative complications, was extracted from these notes.

Data Collection

A chart review was performed for all women who underwent the Uphold procedure at 1 of the 2 study hospitals between 2012 and 2017. Data regarding the defined outcome measurements, surgical parameters, complications, and reinterventions were obtained from these charts.

Patient characteristics, including age, body mass index, parity, medical history, and comorbidities, were obtained. For medical history, 3 categories of previous surgery were identified: hysterectomy, POP surgery, and other abdominal
surgery. In patients who underwent a concomitant procedure, the type of procedure was documented.

The outcome measurements were classified by time of occurrence: intraoperative and postoperative complications, repeat surgery, and recurrence rate. Intraoperative complications included bladder, urethral, and rectal perforation. Postoperative complications included urinary infections, voiding difficulties, wound infection, and hematoma. In cases of reoperation, the indication for surgery and the procedure performed were documented. Finally, cases of recurrent prolapse and de novo stress incontinence were documented.

**Statistical Analysis**

An Excel data collection sheet (Microsoft, Redmond, WA) was used to record the pertinent data for each case. All collected data on the sheets were converted into a database and analyzed using SPSS version 24 (IBM, Armonk, NY). Descriptive statistics were used to provide an overview of the sample population. Frequencies were calculated to demonstrate the prevalence of different complications. The independent t test and χ² test were used to identify preoperative factors associated with operational outcomes. A 95% confidence interval was calculated, and p < .05 was considered significant in all analyses.

**Ethics**

This study was prompted by the request from the Human Ethics Committee of the University of Cape Town for an audit of mesh surgery in our unit, and was deemed exempt from Institutional Review Board or Ethical Committee approval. The findings of this audit have been submitted to and reviewed by the chair of the Ethics Committee. The data were collected in accordance with accepted ethical principles and the Declaration of Helsinki.

**Results**

**Study Population**

A total of 59 patients were eligible for inclusion in this study. The mean patient age was 67 ± 9.3 years (range, 43−91 years). The median duration of follow-up was 2.2 months (range, 3 weeks to 13 months).

Table 1 summarizes patient characteristics. Patient parity ranged from 1 to 7, with a median of 3. All patients were postmenopausal. Of note, 16 patients (27.1%) were smokers. The median duration of hospital stay was 3 days (range, 1−5 days). Forty-nine of the 59 women (83%) had undergone previous pelvic surgery, 43 (72.9%) had undergone hysterectomy, and 20 (33.9%) had undergone a previous operation for POP.

| Table 1 |
|-----------------|-----------------|
| Patient characteristics (N = 59) | Value |
| Characteristic | Value |
| Age, y, mean ± SD | 67 ± 9.3 |
| Parity, median (range) | 3 (1−7) |
| Menopause, n (%) | 59 (100) |
| Smoker, n (%) | 16 (27) |
| Comorbidities, n (%) | |
| Urinary tract infection | 18 (30) |
| Cardiovascular disease | 9 (15) |
| Thyroid disease | 3 (5) |
| Tuberculosis | 1 (2) |
| Chronic obstructive pulmonary disease | 3 (5) |
| Asthma | 2 (3) |
| High blood pressure | 35 (58) |
| Elevated cholesterol | 11 (18) |
| Diabetes | 12 (20) |
| Fibromyalgia | 1 (2) |
| Polymyalgia rheumatica | 12 (20) |
| Previous surgery, n (%) | |
| Hysterectomy | 43 (72) |
| Pelvic organ prolapse surgery | 20 (33) |
| Abdominal surgery | 24 (40) |
| Concomitant surgery, n (%) | |
| TVT | 15 (25) |
| Perineorrhaphy | 16 (27) |
| Paravaginal repair | 3 (5) |
| Hospital stay, d, median (range) | 3 (1−5) |
Intraoperative Complications

One patient experienced an intraoperative complication, resulting in a bladder injury that was recognized during surgery and sutured following cystoscopy. There were no urethral, bowel, or rectal injuries. Concomitant surgeries included vaginal repair of posterior compartment prolapse in 3 patients, perineorrhaphy in 16 patients, and a concomitant MUS procedure in 15 patients.

Postoperative Complications

In the postoperative period, 5 patients (8.5%) developed a urinary tract infection documented by a positive culture. Sixteen patients (27.1%) had incomplete bladder emptying following removal of the catheter on the first postoperative day, and 9 patients (15.2%) left the hospital with a catheter in place. In all of these women, bladder emptying normalized over time. One patient needed a suprapubic catheter for 26 days until bladder emptying normalized. This patient also required surgical loosening of an MUS that had been placed concomitantly. Transient groin pain was reported by 5 patients (8.5%), and resolved spontaneously in all 5. One patient developed a vaginal hematoma. No patient experienced a wound infection in the postoperative period. No patients had a venous thromboembolism or another cardiovascular problem after surgery. No blood transfusions were needed.

Table 2 reports all postoperative complications. A $\chi^2$ test for independence (with Yates continuity correction) indicated no statistically significant association between concomitant surgery and postoperative complications.

Reoperation and Recurrence Rates

The reoperation rate during the follow-up period was 15% (9 of 59 patients). Only 4 (6.7%) of these were for recurrent prolapse and 1 was for pelvic pain, related to fibrosis around the mesh. In this patient, a partial excision of the mesh was performed, which resulted in significant pain reduction. In 3 patients, a concomitantly placed MUS had to be released to treat obstructed micturition, and in 2 patients, MUS placement was required owing to bothersome stress incontinence.

No association was found between a concomitant surgical procedure and the need for reoperation. There were 2 unscheduled readmissions, 1 because of a severe urinary tract infection and the other for a previously mentioned MUS release owing to obstructed micturition with bladder retention.

Discussion

In this moderate-sized review of 59 women undergoing a prolapse procedure with a single incision mesh, we assessed the safety and effectiveness of the Uphold system. Much has been written and debated concerning the utility of vaginal mesh products in surgery for POP, and the present study provides more reliable insight into the safety and effectiveness of this approach. We found a low perioperative complication rate, comparable to that for procedures using native tissue techniques, but a high risk of bladder emptying problems. In our cohort, the reoperation rate was 6.7% for recurrent POP and 1.7% for mesh-related complications, demonstrating that the Uphold system can be considered effective and relatively safe for treating vaginal prolapse.

Altman et al [7] reported an intraoperative complication rate of 1.5%, which is in line with our present findings, with only 1 case of bladder perforation in our cohort. In that patient, the bladder injury was repaired and the Uphold mesh was placed. Closure of the perforation was verified by cystography performed 10 days after the procedure.

Vaginal mesh exposure is one of the most widely reported complications; however, we found no cases of vaginal mesh exposure, comparable to the rates of 1% and 2% in the series reported by Altman et al [7] and Letouzey et al [8], respectively. We found a relatively high rate of voiding difficulties (27.1%) as a postoperative complication. This is a common complication, also reported in other studies. For example, Altman et al [7] reported a 5.7% rate of voiding difficulties. This higher complication rate also has been reported with the use of other mesh kits [9,10]. An explanation for the high rate of voiding difficulties associated with the Uphold system is that the operation inherently alters the position of the bladder and the urethra, which can cause functional changes and bladder emptying difficulties, as noted by Altman and Falconer [10]. The mesh is attached with a single Vicryl 2/0 suture at the bladder neck, and thus the mesh itself might apply some tension on the bladder neck area. There is also a risk of overcorrection, which could disrupt the functional anatomy and cause such complications as postoperative voiding difficulties. Others have associated these complications with the dissection technique used during the procedure [11].

The rate of voiding difficulty in our cohort is higher than the rates reported in the aforementioned studies. A possible
POP, which included sacrocolpopexy in 3 of them. This mesh repair. The indications for concomitant MUS surgery at the time of surgery with the other reported published by Letouzey et al [8] and Altman and Falconer [10]. We believe that this is most likely related to the characteristics of this new-generation mesh.

In conclusion, the complication and reoperation rates following POP surgery using a single-incision mesh kit. The higher rate of voiding difficulties reported in this review and other studies makes it important to find ways to ameliorate this risk or to research the risk factors associated with this complication in more depth. To validate our findings, future studies of complications should take into account the patients’ preoperative conditions. Owing to the risk of de novo stress urinary incontinence after POP surgery, there is an urgent need for good-quality data to aid identification of the indications for concomitant MUS surgery at the time of mesh repair.

In conclusion, the complication and reoperation rates following insertion of the Uphold single-incision mesh kit were low in this retrospective series. Although these relatively low-quality data should be interpreted with caution, we believe that the use of this mesh kit shows promise.

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References


