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BRIEF ARTICLE

Surgical repair of pelvic organ prolapse and follow-up: An institutional multi-center experience

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Abstract

AIM: To investigate the effects of the Elevate Anterior and Posterior transvaginal mesh procedure on 30 patients affected by pelvic organ prolapse (POP) at 12 mo follow-up.

METHODS: Between September 2011 and September 2012, a prospective multicenter observational study enrolled 30 consecutive patients with POP-Q ⩾ stage Ⅱ. After a preoperative evaluation, patients underwent prolapse repair utilizing the Elevate Anterior and Posterior Prolapse Repair System (American Medical Systems, Minnetonka, MN, United States). Operative technique was standardized and performed by the same surgical team under spinal or general anesthesia. Patients were evaluated postoperatively at 1, 3, 6 and 12 mo.

RESULTS: All 30 patients completed the 12 mo follow-up. The mean age was 65.3 years (range 49-81 years) and average hospital stay was 4.5 d. The mean operative time was 65 min (range 40-120 min). Related adverse events reported were mesh extrusions (6.7%) and post void residual urine volume (13.3%). There were no visceral injuries, no infection of the mesh, and no symptoms of recurrent prolapse. All quality-of-life scores significantly improved from baseline.

CONCLUSION: One year's follow-up of our 30 patients confirms the safety and the efficacy of the Elevate Anterior and Posterior transvaginal mesh procedure for POP treatment. Our final results are comforting but longer term follow-up is ongoing.

Key words: Pelvic organ prolapse; Pelvic organ prolapse; Mesh; Vaginal mesh erosion

Core tip: Our initial results show that the vaginal repair of anterior/apical and posterior wall prolapse utilizing a wall mesh placed *via* the Elevate system is an effective, safe and minimally invasive procedure for the treatment pelvic organ prolapse and shows excellent anatomical and functional results. Recent studies of the anatomical and physiological pelvic floor characteristics favored new generation prosthetic surgical techniques with advanced tools and biocompatible mesh in order to allow lower recurrence rates. Our final results are interesting and comforting but longer term follow-up is ongoing.

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INTRODUCTION

Pelvic organ prolapse (POP), including anterior and/or posterior vaginal prolapse, uterine prolapse and enterocele, is a common group of clinical conditions affecting millions of women worldwide[1,2]. Data from the Women's Health Initiative revealed anterior POP in 34.3%, posterior wall prolapse in 18.6%, and uterine prolapse in 14.3% of women[3].

There are approximately 250000 procedures annually in the United States for POP, with a prevalence of 11.1%[1]. POP includes a range of disorders, from asymptomatic disturbed vaginal anatomy to complete vaginal eversion associated with considerable degrees of urinary, defecatory and sexual dysfunction. The pathophysiology of prolapse is multifactorial, including neuromuscular dysfunction and fascial defects in the integrity of the uterosacral-cardinal complex[4]; however, genetically susceptible women more exposed to life events results in the development of a clinically significant prolapse.

Main risk factors are age, obstetric history[5], obesity[6], chronic lung and intestinal disease, history of hysterectomy[7], history of previous prolapse operations, and race[8]. Estrogens have a protective role[9,10] and so menopausal women are mainly involved. The support mechanisms reduction predisposes the herniation of the pelvic organs in the vaginal canal[11], causing several symptoms related to the severity of the prolapse. The most reliable symptom is "to see or to feel a budge in the vagina"[12,13]. The evaluation of women with a prolapse requires a comprehensive approach, focusing on the function in all pelvic compartments based on a detailed patient history, physical examination and investigations.

Detailed *presurgical evaluation* is required to select the *most appropriate treatment* from a variety of medical and *surgical* options[14]. Non-surgical therapy of POP is considered in women with a mild to moderate prolapse, those who desire preservation of future childbearing, those in whom surgery may not be an option, or those who do not desire surgical intervention, and includes conservative behavioral management and the use of mechanical devices. Surgical therapy of POP includes vaginal, abdominal and laparoscopic approaches, or a combination of these approaches, with the aim to relieve or improve symptoms and restore normal vaginal anatomy.

The aim of our study is to assess the efficacy, safety and tolerability of the Elevate Anterior and Posterior transvaginal mesh procedure on 30 patients affected by POP repair at the 12 mo follow-up.

MATERIALS AND METHODS

This study is a prospective multicenter observational experience of 30 consecutive women with symptomatic stage 2 or greater of prolapse that underwent anterior and/or posterior repair using the Anterior and Posterior Prolapse Repair System (American Medical Systems, Minnetonka, MN, United States).

Table 1 Anamnestic data and classification of the patients according to pelvic organ prolapse quantification system

Age (yr)	65.3 ± 8.2 (range 49-81)
Previous hysterectomy	2 (6.7)
Menopausal	28 (93.3)
Pre-menopausal	2 (6.7)
Parity	2.3 ± 0.9 (range 0-4)
Pelvic organ prolapse's stage	
Ⅱ	7 (23.3)
Ⅲ	20 (66.6)
Ⅳ	3 (10)

Data are expressed as absolute *n* (%) or mean ± SD.

Comprehensive preoperative urogynecological exams were completed, including an evaluation of anamnestic data, obstetric history, BMI and chronic disease, a pelvic exam with prolapse quantification utilizing the Half Way System or Baden-Walker scales[15,16], and a ultrasound evaluation. Inclusion criteria were patients with symptomatic anterior or posterior compartment prolapse ≥ stage 2. Our patients received the Anterior and Posterior Elevate surgical procedure, with a consecutive 1 year follow-up at our center.

Operative technique was standardized and the surgery was performed by an expert surgical team under spinal or general anesthesia, according to anesthetist decision and patient's preference. The procedure began with injection of 40-60 cc of hydrodissection solution (25 cc of 1% lidocaine with epinephrine 1:200000 diluted in 250 cc of saline) into the anterior vaginal wall. A 3 to 4 cm vertical incision is then made in the anterior vaginal wall with a full-thickness hydrodissection. Elevate Anterior and Apical utilizes self-fixating tips that allow safe, simple and precise mesh placement in the sacrospinous ligament and the obturator internus muscle. In the Elevate Posterior procedure, the apical mesh arms are anchored to the sacrospinous ligaments and the distant portion of the graft was trimmed at the discretion of surgeon to fit vaginal length attached to the perineal body and rectovaginal septa bilaterally. A prophylactic antibiotic (ceftriaxone 2 g + metronidazole 500 mg) was administered. Subjects were evaluated postoperatively at 1, 3, 6 and 12 mo.

Statistical analysis

The analyzed data were collected and evaluated by an external statistician independent reviewer. Descriptive statistical analysis was performed with continuous variables, summarized using mean ± SD or median, and discrete variables were reported using numbers and percentages.

RESULTS

The mean age of the 30 patients was 65.3 years (range 49-81 years) and their mean parity was two deliveries (range 0-4). The demographic characteristics are summarized in Table 1. Of the 30 patients, 7 (23.3%) had stage Ⅱ prolapse, 20 (66.6%) stage Ⅲ and 3 (10%) had stage Ⅳ

on pre-operative pelvic examination. Two patients (6.7%) had a previous hysterectomy. No patients had a history of previous anterior or posterior vaginal wall repair. Fourteen patients (46.7%) had urinary problems, in particular urinary retention with a preoperative post void residual volume. Twenty-four (80%) patients underwent prolapse repair with Anterior and Apical Prolapse Repair ± Posterior Prolapse Repair System.

Concurrent colpohysterectomy was performed in 6 (20%) patients. There were no major intraoperative complications and the mean duration of operations was 65 min (range 40-120 min). There were no post-operative bleeds or hematomas and the mean postoperative body temperature was 37.1 ± 0.5 ℃.

The average hospital stay was 4.5 ± 1.38 d and the Foley catheter was removed after 72 h. All 30 patients completed the 12 mo follow-up. During follow-up, no patients had symptoms of recurrent prolapse or urinary problems. Four patients (13.3%) had a minimal asymptomatic post void residual urine volume. Two patients (6.7%) had partial mesh erosion; these women were treated with local application of 1 g of vaginal Promestriene (Colpotrophine, TEVA, Milan, Italy) twice a day for 1 mo.

After this therapy, patients returned to the surgery room for partial mesh excision, then the edges of the vaginal epithelium were trimmed where appropriate and re-approximated, with good results in their follow up. No mesh had to be removed secondary to allergic reaction or infections.

DISCUSSION

Over the years, numerous surgical techniques were used in the management of POP but few controlled studies were designed to assess the complexity, costs and long-term efficacy of individual procedures[17].

Surgical mesh has been used since the 1950s to repair abdominal hernias. In the 1970s, gynecologists began using surgical mesh products indicated for hernia repair for abdominal repair of POP and in the 1990s, gynecologists began using surgical mesh for surgical treatment of stress urinary incontinence and transvaginal POP repair. Over the next few years, surgical mesh products for transvaginal POP repair became incorporated into "kits" that included tools to aid in the delivery and insertion of the mesh. Surgical mesh kits continue to evolve, adding new insertion tools, tissue fixation anchors, surgical techniques and absorbable and biological materials.

Recent studies of the anatomical and physiological pelvic floor characteristics[18] favored new generation prosthetic surgical techniques. These involve the use of advanced tools and biocompatible mesh and allow better results and lower recurrence rates. As the implementation of synthetic materials in POP surgery has increased, so has the reporting of complications.

From 2008 to 2010, the most frequent complications reported to the Food and Drug Administration (FDA) from the use of surgical mesh devices for POP repair included vaginal mesh erosion (also called exposure, extrusion or protrusion), pain (dyspareunia), infection, urinary problems, bleeding and organ perforation. There were also reports of recurrent prolapse, neuro-muscular problems, vaginal scarring and shrinkage, and emotional problems. Based on evaluation of adverse event reports and assessment of the scientific literature, the FDA has not seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to a greater risk, as mesh erosion or extrusion.

For instance, when minor mesh erosion or extrusion occurs, observant management alone or the use of topical estrogens cream particularly in asymptomatic women are viable options. More commonly, the excision of exposed mesh with re-approximation of the vaginal defect is performed. However, in severe cases such as infection, complete or total excision of the mesh is required[19].

While the literature suggests an anatomical benefit to anterior repair with mesh augmentation, this anatomical benefit may not result in superior clinical outcomes and the associated risk of adverse events should be considered. Based on these findings, the FDA is considering regulatory changes that may improve our understanding of the safety and effectiveness of these devices and has specific recommendations for patients and healthcare providers[20].

Our surgical treatment utilizing the Elevate Anterior and Posterior Prolapse Repair System showed excellent anatomical and functional results and an objective cure rate of 100% within 12 mo. Subjectively, no patients complained of symptomatic prolapse (100% subjective cure rate) and no patients had urinary symptoms during follow-up.

Olsen *et al*[1] described as many as 29% of women treated with traditional surgical techniques having to undergo repeat surgery. Traditional anterior and posterior compartment repair utilizing the patient's own tissue is a compensatory procedure that utilizes weakened and/or damaged tissue and has reported failure rates in the range of 40%-60%[21]. Additionally, techniques like plication or colporrhaphy do not provide any apical support, which may also contribute to the failure rates seen with this type of repair[22].

Compared to other techniques utilizing synthetic mesh, Moore *et al*[22] believe the Anterior Elevate procedure to be less invasive and a more simplified technique for placing a wall graft.

Our mesh erosion rate (6.7%) was similar with the literature data; Stanford *et al*[23] reported a 5.6% of erosion rate in a 12 mo multicenter study on 142 patients at ICS 2011.

In our practice, the demand for uterine preservation during surgical management of uterovaginal prolapse is increasing. However, the current data of medical literature on this clinical problem are inadequate to assist a surgeon in determining which patients are ideal for uterine preservation[24].

At present, the decision is usually influenced by the patient's preferences, the surgeon's experiences[24] and the presence of uterine or cervical pathology. The current study is limited by its medium term follow-up.

In conclusion, although limited by its short follow-up period, our initial results show that the vaginal repair of anterior/apical and posterior wall prolapse utilizing a wall mesh placed *via* the Elevate system is an effective, safe and minimally invasive procedure for the treatment POP. It allows restoration of the vaginal length without compromising its caliber.

We find our research needs more study for determining the ideal utilized material and the optimal way to place and attach the graft vaginally. However, it can be expected that improvements in technology and techniques will continue. We recommend further prospective studies with longer term follow-up to delineate more deeply the Elevate Anterior and Posterior Prolapse Repair System role in clinical practice.

COMMENTS

Background

Pelvic organ prolapse (POP), including anterior and/or posterior vaginal prolapse, uterine prolapse and enterocele, is a common group of clinical conditions affecting millions of women worldwide. Over the years, numerous surgical techniques were used in the management of POP.

Research frontiers

Further prospective studies are needed to delineate more deeply the Elevate Anterior and Posterior Prolapse Repair System role in clinical practice, with longer term follow-up.

Innovations and breakthroughs

The authors' surgical treatment utilizing the Elevate Anterior and Posterior Prolapse Repair System showed excellent anatomical and functional results and an objective cure rate of 100% within 12 mo. Subjectively, no patients complained of symptomatic prolapse (100% subjective cure rate) and no patients had urinary symptoms during follow-up.

Applications

The initial results show that the vaginal repair of anterior/apical and posterior wall prolapse utilizing a wall mesh placed *via* the Elevate system is an effective, safe and minimally invasive procedure for the treatment POP and showed excellent anatomical and functional results. Recent studies of the anatomical and physiological pelvic floor characteristics favored new generation prosthetic surgical techniques with advanced tools and biocompatible mesh in order to allow better results and lower recurrence rates.

Terminology

POP, including anterior and/or posterior vaginal prolapse, uterine prolapse and enterocele, is a common group of clinical conditions affecting millions of women worldwide, with a prevalence of 11.1%. POP includes a range of disorders, from asymptomatic disturbed vaginal anatomy to complete vaginal eversion associated with considerable degrees of urinary, defecatory and sexual dysfunction. The pathophysiology of prolapse is multifactorial and the main risk factors are age, obstetrics history, obesity, chronic lung and intestinal disease, history of hysterectomy, history of previous prolapse operations, and race. Estrogens have a protective role and so menopausal women are mainly involved.

Peer review

The authors present a prospective multicenter observational study of 30 consecutive female patients with symptomatic stage 2 or greater of prolapse that underwent anterior and/or posterior repair using a new minimally invasive technique with a single vaginal incision. Overall, the results of the study are interesting and clinically relevant. The study design appears clear and straightforward, the statistics are basic, the results are interesting and clinically relevant, and the background review of the literature sufficient and supportive of the specific aims and results.

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