Comprehensive Evaluation of Anterior Elevate System for the Treatment of Anterior and Apical Pelvic Floor Descent: 2-Year Followup

David E. Rapp,* Ashley B. King, Bruce Rowe and Jeff P. Wolters

From the Virginia Commonwealth University School of Medicine (ABK, JPW) and Virginia Urology Center for Incontinence and Pelvic Floor Reconstruction (BR), Richmond (DER), Virginia

Purpose: The Elevate® Anterior and Apical Prolapse Repair System is a polypropylene mesh that is anchored through sacrospinous ligament and obturator fascia fixation points. We present a comprehensive evaluation of this prolapse repair system through 2 years with a focus on safety, operative characteristics, and anatomical, subjective and quality of life outcomes.

Materials and Methods: A total of 42 women underwent repair of stage II or greater anterior/apical compartment prolapse using the repair system, of whom 2 were lost to followup. Anatomical outcomes were assessed using POP-Q (Pelvic Organ Prolapse Quantification) staging. Subjective and quality of life outcomes were assessed by the validated ICIQ (International Consultation on Incontinence Questionnaire)-VS (Vaginal Symptoms), ICIQ-FLUTS (Female Lower Urinary Tract Symptoms) and IIQ-7 (Incontinence Impact Questionnaire-7). Additional outcomes included a 3-day bladder diary and cough test with outcomes assessed preoperatively, at 6 weeks, and at 1 and 2 years.

Results: Mean ± SD blood loss was 93 ± 55 cc and mean operative time was 58 ± 27 minutes. POP-Q points Aa, Ba and C improved from 0.9, 0.8 and −1.3 preoperatively to −2.1, −2.7 and −6.1 cm at 2 years, respectively (each $p < 0.05$). Four patients experienced anatomical recurrence, which was associated in 2 with symptomatic recurrence on the ICIQ-VS. Statistically significant improvements in the ICIQ-VS, ICIQ-FLUTS and IIQ-7 were seen throughout followup. Adverse events included leg pain, vaginal exposure and urinary retention in 1, 2 and 5 patients, respectively.

Conclusions: The Elevate Anterior and Apical Prolapse Repair System was associated with good anatomical restoration and significant improvements in validated symptom and quality of life indexes through 2 years of assessments. Our experience suggests that the system is a safe, effective surgical procedure in appropriately selected patients. Long-term followup is important, given the FDA (Food and Drug Administration) warning regarding the use of surgical mesh in the repair of pelvic organ prolapse.

Key Words: urinary bladder, female, pelvic organ prolapse, cystocele, surgical mesh

Abbreviations and Acronyms

AES = Elevate Anterior and Apical Prolapse Repair System
MUS = mid urethral sling
POP = pelvic organ prolapse
QOL = quality of life
SUI = stress UI
TVT-O = TVT™ Obturator System
UI = urinary incontinence
UUI = urge UI

Accepted for publication August 12, 2013.
Study received Virginia Urology Center institutional review board approval.

* Correspondence: 5829 Ascot Glen Dr., Glen Allen, Virginia 23059 (telephone: 804-385-9511; FAX: 804-746-4015; e-mail: derapp@yahoo.com).

Surgical repair of POP is challenging due to the significant rate of recurrence and the various techniques available.[1] The recurrence-free survival rate was estimated to be less than 75% at 10 years in a study of multiple surgical techniques.[1] Cystocele repair is the most common type of POP surgery

0022-5347/14/1912-0389/0
THE JOURNAL OF UROLOGY®
© 2014 by American Urological Association Education and Research, Inc.
http://dx.doi.org/10.1016/j.juro.2013.08.023
Vol. 191, 389-394, February 2014
Printed in U.S.A.

with anterior colporrhaphy the most frequently chosen surgical approach.[2,3] Unfortunately, the risk of recurrence after anterior colporrhaphy is high, likely due to the poor integrity of the native tissue of the patient.[1,4] As a result, repair reinforced with synthetic grafts became popularized and evolved as a topic of controversy in the surgical community.

Proponents of mesh reinforcement for vaginal reconstruction cite high recurrence rates using nonreinforced techniques. Randomized, controlled trials and recent meta-analysis showed superior anatomical outcomes associated with mesh reinforcement compared to anterior colporraphy.[4–6] These findings are accompanied by a trend toward the development and use of trocar based mesh kits to facilitate mesh placement. Newer generations of mesh kits provide anterior and apical support, which is important due to the notable reports of nonsite specific recurrence rates after prolapse repair.[7,8] Research suggests that apical descent and anterior descent are highly associated and highlights the importance of properly evaluating and treating each compartment.[9]

However, numerous concerns also exist regarding the use of mesh for vaginal reconstruction. Mesh complications, including vaginal extrusion, bladder/urethral erosion, dyspareunia and pelvic pain, cause significant concern.[10] Indeed, the FDA warning regarding serious complications associated with transvaginal placement of surgical mesh[11] has served to further stimulate caution in the surgical community when selecting the type of repair.

The AES is a next generation mesh system that offers anterior and apical support anchored to obturator fascia and sacrospinous ligaments. We found no previous study providing subjective and objective outcomes of the AES with a minimum 2-year followup. Accordingly, we evaluated our experience using the AES with the focus on safety, operative characteristics, and subjective and anatomical outcomes through 2 years of assessments.

METHODS

We retrospectively evaluated the records of female patients who underwent AES surgery. However, data collection and patient enrollment were performed in ongoing, prospective fashion. The study included all patients with symptomatic anterior and apical compartment prolapse stage 2 or greater. Symptomatic was defined as a painful vaginal bulge that was confirmed by the ICIQ-VS domain score to be a bulge of greater than 0. Baseline evaluation included complete history, physical examination, 3-day bladder diary, urodynamics and multiple validated questionnaires. The degree of POP was quantified using the POP-Q system.[12] Urodynamics were performed in accordance with International Continence Society (ICS) recommendations and occult SUI was evaluated using pessary placement.[13] Virginia Urology Center institutional review board approval was obtained for the study protocol.

Using a technique previously reported elsewhere, AES surgery was done by 1 of 2 surgeons (BR and DER), who performed 7 and 33 procedures, respectively.[14] Briefly, the AES is composed of a type I polypropylene Intepro® Lite™ Mesh with bilateral anterior and posterior arms for graft anchoring to the obturator fascia and sacrospinous ligaments, respectively. Graft fixation is performed via self-fixating tips, which avoids blind trocar passage through the obturator and perirectal fossa seen with alternate mesh kit techniques. Concurrent TVT-O placement was offered to patients with clinical or occult SUI after discussing related risks and benefits. When possible, the TVT-O was placed via a separate vaginal incision. Cystoscopy was performed in all cases to rule out iatrogenic injury.

All patients were admitted for 23-hour hospitalization. Foley catheter and vaginal packing with estrogen cream placement were done intraoperatively and removed the following morning. Estrogen cream was not otherwise applied as part of the routine or selective preoperative or postoperative protocol. Post-void residual urine was assessed at 5 to 7 days postoperatively in the absence of urinary retention symptoms during the hospital voiding trial. Urinary retention was considered a post-void residual urine measurement of greater than 100 ml.

Outcome Assessment

Outcomes were evaluated by an abbreviated history, pelvic examination with POP-Q staging, cough test, 3-day bladder diary and validated questionnaire assessment. Examinations were performed by the primary surgeon. Outcomes were assessed at 6 weeks, and 1 and 2 years postoperatively. Additional focus was placed on operative characteristics and adverse events during followup. Mesh complications were classified according to the terminology and classification report of the International Urogynecological Association/ICS.[15]

Validated questionnaire evaluation was done using the ICIQ-FLUTS,[16] ICIQ-VS[17] and IIQ-7.[18] The ICIQ-FLUTS is a patient completed questionnaire to evaluate female lower urinary tract symptoms and the impact on QOL. It was derived from the BFLUTS (Bristol Female Lower Urinary Tract Symptoms) questionnaire. UUI and SUI were assessed separately using ICIQ-FLUTS domain scores. De novo UUI and SUI were defined as a postoperative score of greater than 0, given a baseline score of 0. The ICIQ-VS is a validated measure to assess the impact of vaginal symptoms and associated sexual matters on QOL and treatment outcome. Symptomatic recurrence was defined as anatomical recurrence (anterior or apical POP-Q stage 2 or greater) associated with an ICIQ-VS domain score of greater than 0 for a vaginal bulge. The IIQ-7 is an empirically validated instrument to evaluate QOL. Satisfaction and improvement were assessed using a separate dichotomous (yes/no) questionnaire item and a scaled item (0% to 100%), respectively.

Statistical Analysis

Statistical analysis of data was done using the Student t-test. Quantitative data are shown as the mean ± SD.

Download English Version:

https://daneshyari.com/en/article/3863412

Download Persian Version:

https://daneshyari.com/article/3863412

Daneshyari.com