Gynecology and Minimally Invasive Therapy 4 (2015) 37–40

Contents lists available at ScienceDirect

Gynecology and Minimally Invasive Therapy

journal homepage: www.e-gmit.com

Original article

Objective and subjective outcome 3 years after synthetic transobturator nonabsorbable anterior mesh use in symptomatic advanced pelvic organ prolapse surgery

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ARTICLE INFO

Article history:
Received 9 October 2014
Received in revised form
15 January 2015
Accepted 23 January 2015
Available online 20 April 2015

Keywords:
pelvic organ prolapse
perigee
sacrospinous fixation
transobturator mesh

ABSTRACT

Background: The management of using a mesh graft in the anterior compartment is reported to lead to a higher rate of recurrent prolapse after anterior colporrhaphy than after mesh repair. Several randomized controlled trials (RCTs) have shown no significantly superior subjective cure rates or reoperation rates, despite better anatomical cure rates with synthetic mesh compared with traditional anterior colporrhaphy for anterior compartment defects, however, the follow-up period in most RTCs was only 1 year.

Objective: To evaluate the objective and subjective outcome in women with symptomatic advanced pelvic organ prolapse (POP) who underwent sacrospinous fixation (SSF) with anterior vaginal mesh (AVM). We postulated that in the hands of well-trained surgeons, AVM plus SSF yields better long-term success rates with a low rate of mesh-related complications. We studied the long-term postoperative outcomes of SSF with AVM.

Study design: This was a retrospective study of 114 patients who underwent surgery for POP between January 2006 and March 2010. Patient assessment at baseline and 3-year postoperative follow-up was analyzed. SSF plus AVM was performed for apical and anterior compartment repair. Primary outcome was objective cure (POP Quantification Stage ≤ 1) and subjective cure defined as a negative response to Questions 2 and 3 on the POP Distress Inventory 6. Secondary outcomes were complications, symptoms severity, and quality of life as measured using validated questionnaires.

Results: Postoperative data for 114 patients were analyzed. Median follow up was 59.6 months. All patients completed a minimum of 3 years follow up. The objective cure rate was 100% for anterior and apical compartments and 90.4% for posterior compartment. Regarding the individual compartment, the cure rate was significantly high ($p < 0.001$ for all compartments).

There were four cases (3.5%) of mesh exposure in which all patients were treated under local anesthetic with excision of the exposed mesh without additional suturing of vaginal tissue at the outpatient office. Topical estrogen therapy was prescribed to facilitate re-epithelialization of vaginal wounds. There were no cases of mesh erosion into the bladder or other organs, and no patient needed mesh removal due to chronic pain or infection.

There was no recurrence in the anterior and apical compartment. Eleven patients (9.6%) had recurrence of the posterior compartment during postoperative follow up.

There was a significant improvements in all questionnaires with $p < 0.001$ for POP Distress Inventory 6, Urogenital Distress Inventory, and Incontinence Impact Questionnaire, and $p = 0.001$ for Prolapse/Urinary Incontinence Sexual Function Questionnaire. There was no significant difference for preoperative and 1-year postoperative urodynamic diagnosis. There were seven cases of occult urodynamic stress incontinence.

Conclusion: The Perigee System gave a favorable result in both anatomical and subjective success rates with a low rate of mesh-related morbidities. The strength of the study reported here is its long-term follow up of a relatively large number of patients and the use of validated questionnaires. Limitations are that it is not a RCT; hence, selection and indication bias is unavoidable. The favorable outcome and

Conflicts of interest: All contributing authors declare no conflicts of interest.

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http://dx.doi.org/10.1016/j.gmit.2015.01.004

low morbidities resulting from mesh use is from a single surgeon's perspective and may not be generalized to others.

Introduction

Pelvic organ prolapse (POP) may occur in up to 50% of parous women.[1] The lifetime risk of undergoing surgery for POP in the general female population aged ≤ 85 years has recently been reported to be as high as 19–20%.[2,3] This high likelihood of undergoing surgery for POP combined with the knowledge of anatomic failure rates for native tissue repairs, that range between 30% and 70% for the anterior vaginal wall and approximately 20% for the posterior vaginal wall, has led to the increased use of prosthetic mesh in vaginal prolapse surgery with the main aim to reduce anatomic failure rates and increase the durability of repairs.[4–7] The management of using a mesh graft in the anterior compartment is supported by a recent Cochrane review[1] which reported a higher rate of recurrent prolapse after anterior colporrhaphy than after mesh repair. Several randomized controlled trials (RCTs) showed no significantly superior subjective cure rates or reoperation rates despite better anatomical cure rates with synthetic mesh compared with traditional anterior colporrhaphy for anterior compartment defects,[8] however, the follow-up period in most of these RCTs was only 1 year. Therefore the conclusion made by the Food and Drug Administration based on these findings stated that there is no conclusive evidence that using transvaginally placed mesh in POP repair is an improvement over traditional POP repair without mesh and that it may expose patients to greater risks.[9]

Materials and methods

Medical records of 198 patients who underwent primary POP surgery without concomitant anti-incontinence surgery performed between January 2006 and March 2010 were retrospectively reviewed. In total 114 patients who had transvaginal anterior mesh (AVM) plus sacrospinous fixation (SSF) were evaluated. Inclusion criteria comprised patients with POP stages 3 and 4 who underwent primary POP repair. Patients who needed concomitant anti-incontinence surgery, who had previous POP repair, or who were unfit for surgeries were excluded. All patients had preoperative evaluations, including detailed medical history, physical examination, and pelvic examination. Vaginal examinations were done with patients in the semisupine lithotomy position. A split-speculum technique was used to evaluate descent of the vaginal vault, anterior and posterior vaginal walls, and uterine prolapse with maximum Valsalva maneuver. Prolapse staging was recorded according to the POP Quantification (POP-Q) system.[10]

Investigations included urinalysis, 1-hour pad test, cough stress test, and multichannel urodynamic evaluation. All patients were required to complete a 72-hour voiding diary, the Incontinence Impact Questionnaire (IIQ-7),[11] the Urogenital Distress Inventory (UDI-6),[12] the POP Distress Inventory 6 (POPDI-6),[13] and the Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12)[14] at baseline and during follow up at 12 months and 36 months. Validated Chinese versions were used for all questionnaires.[15] All conditions were defined according to the standards of the International Continence Society.[10]

Patients with poorly controlled medical conditions were optimized before surgery. All patients were counseled on the surgical procedures and informed of the potential benefits and possible complications during and following surgery. Risk of mesh-related complications, e.g., mesh erosion, chronic pelvic pain, dyspareunia, infection, and the possibility of needing additional procedures for mesh removal or trimming in case of mesh complications, were included in the counseling. Patients made an informed decision as to whether to have AVM surgery or not. Postmenopausal patients received preoperative and postoperative topical estrogen treatment unless contraindicated.

Operative procedure

All surgeries were performed by the senior author (T.S.L.), who is experienced in native tissue pelvic reconstructive surgery and trained in vaginal mesh insertion. Surgeries performed include vaginal hysterectomy, anterior vaginal mesh procedure (Perigee System; AMS, Minnetonka, MN, USA) and, if indicated, a posterior colporrhaphy. Right unilateral SSF via a posterior approach, as described by Miyazaki,[16] was adopted for all patients. Details of the surgical procedure for AVM (Perigee) were described previously.[17,18]

Cystoscopy to evaluate the integrity of the lower urinary tract was performed. All patients were given a prophylactic antibiotic of 500 mg cefazolin prior to surgery that continued every 6 hours postsurgery for 1 day. A Foley catheter and a vaginal pack (gauze soaked with povidone iodine) were placed for 72 hours. Catheterization was stopped once the amount of postvoid residual was consistently <20% of that from self-voiding. Patients with a residual urine volume persistently >150 mL for >5 days were taught to use clean intermittent self-catheterization.

Follow-up visits were scheduled at 1 week, 1 month, 3 months, 6 months, 1 year, and annually thereafter. The outcome measure was the objective cure rate at 3 years' follow up, defined as POP-Q ≤ 1 at the anterior vaginal wall and all compartments. Patient feedback on POPDI-6 with no or mild sensation of protruding abdominal organ (Question 3) and no or mild heaviness (Question 2) were considered subjective success.[19]

Descriptive statistics were used for demographics and perioperative data. Paired-sample t test, and either Chi-square or Fisher exact test were applied for comparison of pre- and postoperative continuous and categorical data, respectively. A repeated measures analysis of variance (ANOVA) was used to determine whether a difference in continuous follow up existed between groups in order to decrease the chance of type 1 error. A value of $p < 0.05$ was considered statistically significant for all comparisons. All statistical methods used the commercial software SPSS, version 17 (SPSS, Chicago, IL, USA). The institutional review board of Chang-Gung Memorial Hospital approved the chart evaluation of this study.

Results

Median follow up was 59.6 months. All patients completed a minimum of 3 years follow up. Preoperative demographics are as shown in Table 1. The objective cure rate was 100% for the anterior and apical compartment and 90.4% for the posterior compartment