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Original Article

Factors that affect early recurrence after prolapse repair by a nonanchored vaginal mesh procedure

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ABSTRACT

Objective: Prosima (Ethicon, Somerville, NJ, USA) is a novel procedure for treating pelvic organ prolapse (POP) that uses nonanchored vaginal mesh. However, nonfixation of the mesh may limit effectiveness. The aim of this study was to evaluate the safety, efficacy, and limitations of this procedure.
Materials and methods: From January 2011 through to December 2011, 52 patients with symptomatic POP $\geq$ Stage 2 undergoing the Prosima procedure at a tertiary hospital were enrolled consecutively in this prospective study. A Data and Safety Monitoring Plan (DSMP) was developed to assess the results.
Results: Fifty of the 52 patients (96%) attended the 3–6-month postoperative assessment. Symptom and quality-of-life scores were found to have improved significantly after surgery ($p < 0.05$). Forty-two patients (84%) underwent successful treatment for POP (Stage 0-1). The other eight patients (16%) were found to have recurrent Stage 2 anterior vaginal wall prolapse, although most of them (5/8) were asymptomatic. The highest morbidity, namely vaginal mesh exposure, occurred in four patients (8%) and was managed as a minor issue. Statistical analysis showed that anatomic recurrence was significantly ($p < 0.05$) associated with a "preoperative Ba $\geq$ +4 cm" (odds ratio = 20.57), "conservation of the prolapsed uterus" (odds ratio = 10.56) and "use of a concomitant midurethral sling" (odds ratio = 0.076).
Conclusion: Prosima seems to have limitations when used to manage severe anterior vaginal wall prolapse and concomitant surgery may further affect its effectiveness. The information obtained from this study's DSMP will contribute to developing a strategy to improve the use of nonanchored vaginal mesh for POP repair.

Introduction

Based on the most recent survey, the lifetime risk of undergoing surgery for pelvic organ prolapse (POP) is 19% among the general female population, which is higher than the previously reported rate of 11–12% [1]. However, attempts to correct this problem still result in a high failure rate and a significant number of patients require a second surgical procedure [2]. Most patients (60%) who undergo POP repair are aged < 60 years [3]. Therefore, an ideal surgical intervention for POP should be one that is safe, efficacious, and durable.

Recently, in an attempt to improve surgical outcomes, synthetic mesh has been increasingly used during POP reconstructive pelvic surgery. An updated Cochrane review showed that a native tissue anterior vaginal repair is associated with more failures than when polypropylene mesh is used as an overlay (relative risk = 2.14) or when armed transobturator mesh is used (relative risk = 3.55) [4]. In recent years, various trocar-guided vaginal mesh kits have been widely used for POP repair. High anatomic success rates and satisfactory functional outcomes have been reported over a number of large case series [5–7], various randomized controlled trials [8,9], and various prospective comparison studies using a variety of

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different mesh kits [10]. Furthermore, it seems that anatomic correction is sustained during both short-term [5,8–10] and medium-term [6,7] follow-up.

Recently, a trocar-free POP repair system using nonanchored mesh and a vaginal support device (VSD; Prosima, Ethicon, Somerville, NJ, USA) has been developed and is thought to provide true tension-free support with less vaginal distortion and reduced band formation [11,12]; however, nonfixation of the mesh may result in a suboptimal suspension effect with this procedure. According to recent results reported in the literature, the objective success rates for POP repair (Stage 0–1) using the Prosima procedure are only 76.9% and 69.1% at 1- and 2-year follow-up, respectively. These rates are obviously inferior to those achieved by trocar-guided vaginal mesh kits (from >80% to >90%) over the same or even longer follow-up periods [5–10].

In order to further understand the safety, efficacy, and possible limitations of the nonanchored vaginal mesh procedure (Prosima), we developed a Data and Safety Monitoring Plan (DSMP) to study the surgical results at the 3–6-month follow-up in this prospective clinical trial. The DSMP is a system for appropriate oversight and monitoring of the conduct of a clinical investigation. This oversight ensures the safety of the participants and the validity and integrity of the data. A DSMP should be commensurate with the risks associated with the investigation and can be as simple as the investigators annually submitting their safety and Adverse event (AE) information to the Institutional Review Board [13]. Statistical analysis was performed to evaluate the factors that may affect the POP treatment outcome when the Prosima procedure is used. The information obtained should contribute to the formation of a strategy for the use of nonanchored vaginal mesh as a means of POP repair.

Materials and methods

Patients

Patients were included based on the inclusion and exclusion criteria described by the Prosima study investigators involved in previous multicenter studies [11,12]. In brief, women presenting with symptomatic POP $\geq$ Stage 2 and scheduled for augmented reconstructive pelvic surgery at a tertiary hospital were enrolled consecutively in this prospective follow-up study. The exclusion criteria included previous prolapse mesh repair, hysterectomy within 6 months of the index surgery, diseases known to affect bladder or bowel function, and an inability to complete the study. All patients gave informed consent for both the surgery and the study after a full explanation. Approval for this prospective clinical trial was obtained from the Ethics Committee at our institution (IRB Taichung Veterans General Hospital, TCVGH No. CE11280). A DSMP investigation was conducted targeting the patients who had enrolled during the 1st year of this study from January 2011 through to December 2011.

Study protocol

Prior to the surgery, each patient underwent an interview that included a standard symptom and quality-of-life questionnaire [Urogenital Distress Inventory-6 (UDI-6) and Pelvic Organ Prolapse Impact Questionnaire-7 (POPIQ-7)], a pelvic examination, a cough stress test with a comfortably full bladder, and a multichannel urodynamic study. The formation and validation of the questionnaire that we use in our daily practice and as a research instrument have been detailed previously [14]. The pelvic examination was performed with the patients in a 45° upright position in an examining chair while performing the Valsalva maneuver with maximum effort. POP was quantified according to the Pelvic Organ Prolapse Quantitation (POPQ) system [15]. The multichannel urodynamic study was performed according to methods, definitions, and units that conform to the standards proposed by the International Urogynecological Association and the International Continence Society [16]. The leak point pressure and the urethral pressure profile were both determined with the prolapse protruding and with the prolapse reduced using a vaginal pessary. Patients were identified as having “occult” type urodynamic stress incontinence (USI) if stress-induced urine loss was demonstrated in the absence of a detrusor contraction with the prolapse reduced but not with the prolapse protruding [16]. Follow-up examinations were performed postoperatively at 6 weeks, 3 months, 6 months, and then annually in order to assess the anatomic and functional outcomes of the treatment. A follow-up urodynamic study was not routinely performed but was done if urinary symptoms or a positive cough stress test were indicated the need. The efficacy of the surgery was considered to be “successful” when patients were free of pressure or bulge symptoms and when the vaginal support was POPQ Stage 0–1. A “failed” surgical result was defined as a prolapse with a POPQ Stage $\geq$ 2, even without associated pressure or bulge symptoms.

Surgical procedures

The principal surgeon (M.J.H.) was proficient in vaginal reconstructive surgery with and without mesh. Before this study was conducted, live surgeries by a key member of the Prosima study investigators (M.P.C.) were observed by M.J.H. and the manufacturer's instructions for use of the kit were reviewed. The combined (anterior and posterior) Prosima procedure was performed on all patients. Concomitant surgery for the treatment of a prolapsed uterus, including vaginal hysterectomy with McCall culdoplasty or uterine conservation with McCall culdoplasty and partial trachelectomy, were carried out if necessary [14]. For the management of concurrent USI, either overt or occult type, a midurethral sling (TVT-O, Ethicon) was used. Postoperatively, all patients underwent transurethral bladder drainage. A voiding trial began on postoperative Day 3. A patient's catheter was removed once the patient could void freely and the postvoid residual was < 25% of the total bladder volume on two occasions. The VSD was removed from patients at postoperative Day 25 based on animal studies that have demonstrated that the maximum pullout force of mesh is achieved 25 days after implantation [17].

Statistical analysis

A statistical power calculation was not done because all patients who underwent the Prosima procedure in our institution were asked to register as part of this prospective follow-up study. Clinical data are presented as mean ± standard deviation, median (range), or percentage as appropriate. Univariate analysis was used to compare the pre- and postoperative POPQ stages for all three vaginal compartments and the proportion of pelvic symptoms that were present prior to and after surgery. Fifteen important clinical parameters, namely operation sequence, baseline Ba, C, and Bp (anterior, apical, and posterior) values, POPQ stages, age, parity, body mass index, diabetes mellitus, chronic constipation, occupational/recreational heavy lifting, prior prolapse surgery, concomitant midurethral sling, conservation of the prolapsed uterus, and vaginal mesh exposure, were also compared between the outcome groups by univariate analysis. Additional multivariate logistic regression analysis was conducted to evaluate the association of these clinical variables with surgical outcomes. A p value < 0.05 was considered to be statistically significant. All analyses were performed with statistical software SAS version 9.1.3 (SAS Institute Inc, Cary, NC, USA).