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Original Article

A comparative study of laparoscopic sacrocolpopexy and total vaginal mesh procedure using lightweight polypropylene meshes for prolapse repair

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ABSTRACT

Objective: Use of vaginal meshes for treatment of pelvic organ prolapse (POP) remains controversial. A trend toward abdominal approaches and the development of new meshes has been noted. We compared the 1-year results of two different approaches using new lightweight meshes.

Materials and methods: Sixty-nine (95.8%) of 72 women with POP Stage ≥ 2, who underwent laparoscopic sacrocolpopexy (LSC) ($n = 39$) or a total vaginal mesh (TVM) procedure ($n = 30$) using lightweight polypropylene meshes, were studied. Baseline and follow-up assessments included a pelvic examination and a composite condition-specific questionnaire. A detailed comparison of 1-year outcomes was made. Data were analyzed using appropriate statistical methods.

Results: Compared to the TVM group, the LSC group was characterized by a younger age (53.7 years vs. 64.1 years, $p < 0.001$) and a longer operating time (264 minutes vs. 177.6 minutes, $p < 0.001$). Objective anatomic success (POP Stage ≤ 1) rates were similar between groups after statistical adjustment, i.e., 84.6% (33/39) and 86.7% (26/30) after LSC and TVM ($p = 0.94$), respectively. However, the dominant recurrence sites were different with anterior ($n = 6$) most frequent after LSC and apical ($n = 4$) most frequent after TVM. Reoperations were needed for the four (13.3%) apical recurrences in the TVM group. No serious complications were noted. We found "cystocele as the dominant prolapse" ($p = 0.016$; odds ratio = 6.94) and "suspension of prolapsed (POP Stage ≥ 2) uterus" ($p = 0.025$; odds ratio = 7.00) significantly affected recurrence after LSC and TVM, respectively.

Conclusion: POP repair by LSC or TVM using the new lightweight polypropylene meshes seems to be safe and has comparable outcomes, but limitations may vary.

Introduction

Use of vaginal meshes for treatment of pelvic organ prolapse (POP) has resulted in high success rates in anatomic reconstruction [1,2]. However, widespread use of vaginal meshes remains controversial due to potential serious complications [1–3]. Following the withdrawal of some commercial kits from the market, there has been a shift to abdominal approaches [4–8] and the development of new surgical meshes [7–12].

Abdominal sacrocolpopexy has become the gold standard for POP [13]. An updated Cochrane review showed the procedure has better outcomes than a variety of vaginal procedures, including vaginal meshes, in terms of a higher objective success rate, a lower reoperation rate, and dyspareunia. However, it is also associated with a longer operating time, longer time to return to daily activities, and increased cost [2]. Nevertheless, these disadvantages need to be balanced against the recently introduced less-invasive methods such as laparoscopy or robot-assisted laparoscopy [6,14–16].

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Furthermore, the industry has made great advances in the development of new surgical meshes in an attempt to minimize mesh-related complications [17]. Two such kinds of meshes are available for clinical use at present, i.e., lightweight and partially absorbable polypropylene meshes [7–12]. Favorable results have been reported in both safety and efficacy profiles after sacrocolpopexy procedures using the new lightweight Y-shaped mesh [7,8]. In addition, the use of the lightweight or partially absorbable meshes in vaginal POP repair seems to contribute to a lower rate of vaginal mesh extrusion compared to the original meshes, which may or may not have a higher recurrence rate [9–12].

Maher et al [14] conducted a randomized controlled trial (RCT) to compare laparoscopic sacrocolpopexy (LSC) with a total vaginal mesh (TVM) procedure using original standard-weight polypropylene meshes for prolapse repair. A higher success rate and lower reoperation rate were noted after LSC when compared to TVM [14]. We hypothesized that the two procedures may have comparable surgical outcomes using the new lightweight meshes. The objective of this study was to compare 1-year results of the two procedures.

Materials and methods

Study protocol

This was a non-randomized controlled study conducted at a tertiary referral medical center in Taiwan. Between January 2012 and December 2012, women who were referred for mesh-augmented POP repair were enrolled consecutively. The inclusion and exclusion criteria were described in our previous study [18]. In brief, patients who presented with a symptomatic POP $\geq$ Stage 2 and did not have a previous prolapse mesh repair, hysterectomy within 6 months of the index surgeries, diseases known to affect bladder or bowel function, and were able to complete the study, were enrolled. Patients were either counseled to undergo an LSC using a lightweight Y-shaped polypropylene mesh (Alyte; C.R. Bard, Covington, GA, USA) or a TVM procedure using a partially absorbable polypropylene mesh (Prolift + M; Ethicon, Somerville, NJ, USA). All patients gave informed consent after they received a full explanation of the procedure. The primary outcome measures were objective anatomic success rates and functional results. The secondary outcome measures were surgical complications and reoperations.

Baseline assessment

Prior to the operation, all patients were interviewed and were required to complete a composite condition-specific questionnaire containing the short-form Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7) [19], and the short-form Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) [20]. All patients also underwent a pelvic examination and a multichannel urodynamic study. POP was quantified according to the Pelvic Organ Prolapse Quantification (POPQ) system [21]. The urodynamic study was performed according to the methods, definitions, and units which conform to the standards proposed by the International Urogynecological Association and the International Continence Society [22].

Surgical intervention

Operations were performed according to the surgical technique that was described by Maher et al [14] with some modifications to LSC for uterine preservation similar to the methods described by Lee et al [23]. The lightweight Y-shaped mesh (Alyte; C.R. Bard) used in LSC has a density of <20 g/m^2 in contrast to the original heavy (95 g/m^2) mesh (Marlex; C.R. Bard) [8]. The mesh was fashioned to suit the individual with the anterior leaf 5 cm and the posterior leaf 7 cm in length, respectively. The partially absorbable polypropylene mesh (Prolift + M; Ethicon, Somerville, NJ, USA) used in TVM was reported to have a density of 57 g/m^2 and, after a full absorption following implantation, has a final density of 31 g/m^2 as opposed to the 45 g/m^2 of the original mesh [10]. The surgical team (M.-J.H. and C.-P.T.) was skilled in laparoscopic and vaginal reconstructive surgeries with or without meshes. Concomitant surgeries were performed as indicated, including a hysterectomy (total or subtotal), a mid-urethral sling (TVT-O; Ethicon) and a perineorrhaphy. Hysterectomy was performed only if uterine or cervical pathology was found at baseline assessment or on patient request. 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 post-void residual was <25% of the total bladder volume and <100 mL on two occasions.

Follow-up investigation

Follow-up examinations were performed at the postoperative 3-, 6-, and 12-month visits, and then annually. Follow-up assessment and data collection were performed by a clinical research fellow (C.-K.L.) who was blinded to patient baseline data to eliminate bias. The surgery was considered successful in patients who were free of bulge or pressure symptoms and in whom the vaginal support was POPQ Stage $\leq$ 1. Functional outcome was measured by comparing the pre- and postoperative scorings on the PFDI-20, PFIQ-7, and PISQ-12, respectively. Patients were encouraged to engage in sexual intercourse 3 months after surgery. Dyspareunia was defined as an answer of $\geq$2 ("sometimes") to Question 5 of the 12-month PISQ-12. During each postoperative pelvic examination, the research fellow looked for evidence of vaginal mesh extrusion and stress urinary incontinence by using a cough stress test.

Statistical analysis

Clinical data are presented as mean ± standard deviation, median (range), or percentage when appropriate. Univariate analysis was used to compare the demographic and surgical data, POPQ stages and various parameters, and functional results between groups. The association between objective anatomic outcome and important clinical variables was examined by a multivariate logistic regression analysis. Sixteen variables [i.e., age, body mass index, parity, diabetes, point B anterior (Ba), cervix or vaginal cuff (C), point B posterior (Bp), and genital hiatus (GH) values, three individual and the total POPQ stages, dominant prolapse sites, previous prolapse surgery, suspension of prolapsed ($\geq$Stage 2) uterus, and concomitant mid-urethral sling] were tested by using forward selection methods. A p value of <0.05 was considered as statistically significant. Statistical analyses were performed using SAS 9.2 software (SAS Institute Inc, Cary, North Carolina, USA).

Results

Patient characteristics

Of the 72 patients enrolled, three (1 LSC and 2 TVM) were lost to follow-up at 1 year. The remaining 69 (95.8%) women, who underwent an LSC ($n = 39$) or a TVM procedure ($n = 30$), were studied. Demographic data are shown in Table 1. Compared to the TVM group, the LSC group was characterized by a significantly younger age at operation, lower parity, lower body mass index, and a lower percentage of menopause. The majority of patients enrolled did not