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Original Article

Single incision anterior apical mesh and sacrospinous ligament fixation in pelvic prolapse surgery at 36 months follow-up

Tsia-Shu Lo [a, b, c, *], Ahlam Mahmoud Al-Kharabsheh [d, e], Yiap Loong Tan [f], Leng Boi Pue [g], Wu-Chiao Hsieh [b, d], Ma. Clarissa Uy-Patrimonio [d, h]

[a] Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Keelung, Medical Center, Keelung, Taiwan, Republic of China
[b] Division of Urogynecology, Department of Obstetrics and Gynecology, Linkou, Chang Gung Memorial Hospital, Linkou Medical Center, Taoyuan, Taiwan, Republic of China
[c] Chang Gung University, School of Medicine, Taoyuan, Taiwan, Republic of China
[d] Fellow of the Division of Urogynecology, Department of Obstetrics & Gynaecology, Chang Gung Memorial Hospital, Taoyuan, Taiwan, Republic of China
[e] Department of Obstetrics and Gynecology, Mu'tah University, Al-Karak, Jordan
[f] Department of Obstetrics and Gynecology, Kuching Specialist Hospital, KPJ, Sarawak, Malaysia
[g] Department of Obstetrics and Gynecology, Subang Jaya Medical Centre, Selangor, Malaysia
[h] Department of Obstetrics and Gynecology, Dr. Pablo O. Torre Memorial Hospital, Bacolod City, Philippines

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ABSTRACT

Objective: To compare the clinical efficacy, recurrence, complications and quality of life changes 3 years after Elevate-A/single incision mesh surgery anterior apical (SIM A) and sacrospinous ligament fixation (SSF) in the management of pelvic organ prolapse (POP).

Materials and methods: A prospective cohort study, 139 women, underwent transvaginal surgery for anterior and/or apical POP > stage 2, 69 patients had SIM A and 70 patients had SSF. The objective cure was defined as POP ≤ stage 1 anterior, apical according to POP-Q. Subjective cure is patient's negative feedback to question 2 and 3 of pelvic organ prolapse distress inventory 6 (POPDI-6). Patient's satisfaction was reported using validated quality of life questionnaires. Multi-channel urodynamic study was used to report any voiding problems related to the prolapse surgery 6 months after surgery.

Results: 119 patients completed a minimum of 3 years follow-up. 89.8% is the overall prolapse correction success rate for SIM A and 73.3% for SSF group ($p = 0.020$), and 96.6% versus 73.4% at the anterior vaginal compartment respectively ($p \leq 0.001$). Statistically significant difference was noticed in apical compartment with 98.3% with SIM A and 85.0% with SSF ($p = 0.009$). The subjective success rate, 86.4% in the SIM A and 70.0% in the SSF arm ($p = 0.030$) was significantly noted. Only, Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6) showed significant improvement. Operation time and intra-operative blood loss tend to be more with SIM A.

Conclusion: SIM A has better 3 years objective and subjective cure rate than SSF in the anterior and/or apical compartment prolapse.

Introduction

Approaches to the surgical management of pelvic organ prolapse (POP) have undergone several paradigm shifts over the last few decades [1]. Innovative technologies are being incorporated into treatment modalities, specifically in the arena of surgical devices. An ideal prolapse repair would be simple, effective, and durable procedure with less morbidity and short recovery time. Numerous surgical procedures have been described either vaginally or abdominally in the attempt to provide the best surgical repair for POP. One of the most common procedures performed for the correction of apical prolapse is the sacrospinous ligament fixation (SSF).

Although the efficacy of unilateral SSF in preventing and treating apical prolapse ranged between 78 and 96% [1], the recurrence of anterior prolapse after the surgery led to its popularity waning

* Corresponding author. Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Keelung, Medical Center, 222, Maijin Road, Keelung 204, Taiwan, Republic of China. Fax: +886 2 24313131.
E-mail address: 2378@cgmh.org.tw (T.-S. Lo).

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between surgeons especially with the development of graft used in pelvic reconstructive surgery. Lo et al. reported a favorable and sustainable anatomical and subjective outcomes result over 5 years in cases of advanced POP, comparing SSF with non-absorbable anterior vaginal mesh and anterior colporrhaphy [2].

Transvaginal mesh (TVM) augmented surgery for the treatment of POP has been introduced in an attempt to improve long-term durability of vaginal POP surgery. Regaining popularity currently is the mesh kit which includes apical support apart from the normal anterior and posterior compartment support. One such kit is the Elevate-A (Elevate® Anterior and Apical Prolapse Repair System, American Medical Systems, Minnetonka, MN, USA) (SIM A, single incision mesh-anterior apical) which is now used for anterior and apical prolapse repair.

Literature reviews on SSF and anterior apical prolapse repair are still lacking. Thus, our aim is to evaluate the objective and subjective success rates and safety issue regarding the use of SIM-A compare to SSF and to establish any superiority for one over the other at third year post-operatively.

Materials and methods

Institutional Review board approval was obtained for this prospective cohort study, (IRB#: 99-0037B), which was carried out between May 2010 and April 2012 in CGMH Taipei and Linkou. All patients who attended the urogynecology clinic during the study period with symptomatic anterior or apical prolapse >stage 2 according to the pelvic organ prolapse quantification system (POP-Q)/international continence society (ICS) [7] were enrolled. Patients from Taipei were offered SIM-A while patients from Linkou were offered SSF repair.

Women who had preoperative stress urinary incontinence (SUI), previous POP mesh-augmented surgery, previous anti-incontinence procedures and who were medically unfit for surgery were excluded. Preoperative SUI was diagnosed based on clinical symptoms, cough stress test and multichannel urodynamic evaluation (UDS); which were performed in semi-lithotomy position with a ring pessary for prolapse reduction. Urodynamic stress incontinence (USI) was defined as an involuntary urinary leakage with the increased in intraabdominal pressure in the absence of detrusor contraction during filling cystometry. Patients who had SUI only when prolapse has been repositioned were considered to have occult SUI. All women with overt or occult SUI were excluded in this study.

Preoperative baseline assessments included detailed clinical history and physical examination; including pelvic examination, cough stress test, baseline urine analysis, 1-h pad test, 72-hr micturition diary. Multichannel UDS with a ring pessary for prolapse reduction were done regardless of complaints of urine leakage in order to diagnose occult SUI. POP staging was recorded according to POP-Q system [3]. All patients were required to fill up questionnaires, i.e: Incontinence Impact Questionnaire-7 (IIQ-7) [4], Urogenital Distress Inventory 6 (UDI-6) [5], Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) [6], and Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12) [7]. Validated Chinese versions were used [8]. All conditions were defined according to ICS standards [3].

Pre-operatively, all women were counseled regarding treatment options including the potential benefits and complications during the operation and post-operatively. Informed consent was secured prior to treatment.

Operative procedure

All surgical procedures were performed in the following order: vaginal hysterectomy, Elevate A: Elevate® Anterior and Apical Prolapse Repair System implantation or right-sided posterior approach SSF. Anterior and posterior colporrhaphy were performed if indicated.

For patients who developed USI after the operation and required surgical interventions, interval anti-incontinence surgery was performed using midurethral sling (MUS).

In brief, for SIM-A: after hydrodissection of the vesicovaginal space, a single full thickness vertical incision was made on the anterior vaginal wall. The paravesical fossa was dissected bilaterally from the level of the ischiopubic ramus to the ischial spine until both the sacrospinous ligaments (SSL) were identified. The vaginal apex was transfixed at the proximal end of the mesh and both the apical self-fixating strips were inserted into SSL bilaterally. The distal end of the mesh was transfixed to the urethrovesical junction while the distal self fixating tip was anchored to the obturator internus muscle. SIM-A mesh was trimmed intra-operatively approximately at the junction of the two distal arms which resulted in an implanted mesh measurement of 5.0 × 6.5 cm.

In the SSF group: the vaginal vault was attached to the SSL via a posterior approach using monofilament polypropylene number 1 (Prolene™, Ethicon, Nashville, TN, USA) following the unilateral right-sided procedure described by Miyazaki [9].

Intraoperative cystoscopy was performed for all patients to evaluate the integrity of the lower urinary tract. Prophylactic antibiotic intravenous Cefazolin 500 mg were given preoperatively and every 6 h for 24 h. Vaginal packing was done with gauze soaked with Povidone Iodine and was removed after 24 h. Foley's catheter was inserted during the operation and left in place for 24 h. Patients were encouraged to void freely following Foley's catheter removal and discharged home if residual urine (RU) was consistently <20% of the voided volume. Bladder was scanned (BVI 3000; Diagnostic Ultrasound Corp., Bothell, WA, USA) for post-void residuals every 4 h after catheter removal. Sterile, intermittent catheterization was performed when the post-void RU exceeded 150 ml and will stop only once the RU is <150 ml. Clean intermittent self-catheterizations were recommended to patients with persistent large RU.

Follow-up visits were scheduled at 1-week, 1-month, 3-months, 6-months, 1-year and annually thereafter. POP-Q evaluation on each patient were done. UDS were performed at 6–12 months post-operatively. Questionnaires were completed at 1 year and then annually post-operatively.

Outcome measures

The primary outcome measures were the objective cure rate which was defined as stage ≤1 prolapse at anterior or apical vaginal wall and all other compartments at 3-year after surgery. Subjective cure rate based on the patient negative feedback to question 2 (no or mild heaviness) and 3 (no or mild abdominal organ falling sensation) in POPDI-6 questionnaire [5]. The secondary outcome measures were the changes in quality of life that were assessed by the self-administered questionnaires patients were asked to complete. Peri- and postoperative complications were also recorded. Bladder outlet obstruction (BOO) was defined as peak flow rate (Qmax) of 15 ml/s or less and a detrusor pressure at maximal flow (Dmax) of 20 cm H_2O or more [10].

Statistical analysis

Descriptive statistics were used for the demographics and preoperative data. Student t-test was applied for comparison of continuous data. Intergroups comparisons were made for categorical variables using the chi-square or Fisher's exact tests. When the assumption of the chi-square test was violated (i.e., when > 1 cell had an expected count of <1 or >20% of the cells had an expected