Bilateral Sacrospinous Vault Fixation With Tailored Synthetic Mesh Arms: Clinical Outcomes at One Year

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Abstract

Objectives: Bilateral sacrospinous fixation with tailored mesh arms (bSSVF) uses polypropylene mesh to suspend the vault to the sacrospinous ligaments bilaterally with minimal tension, recreating nulliparous midline anatomy. It can be used with uterine conservation. Our primary objective was to determine objective cure rate at one year following bSSVF compared with a control group undergoing abdominal sacrocolpopexy (ASC). Secondary objectives were to compare symptoms, quality of life, sexual function, pain, and global satisfaction before and after surgery and between bSSVF and ASC groups at one year.

Methods: This prospective cohort study enrolled patients with symptomatic prolapse who chose to undergo bSSVF or ASC. Baseline demographics were obtained. Prolapse quantification, validated symptom questionnaire scores, and McGill pain scores were obtained at baseline, six weeks, and one-year postoperatively. Global satisfaction was recorded. The primary outcome measure was the difference in cure rate (vault stage ≤ 1) between groups.

Results: Fifty patients were recruited: 30 underwent bSSVF and 17 ASC. Forty-three patients were available for one-year follow-up. Baseline data were similar. There was no difference in vault stage between bSSVF and ASC groups at one year. Five women who underwent bSSVF had cervical elongation, and four of these were classified as POP recurrence. Women who underwent bSSVF had more anterior recurrences but fewer postoperative complications, shorter hospital stay, and less use of narcotics than controls. Questionnaire scores were similar at one year. All respondents felt subjective improvement after either surgical procedure.

Conclusions: Objective and subjective cure rates are comparable after bSSVF and ASC. Hysteropexy may cause cervical elongation that merits further research.

Key Words: Pelvic organ prolapse, bilateral sacrospinous fixation, synthetic mesh

Competing Interests: None declared.

Received on July 20, 2014

Accepted on October 15, 2014

Résumé

Objectifs : La fixation sacro-vertébrale bilatérale du dôme vaginal au moyen de languettes de treillis adaptées (bSSVF) fait appel à du treillis de polypropylène pour suspendre bilatéralement le dôme vaginal aux ligaments sacro-vertébraux en n'ayant recours qu'à une tension minimale, ce qui permet de recréer une anatomie alignée sur le plan médian semblable à celle de sujets témoins nullipares. Son utilisation peut s'accompagner d'une préservation de l'utérus. Nous avions pour objectif principal de déterminer le taux de guérison objectif à un an à la suite de la bSSVF, par comparaison avec un groupe témoin faisant appel à la sacrocolpopexie abdominale (SCA). Nos objectifs secondaires étaient de comparer les symptômes, la qualité de vie, la fonction sexuelle, la douleur et la satisfaction globale avant et après la chirurgie, et entre les groupes « bSSVF » et « SCA » à un an.

Méthodes : Cette étude de cohorte prospective a sollicité la participation de patientes présentant un prolapsus symptomatique qui avaient choisi de subir une bSSVF ou une SCA. Leurs caractéristiques démographiques de base ont été documentées. Nous avons également documenté la quantification du prolapsus, les scores obtenus à un questionnaire validé portant sur les symptômes et les scores de douleur McGill au départ, ainsi qu'à six semaines et à un an à la suite de l'opération. La satisfaction globale a été consignée. La différence constatée en matière de taux de guérison (stade du dôme ≤ 1) entre les deux groupes constituait le critère d'évaluation principal.

Résultats : La participation de 50 patientes a été sollicitée : 30 ont subi une bSSVF et 17, une SCA. Nous avons pu joindre 43 de ces patientes aux fins du suivi à un an. Les données de base étaient semblables. Aucune différence en ce qui concerne le stade du dôme n'a été constatée entre les groupes « bSSVF » et « SCA » à un an. Cinq des femmes ayant subi une bSSVF ont connu une élongation du col utérin; quatre de ces cas ont été classés comme constituant une récurrence du prolapsus des organes pelviens. Bien que les femmes ayant subi une bSSVF aient connu un plus grand nombre récurrences antérieures, elles ont également connu moins de complications postopératoires, leur hospitalisation a été de plus courte durée et on leur a administré moins de narcotiques, par comparaison avec les témoins. Les scores obtenus aux questionnaires étaient semblables à un an. Toutes les répondantes ressentaient une amélioration subjective après avoir subi l'une ou l'autre de ces interventions chirurgicales.

Conclusions : Les taux de guérison objective et subjective sont comparables à la suite d'une bSSVF et d'une SCA. L'hystéropexie pourrait causer une élongation du col utérin qui justifie la poursuite de la recherche.

J Obstet Gynaecol Can 2015;37(2):129–137

INTRODUCTION

Pelvic organ prolapse is a bothersome, common condition of aging women. One half of parous women experience pelvic relaxation symptoms,[1] and up to 19% of women may require reconstructive surgery.[2–4] Abdominal sacrocolpopexy remains the standard procedure for apical POP, but is not without complications or recurrence.[1,5] While sacrocolpopexy is associated with a lower rate of recurrent vault POP and dyspareunia, vaginal apical repairs may be preferable because of a shorter operating time, quicker recovery, and avoidance of any abdominal incisions.[1] The advantages of the vaginal approach increase with multiple previous abdominal surgical procedures, or significant concomitant comorbid conditions. The standard operation involving vaginal unilateral sacrospinous attachment has a high recurrence of prolapse in the anterior wall, presumably due to posterior deflection of the vaginal apex.[6,7] Efforts to overcome this include bilateral attachment with or without mesh.[1] However, vaginal mesh insertion causes significant complications, including erosion, pain, dyspareunia, and reoperation for mesh removal. For example, two mesh kits marketed for apical POP correction (Prolift[8] and intravaginal slingplasty[9]) had such unacceptably high erosion rates that patient recruitment was halted for safety reasons, and ultimately the mesh kits were discontinued or withdrawn. Such evidence was considered in a recent Health Canada safety information document warning that "transvaginal mesh procedures for POP are evolving procedures that may carry higher risk of complications than established traditional abdominally placed mesh."[10] Authorities in the field of urogynaecology[1,11] have issued urgent calls for improved research on surgical techniques and materials.

With this in mind, the lead author (R.G.) designed a variation on the standard unilateral sacrospinous fixation, which uses two synthetic polypropylene mesh arms to suspend the vaginal apex (with or without a uterus in place) to the sacrospinous ligaments bilaterally. Bilateral sacrospinous vault fixation with tailored synthetic mesh arms restores uterosacral support, creating an anatomically correct midline configuration of the vaginal axis with minimal tension. By limiting the use of mesh to the deep pelvis without direct contact of mesh and vaginal incisions, we hoped to minimize the side-effects of erosion, pain, dyspareunia, and need for mesh removal described with other vaginal mesh repairs.[1] Similarly, avoiding concurrent hysterectomy in uterine prolapse could further minimize the exposure of mesh to the incision, providing a theoretical basis for retaining the uterus.[12] Magnetic resonance imaging after bSSVF has shown preservation of distances between the vaginal apex and the ischial spines, with anterior inferior displacement of the apex only a few millimetres different from the same distances in nulliparous control patients; this likely translates into no clinically relevant differences in anterior vaginal support.[13]

The aim of our prospective study was to determine clinical outcomes one year after bSSVF when compared with a group of women undergoing ASC. We hypothesized that bSSVF would provide anatomical outcomes similar to those after ASC. This should also translate into similar improvement in symptoms, but with the faster recovery and lower complication rate of a vaginal approach.

ABBREVIATIONS

ASC	abdominal sacrocolpopexy
bSSVF	bilateral sacrospinous vault fixation
POP	pelvic organ prolapse
POP-Q	pelvic organ prolapse quantification system
TVT	tension-free vaginal tape

METHODS

This study was an exploratory, pilot, prospective cohort study conducted at a tertiary care urogynaecology practice. As bSSVF is a new procedure, this study was designed to collect outcomes and safety data for a future randomized controlled trial and a convenience sample of 50 patients was deemed appropriate. Our primary outcome was objective cure, defined as a pelvic organ prolapse quantification system[14] stage of ≤ 1 in the apical compartment one-year postoperatively. Secondary outcomes included subjective cure via global impression of improvement and validated symptom and quality of life questionnaires addressing pelvic floor function and sexuality one-year postoperatively, as well as the incidence of complications and persistent pain.

Patients with symptomatic apical POP desiring surgical intervention (between 2009 and 2012) gave informed consent for surgery at a single tertiary care urogynaecology clinic in Vancouver, British Columbia. They received counselling, beginning with the results of the Cochrane review on POP treatment, and followed by the discussion of two methods of surgical repair of apical POP, bSSVF and ASC, both with synthetic mesh.[15] Patients were told that bSSVF is a new variation on a standard sacrospinous