Original article

Single incision un-anchored small mesh for surgical reconstruction of moderately prolapsed pelvic floor

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Abstract: Aims: To evaluate whether the use of single incision un-anchored small mesh implants is feasible, safe and effective for women with moderate pelvic organ prolapse. *Methods*: Patients diagnosed with moderate pelvic organ prolapse were enrolled to undergo a single incision un-anchored mesh operation. Follow-up was 12 to 31 months. The outcome measures for this study were the operative safety and post-operative pain, adverse effects and anatomical as well as functional cure. The operations were performed under general anesthesia according with the reported surgical techniques at university and private hospitals. One hundred and fifty-seven patients diagnosed with moderate pelvic floor prolapse participated in this study. Data regarding cure rate, complications and patient's satisfaction were collected prospectively; patients were interviewed and examined at the end of the first month and interviewed again at the study conclusion. *Results*: Peri-operative and post-operative data were collected from patient's charts. Anatomical findings were measured with the POP-Q system, pain levels were estimated with visual analogue scales and outcome by UDI-6 and IIQ-7 questionnaires. No significant intra- or post-operative complications were reported. At the first and twelve months postoperative follow-up both the recorded observations and patient interviews and physical check-up, as well as tele-interview at the study conclusion, indicated satisfactory cure rates and minimal adverse effects. *Conclusions*: The data presented support the proposition that single incision un-anchored small pelvic floor meshes might be used successfully in patients with moderate pelvic floor prolapse.

Key words: Single incision un-anchored small mesh; Moderate pelvic organ prolapse; Surgical reconstruction; Cure rates; Adverse effects.

INTRODUCTION

Pelvic organ prolapse (POP) occurs in some women when the supporting pelvic floor becomes weakened or stretched, usually caused by childbirth and pre-existing fascial weakness, leading to descent of the pelvic organs to the vagina and beyond. This leads to impairment of pelvic organ function and negatively affects the patient's quality of life. Pelvic floor relaxation and POP is regarded by many as a "pelvic floor herniation" process. Patients with mild, symptomatic POP may benefit from conservative management, such as physiotherapy or the use of vaginal pessaries. However, moderate and advanced POP necessitates surgical reconstruction. Mesh augmentation for pelvic floor reinforcement has been shown to improve reconstruction.[1-2] However, mesh implantation is associated with specific complications such as mesh exposure, pelvic and vaginal pain and dyspareunia, as reported in a recent FDA notification.[3] The AUGS (American Urogynecologic Society), SUFU (Society of Female Urology and Urodynamics) and ACOG (American Congress of Obstetricians and Gynecologists) have all responded to this recent FDA announcement[4-6] on the nature and frequency of POP-mesh complications in comparison with the non-mesh POP reconstruction operations.

Those societies emphasize the importance of looking for new ways to reduce the mesh complication rates. One of the significant mesh complications is post-operative pelvic pain, which is probably related to the mesh surface area and its anchoring arms.This study looked at the feasibility, safety and outcome of a single incision un-anchored small mesh insertion for pelvic floor reconstruction in physically active patients suffering from moderate pelvic floor herniation.

Patients suffering from advanced pelvic floor herniation are unlikely to benefit from reduced size un-anchored meshes, and we are not proposing that approach for this group of patients.

PATIENTS AND METHODS

This study was designed to be open cohort. Patients suffering from moderate prolapse of the pelvic floor, with Ba, Bp or C points from +1 to +3 according to the ICS POP-Q system,[7] were enrolled. Informed consent was obtained after detailed information was presented to the patients. The study procedure was approved by the institutional board committee (Helsinki committee) and carried out according to the previously reported surgical method for anterior mesh implantation.[8-9] The single incision un-anchored small mesh used was Prosima® anterior and/or posterior (Gynecare, Somerville, NJ, USA); the implants were not secured to pelvic ligaments.

All patients were given 1 gr Monocef® (Cefonicid, Beecham Healthcare, Middlesex, UK) intravenously one hour prior to surgery. They all underwent an iodine antiseptic vaginal wash before surgery. General or regional anesthesia was employed, depending on the patient's request. Urinary bladder catheterization or diagnostic cystoscopy were not carried out routinely. Patients also presenting with contralateral vaginal wall relaxation underwent either colporrhaphy or pelvic floor mesh augmentation reconstructive surgery (by Prosima® or Prolift+M®, Gynecare, Somerville, USA), depending on the severity of the herniation process. Mild degree of prolapse was treated with native tissue colporrhaphy, moderate degree with single incision small mesh, and advanced prolapse was treated with needle guided large mesh. Anti-incontinence surgery, using TVT-Obturator®, TVT-SECUR® or TVT-Abbrevo® (Gynecare, Somerville, USA), was added when indicated. Patients were followed up at one month after surgery and again at the study conclusion. All operations were carried out by a single surgeon at both private and university (public) hospitals.

The outcome measures were the anatomical and functional cure rates and the levels of post-operative pain and dyspareunia, which were recorded on special forms and a 0-10 Visual Analog Pain Scale (VAPS). Data were collected by a researcher not involved with the patients' care, based on patients' charts, interviews and pelvic examinations. Subjective data regarding urinary and fecal urgency, frequency, stress and urge incontinence, impairment of sexual function, voiding function, pelvic pain and bulging were obtained at the study conclusion

TABLE 1. – Patient characteristics.

	Patient's group (N=155)	
Age (mean and standard deviation)	59.31 ± 10.7 SD years (range 32-86)	
Parity (mean and standard deviation)	2.72 ± 1.2 SD (range 0-6)	
Ba point (mean and standard deviation)	2.24 ± 1.11 Cm. SD (range 0-2)	
Bp point (mean and standard deviation)	2.24±1.8 SD Cm. (range -3-4)	
C point (mean and standard deviation)	1.5 ± 2.75 SD Cm. (range 2-3)	
Hiatal lump	155 Pts (100%)	
	Mild	Moderate
Frequency	46 Pts (29%)	5 Pts (3%)
Urgency	38 Pts (24%)	9 Pts (6%)
Nocturia	20 Pts (13%)	4 Pts (3%)
Recurrent UTI	1Pt (1%)	0 Pts (0%)
Bladder outlet obstruction	1Pt (1%)	0 Pts (%)
Sexual discomfort	7 Pts (4%)	1 Pt (1%)
Dyspareunia	1 Pt (1%)	0 Pts (0%)
Constipation	0 Pts (0.0%)	0 Pts (0%)
Fecal incontinence	0 Pts (0.0%)	0 Pts (0%)
Stress urinary incontinence	115 Pts (73%)	
UDI 6 (mean and standard deviation)	3.17 ± 1.66 SD (range 0-9)	
Background chronic illness	38 Pts (24%)	
Duration of follow-up (mean and standard deviation)	16.41 months ± 3SD (range 4-23)	

TABLE 2. – Previous operations.

Previous operations (N=155)	**No. Pts.**	**%**
Hysterectomy (Abdominal/vaginal hysterectomy)	28 (22/6)	18% (14%/4%)
Pelvic floor reconstruction (Mesh/No mesh)	16 (10/6)	10% (6%/4%)
Anti-incontinence surgery (Burch/TVT)	11(3/8)	7% (2%/5%)
Total	**55**	**35%**

TABLE 3. – Operation performed.

Operation type (N=155)	**No. of Operations**	**%**
Un-anchored mesh (Anterior/Posterior)	196 (96/100)	126% (62% / 64%)
Anchored mesh (Anterior/Posterior)	33 (6/27)	21% (4% / 17%)
Colporrhaphies (Anterior/Posterior)	55 (39 / 16)	35% (25% / 10%)
Elongated cervix amputation	11	7%
Vaginal Hysterectomy	1	1%
Anti-incontinence surgery (TVTS/TVTA/TVTO)	116 (66 / 11 / 39)	74% (42% / 7% / 25%)

interview by the same uninvolved researcher using the UDI-6 and the IIQ-7 questionnaires. Subjective outcome successes were defined as patient's self-determined satisfaction of the over-all operative results higher than

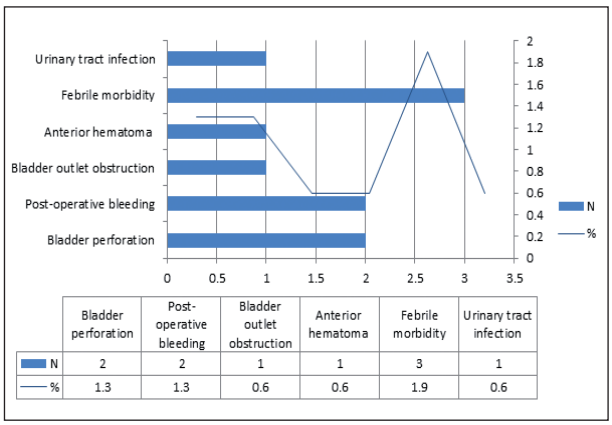

Figure 1. - Operative complications rate.

80. The follow-up period ranged from 12 to 31 months (mean 16.41 months). Objective outcome successes was defined as absence of prolapse of more than 2cm beyond the different POP-Q points, assessed by pelvic examination in accordance with the POP-Q standard ICS-IUGA terminology at the end of the first post-operative year.[7]

Statistical analysis was performed by the Wilcoxon signed-ranks test and Kruskal-Wallis Test (Nonparametric test for the significance of the difference among the distributions of k independent samples, A, B, etc., of sizes na, nb, etc., respectively) that were used to measure "before" and "after" quantitative parameters between groups. Significance was set at $P < .05$.

RESULTS

One hundred and seventy-two patients suffering from moderate pelvic floor prolapse, with either uterine prolapse or post-hysterectomy vaginal vault prolapse (Ba, Bp or C points +1 to +3) were referred for surgery with single incision un-anchored mesh implants. Six patients were excluded from the study because of refusal, 11 patients were not available for follow-up, and thus 155 were enrolled into the study. The operations were performed since January 2010 through December 2011.

The patients' pre-operative personal characteristics are tabulated in tables 1 & 2. Of the 155 study patients 82.1% also had contralateral pelvic floor reconstruction (47.3% with mesh implants) and 73.3% had a concomitant anti-incontinence TVT procedure. Operative details and operative and post-operative complications are shown in

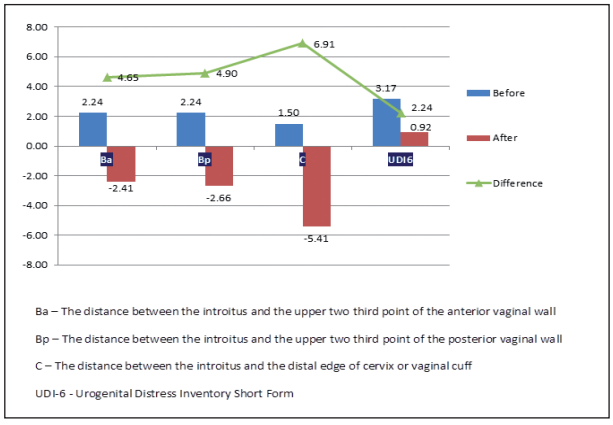

Figure 2. - Pre-operative and post-operative POP-Q system and UDI-6 measurements.

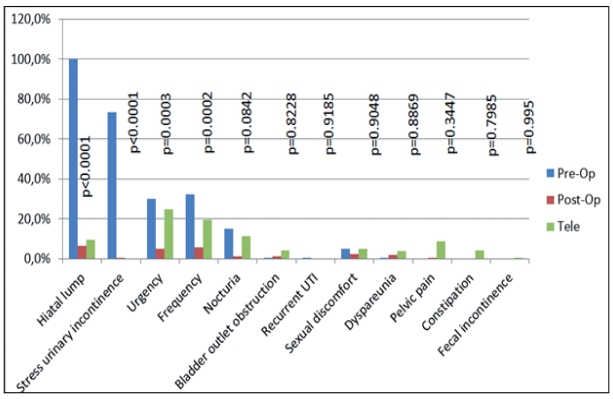

Figure 3. - Pre-operative and post-operative functional status.

table 3 and figure 1. No major complications were reported, two cases of bladder penetration that were repaired vaginally at the time of the primary procedure with no morbid sequelae; no other viscera were injured. Blood transfusion was not indicated, pain rates and severity were mild to moderate. The outcome, shown in figures 1, 2 and 3, was satisfactory both subjectively and objectively. There was anatomical improvement in terms of the various POP-Q points as well as improvement in urinary, sexual and ampular functions, based upon the patients' detailed satisfaction reports.

The POP-Q points measurements showed marked improvements: for the Ba point the average change was 4.65 cm, for the Bp point the change was 4.90 cm, and for the C point it was 6.91 cm. These measurements were all statistically significant. Bladder overactivity symptoms, viz. urgency, frequency and nocturia, were all found to be significantly reduced, as was the sexual discomfort rate. Fecal incontinence, pelvic pain and constipation rates were reduced as well, but these did not achieve statistical significance.

DISCUSSION

It is well recognized that mesh implants provide reinforcement in surgical reconstruction of the prolapsed pelvic floor. However, mesh-related adverse effects pose a troublesome problem, and means should be sought to reduce these adverse effects. Reducing the mesh surface area and removing the anchoring arms might decrease the incidence of complications, while still maintaining the desired beneficial effects.

The cohort of 155 patients presented here, reflects the common population presenting to pelvic floor clinics (Tables 1 and 2), and the outcome data suggest that reduced size single incision un-anchored mesh augmentation is safe and effective for moderate pelvic floor prolapse repair. This technique, requiring less dissection for implantation, is also less hazardous (Figure 1), than are the commonly performed operations.[1,2] The overall outcome results are promising and show statistically significant improvement. This holds true for both the anatomical outcome – demonstrating successful and stable architectural reconstruction of the pelvic floor as measured according to the POP-Q ICS method, and also in terms of the functional results (Figures 1-3). Functional outcome in terms of bladder overactivity symptoms were found to deteriorate over the period of follow-up course for reasons that are not clear. The pain levels reported here, including dyspareunia, vaginal and pelvic pain are markedly lower than those reported previously following pelvic floor reconstruction, both with and without mesh implants (Figure 3). These findings are in accordance with previously reported data regarding new single incision anchored meshes[8-9] and probably better than the data regarding the large anchored meshes.[1-2] This approach is likely to be effective in women with a moderately affected pelvic floor, but probably will not be sufficient for advanced prolapse.

This study strength is limited by being single armed and by having a rather short term follow-up. Further studies should be designed and carried out to shed more light on the issue of optimal anchoring points for reduced size single incision un-anchored versus full size needle guided mesh augmentation. As the particular mesh implant studied here is not available any more, the first author is using since 2012 another small implant, the SeraTom (Serag Wiessner, Naila, Germany).

DISCLOSURE:

Prof. M. Neuman was consultant for J&J before the Prosima production was stopped, and now is consultant to Serag Wiessner; Dr. Sumerova has no conflicts of interests.

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