Original Article

Trans-vaginal anterior vaginal wall prolapse repair using a customized tension-free bell-shaped prolene mesh: A single-center experience with long-term functional analysis

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ABSTRACT

Introduction: The existing literature shows that mesh reinforcement improves the anatomical success rate of cystocele repair. We report the long-term results of a custom bell-shaped mesh with simultaneous urethral support for the repair of cystocele.

Materials and Methods: The present study was a single-center, single-surgeon case series of 36 patients. Only patients with Pelvic Organ Prolapse Quantification system (POP-Q) stage 2 and above were included in the study. Patients having rectocele or uterine/vault prolapse were excluded. Body of the mesh was used for reinforcement of the cystocele repair and two limbs were left tension free in the retropubic space. Patients were followed 3 monthly for the first year and yearly thereafter. Recurrence was defined as cystocele ≥stage 2 (Aa or Ba 0) any time after the first follow-up.

Results: Mean patient age was 58.5 ± 6.2 years. The mean parity was 3.2 ± 1.6. Of 36 patients, 11 (30.5%) of the patients were POPQ stage 2, 15 (41.7%) were stage 3 and 10 (27.7%) were stage 4 cystocele. The mean follow-up period was 53.4 months, with 32 patients reporting for follow-up till date (88.9%). There was no bladder injury, no mesh erosion or infection. No patient required CIC (clean intermittent catheterization) or had stress urinary incontinence post-operatively at 5 years of follow-up.

Conclusion: The bell-shaped mesh is a simple, effective and safe procedure in the surgical management of cystocele with excellent long-term outcome.

Key words: Cystocele, female urology, transvaginal mesh

INTRODUCTION

Anatomical repair (colporrhaphy) of anterior vaginal prolapse (cystocele) has a high recurrence rate up from 3% to 70% depending on the follow-up interval. Many methods have been proposed to reinforce the anatomical repair, including various mesh-based methods as well as commercially available kits like prolift.

Most clinical research on this topic has focused on the feasibility and anatomic and functional results and many have underlined the potentially serious morbidity associated with mesh. Long-term functional data are scanty.

We report the long-term results of a custom bell-shaped mesh in cystocele repair with simultaneous urethral support by a single surgeon and at a single center, with a focus on functional results, and present the long-term follow-up of the same.

MATERIALS AND METHODS

This was a single-center cohort study involving 36 patients from June 2005 to December 2013. The surgeries were

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performed by a single surgeon with extensive experience in uro-gynecology and pelvic organ prolapsed (POP) repair. An informed consent was taken from the patients and an institutional ethics committee clearance was obtained before the start of this study. Demographic characters of the patients including age, parity and menopausal status were noted. Grading of the cystocele was performed according to the Pelvic Organ Prolapse Quantification system (POPQ) in the maximum valsalva effort in a semi-lithotomy position. Only patients with POPQ stage 2 and above were included in the study. Patients having rectocele or uterine/vault prolapse were excluded from the study to avoid bias. Anterior vaginal wall prolapse repair with mesh was the sole procedure in all the cases.

After taking proper consent and informing the patient about the pros and cons, including potentially serious morbidity associated with use of mesh, patients underwent anatomical repair of the cystocele followed by custom bell-shaped mesh insertion without concomitant hysterectomy. The patients were followed up at 3 monthly intervals in the first year and then yearly thereafter. Cost analysis was performed taking into account the cost of the mesh, hospital stay, additional procedures, follow-up visits and absence from work and sexual activity and were compared with the existing literature.

The procedure was carried put under epidural or spinal anesthesia in the lithotomy position. Infiltration was performed with normal saline under the vaginal mucosa. A longitudinal midline incision was made on the vaginal mucosa anteriorly extending from the level of the mid-urethra till the cervix. Vaginal flaps were raised taking care to raise thick flaps and the cystocele was dissected and reduced and uterosacral ligaments were sutured in the midline. The polypropylene mesh was then cut into a bell shape with the vertical limb shaped in an oval fashion and the horizontal limbs 10 cm long and 1 cm wide [Figure 1]. The horizontal extensions of the mesh were introduced in the paravesical spaces, which were created by perforating the endopelvic fascia distal to the bladder neck bilaterally with a finger and then making a single pass of double-pronged Raz needle under finger guidance. Both the horizontal limbs in the retropubic space were then sutured to the anterior abdominal wall in a tension-free manner [Figures 2 and 3]. Vaginal flaps were then closed over the mesh. A check cystoscopy was performed at the end of the procedure to ensure that the mesh was under no tension and also to check for any mesh exposure in the bladder. The perurethral catheter was removed on the second post-operative day and patients were discharged after getting uroflowmetry and post-void residue estimation with an advice to avoid sexual activity for 3 months.

Patients were followed 3 monthly for the 1st year, following which they were assessed yearly. Follow-up included

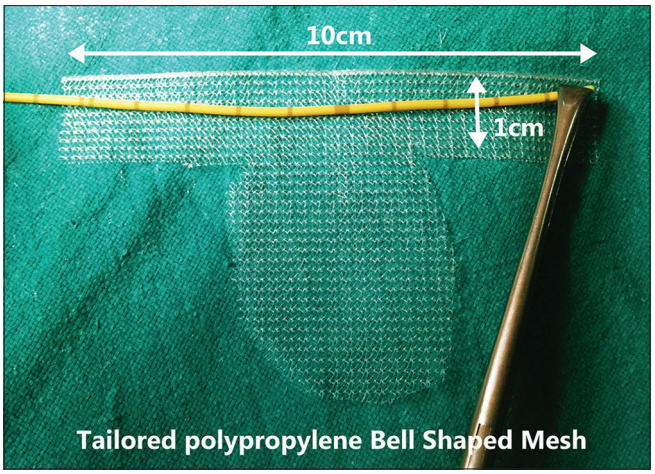

Figure 1: Preparation of the polypropylene mesh

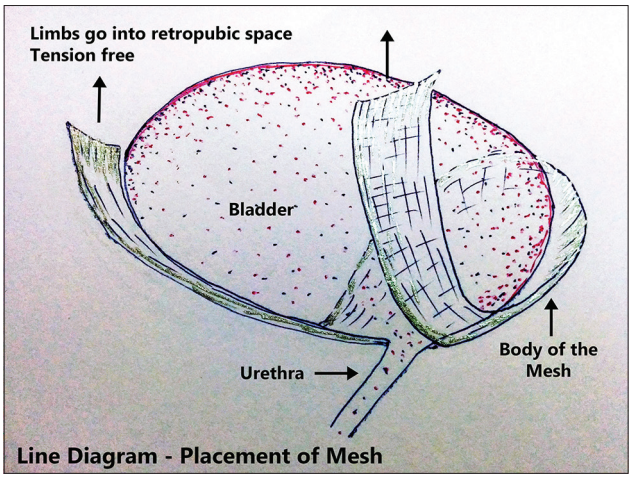

Figure 2: Line diagram showing the placement of customized bell-shaped mesh

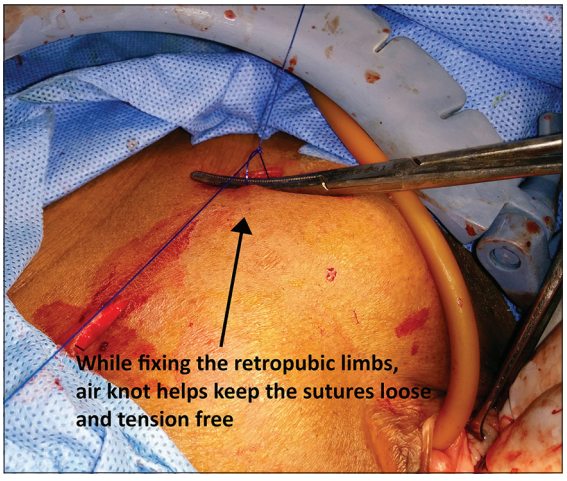

Figure 3: Air knot placement to ensure tension-free placement of the mesh

questionnaire about patient satisfaction, obstructive and irritative lower urinary tract symptoms (LUTS), bladder or pelvic pain, sexual function and dyspareunia. Examination at follow-up included a local examination and a per-vaginal exam to rule out mesh erosion and recurrence. Failure was

defined as stage 2 or greater cystocele at first follow-up. Recurrence was defined as cystocele stage 2 (Aa or Ba 0) or more any time after the first follow-up. Length of follow-up was defined as the interval from the date of surgery to the date of the last outpatient visit.

RESULTS

A total of 36 patients were studied. Mean patient age was 58.5 ± 6.2 years. The mean parity was 3.2 ± 1.6. Thirty-two (88.8%) of the patients were post-menopausal. None of the post-menopausal patients were on hormone replacement therapy. Primary repair was carried out in 34 patients, whereas two patients had a history of anatomic repair of cystocele in the past and were operated for recurrence. According to the POPQ system, 11 (30.5%) of the patients were stage 2, 15 (41.7%) were stage 3 and 10 (27.7%) were stage 4. LUTS were present in 20 (55.6%) of the patients pre-operatively. Obstructive symptoms, mainly straining to void, and sense of incomplete emptying were present in 10 (27.8%) patients and storage symptoms, mainly frequency, were present in 14 (38.9%) patients. Dyspareunia was present in two patients. Mean operative time was 56.3 ± 9.2 min. Median hospital stay was 4 days (range 4–6). The mean follow-up period was 53.4 months (range 12–104), with 32 patients reporting for follow-up till date (88.9%). Twenty-five patients had a follow-up period of more than 60 months.

There was no bladder injury in any patient during the procedure. None of the patient required blood transfusion in the post-operative period. There were no mesh infections or erosions. Two cases had post-operative urinary retention that resolved within 1 week in both the cases. Of the 20 patients who had LUTS pre-operatively, only two had persistent LUTS at 2 years and none at 5 years. No patient required clean intermittent catheterization or had stress urinary incontinence post-operatively at 5 years of follow-up. Thirty-four patients (94.4%) expressed satisfaction from the surgery till the time of the last follow-up.

There was no immediate recurrence of the cystocele. Four patients had asymptomatic stage 2 prolapse at 2 years of follow-up and two at 5 years of follow-up. All these patients had stage 3 prolapse to begin with. No patient had a recurrence with higher stage. Assuming the lost to follow-up cases as failures, anatomical success rate at a mean follow-up of 53.4 months is 83.3%. Of the cases that completed 5-year follow-up, the success rate is 92% [Table 1].

Sexual function of the patients was assessed using the PISQ-12 questionnaire. Twenty patients reported sexual activity post-operatively. The mean pre-operative score was 22.0 ± 2.2 while the mean post-operative score was 29.0 ± 3.1. Significantly, five patients had dyspareunia at 2 years and two at 5 years. Of these two patients, one had *de novo* dyspareunia before the surgery.

Table 1: Pre-operative and post-operative pelvic organ prolapse quantification

	Pre-operative (*n*=36)	Post-operative 2 years (*n*=35)	Post-operative 5 years (*n*=25)
Point Ba (anterior wall)	1.55±1.14	−2.05±1.09	−2.25±0.74
Point Bp (posterior wall)	−1.17±0.49	−1.21±0.61	−1.25±0.59
POPQ stage 0	0	24 (68.6%)	16 (64.0%)
POPQ stage 1	0	7 (20.0%)	7 (28.0%)
POPQ stage 2	11 (30.6%)	4 (11.4%)	2 (8.0%)
POPQ stage 3	15 (41.7%)	0	0
POPQ stage 4	10 (27.8%)	0	0

DISCUSSION

Traditional repair of anterior vaginal wall prolapse including cystocoele involves plication or colporrhaphy, and was first done in 1913 by Kelly.[1] Anterior colporrhaphy alone has a high failure rate (up to 70%)[2] and can result in vaginal shortening and/or constriction and is useful only for the midline defects. The use of mesh for repair of cystocoele was first described by Julian, who described the use of marlex mesh for tissue support.[3] The transvaginal route of mesh insertion for anterior prolapse has reported good success rates in various non-randomized trials, ranging from 75% to 100%.[4-11] In the present study, the 5-year anatomical success rate is 83.33%.

Altman *et al*. performed a multicenter, randomized, controlled trial involving 389 patients and concluded that the use of mesh via the transvaginal route resulted in a higher short-term success rate compared with anterior colporrhaphy (60.8% vs. 34.5%)[12] De Tayrac *et al*. reported the long-term anatomical and functional outcomes of transvaginal retropubic cystocoele repair using a tension-free polypropylene mesh. In this descriptive case series, 63 patients were followed-up for up to 60 months (mean 37 months) and were found to have high cure rates (subjectively 98.2% and objectively 89.1%).[13]

A recently conducted multi-center, randomized equivalence trial (TOMUS) compared the results of 597 women with SUI (stress urinary incontinence) who underwent retropubic versus transobturator midurethral sling placement.[14] Equivalent success rates (80.8% in the retropubic group and 77.7% in the transobturator group) were reported.

Wong *et al*. performed a retrospective analysis of anterior colporrhaphy with and without the use of mesh with sonographic imaging of the mesh. They found significantly better objective anatomical outcomes, both clinically and on sonographic imaging, with the use of mesh.[15]

The most common major complication of transvaginal mesh placement is mesh exposure or extrusion,[16] reported in

the range of 3–35%.[17] The most significant factor affecting the rate of mesh erosion is the depth of vaginal dissection, i.e. raising full-thickness vaginal flaps is believed to minimize erosions.[18] The importance of short incision length and tension-free closure was emphasized by Ganj *et al*.[19] In the present study, no patient had mesh erosion during 5 years of follow-up. This might be due to proper pre-operative vaginal preparation, thick vaginal flaps and tension-free vaginal closure. To make the placement of the mesh tension free, air knot fixation of the retropubic limbs of the mesh was performed as described in the modified Raz technique [Figure 3].[20]

Occult SUI in patients with POP can be unmasked after isolated cystocoele repair due to straightening of a kinked urethra.[21] The incidence of such *de novo* stress incontinence is around 20%. This risk can be decreased by performing continence surgery at the time of prolapse surgery.[22] Because cystocele is a weakness of the anterior compartment, repairing it in isolation without a sling will result in a very high rate of post-operative stress incontinence, requiring a secondary procedure.

The TOMUS trial reported a higher incidence of bladder outlet obstruction in the retropubic group (2.7% vs 0%) as compared with the transobturator group. In our study, no patient had any voiding dysfunction at 5 years of follow-up. A key step to preventing this complication is to keep the retropubic limbs tension free. Raz *et al*. described an intraoperative assessment of the "elastic mobility" of the cystscopic sheath. We used this technique in our study as well.[23]

One of the complications of transvaginal mesh repair of cystocele is bladder perforation, which is more than that reported with anatomical repair alone.[12] This can be prevented with the injection of a vasoconstrictive solution in the submucosal plane, making it easier to enter the right plane.[24] In our series, we report injection of saline for the same purpose. No bladder injury occurred in our series.

The Food and Drug Administration (FDA) initially issued a safety communication regarding the use of mesh in pelvic reconstructive surgery. In 2011, an update was issued mentioning that transvaginal mesh complications are not rare. Further, it was mentioned that transvaginal mesh in the apical and posterior compartments does not provide substantial added benefit but may provide anatomic benefit in the anterior compartment.[25] It must be stressed that the FDA did not specifically recommend against the use of mesh for repair of POP. Both the American urological association and the FDA recommend that a thorough informed consent should be conducted prior to the use of mesh products for POP. The AUA also does not specifically condemn the use of mesh; instead, it recommends that surgeons who wish to utilize mesh techniques for POP should (1) Undergo rigorous training in the principles of pelvic anatomy and pelvic surgery, (2) be properly trained in specific mesh implantation techniques and (3) be able to recognize and manage complications associated with vaginal mesh.

The strength of the present study is the prospective nature, long follow-up and uniformity of the procedure as it is a single-center, single-surgeon study using the same technique. Bias has been minimized by excluding cases with concomitant procedures such as posterior POP and hysterectomy.

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