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RESEARCH ARTICLE

Efficacy of Transvaginal Anterior Colporrhaphy reinforced with Mesh in the Treatment of Severe Cystocele

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ABSTRACT

Aim: Repair of cystocele with good anatomic success rate remains the challenge for the gynecologists. Use of mesh in cystocele repair is still a controversy with regard to its efficacy and safety. The aim of our study is to evaluate the efficacy and safety of transvaginal anterior colporrhaphy reinforced (ACR) with partially absorbable mesh in the management of severe cystocele.

Materials and methods: This was a retrospective study conducted in the Department of Obstetrics and Gynecology based on the surgeries performed between 2011 and 2013. The inclusion criteria were women with grades III and IV cystocele and had undergone vaginal hysterectomy with ACR with mesh.

Results: Forty-two women were included in the study. The primary outcome measured was the efficacy of the mesh in terms of anatomical success rate. The secondary outcome was mesh safety. The anatomic success rate was 93% and the mesh erosion rate was 2.3%.

Conclusion: Transvaginal ACR with partially absorbable mesh in the management of severe cystocele is safe and associated with encouraging anatomic success rate. However, the choice of surgery needs careful selection, considering patients at risk for recurrence.

Clinical significance: The choice of mesh inlay cystocele repair may be individualized and recommended especially in grade IV cystocele, recurrent cystocele, scanty and weak perivesical fascia, to improve long-term outcome.

Keywords: Anterior colporrhaphy, Cystocele, Mesh, Retrospective.

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INTRODUCTION

Prolapse is a protrusion of the vaginal wall and/or uterus, resulting from descent of the pelvic organs. Pelvic organ prolapse (POP) is a significant health issue in females worldwide. The exact prevalence of POP is unknown as the literature suggests various criteria for diagnosis of POP. The prevalence of POP increases with age and is approximately 31% across all age groups.[1] The likelihood of requiring surgical repair by age 80 is approximately 11%,[2] and 29 to 40% undergo reoperation within 3 years following traditional surgery.[1] The projected population for the year 2030 of those aged 65 and older is 71.5 million, representing 20% of the population. Recent projections estimate that the number of women undergoing surgery for POP will increase to approximately 250,000 by 2050.[2] Thus, the estimated direct costs of prolapse surgery are over $1 billion per year and are likely to increase.

Numerous obstetric and gynecological risk factors have been identified and genetic influences have been attributed to increased collagenase activity with aging. Traditional anterior repair of cystocele utilizing the patient's own tissue is a compensatory procedure that has been reported with high failure rates (30–70%) and results in vaginal shortening.[3] With the constantly improvising techniques in management of utero-vaginal prolapse, mesh repair has been in vogue since 2001. However, the efficacy and safety of use of mesh is still a concern for the operating gynecologist. There are very few studies on cystocele repair with mesh in the population in Puducherry, India.

We embarked on this study to determine the efficacy and safety of transvaginal ACR with partially absorbable mesh with 24 months mean follow-up period in the management of severe cystocele.

MATERIALS AND METHODS

This is a retrospective study conducted in the Department of Obstetrics and Gynecology, Tertiary Care Center, Puducherry, India, based on the data, and follow-up of the surgeries was performed from February 2011 to December 2013. Institutional Ethical Committee approval was obtained. The inclusion criteria were: Women with grades III and IV cystocele according to Baden–Walker halfway system of classification (Table 1) and had

Table 1: Baden–Walker halfway system for grading prolapse

Grade 0	Normal position for each respective site
Grade I	Descent halfway to the hymen
Grade II	Descent to the hymen
Grade III	Descent halfway past the hymen
Grade IV	Maximum possible descent for each site

Notes for using the grading system: (1) Prolapse is graded at each site (cystocele, uterine prolapse, vault prolapse, rectocele, and enterocele) with patient straining maximally. The upright position may also be used (2) When choosing between two grades, choose the higher grade

undergone vaginal hysterectomy with ACR with mesh by a single surgeon during the study period. Women who had rectocele, enterocele, or stress urinary incontinence were excluded from the study.

The clinical diagnosis of prolapse uterus with cystocele was made with the women in supine position at maximum strain in the outpatient clinic as well as intraoperatively under anesthesia. All the patients with urinary tract infection were treated with antibiotics before the procedure. The procedure was carried out with patient under regional anesthesia. Prophylactic antibiotics were administered. An inverted T-shaped incision was made on the anterior vaginal wall 1 cm below the urethra with circumferential extension to the posterior. Vaginal flaps were raised. Bladder pushed up after cutting the vesicouterine ligament. Vaginal hysterectomy was performed. Using blunt dissection with index finger, a channel was created laterally up to the arcus tendinous fascia on both sides. Plication of perivesical fascia was done.

A partially absorbable polyglactin mesh was cut to an appropriate size with central part to cover the cystocele and wings of 1 cm width laterally. The central part of the mesh was anchored to the pubocervical fascia using 2-0 Vicryl (polyglactin 910 braided absorbable suture) at four sites and wings anchored laterally in the channel. Vault closure was done after complete hemostasis. All patients were on continuous bladder drainage for 72 hours. Postvoidal residual urine was measured before discharge. Postoperatively, patients were reviewed initially at 1, 3 and 6 months, and then annual follow-up. Follow-up included questionnaire about patient satisfaction, lower urinary tract symptoms, lower abdominal pain, dyspareunia, and vaginal discharge along with detailed pelvic examination to diagnose any recurrence, vault prolapse, or mesh erosion.

Mesh erosion was quantified according to International Urogynecological Association (IUGA) classification of mesh complications necessitating extrusion. Patients with urinary symptoms were investigated for urinary tract infection and treated according to the sensitivity. Recurrence was defined as grade II or more cystocele at any time during follow-up.

RESULTS

A total of 42 women were included in the study. The demographic characteristics of these patients are summarized in Table 2. The mean age of the women was 60.2 + 4.8 years and mean parity was 3.4 + 1.6. Majority of the women were postmenopausal (95.2%) and none of them were on hormone replacement therapy. The preoperative clinical parameters of the patients are summarized in Table 3. According to Baden–Walker's classification, 31 patients (73.8%) were with grade III cystocele and 11 (20.11%) of the patients had grade IV cystocele.

Almost 66.6% of women had significant grades of uterovaginal prolapse along with cystocele. None of them had previous surgery done for urogenital prolapse; 22 patients (52.4%) had urinary tract infection on admission and they were treated preoperatively, and 85% of patients had urinary symptoms like straining during micturition, hesitancy, and frequency. The mean hospital stay of these patients was 6 days.

The intraoperative and postoperative outcome is summarized in Table 4. With respect to intraoperative outcome, the mean operative time for mesh repair by the single surgeon was 36.5 minutes. There was no organ injury reported in any of the patients during the procedure. Regarding postoperative complications, 5 patients had pyrexia and vault infection was observed in 4 patients. Two patients needed prolonged catheterization and 6 patients developed urinary tract infection postoperatively.

Table 2: Demographic characteristics

Characteristics	*Value/number of patients (n = 42)*
Mean age ± SD	60.2 ± 4.8 years
Mean parity ± SD	3.4 ± 1.6
Mean body mass index	20.2
Postmenopausal	40 (95.2%)
Sexually active women	22 (52.38%)
Patients on hormone replacement therapy	0

Table 3: Preoperative clinical parameters—Baden–Walker's classification

Clinical parameters		*Number of patients (n = 42)*	*Percentage*
Cystocele	Grade III	31	73.8
	Grade IV	11	26.1
Uterovaginal prolapse	Grade II	14	33.3
	Grade III	24	57.1
	Grade IV	4	9.5
Urinary symptoms	Difficulty	13	30.9
	Hesitancy	8	19
	Frequency	21	50
Urinary tract infection		22	52.3

Table 4: Intraoperative and postoperative outcome

Intraoperative outcome		
Mean operative time	68.6 min	
Mean blood loss	55 ± 6 mL	
Mean hospital stay	6 days	
Organ injury	0	
Postoperative complications	*Number of patients*	*Percentage (n = 42)*
Pyrexia	5	11.9
Urinary tract infection	6	14.2
Hematuria	0	0
Vault infection	4	9.5
Prolonged catheterization (>72 hours)	2	4.7
Mesh erosion	1	2.3
Vault prolapsed	1	2.3
Recurrence of cystocele: grade III	3	7

The primary outcome measured was the efficacy of the mesh. The secondary outcome was mesh safety. During mean follow-up of 24 months, 2 patients had grade II cystocele and 3 patients had grade III cystocele but they were totally asymptomatic. One (2.3%) patient developed vault prolapse after 18 months.

Thus, the anatomic success rate which represents the efficacy is 93% after a follow-up of 24 months. One (2.3%) patient presented with mesh erosion of Category 2B according to IUGA classification of mesh complications.

DISCUSSION

Surgical correction of cystocele remains one of the most challenging problems for pelvic floor surgeons. The ideal method of reconstruction of severe cystocele should be repair of bladder herniation along with correction of coincident stress urinary incontinence. Attempts to rely on the anatomic tissue, like pubocervical fascia, may result in recurrence since the tissue is weak. Increasing awareness among surgeons of the high rate of cystocele recurrence with conventional procedure techniques using mesh have been evolving.

The use of mesh for repair of cystocele was first described by Julian.[4] Graft use in pelvic surgery has been reported on for many years; however, it is only recently that its popularity has taken strides and has been more widespread in use.[5] Synthetic meshes are classified into types I to IV of their physical characteristics.[6] Type I mesh, which is used most frequently in vaginal reconstructive surgery, has a pore size greater than 90 microns and is constructed using monofilament fibers. The pore size allows macrophage access and fibrous tissue in growth.

In our study, majority of patients were postmenopausal, multiparous, and in the old age group, the attributable risk factors for uterovaginal prolapse being aging and postmenopausal status. Baden–Walker's system of grading of cystocele is the standard classification for assessment and was used in our study to bring accuracy in grading.[7] International Continence Society considers POP-Q stages 0 and I as anatomic success. However, during analysis, most patients with grade II were asymptomatic and they cannot be considered as failure.

A Cochrane systematic review suggested that the use of a polyglactin mesh overlay at the time of anterior vaginal wall repair may reduce the risk of recurrent cystocele. Anterior vaginal wall prolapse with standard ACR showed recurrent cystoceles than with polyglactin mesh inlay [relative risk (RR): 1.39, confidence interval (CI): 1.02–1.90]. Vaginal mesh erosion is a significant complication (up to 11.4% of cases) but it is related to surgical experience, surgical technique, and synthetic material used.[8] Based on the review, use of mesh is recommended for patients at risk of failure—recurrent prolapse, POP-Q stages 3 or 4, collagen disorders, and factors relating to chronic stress to pelvic floor. Literature review suggests that the transvaginal route of mesh insertion for anterior prolapse is with good success rates ranging from 75.7 to 94%, which is in accordance with our study.[7-11] In our study, a questionnaire along with objective assessment achieved an anatomical success rate of 93% after a mean follow-up of 24 months.

Table 5 illustrates the anatomical success rate and complication rates observed by different authors in comparison with our study. However, it is difficult to compare the findings of each study with other trials owing to variations in the surgical procedures, implant materials, outcome measurements, and objective cure criteria.

Arora et al[9] reported in their study that of 36 women who underwent anterior colporrhaphy with mesh reinforcement with a mean age of 58.5 ± 6.2 years, the anatomical success rate was 83.3%. No patient had a

Table 5: Review of literature of cystocele repair with mesh and outcome

Studies	*Sample size*	*Success rate*	*Mesh erosion*	*Mesh type*
Arora et al[9]	36	83.3%	0	Polypropylene
Maher et al[10]	5954	RR 3.15	18%	Polypropylene
Multicentered trial		RR 1.39	11.4%	Polyglactin
Altman et al[11]	389	82.3%	3.2%	Polypropylene
Nieminen et al[12]	202	87%	19%	Polypropylene
Nguyen and Burchette[13]	76	87%	5%	Polypropylene
de Tayrac et al[15]	63	96.4%	9.1%	Polypropylene
Ng and Chong[21]	37	75.7%	0	Polypropylene
Adhoute et al[17]	52	93%	2.3%	Polypropylene
Dwyer and O'Reilly[14]	47	94%	0.9%	Atrium polypropylene mesh
Our study	42	93%	2.3%	Polyglactin

recurrence with higher stage. There was no bladder injury and no mesh erosion or infection.

Maher et al[10] reviewed 10 trials comparing anterior colporrhaphy with and without mesh repair for cystocele. Conventional anterior repair was associated with more recurrence of cystocele than when supplemented with a polyglactin (absorbable) mesh inlay (RR 1.39, 95% CI 1.02–1.90); however, there was no difference in subjective recurrence (RR 0.96, 95% CI 0.33–2.81). Altman et al[11] performed a multicenter, randomized, controlled trial involving 389 patients and concluded that the use of mesh resulted in a higher short-term success rate compared with anterior colporrhaphy (60.8 *vs*. 34.5%). In a study by Nieminen et al,[12] 202 women with anterior prolapse were assigned to undergo colporrhaphy alone or reinforced with a tailored polypropylene mesh and were followed up at 2, 12, 24, and 36 months after surgery. Recurrences of anterior vaginal prolapse were noted in 40 of the 97 (41%) in the colporrhaphy group and 14 of 105 (13%) in the mesh group ($p < 0.0001$). The mesh erosion rate was 19%.

Nguyen and Burchette[13] in their study reported 87% success in mesh repair patients and 55% in ACR group ($p = 0.005$) after 1 year follow-up. In a study by Dwyer and O'Reilly,[14] where polypropylene mesh was used for anterior repair, the success rate was 94% and mesh erosion occurred in 0.9%. de Tayrac et al[15] and Milani et al[16] studied the efficacy of prolene mesh reinforcement on grade IV cystocele, which showed a success rate of 96.4 and 94% respectively and a higher rate of complications like dyspareunia.

Adhoute et al[17] studied 52 patients with synthetic mesh repair and observed a success rate of 95% and mesh erosion of 3.8%. Wong et al[18] performed a retrospective analysis of anterior colporrhaphy with and without the use of mesh with sonographic imaging of the mesh. They found significantly better anatomic outcomes, both clinically and on sonographic imaging with the use of mesh. In a study by Sola et al[19] on use of tension-free monofilament mesh in female genital prolapse, a review of intraoperative and postoperative complication was done and he concluded that the use of prosthetic polypropylene monofilament macropore mesh in the correction of cystocele and rectocele, by transvaginal route with tension-free technique seems to be a safe and effective surgery procedure.

In a large study by Chughtai et al,[20] there was an increased risk for recurrence and urinary retention in the mesh group. In 45.1 weeks follow-up of a total of 27,991 patients, 7,338 and 20,653 underwent prolapse repair procedures with and without mesh respectively. Patients in mesh group had a higher chance of having risk for intervention within 1 year [mesh 3.3% (n = 240) *vs* no mesh 2.2% (n = 164)], hazard ratio 1.47 (95% CI 1.21–1.79), and also urinary retention within 90 days [mesh 7.5% *vs* no mesh 5.6%, risk ratio 1.33 (95% CI 1.18–1.51)], compared with those who underwent traditional anterior colporrhaphy.

Complications following mesh repair include mesh infection, erosion, extrusion, and perforation. Less common symptoms are dyspareunia and chronic pelvic pain. Incidence of mesh infection ranges from 0 to 8%.[21] Factors related to the development of mesh infection include types of mesh material, procedure, preventive measures taken, age, and underlying comorbidity of the subject. Types II, III, and IV meshes due to their inherent property are predisposed to develop mesh infection. Halstedian principle of handling of wound was perioperative.

Antibiotic prophylaxis, thorough antisepsis of the perineum, vulva, vagina, and anus at surgery are important infection prevention strategies.

Mesh erosion poses as a major complication with the use of mesh in pelvic reconstructive surgeries. The IUGA has classified the complications of mesh use being specified as mesh contraction, prominence exposure, and extrusion.[22] In our study, 1 patient (2.3%) had mesh erosion, which is comparable to various other studies where the reported mesh erosion is in the range of 0 to 19%.[9-17,23] Extreme of age and estrogen deficiency, severe genital atrophy, prior surgical scarring, diabetes, steroid use, and smoking are the reported patient-related risk factors in literature.[5,24-26]

Ganj et al[27] reported that the two key factors to reduce mesh complications are to minimize the length of the incisions and closure of the incisions without tension. Raising full-thickness vaginal flaps during vaginal dissection is believed to minimize erosions and extrusion rate. Dyspareunia may be caused by mesh erosion, mesh infection, mesh shrinkage, or extensive fibrosis. A recent meta-analysis reported an overall incidence of 9.1% in 70 studies analyzed.[28]

The drawbacks of this study are small sample size and no arm for comparison in the design. Much longer follow-up is recommended to assess the outcome in the long run. There is insufficient data in the literature to recommend routine mesh repair in cystocele repair with a heterogeneous yardstick for comparison to assess outcomes with statistical significance. However, further prospective randomized controlled trials involving larger population with clear definitions of results, complications and outcomes, surgical implants, expertise, and a longer follow-up are required to assess and determine the safety of the mesh use. The outcome is influenced by the grade of cystocele, tensile strength of the native tissue, the choice of mesh and its specifications, the expertise in technical intricacies, tension-free approximation, the thickness of the vaginal muscularis mucosa for approximation, and comorbidities. It is mandatory for counsel to

explain the potential risks like mesh erosion, dyspareunia, hispareunia, pelvic pain, the justification for the choice, and the benefits outweighing risks before electing the procedure. Also, specific training in mesh repair deserves to be considered as a principal prerequisite for the repair.

CONCLUSION

The choice of mesh inlay cystocele repair may be individualized and recommended, especially in grade IV cystocele, recurrent cystocele, scanty and weak perivesical fascia, to improve long-term outcome. Hence, patients with high risk for recurrence may be recommended for mesh repair with the appraisal of available alternate surgical methods.

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