Recurrence of cystocele after Anterior Colporrhaphy versus Anterior Polypropylene Mesh Repair: A Randomized Controlled Trial

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ABSTRACT

Objective: To assess the recurrence of cystocele at post-surgical follow up after Anterior Mesh repair versus Anterior Colporrhaphy.
Study Design: A Randomized Clinical Trial.
Place and Duration: At Obstetrics and Gynecology Department of Pakistan Institution of Medical Sciences & Hospital, Islamabad from 1st March 2012 to 30th June 2018.
Methodology: Eighty-Four patients with age of 21 years or more were selected who had 2nd degree cystocele or more. Forty-two patients were operated by Anterior Mesh repair (Group A) and forty-two patients were operated by Anterior Colporrhaphy (Group B). The anterior vaginal wall prolapse recurrence was noted clinically in line with POP-Q Scoring method. Postoperative evaluations were performed at 1 year and 5 years for recurrence of prolapse.
Results: At one year follow-up visit recurrence of prolapse was noticed more in case of anterior Colporrhaphy (9.5%), versus anterior Mesh repair (0%, P=0.03). At 5-year follow-up, no new recurrence was found in remaining patients in both groups. The study shows no statistically significant difference (p-value- .087) between the means of the Recurrence at different levels and type of treatment (Mesh Operation and Anterior colporrhaphy).
Conclusion: Polypropylene anterior Mesh repair is equivalent to anterior Colporrhaphy in the management of cystocele in terms of post-surgical recurrence.
Keywords: Vaginal wall prolapse, Treatment, Anterior mesh repair, Anterior colporrhaphy, Cystocele, Complications, Recurrence, Outcome, Polypropylene mesh

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INTRODUCTION

"Pelvic organ prolapse" is defined as downward and forward substitution of one of the pelvic organs from its normal position. A variety of terms are used to define woman genital organ displacement. A Cystocele is a downward displacement of upper 2/3rd of anterior vaginal wall, which is most common one and it occurs when there is a weakness in the structures of the pelvic floor that are supporting the pelvic viscera. A patient having anterior vaginal wall prolapse may be symptom free, mostly in the early stages. Patients with symptoms may experience perineal heaviness or a "lump" or" ball" bulging from the vagina, back pain, difficulty in bladder evacuation or bowel movements, vaginal bleeding or painful intercourse. Many surgical procedures have been described for cystocele repair. Among them anterior colporhaphy is most commonly used procedures and has been a recommended management for pelvic wall descent over the last century but it is known for high risk of recurrence[1]. As primary native tissue repair is known for significant recurrence of prolapse so Mesh repairs were introduced to reinforce the native tissues aiming to reduce recurrence rates[2]. Since the overview of Polypropylene mesh in the repair of pelvic organ prolapse, good anatomical

reconstruction appears to be linked with lower rate of recurrence and good functional consequence[3].

Both surgeries are associated with Post-operative complications as UTI, mild granulation tissue at suture site, mesh erosion, vaginal infection, hematoma formation, urinary retention, recurrence of prolapse and vesico-vaginal fistula. But the incidence of these complications is more in case of mesh repair[4]. Post-operative sexual dysfunction and dyspareunia are found to be similarly associated with both surgeries[5]. In 2016, the Food and Drug Administration reevaluated Polypropylene entanglement for trans-vaginal repair of POP from a moderate-risk category (class II) to a high-risk one (class III) and gave makers 30 months to enhance their commodity and make it more safe and effective[4,6]. The long-term risk of recurrence of prolapse is always concerning to urogynecologists and their patients because initial surgery has the best outcome and repeat surgeries are bound to fail due to fibrosis and there is currently a paucity of long-term data evidence in this regard. A reevaluation of successful outcome is necessary as many surgeons have move away from the use of mesh for pelvic organ prolapse. This study aimed to look at the long-term recurrence of anterior vaginal wall prolapse after anterior Colporrhaphy and Anterior Polypropylene Mesh Repair. This study would see the outcome of cystocele repair at post-surgical follow ups after anterior Mesh repair and anterior colporrhaphy; help in deciding that which one is better for cystocele repair and least associated with recurrence. So this study was conducted with an objective to assess the recurrence of cystocele at post-surgical follow ups after anterior Mesh repair versus anterior Colporrhaphy.

METHODOLOGY

This Randomized Clinical Trial was conducted in Obstetrics and Gynecology Department (Unit-II) of Pakistan Institution of Medical Sciences Hospital Islamabad from 1st March 2012 to 30th June 2018. As this trial started in March 2012 and primary completion time (operative) was June 2013 during which surgical procedures were done and actual completion date of study was June 2018 as postoperative follow-up were performed at 1 week, 8 weeks, 1 year and 5 years for recurrence of prolapse.

Inclusion Criteria comprise of 2nd degree or 3rd degree cystocele in woman of 30-60 years' age. Exclusion Criteria included patients with less than stage-II anterior vaginal wall prolapse, pregnant patients, latent /active systemic infection, immuno-compromised, previous pelvic CA or irradiation and those unwilling to give valid informed authorization. Informed consent was taken from all patients after proper procedure explanation. Patients were allocated randomly by a computer-created table of random number's roster to either Anterior Mesh repair (Group A) or Anterior Colporrhaphy (Group B). Baseline assessment included history, quality of life assessment (Pelvic Floor Impact Questionnaire, Pelvic Floor Distress Questionnaire and Urinary Incontinence)[7], pelvic viscera descent evaluation (POP-Q)[8], urinalysis plus urodynamic study. All operating sufferers received perioperative prophylactic antibiotic. Patients were operated by Consultant Gynecologist.

The Mesh repair (Group A) was performed by giving a midline incision in anterior vaginal wall. The vaginal mucosa separated from fibro muscular tissue by both blunt and sharp dissection. Midline fascial defects were repaired before placing graft. The Polypropylene Mesh was just loosely placed in para urethral space. It was loosely tensioned and the Mesh arms were not enlightened. The incision was concluded using 2-0 Polyglactin closures.

Anterior Colporrhaphy (Group B) was performed by giving midline incision in anterior vaginal wall, after separation of vaginal tissue from the underlying fibro muscular tissue, the pubo-vesical fascia was plicated using intermittent 2–0 absorbable sutures (Kelly's), redundant vaginal mucosa was excised and closed using a running absorbable suture. The vagina was packed for 24 hours and bladder catheterized for 48 hours. Postoperative analysis was performed at 1 week and 8 weeks for post-surgical care, at 1 year and 5 years for recurrence of cystocele. This was ensured by keeping telephone contact of patients and hospital MR numbers. The reappearance of anterior vaginal wall prolapse was noted clinically by POP-Q System. Follow up was done by Trainee Registrar personally by calling patients, asking them about any symptoms of mass coming from vagina and if any then requesting them to come for examination and management. All patients were available at 1 year follow up bur at 5-year follow-up, five patients were lost in group A and six in group B. Drop-out of patients was mainly the result of a lack of interest in attending a new examination because they had no symptoms thus they declined a visit and few telephone numbers were lost from the record.

Data Analysis: The data was analyzed on SPSS (version 17). Mean ± S.D was calculated for quantitative variables. Qualitative variables i.e. recurrence of cystocele and its stages were presented by frequencies and Chi-square test was used to assimilate two groups. $P<0.05$ was statistically significantly. The one-way analysis of variance (ANOVA) was used to determine whether there was any statistically significant difference between the means of the Follow up groups (Recurrence at different levels) and type of treatment (Mesh Operation and Anterior colpo-rraphy).

RESULTS

On the review, 84 patients were enrolled out of which 42 were operated by anterior Mesh repair (Group A) and 42 operated by anterior Colporrhaphy (Group B). The age distribution between the two groups was found to be similar. The average age included was 48.62 years in anterior Mesh group (Group A) and 54.16 years in anterior Colporrhaphy group (Group B). The parity between the two groups was also taken into consideration. The mean parity of the patients included was 4 in both groups. Preoperatively POPQ Staging System of assessing grading of Cystocele showed that in anterior Mesh group (Group A), 30 (76%) had 2nd degree Cystocele preoperatively and 12 (24%) had 3rd degree Cystocele. While in anterior Colporrhaphy group (Group B), 28 (68%) had 2nd degree Cystocele and 14 (32%) had 3rd degree Cystocele. (Table-I)

Table-I: Frequency of demographic characteristics of study patient, (N=84)

Preoperative Variables	Anterior Mesh Group, A (n=42)	Anterior Colporrhaphy Group, B (n=42)	P-Value
Age	48.6 y	54.1 y	N.S
Parity	4	4	N.S
2nd degree cystocele	30(76%)	28(68%)	N.S
3rd degree cystocele	12(24%)	14(32%)	N.S

Postoperatively recurrence of prolapse according to POPQ Scoring System at 1-year follow-up visit was also compared between these two Surgical treatment groups, which showed that recurrence occurred in 04 (9.5%) patients after anterior Colporrhaphy group (Group B) while no recurrence of prolapse noted after anterior Mesh repair group (Group A) (Table-II). No new recurrence was found in any group at 5 year follow up. This means there is no statistically significant difference between the means of the Follow up groups (Recurrence at different levels) and type of treatment (Mesh Operation and Anterior colpo-rrhaphy). The p-value is .087 (which is more than the .05 alpha level). Table-II. At 5-year follow-up, five patients were lost in group A and six in group B with no new recurrence.

Table-II: Comparison of Anatomical Outcome i.e. recurrence of prolapse. (N=84)

	1 year follow up		5 year follow up recurrence	P-Value
	Recurrence	No Recurrence		
Anterior Mesh Group (n=42)	00 (0%)	42 (100%)	00 (0%)	.087
Anterior Colporrhaphy Group (n=42)	04 (9.5%)	38 (90.5%)	00 (0%)	

n= number of patient

DISCUSSION

The long-term data on vaginal mesh surgeries remains challenging to evaluate. There are limited long-term series published, and they are diverse involving primary and secondary cases, varying pelvic compartments and concomitant procedures with varying follow-up. Long-term research evaluating a single procedure in a discrete population stays scarce. In our randomized trial, we linked the serviceable and anatomical effects of an anterior Colporrhaphy with anterior mesh repair for treatment of anterior vaginal wall prolapse. After 1 year, anatomical outcome was good in the anterior Mesh repair technique but few recurrences were seen in colporrhaphy group as similarly seen by Lavelle RS where 33% patients required secondary surgery after colporrhaphy[9]. In 2019, Allègre L found that functional outcomes for mesh and native tissue repair are similar but anatomical recurrence was less in mesh group these results are similar to our study where no recurrence was there with mesh group at 1 year follow up as compared to native surgery[10]. In a study, to compare and contrast the effectiveness of mesh repair with the tissue repair surgeries in the handling of cystocele showed, after a 1 year follow up, that the anterior mesh repair generated best structural consequence. Suitable structural treatment rates were 91% and 72% in the mesh repair group and site-specific repair group, correspondingly. Among those three cases (6.9%) of mesh attrition were reported. Like our study at short term follow up, they stated that surgery with synthetic mesh is superior to the site-specific surgery in the repair of cystocele[11,12].

In a trial, 202 women with cystocele were ascribed to endure anterior Colporrhaphy unaccompanied or reinforced with a synthetic mesh. The results were like our study as recurrence of cystocele was noted in 41% in the Colporrhaphy group and 13% in the mesh group (P < .0001). The frequency of mesh attrition rate was 19%. At 3-year follow-up, anterior vaginal wall prolapses with mesh reinforcement significantly abridged anatomic recurrences of anterior vaginal wall descent, but no modification in symptomatic recurrence were noted and the mesh erosion rate was elevated[13]. Additional study conducted on clinical outcome and snags of mesh-enhanced vaginal surgery in remedy of pelvic organ prolapse stage III-IV brought the contented clinical consequence. The frequency of mesh-related hitches was low and secondary operative engrossments were impressive[14,15]. Another prospective study managed to assess 1.5-year results with synthetic mesh repair; displays pelvic organ prolapse improved in 98.6% patients but mesh-associated risks with this approach was a priority concern that requires further investigation of risk factors and better definition of patient selection criteria[15]. The evidence suggests that anterior vaginal wall mesh repair might be more efficacious than traditional anterior Colporrhaphy. Both safety and efficacy differ with different types of mesh.

Various publications have described different procedures using Polypropylene mesh in the anterior vaginal prolapse repair, but most trials follow the patients for not more than one year[16,17]. The use of Polypropylene mesh in repair of pelvic organ descent has provoked a unique and new media frenzy. In spite of public opinion, there are enough randomized controlled trials (RCTs) reporting the benefits of vaginal grafts over native tissue repair[18]. Synthetic mesh is permanent and, if properly used and placed yield better long-term results; still, they are associated with higher incidence of extrusion (into the vagina), erosion (into the bladder and or urethra) and infection. When Polypropylene Mesh is used for anterior vaginal wall repair, extrusion rates up to 25% have been noticed. Nonetheless, most of studies suggest that the use of synthetic Polypropylene mesh for anterior vaginal wall repair decreases the chance of recurrence[19]. In review of 144 patients with marked anterior vaginal wall prolapse, 86 were treated with anterior Mesh repair and 58 by anterior Colporrhaphy. The amount of recurrence of cystocele on follow up was 12.8% in anterior mesh repair group and 36.2% in anterior Colporrhaphy group[20] but these findings are contrary to our results which showed that both polypropylene anterior mesh repair and anterior colporrhaphy are alike for in the management of cystocele in terms of post-surgical recurrence.

Clinicians desiring to carry out invasive restoration of vaginal

wall prolapse using mesh should view and audit clinical outcomes of all patients. It should also comprise indication of patient-reported results and long-term outcomes, such as sexual function and quality of life.

CONCLUSION

Polypropylene anterior Mesh repair is equivalent to anterior Colporrhaphy in the management of cystocele in terms of post-surgical recurrence

Limitations: Principle limitation was time factor, inability to match the two groups for different confounding factors like patients age, parity, BMI, risk factors, expertise of operator for performing two different procedures, less number of patients and lake of blinding at follow up visits).

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AUTHOR'S CONTRIBUTION

Amir S: Conceived idea, Data collection, Data Analysis, Manuscript writing
Faisal J: Literature search, Manuscript writing
Kanwal S: Data collection, Data analysis, Literature search
Nisa ZU: Sample analysis, Literature search
Aziz H: Literature search, Data collection
Critical analysis

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