Transvaginal Repair Using Acellular Collagen Biomesh for the Treatment of Anterior Prolapse

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Purpose: To determine the results and satisfaction of the patients underwent transvaginal repair of cystocele in our clinic.

Materials and Methods: From January 2006 to October 2010, 15 patients with a mean age of 64 years (ranged 47-85 years) underwent transvaginal cystocele repair using acellular collagen biomesh. The patients were presented with vaginal mass in 10, dyspareunia and urge incontinence in 5 while 4 of them had both stress and urge incontinence. Grade 4 cystocele was determined in 2 patients, grade 3 in 9 and grade 2 in 4. Concomitant transobturator tape (TOT) was performed in 4 patients. Patient satisfactions were determined after the operation.

Results: The mean follow-up time was 23.5 (12-60) months. There was no postoperative complication in early follow-up period. Cystocele was recurrent in 1 patient. The success rate was 93.4%. Urinary incontinence was continued in 1 patient after TOT. Nearly all of the patients (14/15) were satisfied from the operation.

Conclusion: Transvaginal cystocele repair with using acellular collagen biomesh appears to be a safe and effective method. Further prospective and randomized controlled studies including large series of patients are needed.

Keywords: urinary bladder diseases; surgery; cystocele; vagina; treatment outcome; urinary incontinence; surgical mesh.
INTRODUCTION

Pelvic organ prolapse (POP) is accepted as the herniation of the pelvic organs from the vagina. International Continence Society (ICS) describes this condition as downward displacement of the reproductive organs during Valsalva maneuver.\(^1\) POP is a condition that can affect women at any age. According to epidemiological studies, life-long risk in women to be operated due to prolapse or urinary incontinence is between 7% to 19\%.\(^2,3\) In a study from the USA, the number of women having POP is expected to increase by 46% in 2050.\(^4\)

Treatment of POP aims to eliminate the symptoms, repair the anatomy, protect or improve the functions, prevent new problems related to the other compartments and to protect the quality of life in long term. Surgical treatment of POP can be made with methods performed through vaginal or abdominal routes. The studies demonstrated that vaginal route is preferred more for treatment of POP.\(^2,5,6\) In fact, recurrence rates are high following anterior colporrhaphy performed especially because of anterior vaginal POP, and this rate is given as 40% in a recent randomized controlled trial.\(^7\) Thus, use of synthetic or biological grafts can be argued in order to strengthen POP repair. In fact, International Consultation on Incontinence (ICI) emphasizes as a first level of evidence that the repairs carried out by vaginal route using synthetic polypropylene meshes yield more excellent anatomic outcomes in the first-year follow-ups than anterior colporrhaphy, while it reports an acceptable efficiency and lower risk of complications in the repairs alternatively performed with biological grafts.\(^8\)

In this study, we investigated the success, complication rates and patients satisfaction in patients undergone cystocele repair by vaginal route using acellular collagen bio mesh.

MATERIALS AND METHODS

Between January 2006 and October 2010, 15 patients having anterior prolapse were investigated. Repair of anterior wall prolapse through vaginal route using acellular collagen bio mesh (PelviSoft BioMesh, CR Bard, Cranston, R.I., USA) was performed to all patients. Ten of the patients presented with a palpable mass and 5 with pain during sexual intercourse and urge urinary incontinence. The mean number of pregnancies was 4.5 (1-9), and the mean number of births was 2.8 (1-7) (Table 1). None of the patients had a history of prolapse surgery. Two of the patients had diabetes mellitus while no any other comorbidity was detected in any of the patients preoperatively. The grade of prolapse was preoperatively assessed according to Baden-Walker system and/or Pelvic Organ Prolapse Quantification System (POP-Q) classification.\(^1\) Grade 4 cystocele was found in 2, grade 3 in 9 and grade 2 in 4 patients. Four of the patients complained of mixed (stress + urge) incontinence. These patients were asked to fill Turkish validated International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF).\(^9\)

Patients scheduled for concurrent surgery for stress urinary incontinence had undergone urodynamic study. Transobturator midurethral sling (Transobturator tape, TOT) was planned for patients who defined to have urodynamic stress urinary incontinence (USUI).

The operation was performed at lithotomy position under general anesthesia. All the patients were administered 1 g cefazolin preoperatively. Following insertion of the urethral catheter, an incision was made in the anterior vaginal wall from the level of the bladder neck towards to the vaginal apex. The incision was expanded to the sideways from inferior and superior, providing a horizontal ‘H’ shape (Figure). Thus, a wider area of dissection was obtained. The dissection plane was defined with the bright, white pubocervical fascia and expanded until infralevator obturator fascia was palpated. Two anchoring sutures were placed through the fascia as to be at 1 and 11 o’clock positions, and the other two sutures were inserted through the cardinal ligament as to be at 5 and 7 o’clock positions. In the meantime, acellular collagen biomesh of 4 × 7 cm in size was cropped and tailored to the size of the defect, and the sutures were crossed from the proper pore openings in the mesh and tied. After the mesh was inserted, excess of the vaginal wall was properly cut and the process was ended by closure of the anterior wall. In 4 patients who were found to have USUI, a separate suburethral and longitudinal incision was made, and TOT was properly placed. The urethral catheters were withdrawn immediately after or at the night of the operation.

Postoperative follow-up of the patients were carried out in the first, 3rd and 6th weeks of the operation and then annu-
ally. The follow-up procedure was planned as questioning in terms of urinary incontinence (ICIQ-SF) and prolapse recurrence (palpable mass), full urine test, vaginal examination and determination of post void residual urine. In the follow-up, patients having not complaints of prolapse or those with anterior wall prolapse under grade 2 at the vaginal examination were considered as cure, while patients with complaints or those having a recurrence of grade 2 and above were considered as failed. Patient to be dry was accepted as success for the treatment of stress urinary incontinence. In addition, patient satisfaction was evaluated by asking them whether they would recommend this operation to a relative, and if they would want to be operated again if it is necessary, in order to learn their reviews for the operation.

RESULTS
Mean age of the patients was 64 years (ranged 47-85 years). Body mass index (BMI) was calculated as 26.5 (range, 24.2-28.4) for the patients. There was no any obese patient according to BMI while 5 of them were overweight. Mean operation time was 57.2 minutes (range, 30-75), while mean hospitalization stay was 18.4 hours (range, 12-36) (Table 2). There were no postoperative complications for the patients in early period. Mean follow up time was 23.5 months (range, 12-60). In one patient the palpable mass observed to persist. In this patient the examination revealed recurrence of grade 2 anterior prolapse. The patient did not want to be re-operated and was taken to follow-up. The success rate for repair of prolapse was found as 93.4%. None of the patients developed de novo dyspareunia or SUI. Two of the 4 patients who had urgency at the preoperative period were improved after the operation. De novo urgency was detected in 2 patients. A total of 4 patients, including those having urge urinary incontinence preoperatively and continued postoperatively, responded to anticholinergic therapy.

Combination treatment (prolapse repair + anti-incontinence surgery) was performed in 4 of our patients. Although decreasing, urinary incontinence was observed to continue in one of 4 patients in whom TOT was inserted and the rate of success for stress urinary incontinence was 75%. In patients with urinary incontinence, the mean preoperative and postoperative ICIQ-SF values were 14.33 (8-21) and 2.3 (0-11) respectively. Of 15 patients evaluated for satisfaction, 14 (93.4%) stated that they were completely well; they could be re-operated if necessary and would recommend the operation to their relatives. In one patient the palpable mass observed to persist and dissatisfaction was observed because of the failure and unnecessary anesthesia.

DISCUSSION
Rates of recurrence are reported between 3% and 70% following anterior colporrhaphy and between 5% and 50% after paravaginal repair by vaginal route in the treatment of anterior wall prolapse.(7,10-12) This is because the classical anterior colporrhaphy primarily focuses on central defects, while paravaginal repair targets lateral defects.(12) Since the central defects alone are rare,(13) the dissection should be expanded toward the lateral to provide adequate support both for lateral and central defects in all anterior prolapse repairs. By the technique and incision form we used and by expanding the dissection area toward the lateral, we aimed to realize an anterior wall repair supporting not only central but also lateral defects and to reduce the rates of recurrence. Besides the surgical method, use of support material is proposed in the literature in order to achieve a higher anatomic success compared to traditional anterior colporrhaphy.(8) Indeed, increased rates of anatomic success were demonstrated in the repair of central and lateral defects using additional support material.(14) Govier and colleagues also suggested a method similar to above mentioned using mesh.(15) Polypropylene...
type 1 synthetic meshes have priority as support material, while despite their low rate of success, biological grafts are also reported and can be preferred due to their lower risk of complications.\(^{(8,15)}\)

In addition to repair of the anterior wall through vaginal route with synthetic meshes,\(^{(16,17)}\) there are several studies in the literature about posterior wall,\(^{(18)}\) vaginal stump\(^{(19)}\) and total genital prolapse treatment.\(^{(20)}\) However, as it is reported by ICI, there is no sufficient scientific evidence showing that support material in the posterior wall repair or use of any specific technique in apical wall repair through vaginal route is superior to native tissues.\(^{(8)}\) In a study by Flood and colleagues, in the mean follow-up duration of 3.2 years following use of synthetic meshes for treatment of anterior wall prolapse, none of 142 patients developed recurrent prolapse and, only in 3 patients meshes had to be removed due to vaginal erosion.\(^{(21)}\) In a prospective, randomized controlled trial with 161 women recurrence rates of anterior wall prolapse was found to be statistically significantly decreased with use of mesh.\(^{(22)}\) In a study by Sand and colleagues, a higher rate of success was reported in the patients undergone repair of anterior wall prolapse using mesh compared to the traditional colporrhaphy methods.\(^{(22)}\)

Table 1. Patients characteristics.

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years (range)</td>
<td>64 (47-85)</td>
</tr>
<tr>
<td>Body mass index (mean)</td>
<td>26.5 (24.2-28.4)</td>
</tr>
<tr>
<td>Underweight (&lt; 18.5)</td>
<td>0</td>
</tr>
<tr>
<td>Normal weight (18.5-24.9)</td>
<td>10 (66.7%)</td>
</tr>
<tr>
<td>Overweight (25-29.9)</td>
<td>5 (33.3%)</td>
</tr>
<tr>
<td>Obesity (≥ 30)</td>
<td>0</td>
</tr>
<tr>
<td>Mean pregnancy, no. (range)</td>
<td>4.5 (1-9)</td>
</tr>
<tr>
<td>Mean delivery, no. (range)</td>
<td>2.8 (1-7)</td>
</tr>
<tr>
<td>Sexual activity, no. (%)</td>
<td>100</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (60.0)</td>
</tr>
<tr>
<td>No</td>
<td>6 (40.0)</td>
</tr>
<tr>
<td>Presentation of the patient</td>
<td></td>
</tr>
<tr>
<td>Palpable mass</td>
<td>10 (66.7)</td>
</tr>
<tr>
<td>Dyspareunia, urinary incontinence</td>
<td>5 (33.3)</td>
</tr>
<tr>
<td>POP-Q classification (no.)</td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td>4</td>
</tr>
<tr>
<td>Grade 3</td>
<td>9</td>
</tr>
<tr>
<td>Grade 4</td>
<td>2</td>
</tr>
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</table>

Key: POP-Q, Pelvic Organ Prolapse Quantification.

On the other hand, it should be noted that the anatomic success is not always compatible with subjective results.\(^{(29)}\) In fact, before the surgery to be performed using mesh, the patients should be informed in details about functional results such as sexual function, continence, detrusor over activity and about the operation. De novo dyspareunia was reported between 2% and 15% in patients undergone repair of the anterior wall with recently described transobturator four arms mesh which is inserted using trocar.\(^{(30-33)}\) In this method, dyspareunia may be both due to the mesh,\(^{(34)}\) and the tool used to insert the mesh.\(^{(35)}\) On the other hand, a randomized controlled study comparing porcine dermis with standard repair anterior colporrhaphy without using graft reported that insertion of biomesh does not increase the risk for dyspareunia.\(^{(27)}\) In another randomized, controlled study, synthetic
polypropylene mesh Gynemesh PS (Ethicon, INC, Somerville, NJ, USA) and Pelvicol (C.R. Bard, Mol, Belgium) were compared, and sexual functions were found to be better in biomesh group, and this was attributed to propylene mesh to impair vaginal flexibility.\(^\text{(36)}\) In accordance with the literature, in this study with biomesh, none of the sexually active patients developed dyspareunia.

Development of de novo SUI in anterior repairs through vaginal route using mesh is reported between 12% and 17% in the literature.\(^\text{(33,37,38)}\) In a randomized controlled trial, this rate was stated as 12.3% following insertion of mesh using trocar, and it was reported to be statistically more frequent than anterior colporrhaphy.\(^\text{(37)}\) In another randomized controlled study, no statistically significant difference was found between the mesh group and standard methods.\(^\text{(39)}\) In our study, de novo SUI was not found in any patient. In addition, following the repairs with biological mesh, rate of detrusor overactivity was found as 17.4%, but this was not found statistically significant compared to the standard techniques.\(^\text{(36)}\) In the present study, 13% of the patients developed complaints of de novo urgency, and responded to anticholinergic therapy.

In the reviews of Cochrane's database, conflicting data are mentioned about the prophylactic surgery for concurrent incontinence during the repair of anterior wall prolapse.\(^\text{(23,24)}\) In our study, we simultaneously inserted TOT in 4 patients who was found to have USUI. None of these patients developed per- or postoperative additional complications. TOT was failed in one patient, although the patient was satisfied with the operation. The mean ICIQ-SF value was declined to 2.3 (0-11) postoperatively which was 14.33 (8-21) preoperatively. Use of mesh leads to additional complications requiring special treatment. The most common ones are mesh exposition or extrusion, and the complications related to the mesh shrinkage.\(^\text{(40)}\) In fact, rates of vaginal exposition or extrusion may show an increase up to 11.9% according to the type of mesh used.\(^\text{(41)}\) However, these types of complications are rare when using biological mesh because of the lower tissue rejection and less risk of infection.\(^\text{(27)}\) Nevertheless, these complications should be considered in follow-up in the patients with complaints such as vaginal bleeding, vaginal discharge, vaginal or pelvic pain and dyspareunia. In this study, none of the patients developed such a biomesh specific complication. In addition, it should be remembered that despite they are prepared with aseptic techniques, all the allografts like biomeshes are under the risk for transmission of diseases such as human immunodeficiency virus (HIV) and hepatitis B.

There are several limitations to our study. One weakness of our study is that our data were collected retrospectively. Second, our series is small and not a long term study. Although it was not a randomized controlled study, this technique seems to be an alternative treatment in POP surgery. Further prospective, randomized and comparative studies with a high level of evidence are needed. In conclusion, in this study outcomes and complication rates seem to be acceptable in the anterior repair through vaginal route using acellular collagen biomesh.

**CONFLICT OF INTEREST**

None declared.

**REFERENCES**


