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USE OF CADAVERIC SOLVENT-DEHYDRATED FASCIA LATA FOR CYSTOCELE REPAIR—PRELIMINARY RESULTS

ASNAT GROUTZ, DAVID C. CHAIKIN, ELIZABETH THEUSEN, AND JERRY G. BLAIVAS

ABSTRACT

Objectives. To present a surgical technique in which cadaveric fascia lata is used for cystocele repair.

Methods. Twenty-one consecutive women (mean age 67 ± 10 years) with severe cystocele were prospectively enrolled. All patients underwent meticulous clinical and urodynamic preoperative evaluations. Solvent-dehydrated, Tutoplast-processed, cadaveric fascia lata was used for cystocele repair. The fascia was anchored transversally between the bilateral arcus tendineus and the cardinal and uterosacral ligaments. Standard endopelvic plication was performed thereafter as a second layer. Patients with overt or occult sphincteric incontinence underwent concomitant pubovaginal sling (PVS) surgery as well, using the same material. The main outcome measures included recurrent urogenital prolapse, persistent or de novo urinary incontinence (stress or urge), and dyspareunia.

Results. Of the 21 patients, 19 underwent concomitant PVS, 3 concomitant vaginal hysterectomy, and 8 posterior colporrhaphy in addition to their cystocele repair. The mean follow-up was 20.1 ± 6.7 months (range 12 to 30). No postoperative complications related to the material or technique occurred. None of the patients developed a recurrent cystocele. Two patients (9%), one of whom underwent concomitant posterior colporrhaphy, developed mild recto-enterocele at 4 to 6 months postoperatively. Six patients underwent concomitant PVS for occult sphincteric incontinence. None developed postoperative stress incontinence. Thirteen other patients underwent concomitant PVS for overt sphincteric incontinence. All but two were stress-continent postoperatively. One half of the patients with preoperative urge or mixed incontinence had persistent urge incontinence postoperatively. None of the patients developed postoperative de novo urge incontinence or dyspareunia.

Conclusions. The use of solvent-dehydrated cadaveric fascia lata for cystocele repair, as well as PVS, is associated with encouraging short and medium-term results. Long-term follow-up is needed to evaluate whether these results are durable.

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A wide variety of surgical techniques have been devised for the repair of severe urogenital prolapse, but no single technique has met with widespread acceptance. Historically, anterior colporrhaphy, with many modifications of the vaginal incision and/or the fascia plication, has been the most popular technique for cystocele repair. Although recurrent cystocele has been reported in up to 20% of patients,[1] long-term outcome studies regarding the effectiveness and durability of anterior colporrhaphy or other techniques are surprisingly scarce.[2] Furthermore, 50% to 70% of clinically continent women with severe urogenital prolapse may become incontinent once the prolapse is reduced.[3–5] Repair of the prolapse per se in these women may lead to the development of postoperative de novo stress urinary incontinence. However, the concept of a prophylactic anti-incontinence procedure in clinically continent patients undergoing genitourinary prolapse repair is still controversial.[5–9]

We present a surgical technique in which cadaveric fascia lata is used to repair severe cystocele. A concomitant pubovaginal sling (PVS), using the same material, is performed in patients with overt or occult sphincteric incontinence.

MATERIAL AND METHODS

Twenty-one consecutive women with severe cystocele were prospectively enrolled. All patients underwent a meticulous

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From Weill Medical College, Cornell University, New York, New York; and Morristown Memorial Hospital, Morristown, New Jersey

Reprint requests: David C. Chaikin, M.D., 261 James Street, Suite 1A, Morristown, NJ 07960

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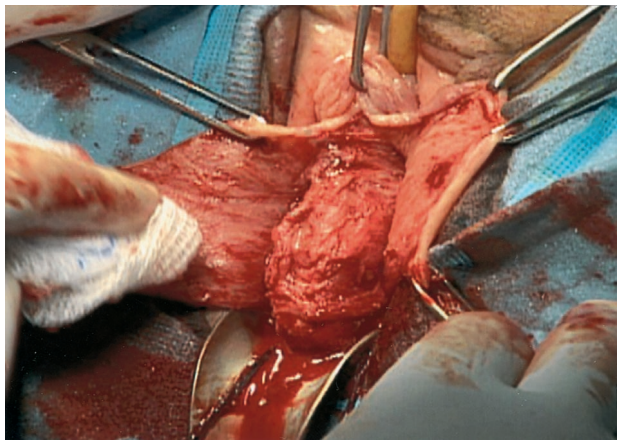

FIGURE 1. *Cystocele repair was performed through a vertical incision in the anterior vaginal wall. Skin flaps were developed in a bloodless plane.*

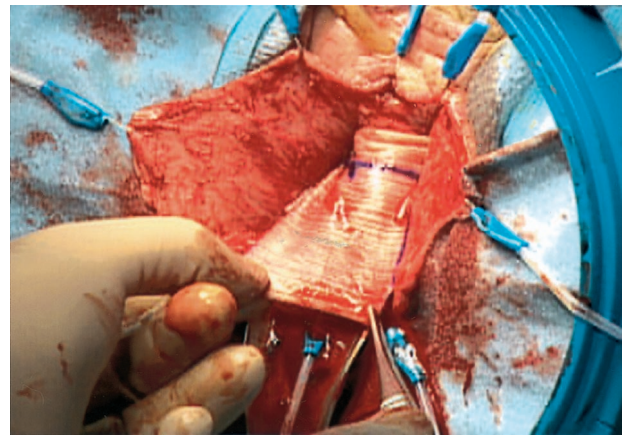

FIGURE 2. *The cadaveric fascia patch was tailored to the vagina size and shape, but typically a 5 × 7-cm patch was more than adequate.*

baseline evaluation, which included a complete history and physical examination, standardized urinary questionnaire, 24-hour voiding diary, 24-hour pad test, urine culture, noninvasive uroflowmetry, postvoid residual urine volume, video urodynamic studies, and urethrocystoscopy. The degree of the prolapse was assessed in the lithotomy position in accordance with the modified Baden and Walker classification.[10] With a comfortably filled bladder, the patient was asked to cough or strain with increasing degrees of force. First-degree prolapse is defined when the presenting part descends less than halfway to the hymenal ring. Second-degree prolapse is defined when the presenting part descends to the hymenal ring. In third degree, the presenting part protrudes beyond the ring; and in fourth degree, it is well beyond it.

Multichannel video urodynamic studies were performed according to the recommendations of the International Continence Society, except for cystometry.[11] Contrary to these recommendations, the patient was not instructed to try to inhibit micturition during the filling phase, but rather to report the sensations to the examiner. The cystometrogram was performed using radiographic contrast and a 7F double-lumen catheter with constant infusion at a medium-filling rate, with rectal pressure monitoring. A repeated urodynamic evaluation was performed with repositioning of the prolapse by a fitted ring pessary. Care was taken to ensure complete reduction of the prolapse without expulsion during coughing and without undue discomfort for the patient. Sphincteric incontinence was defined as visible urinary leakage during increased abdominal pressure in the absence of concomitant detrusor overactivity. Sphincteric incontinence was considered as overt in symptomatic stress-incontinent patients and as occult when stress-induced leakage was demonstrated only during repositioning of the prolapse in otherwise clinically continent patients.

Patients with urodynamic evidence of stress incontinence were then categorized, on the basis of the leak point pressure (LPP) and degree of urethral mobility, as having type 1 (LPP greater than 60 cm H_2O and Q-tip test less than 30°); type 2 (LPP greater than 60 cm H_2O and Q-tip test greater than 30°); or type 3 (ie, intrinsic sphincteric deficiency; LPP less than 60 cm H_2O, regardless of the degree of urethral mobility).

All patients underwent cystocele repair using solvent-dehydrated, gamma-irradiated, Tutoplast-processed, cadaveric fascia lata. Additional surgical procedures were tailored according to the clinical and urodynamic findings: women without any (overt or occult) sphincteric incontinence underwent prolapse repair only, and women with either overt or occult sphincteric incontinence underwent concomitant PVS, using the same material. Women with rectocele, enterocele, or uterine prolapse underwent concomitant posterior colporrhaphy, enterocele repair, or vaginal hysterectomy, respectively.

The PVS was performed through a slightly curved transverse incision over the bladder neck in strict accordance with the technique described in previous reports.[5,12] Cystocele repair was performed through a separate vertical incision in the anterior vaginal wall, extending from the bladder neck to the apex of the vaginal vault. Skin flaps were developed in a bloodless plane (Fig. 1). The pubocervical fascia was identified by carrying the dissection laterally to the arcus tendineus and cardinal ligaments and, posteriorly, to the uterosacral ligaments, in cases in which vaginal hysterectomy or enterocele repair was performed. A pair of 2-0 Vicryl sutures was attached to the arcus tendineus bilaterally using a suture driver. An additional two pairs of 2-0 Vicryl sutures were placed in the cardinal ligament complex and posterior pubocervical fascia bilaterally. The cadaveric fascia patch was tailored to the vaginal size and shape, but typically a 5 × 7-cm patch was more than adequate (Fig. 2). The free edges of the patch were then attached to the pre-placed sutures using a tapered free needle. The sutures were tied so that no tension was applied to the bladder from the fascial patch. After securing the patch, the pubocervical fascia was plicated in the midline as a second layer using interrupted 2-0 Vicryl sutures.

Postoperatively, the women were evaluated at 1, 3, 6, and 12 months and annually thereafter. At each visit, a history, focused examination with a full bladder, 24-hour voiding diary, 24-hour pad test, uroflowmetry, and postvoid residual urine volume were obtained. The main outcome measures included recurrent urogenital prolapse, persistent or de novo urinary incontinence (stress or urge), and dyspareunia. The outcome results of the PVS were assessed by a urinary incontinence score.[13] In brief, the new outcome score has a possible total of 6 points. Cure (total score 0) was defined by strict criteria: (a) 24-hour voiding diary with no urinary incontinence episodes (urge or stress); (b) 24-hour pad test with weight gain of 8 g or less; and (c) questionnaire answer stating that the patient considered herself cured. Failure (total score 6) was defined when the objective results were poor and the patient considered her treatment to have failed. Patients who did not fulfill the above cure/failure criteria were considered to have improved and were further classified as having a good (total score 1 to 2), fair (total score 3 to 4), or poor (total score 5) response.

RESULTS

Twenty-one women with severe (grade 3 or 4) urogenital prolapse were prospectively enrolled. The mean age and parity of the patients was 66.8 ± 10.1 years and 3.2 ± 1.6, respectively. Nineteen patients (90%), 9 (47%) of whom were using hormonal replacement therapy, were postmenopausal. Of the 21 patients, 8 (38%) had previously undergone hysterectomy, 5 (24%) prolapse repair, and 1 (5%) an anti-incontinence procedure (bone anchors).

All patients presented with severe prolapse as the main complaint; however, 1 patient (5%) had concomitant pure urge incontinence, 7 (33%) had overt stress incontinence, and 6 patients (29%) had overt mixed (stress and urge) incontinence. The mean number of preoperative incontinence episodes was 3.7 ± 3.2 and the mean urine loss per 24-hour micturition diary and pad tests was 37 ± 42 g.

On cystometry, all patients had normal bladder compliance, and 6 (29%) were found to have detrusor instability. Thirteen patients (62%) had urodynamically proven overt sphincteric incontinence. After reduction of the prolapse with a pessary, occult sphincteric incontinence was diagnosed in 6 other patients (29%). The mean Valsalva LPP was 73.8 ± 17.8 cm H_2O. Pressure-flow studies without prolapse reduction revealed bladder outlet obstruction in 4 patients (19%). In all 4, the obstruction was resolved by repositioning the prolapse with a ring pessary.

Overall, 19 patients (90%) had either overt or occult sphincteric incontinence and therefore underwent concomitant PVS. Three patients underwent concomitant vaginal hysterectomy, and eight underwent posterior colporrhaphy in addition to their cystocele repair. The mean estimated blood loss was 404 ± 199 mL, and the mean hospital stay was 3.9 ± 6.4 days. All patients, except one, resumed spontaneous voiding during the first postoperative week (range 1 to 6 days). One patient required catheterization for 1 month. No intraoperative or immediate postoperative complications related to the material or technique occurred.

The mean follow-up was 20.1 ± 6.7 months (range 12 to 30). None of the 21 patients developed a recurrent cystocele. Two patients (9.5%), one of whom underwent concomitant posterior colporrhaphy, developed mild recto-enterocele at 4 to 6 months postoperatively. A focused postoperative evaluation failed to reveal postoperative vaginal stenosis, any new onset dyspareunia, or pelvic pain among our patients.

None of the 6 patients who underwent concomitant PVS for occult sphincteric incontinence developed postoperative stress urinary incontinence. Of the 13 patients who underwent concomitant PVS for overt sphincteric incontinence, 11 (85%) were cured of their stress incontinence symptoms. Two other patients complained of persistent mild stress incontinence, one of whom was successfully treated by periurethral collagen injections; the other required no treatment. Three patients (43% of the patients with preoperative urge or mixed incontinence) had persistent urge incontinence. None of the other patients developed postoperative de novo urge incontinence. We further analyzed our results by the very stringent criteria used in the new urinary incontinence outcome score. Overall, 7 (37%) of the 19 PVS procedures were classified by the outcome score as cure, 11 (58%) as a good response, and 1 (5%) as a poor response.

COMMENT

Surgical repair of severe urogenital prolapse is one of the most challenging tasks in pelvic reconstructive surgery. Successful repair requires full restoration of normal anatomy and function, as well as the prevention of prolapse recurrence and the development of postoperative de novo voiding and sexual or anal dysfunction. A wide variety of surgical techniques have been devised for the treatment of urogenital prolapse; however, the reproducibility and long-term efficacy of these techniques have never been thoroughly studied. Weber and Walters[2] reviewed 80 studies regarding anterior vaginal prolapse that were published in peer-reviewed journals or textbooks. Forty-nine of these studies described surgical techniques for cystocele repair; however, the postoperative outcomes were available in only 24 studies. The reported recurrence rates were up to 20% for anterior colporrhaphy; 22% to 92% for anterior colporrhaphy combined with sacrospinous ligament suspension; and 3% to 14% for paravaginal repair.

In women, the levator ani muscle complex forms a broad hammock on which the pelvic viscera lie. The fascial covering of the levator ani consists of two leaves: the endopelvic fascia (abdominal side) and the pubocervical fascia (vaginal side). The two leaves fuse laterally, forming the arcus tendineus ligament, or "white line," that extends bilaterally from the symphysis pubis to the ischial spines.[2,14] Historically, the commonly held view was that two distinct pathophysiologic mechanisms may lead to anterior vaginal wall prolapse: stretching of the vaginal support ("distension" type cystocele) or detachment of the lateral support at the white line ("displacement" type cystocele). Theoretically, if the cystocele is due to lateral detachment, midline vaginal plication, as is done in anterior colporrhaphy, may worsen the lateral detachment, whereas paravaginal repair will restore these attachments.[2]

However, studies comparing different surgical techniques with regard to this theory are still lacking. Recently, a new surgical approach, using a hammock-like shaped mesh, fixed bilaterally to the arcus tendineus, was suggested.[15] Conceptually, since the mesh is anchored to relatively fixed lateral structures, it should repair both distention and displacement type cystocele. Of 44 patients who underwent prolapse repair using this technique (23 of whom had severe cystocele), none had cystocele recurrence at a follow-up of 9 to 23 months. However, 1 case of mesh-induced vaginal wall erosion occurred that required surgical intervention. Other investigators have suggested repairing severe cystocele by anchoring a mixed fiber mesh to the urethropelvic and cardinal ligaments.[16] Of 15 patients who underwent prolapse repair using this technique, 1 (7%) had recurrent grade 3 cystocele and 3 (21%) had recurrent or new onset enterorectocele at a follow-up of 18 to 39 months.

We believe that reinforcing the conventional anterior repair by additional support may indeed be more efficient; however, we are concerned regarding the possible long-term complications associated with the use of synthetic materials for this purpose. Erosion and fistula formation may occur remote from the place of surgery, and an increased risk (as high as 14%) of these complications has been previously reported with synthetic slings.[17] Human cadaveric fascia lata allografts have been successfully used in orthopedic and ophthalmologic practice for more than 25 years and have proved safe and durable. Recently, fascia lata allografts have been increasingly substituted for autologous tissue in PVS surgery. The benefit of using this tissue is the elimination of the abdominal dissection to harvest the rectus fascia or the thigh dissection to harvest the fascia lata and, thus, a lessening of the morbidity for the patient. The disadvantage of using this cadaveric tissue, although mostly theoretical, is the risk of transmissible disease from the donor, graft rejection, and the lack of long-term results. The local tissue response to allograft material is comparable to that of autologous fascia, and, so far, no rejection response has been noted after transplantation of frozen or freeze-dried allografts.[18] Several techniques are now used in the preparation of allograft tissues, including ethanol extraction, high-pressure agitation, lyophilization (freeze-drying), and gamma irradiation. We have recently compared the mechanical properties of autologous rectus fascia and two types of commercially available cadaveric fascia lata: freeze-dried and solvent-dehydrated.[19] Solvent-dehydrated cadaveric fascia lata was found to be indistinguishable from native autologous rectus fascia in terms of tensile strength and tissue stiffness. The freeze-dried cadaveric fascia was found to be significantly less strong than the native fascia or solvent-dehydrated allograft. These results are in accordance with a previously published study in which a significantly higher strength and stiffness was found when the cadaveric fascia lata was dried with solvent rather than freezing.[20]

The results of the present study suggest that solvent-dehydrated cadaveric fascia lata may be successfully used for both cystocele repair and PVS surgery. Of the 21 patients, all of whom presented with severe cystocele, none developed recurrent cystocele, de novo stress or urge incontinence, or dyspareunia at a follow-up of 12 to 30 months. However, 2 patients (9%), one of whom underwent concomitant posterior colporrhaphy, developed mild recto-enterocele at 4 to 6 months postoperatively. We also have found the preoperative urodynamic evaluation, with and without prolapse reduction, to be essential in making the correct diagnosis of occult sphincteric incontinence in clinically continent women with urogenital prolapse. We believe the decision to perform a concomitant prophylactic anti-incontinence procedure should be tailored to the individual urodynamic findings. None of our preoperatively continent patients who underwent prophylactic PVS for occult sphincteric incontinence, or prolapse repair only when occult incontinence was ruled out, developed postoperative stress incontinence. Although the present series was small and the follow-up relatively short, these findings are in accordance with our previously published series.[5]

CONCLUSIONS

The use of solvent-dehydrated cadaveric fascia lata for cystocele repair, as well as PVS, is associated with encouraging short-term results. Long-term follow-up is needed to evaluate whether these results are durable.

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