

Long-term surgical outcome of anterior colporrhaphy and autologous fascial sling (AFS) reinforcement for treatment of high-grade cystocele

Journal of Clinical Urology
1–6

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DOI: 10.1177/20514158211062476

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Abstract

Objective: To determine the long-term outcomes of anterior colporrhaphy with pubovaginal sling reinforcement in the management of high-grade cystocele and significant urethral dysfunction.

Materials and Methods: This is a retrospective case series. From May 2008 to October 2017, all patients who underwent concurrent anterior colporrhaphy and pubovaginal fascial sling performed by a single surgeon were included. Subjective success rates were determined from patient-reported outcomes on follow-up questionnaires using The Patient Global Impression of Improvement (PGI-I) scores. Primary outcome of this study was subjective cystocele recurrence-free survival. Secondary outcome was complication rate.

Results: Eighty patients were included with a median age of 63 years. All women had urethral dysfunction (type II urethral hypermobility or intrinsic sphincter deficiency) on fluoroscopic urodynamics in association with a high-grade cystocele. The median follow-up time for recurrence of cystocele was 36 months. The 1- and 5-year estimated cystocele recurrence-free survival was 97.2% and 84.8%, respectively.

Conclusion: Anterior colporrhaphy with concurrent pubovaginal sling reinforcement for treatment of high-grade cystocele is a safe procedure with a high rate of success durable up to 5 years. The risk of complications is low with no patient developing chronic pain or rejection of the fascial graft.

Level of evidence: Not applicable.

Keywords

Cystocele, prolapse, colporrhaphy, autologous fascial sling, urinary incontinence

Date received: 28 May 2021; accepted: 2 November 2021

Introduction

Pelvic organ prolapse (POP) carries significant morbidity and impact on quality of life for women worldwide. The lifetime risk for needing surgery for POP may be as high as 11–19%.^{1,2} In addition to typical POP symptoms of vaginal bulge, postural dragging and heaviness, cystoceles may also cause voiding dysfunction, recurrent urinary tract infections, hydronephrosis and mucosal erosion.³

Patients with symptomatic POP which is not resolved with conservative treatments including physiotherapy and

pessaries are offered surgical repair, most commonly anterior colporrhaphy. Rates of recurrence following anterior colporrhaphy are as high as 55%.⁴ Multiple studies have

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shown mesh or cadaveric and autologous graft reinforcements for vaginal repair to be superior to anterior colporrhaphy alone.^{4–8} However, the use of vaginal mesh has been associated with significant complication rates,^{5,9} and has been the subject of intense media scrutiny and medico-legal action.¹⁰ Since the 2008 and 2011 Food and Drug Administration (FDA) announcement regarding risks of synthetic mesh in vaginal prolapse repair, there has been a shift away from using synthetic materials and towards native tissue repairs.^{11,12}

A technique using a fascial sling to accompany anterior colporrhaphy was first described in 1991.¹³ Cadaveric fascia reinforcement following anterior colporrhaphy has also been described in the management of cystocele with reported excellent short-term success rates.^{8,14} Despite this, anterior colporrhaphy alone was used in cystocele repair for 54% of gynaecologists in Australia and New Zealand with only 20% combining vaginal repair with a graft.¹⁵ While fascial slings have a recognised role in overt stress incontinence, it is not clear whether their use may fortify anterior colporrhaphy and reduce the risk of recurrence. This study aims to determine the long-term outcomes of the use of anterior colporrhaphy with pubovaginal sling reinforcement in the management of high-grade cystocele and urethral dysfunction.

Materials and methods

This is a retrospective single surgeon case series of women over the age of 18 years who underwent anterior colporrhaphy and pubovaginal sling insertion for the management of high-grade cystocele from May 2008 through to October 2017. All patients underwent fluoroscopic urodynamic studies (FUDS) prior to operation and all women showed urethral dysfunction (type II urethral hypermobility or intrinsic sphincter deficiency) in association with a high-grade cystocele. Stress urinary incontinence (SUI) was defined as subjective symptoms or a positive cough test on FUDS. Cystoceles were graded using the Baden–Walker halfway classification system (HWS). High-grade cystocele is defined as a grade 3 or 4. Routine follow-up of these women included clinic appointments and phone reviews. Patients were invited to participate in a long-term follow-up questionnaire using Patient Global Impression of Improvement (PGI-I). The PGI-I survey asked patients to compare their overall symptoms now, as compared with how it was prior to before the operation. Recurrence as defined as symptomatic recurrence of a bulge.

Clinicopathological data were extracted from medical records and included age, bulge, and incontinence symptoms pre- and post-operatively, type of incontinence, FUDS result and post-operative complications (retention, urinary or wound infection and seroma). The primary outcome of the study is cystocele recurrence-free survival. The secondary outcome is the complication rate following

the procedure. Residual volumes were measured post-operatively and if found to be rising of greater than one-third of the total volume, self-catheterisation was instigated.

Baseline, demographics and PGI-I data were reported as median values or proportions. Fisher's exact test or chi-square test were used to compare proportions. Survival analyses were performed using the Kaplan–Meier curve to calculate estimated cystocele recurrence-free survival. A subgroup analysis was used to compare the outcomes for women who had a loose versus 'not-loose' pubovaginal sling insertion to determine if the tightness of pubovaginal sling had an impact on cystocele recurrence. Log-rank test was used to compare the survival curves for the subgroup analyses. Statistical analyses were performed using the *Stata Statistical Software: Release 16* (StataCorp LLC, Texas, USA). Ethics approval was obtained from our institution's human research and ethics committee (QA2019085).

Operative method

Women who exhibited symptomatic cystocele underwent clinical evaluation and treatment was offered depending on the severity and degree of symptoms. Grade 1 and grade 2 cystoceles were generally managed with conservative measures such as weight loss, pelvic floor physiotherapy and topical oestrogen.

Women with symptomatic high-grade cystocele or refractory to pessary management were offered anterior colporrhaphy with pubovaginal sling reinforcement. If patient has concurrent significant apical prolapse or rectocele, concomitant procedures such as sacrospinous fixation, sacrocolpopexy or posterior repair were offered to the patient, these patients were not included in the study. Mesh repair was not offered to any patients. If patients did not have any contraindications to autologous fascial sling (AFS), then AFS and cystocele repair was the used repair method. Contraindications included good urethral support and no SUI, pelvic pain, poor bladder contractility or frailty. The treatment algorithm is adapted from the Australian Commission on Safety and Quality in Healthcare (ACSQHC)¹⁶ Care Pathway for the management of pelvic organ prolapsed.

A standardised technique was used to harvest the AFS. A fascial graft of 8 cm × 1.5 cm was harvested via a 4–6 cm lower abdominal transverse incision as determined by body habitus, with a 4-cm incision used for thin patients. A double length of zero polypropylene sutures was attached to the lateral ends of the fascia in a figure of eight fashion with the sutures placed perpendicular to the line of the fibres to prevent pull through of the sutures. After hydrodissection with bupivacaine 0.5% and adrenaline, anterior colporrhaphy was performed in a standardised fashion via a midline anterior compartment vaginal incision.

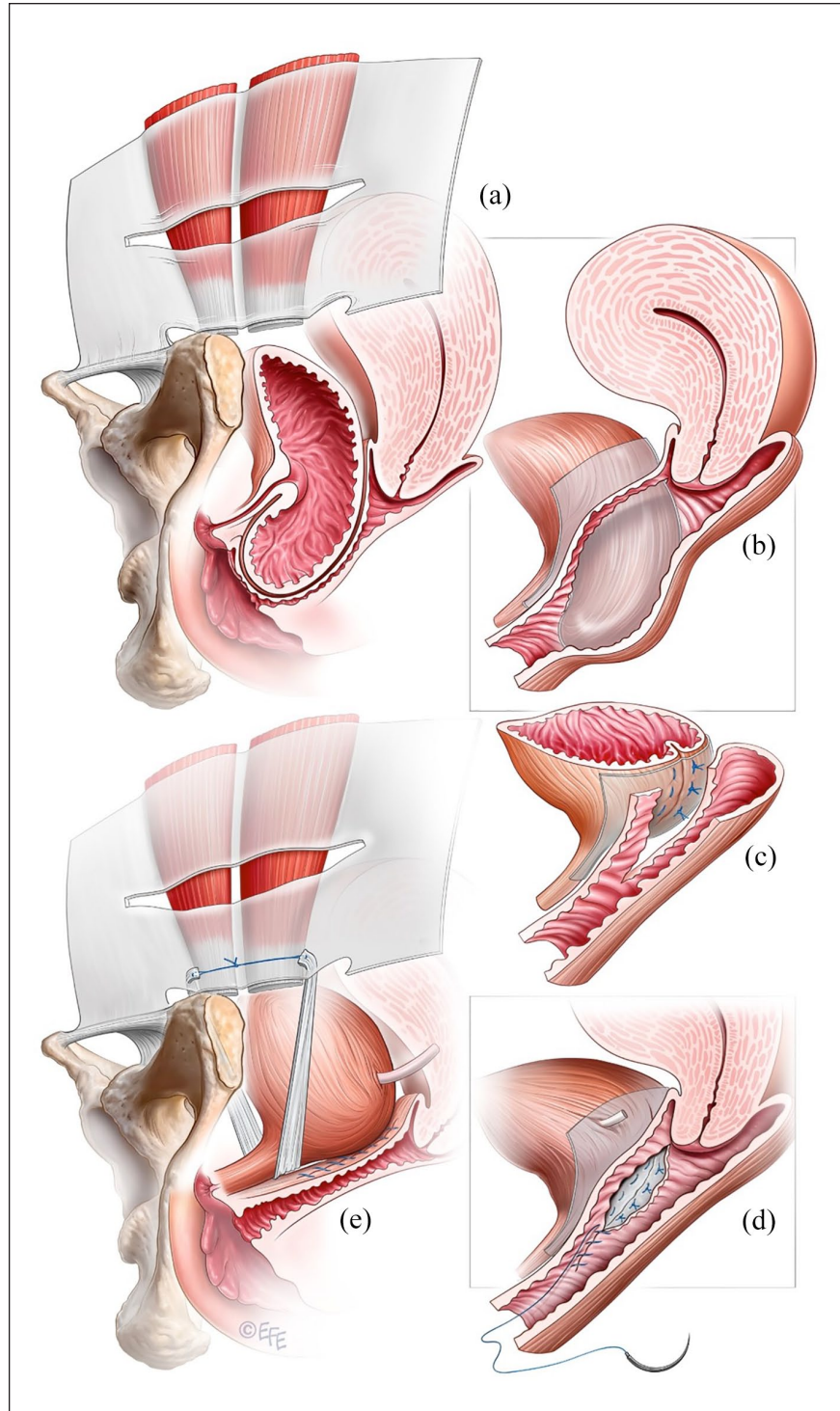


Figure 1. Illustration demonstrating the anterior colporrhaphy and fascial sling technique.

(a) Fascial graft harvesting (b) Bladder wall is dissected away from vaginal wall (c) Plication of the redundant prolapse sac (d) After tunneling and securing the AFS to the periurethral fascia, the vaginal wall is closed (e) AFS is secured in position anteriorly.

The bladder wall of the cystocele was dissected out to the pelvic side wall separating it from the vaginal 'skin' (Figure 1(b)). The cystocele was plicated with 3/0 polyglactin suture to infold the redundant sac of the prolapse, thereby reducing the task to be completed by the next layer of horizontal mattress sutures (Figure 1(c)). A retropubic

tunnel was developed lateral to the rectus abdomini muscles on each side leading to the vaginal incision. The sutures on the AFS were brought through the tunnels. Prior to closure of the vaginal wall, the AFS was sutured to the periurethral fascia in the midline in the proximal urethra, to prevent movement of the sling which could predispose

Table 1. Patient demographics.

	n (%)
Age in years, median (IQR)	63.5 (IQR 54.8–70.0)
Presenting complaint	
Bulge	40 (50.0)
Urinary incontinence	60 (75.0)
Stress urinary incontinence	19 (31.7)
Urge urinary incontinence	16 (26.7)
Mixed urinary incontinence	24 (40.0)
Previous prolapse surgery (yes)	11 (13.8)
Previous incontinence surgery (yes)	3 (3.8)
Post-operative complication	
Urinary retention	6 (7.5%)
UTI	3 (3.8)
Seroma	2 (2.5)
Wound infection	5 (6.3)

IQR: interquartile range; UTI: urinary tract infection.

to urethral obstruction (Figure 1(d)). Care was taken to ensure the sling was 1 cm from the bladder neck when sutured in position (Figure 1(e)). Sling tension was adjusted according to the severity of concomitant urethral dysfunction. Women who had closed bladder neck and high leak point pressure but 2 cm or more of rotational descent of their urethra on FUDS had placement of a ‘loose’ sling. A ‘not-loose’ sling placement was performed for women who had demonstrable wide-open bladder neck on FUDS. The authors have described details regarding the sling tensioning technique in a previous study.¹⁷ Loose was defined as closed with no tension (at least three finger-breadths’ space under the knot) whereas a not-loose sling was tied with two finger-breadths’ space under the knot. The abdominal wound was closed in layers. Post-operatively patients followed a care pathway which included close monitoring of residual volumes and self-catheterisation education when required. The technique used was the same for all patients.

Results

A total of 80 women were included in this study. The median age of women at the time of cystocele repair was 63.5 years (interquartile range (IQR)=54.8–70.0). Women presented with symptoms of bulge sensation in 50% ($n=40$) of cases and had urinary incontinence in 75% ($n=60$) of cases. For women presenting with urinary

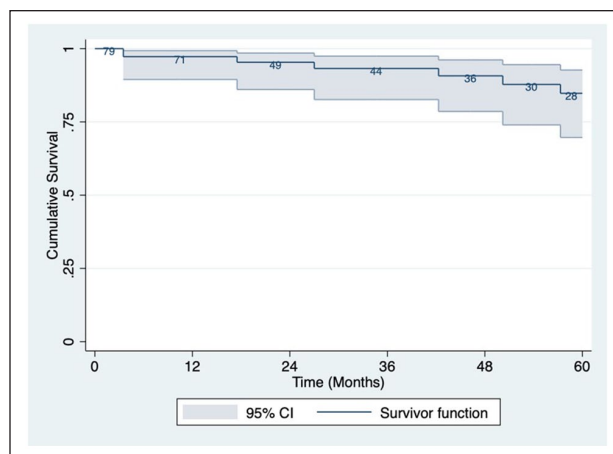


Figure 2. Cystocele recurrence-free survival for women who underwent anterior colporrhaphy and pubovaginal sling reinforcement for management of high-grade cystocele.

incontinence, it was characterised as SUI for 31.7% ($n=19$), mixed urinary incontinence for 40% ($n=24$) and urge urinary incontinence (UUI) for 26.7% ($n=16$).

All patients in this study were found to have a cystocele on examination and/or at upright FUDS despite only half of women presenting with a sensation of a bulge. SUI was demonstrated on FUDS in 47.5% ($n=38$) of women. All women had urethral dysfunction (type II urethral hypermobility or intrinsic sphincter deficiency) on FUDS. The majority ($n=59$, 73.8%) of patients had a HWS grade 3 cystocele, and 12.5% ($n=10$) had an HWS grade 4 cystocele. Previous prolapse and incontinence surgery were present in 13.8% ($n=11$) and 3.8% ($n=3$) of women, respectively. Patient demographics are outlined in Table 1. One patient was lost to follow-up, and 79 patients had follow-up data available. The median clinic follow-up time for recurrence of cystocele was 36 months. The 1-, 2-, 3-, 4- and 5-year estimated recurrence-free survival was 97.2%, 95.4%, 93.2%, 90.7%, and 84.8%, respectively (Figure 2).

A subgroup analysis of 65 women who had recorded loose versus not-loose pubovaginal sling placed showed there was no statistically significant difference found between the two groups ($p=0.525$).

Post-operative complication rates were low and included temporary urinary retention in 7.5% ($n=6$) (Clavien–Dindo I), urinary tract infection in 3.75% ($n=3$) (Clavien–Dindo II), wound seroma in 2.5% ($n=2$) (Clavien–Dindo IIIa) and superficial wound infection in 6.25% ($n=5$) (Clavien–Dindo II) of women. There was no Clavien–Dindo IIIb or higher complications. There were not incisional hernias or development of chronic pain within the follow-up period. For patients with high post-void residual volumes, the high volumes all settled by 3 months. No patient required ISC beyond this time, nor required urethrolisis or division of sling. No patient required repeat cystocele repair surgery.

Forty-three patients completed a PGI-I questionnaire at a median follow-up time of 69.7 months (IQR=43.7–113.2). Out of these patients, symptoms were reported to be ‘very much better’ in 30.2% ($n=13$), ‘much better’ in 20.9% ($n=9$), ‘a little better’ in 9.3% ($n=4$), ‘no change’ in 23.3% ($n=10$), ‘a little worse’ in 11.6% ($n=5$), and ‘very much worse’ in 4.7% ($n=2$).

Discussion

This study demonstrates that anterior colporrhaphy and reinforcement with pubovaginal sling for management of high-grade cystocele is a safe technique and can provide a good outcome for women. The addition of an AFS is used to reinforce the repair, but also to prevent uncovering occult SUI by supporting the bladder neck. The fascial sling helps to treat urethral hypermobility and intrinsic urethral sphincter deficiency. This effect is sustained in the long term with an 84.3% recurrence-free survival at 5 years. To our knowledge, this is the largest case series with long-term outcome data for this surgical approach.

The cystocele recurrence-free rates reported in this study are consistent with other case series examining the use of a sub-urethral sling in the treatment of high-grade cystoceles. A previous study on the use of cadaveric dermal allograft as pubovaginal sling for the treatment of concurrent SUI and HWS grade 3 cystocele showed favourable estimated recurrence-free rate of 84.2% at 2 years.⁸ Similarly, another study examining the use of Xenoderm Corium Bladder Sling (Ethicon) with concomitant anterior colporrhaphy demonstrated similar short-term success rate of 85%.¹⁸ A study examining the use of distal urethral polypropylene sling, paravaginal polypropylene mesh augmentation in adjunct to anterior colporrhaphy in POP-Q grade 3 and 4 cystoceles have demonstrated 85% success rate of achieving POP-Q grade 0–1 post-operatively.¹⁹

Due to the nature of a case series, there is no comparative group to determine whether the addition of pubovaginal sling to anterior colporrhaphy is superior to anterior colporrhaphy alone. However, previous comparative studies involving anterior colporrhaphy plus or minus xenografts have consistently reported superior results with graft or mesh augmentation than without.^{20,21} This has also been seen in studies using synthetic mesh or transobturator tape augmentation of cystocele repair.^{4,6,22,23} The use of synthetic tapes and meshes needs to be weighed up against the increased risk of adverse events such as retention, infection, bladder perforation, erosion, and chronic pain syndromes.²⁴ The major concern regarding the use of transvaginal mesh for prolapse repair is the significant complication rates including mesh erosion, which have been reported to be as high as 11.6–15%.^{6,23} Even the use of non-autologous grafts have been reported to cause erosions.⁹ Both prosthetic materials are associated with higher complication rates of 15.8% for porcine mesh and 29.2%

for polypropylene mesh, with the risk of extrusion being higher for polypropylene mesh.⁹ The AFS carries no risk of causing erosion or rejection and is associated with a low risk of chronic pain. This was demonstrated in this study with no patient developing chronic pain. No abdominal wounds required revision and no abdominal hernia developed during the period of review. Despite the risk of acute urinary retention using an AFS, the rate was low at 6%, with all of them temporary and none needing long-term self-catheterisation or urethrolisis.

There are several limitations to this study. This is a retrospective case series and has the associated limitations of this study design. Incomplete data may under-report the actual rates of patients with symptoms of bulge and SUI at presentation. Patient follow-up beyond 12 months were conducted by questionnaire at non-regular intervals. This affects the analysis of cystocele recurrence rates at timed intervals. To overcome this limitation, Kaplan–Meier survival analysis was used to calculate the actuarial recurrence-free survival rates to account for recurrences reported at non-regular intervals. This study uses a subjective measure rather than objective measure of recurrence using PGI-I questionnaire. This may result in an under-reporting of cystocele recurrence. However, this has little clinical significance as an asymptomatic patient is unlikely to have a high-grade cystocele recurrence nor necessitate any further treatment. Similarly, the lack of physical examination may have resulted in an over-reporting of cystocele recurrence as some patients may have apical or posterior compartment prolapse rather than a cystocele recurrence. The PGI scoring system is non-specific and gives only an overall impression of symptoms. This explains why the PGI-I outcomes appear inferior to the recurrence-free survival outcomes demonstrated in this study. The lack of a comparator group means that conclusions about whether the use of an AFS is better than anterior colporrhaphy alone are unable to be made; however, this has been covered in previous studies.

Despite these limitations, this project is a long-term case series of patients undergoing an alternative technique that is safe and has good outcomes, with no patient requiring repeat cystocele repair. This technique builds upon previous knowledge of benefits of concomitant cystocele repair with a sling, but without the risks of mesh insertion.

Conclusion

The study demonstrates that the use of AFS reinforcement in anterior colporrhaphy may achieve a good medium to long-term cystocele recurrence-free survival with a low rate of complications. With a shift away from prolapse mesh repair, prospective multicentre comparative studies are needed to determine the role of autologous pubovaginal sling reinforcement in place of mesh augmentation in the prevention of recurrent high-grade cystocele.

Conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship and/or publication of this article.

Ethical approval

Ethics approval was obtained from the Western Health human research and ethics committee (QA2019085).

Guarantor

H.E.O.C. is the guarantor for this article.

Contributorship

H.E.O.C., H.H.Y. and D.T. formula the idea for the project. D.T. collected the data. H.H.Y. and D.T. performed the statistical analysis. D.T. wrote the draft of the manuscript. All authors reviewed, edited and approved the final manuscript.


Acknowledgements

The authors acknowledge Dr Levent Efe for his work in producing the illustrations in Figure 1.

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