

Original Article

## Is it the Time to Revisit Historical Bladder Neck Buttressing for the Treatment of Stress Urinary Incontinence?

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### ABSTRACT

**Objectives:** The aim of our study was to assess improvement in bladder function and quality of life using Australian Pelvic floor questionnaire as Patient Reported Outcome tool following anterior repair and urethral buttressing for treating stress urinary incontinence (SUI) with prolapse using polydioxanone sutures.

**Material and Methods:** This was the prospective review of retrospective data. The data were collected through telephone or postal questionnaire by an independent researcher who was not involved in the patient care directly and analyzed with Stata (14.2).

**Results:** About 78% (61/78) of women responded to the questionnaires. Statistically significant improvement in bladder function scores was noted after surgery ( $5.12 \pm 2.06$  vs.  $3.69 \pm 2.26$ ;  $P = 0.001$ ) along with an overall improvement in the quality of life scores ( $17.88 \pm 8.03$  vs.  $11.56 \pm 9.01$ ;  $P = 0.005$ ) at mean follow-up of 31 months. Overall, 54% patients reported improvement in their symptoms. The re-operation rate for second continence procedure for SUI was 1/61 (1.6%).

**Conclusion:** This procedure can be offered to patients as a treatment option for SUI with prolapse.

**Keywords:** Mesh tape, Anterior repair and urethral buttress, Stress urinary incontinence

### INTRODUCTION

Stress urinary incontinence (SUI) is a common condition with a prevalence of 15–72%<sup>[1,2]</sup> and the lifetime risk of primary surgery is 20% by the age of 80 years.<sup>[3]</sup> By 2000, mid-urethral slings (MUS) using synthetic mesh (tension-free vaginal tape [TVT]/TVT-obturator [TVT-O]) had become the procedure of choice, for this condition, with the number of surgeries performed from 2706 in 2000/2001, to a peak of 11,793 by 2008/2009 in England, that is, an increase of over 300%.<sup>[4]</sup> However, in the period of April 2016–March 2017, there was reduction of 48% in patients who had a tape insertion.<sup>[5]</sup> This is because of increased awareness of the small but serious risks associated with mesh implantation (such as mesh erosion, chronic pain, and sexual dysfunction).<sup>[6]</sup> It is acknowledged now that there is a need to explore alternative surgical options for SUI, including revisiting traditional procedures such as urethral buttressing (UB).

In our unit, UB along with anterior vaginal wall repair (AR) is offered to patients with Grade 2 cystocele and SUI following failed conservative management, that is, pelvic floor muscle training (PFMT). Our aim was to assess global impression of improvement (PGI-I), improvement in

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bladder function, re-operation rate, and effect on quality of life and sexual function following UB surgery for prolapse and stress incontinence.

## MATERIAL AND METHODS

This was the prospective review of retrospective data. This was registered as a service evaluation audit with local audit board and did not require ethical approval. The study was conducted in a tertiary teaching hospital between the period of October and December 2017. All patients who had AR and UB in the period of August 2013–March 2017 were identified from British Society of Urogynecologist database. All patients identified from the database were included and consented to complete questionnaires at the time of study. All the surgeries were performed by three urogynecology consultants working in the unit.

The operation was offered to patients with grade  $\geq 2$  cystocele with SUI or stress predominant mixed urinary incontinence (MUI), who did not wish to have a mesh procedure, natural short sling surgery or colposuspension. All patients had conservative management including supervised PFMT by specialist physiotherapist before considering surgery as recommended by National Institute for Health and Care Excellence (NICE).

The surgery was performed as described: The first invaginating mattress suture is placed in the paraurethral tissue 1 cm proximal to the external urethral meatus using polydioxanone sutures (Polydioxanone) suture material. The interrupted Kelly plication is continued from the paraurethral tissue to the vesicovaginal fascia up to the anterior fornix as originally described by Kelly.<sup>[7]</sup> The fascial repair was then performed with interrupted horizontal mattress sutures with 2/0 Polydioxanone. The vaginal skin is closed with interrupted vertical mattress sutures with 2/0 Polyglactin-910 with/without trimming the excess skin. All women received prophylactic antibiotics; thromboprophylaxis and the procedure were undertaken under either general or spinal anesthesia. All patients had a vaginal pack to support the repair and catheter up to 24 h.

Following questionnaires were used in the study: (1.) The Australian Pelvic floor questionnaire (APFQ) which integrates information on bladder, bowel, sexual function, and pelvic organ prolapse including severity, bothersomeness, and condition-specific quality of life. This validated questionnaire can easily and reliably be integrated into routine clinical practice.<sup>[8]</sup> We chose to focus on the bladder symptom score, which comprised 15 questions. The total bladder score (42) represents the total score for the bladder function domain. Each question is scored from 0 to 3 with 0 representing no symptoms; one representing occasional symptoms, two representing frequent symptoms, and three representing daily symptoms. As well as looking

at the total bladder score, we also looked in more detail at individual scores for urgency (Q4); SUI (Q6); social life score (Q14); and bladder bothersome score (Q15). See Appendix 1 for a detailed outline of the questionnaire.

(2.) The global impression of improvement (PGI-I), which is a validated seven-point scale that comprised a single question asking patients to rate their improvement of SUI following treatment on a scale from 1 (very much better) to 7 (very much worse). PGI-I has increasingly been recognized as important in the field of urogynecology as an indicator for patient related outcome measures (PROMS).<sup>[9,10]</sup> We considered patients feeling “a little better,” “much better” or “very much better” in this study to indicate aspects of successful surgical outcome. See Appendix 2 for the outline of the PGI-I score.

All patients who participated in the study were asked to complete these questionnaires at the time of study. The data were collected through telephone or postal questionnaire by an independent researcher who was not involved in the patient care directly. The information regarding demographics and pre-operative APFQ was collected from the patient’s case notes.

All methods and terminology used are in keeping with the International Urogynecological Association/International Continence Society’s recommendations for reporting outcomes of prolapse surgery.<sup>[11]</sup>

Sample calculation and statistical analysis: This was the audit of cohort of patients who already had UB surgery and was identified from the database in the unit therefore, power calculation was not required. The mean scores with standard deviations (SD) were calculated. Microsoft Excel and Stata 14 were used for data analysis.

## RESULTS

Seventy-eight patients who had BNB were identified from the British Society of Urogynaecology database. Sixty-one (78%) completed the questionnaires. Out of the remaining 17, three patients had died from unrelated causes, one patient was excluded as unable to read or write English and 13 were lost to follow-up.

All women were Caucasian with the mean age of 61 (32–89) years, median parity of 2 (1–5) and mean BMI of 28 (20–43) with median follow-up of 31 months (9 months–60 months). Twenty-eight (46%) presented with predominant SUI and prolapse, two (3%) presented with SUI alone, and 31 (51%) presented with stress predominant mixed urinary incontinence (MUI) and prolapse symptoms. Out of 19 (31%) who had urodynamics (UDS) performed preoperatively, nine patients had urodynamic stress incontinence (USI), six patients had mixed urge and stress incontinence (MUI), and four patients had normal urodynamics. Patients with normal

**Table 1:** Prolapse classification and concomitant surgery.

		n (%)
Prolapse classification	Anterior wall ( $\geq$ Grade 2) prolapse	57 (93)
	Apical/uterine ( $\geq$ Grade 2) prolapse	25 (41)
	Posterior wall ( $\geq$ Grade 2) prolapse	42 (69)
Prolapse surgery	Anterior repair alone	14 (23%)
	Anterior repair + vaginal hysterectomy	11 (18%)
	Anterior + Posterior + vaginal Hysterectomy	15 (25%)
	Anterior Repair + Posterior Repair	21 (34%)

UDS had AR + UB because of the presence of significant prolapse alongside the clinical presentation of SUI. On examination, 57 (93%) had anterior wall prolapse  $\geq$  grade 2 [Table 1] and 47 (82%) underwent concomitant surgery for prolapse in different compartment, as shown in Table 1.

Comparison between pre-operative and post-operative APFQ scores was possible only in 27/61(44%) patients due to unavailability of pre-operative APFQ data in rest of patients. Statistically significant improvement was seen in bladder ( $P = 0.001$ ), prolapse ( $P = 0.009$ ), and total APFQ ( $P = 0.005$ ) scores postoperatively. There was also significant improvement seen in the scores of Q6 of bladder domain (specific question for SUI) ( $P = 0.004$ ) [Table 2].

On evaluating post-operative APFQ in 61 patients, 33 (54%) of them either did not experience SUI or experienced SUI occasionally (Q6). Twenty-five (41%) felt that SUI still interfered with their daily activities (Q14), and 32 (53%) of patients found their SUI to be bothersome post-surgery (Q15) [Table 3]. It was an interesting observation that around one-third (32%) who were experiencing SUI occasionally were still bothered by it whereas 4/28 (14%) who were still experiencing SUI frequently or daily found it less bothersome as there was some improvement. Hence, it would not be wrong to say that patients' perception of bothersomeness is not related to the severity of problem.

Regarding sexual function, only 22/61(36%) questionnaires were available to compare. Out of these, ten patients were not sexually active, three had improvement in their sexual scores while three had no change and one patient reported worsening of sexual function. Five (23%) patients reported loss of their sexual activity due to other reasons (such as partner unable/no partner) and hence, data could not be compared and no meaningful conclusion could be drawn regarding effect of AR and UB on sexual function due to small numbers.

On PGI-I scale 58% of patients reported that they "felt better" after the operation at a mean follow-up of 31 months (9–60 months).

There were no serious complications noted. Thirteen (21%) patients had temporary voiding difficulty requiring

**Table 2:** Pre-operative and post-operative APFQ.

	Pre-operative (n=27) mean, SD	Post-operative (n=27) mean, SD	P-value*
Bladder	5.12 $\pm$ 2.06	3.69 $\pm$ 2.26	0.001
Bowel	3.27 $\pm$ 1.89	3.02 $\pm$ 1.90	0.23
Prolapse	4.74 $\pm$ 3.11	2.14 $\pm$ 2.68	0.009
Sex	3.73 $\pm$ 4.01	2.45 $\pm$ 3.63	0.41
Total	17.88 $\pm$ 8.03	11.56 $\pm$ 9.01	0.005
Q6 (SUI specific)	2.185 $\pm$ 0.87	1.37 $\pm$ 1.07	0.004

\*Paired *t*-test.

intermittent self-catheterization or indwelling catheter, but for no longer than 4 weeks. The re-operation rate for a second continence procedure for SUI was 1/61 (1.6%). This patient, subsequently, underwent an autologous fascial sling.

In the mean follow-up period of 31 months for our study, 54% (33/61) of patients did not experience any significant SUI post-surgery. Of the other 46% (28/61), patients who did have persistent or resistant SUI, 25 patients had recurrence within 1–3 years and three had recurrence between 3 years and 5 years. One of the four patients requested further assessment and proceeded to further treatment.

## DISCUSSION

Our study demonstrated that 54% of patients had improvement in their symptoms with a low reoperation rate of 1.6%. This suggests that the expectation from surgery was not to be completely dry but to have sufficient improvement in their symptoms for betterment in their quality of life.

Due to the different ways of interpreting results, it is difficult to draw robust conclusions about the success rate of urethral buttress for SUI. However, our results indicate that the success rate for AR and UB is around 40–50% at 2–5 years. This is comparable to the existing data, which indicate subjective outcome for this procedure is 80% at 1 year and 37–60% at 5–7 years.<sup>[12-14]</sup>

Recently, the minimal important difference (MID) is considered important to report outcomes of a questionnaire and reporting treatment effects. It is reported that the MID for APFQ is 1.3 for bladder domain and 1.0 for prolapse domain.<sup>[15]</sup> In our group of patients, 12/27 (44%) patients had MID more than 1.3 in bladder domain and 17/27 (63%) had MID more than 1.0 for prolapse score. This suggests that the surgery made meaningful difference to UI in 44% of women in bladder domain. The MID in other domains has not been reported as it was beyond the scope of this paper based on the information available.

**Table 3:** Comparison of specific question scores on APFQ (Q4 - urgency, Q5 - UUI, Q6 - SUI, Q14 - impact on social life, Q15 - bothersome scale).

	QOL scores					
	Pre-operative (n=27)		Post-operative (n=27)		Total (post-operative) (n=61)	
Symptom score	0/1 <sup>a</sup>	2/3 <sup>b</sup>	0/1 <sup>a</sup>	2/3 <sup>b</sup>	0/1 <sup>a</sup>	2/3 <sup>b</sup>
Q4	7 (26%)	20 (74%)	11 (40%)	16 (60%)	23 (38%)	38 (62%)
Q5	10 (37%)	17 (73%)	14 (52%)	13 (48%)	32 (53%)	29 (47%)
Q6	6 (22%)	21 (78%)	17 (73%)	10 (37%)	33 (54%)	28 (46%)
Q14	9 (33%)	18 (67%)	18 (67%)	9 (33%)	36 (59%)	25 (41%)
Q15	12 (44%)	15 (56%)	16 (59%)	11 (41%)	29 (47%)	32 (53%)

0/1<sup>a</sup>: No or occasional symptoms, 2/3<sup>b</sup>: Frequent or daily symptoms.

NICE, currently, does not recommend AR and UB for the treatment of SUI. This recommendation is largely based on the Cochrane Review from 2000<sup>[16]</sup> and 2017,<sup>[17]</sup> which concluded that open abdominal retropubic suspension appeared to be better than anterior vaginal repair judged on subjective cure rates in six trials, in women who had prolapse in addition to stress incontinence.

All the studies included in the Cochrane review used Polyglactin-910 as the suture material for the AR and UB (Bergmann 1989, Kammerer-Doak 1999, Holmes, 1985) or chromic catgut (Colombo 2000) whereas there was no specification about the suture material in two trials (Qadri 1985 and Liapis 1996). In our study, we carried out the plication with Polydioxanone as described in the methodology. The rationale for using Polydioxanone is that the polydioxanone material is stronger than Polyglactin-910 or catgut used in studies considered in Cochrane review leading to current NICE recommendations; however, our results with Polydioxanone were no more successful than anticipated historical results of AR + UB using Polyglactin-910. This suggests that the longer lasting and stronger suture with less tissue inflammation does not appear to be better than a weaker but more inflammatory suture.

The lack of standardization in the surgical technique for AR and UB may help explain some of the varying success rates reported across studies. One possible explanation for fewer success rates in this operation as compared to MUS may be that all patients had anterior vaginal wall supported from external urethral meatus to vaginal vault and there is no rotation of bladder base distal to the proximal internal urethral meatus. Hence, supporting the urethra and anterior vaginal wall in entirety did not change the relationship of the urethra with the bladder base.

Following international anxiety regarding polypropylene mesh, our cohort of patients was interested in procedures that did not involve permanently implanted materials. Short autologous MUS and colposuspension could be offered using absorbable sutures as they are superior to AR and UB;

nevertheless, they require more extensive surgery and were not chosen by this cohort of patients.

It is our current practice to only offer AR and UB to women with prolapse and UI. Patients are informed that AR and UB are not as successful as natural short sling or colposuspension. The surgery has a low risk of obstructive voiding dysfunction, and other procedures are available if their symptoms remain bothersome.

Recently, NICE has recommended that bulking agents should be offered if patients do not want to undergo major surgery and are happy to accept lower success rates.<sup>[18]</sup> We recommend a similar approach to AR + UB in view of less morbidity and 40–50% subjective improvements.

We demonstrated that our subjective success rate was 54% with statistically significant improvement in bladder and prolapse scores on quality of life questionnaire. There were no long-term complications during the follow-up period of 3 years, and only one patient (1.6%) underwent a second continence procedure.

The strengths of our study are: Robust data collection with the use of standardized questionnaires, patient-related outcome measures considered as a success rather than objective success rates, low attrition rate (78% responded to questionnaires), medium-term follow-up (up to 5 years), and data collection by an independent researcher.

The main limitations of our study are: Small sample size and the inability to measure outcomes for those who did not respond to questionnaires despite three attempts. Our attrition rate was 17/78 (22%). If we include all these patients as failures, our success rate would have been 33/78 (42%). In addition, the PGI-I score may have been affected by perception of outcome of prolapse repair and it is hard for us to separate all pelvic floor symptom relief in isolation.

## CONCLUSION

This study concludes that patients can be offered surgical intervention with lower success rates as part of shared decision-

making. Polydioxanone is no better than Polyglactin-910 in terms of success rate for SUI as per our study. To clarify further regarding the type of suture material, randomized controlled trials are needed comparing Polyglactin-910 with Polydioxanone. More work is needed to optimize the surgical technique of UB especially relating to bladder neck mobility.

Despite the need for further research, we believe that given the current uncertainty surrounding implantable mesh tape, AR and UB can be offered as one of the treatment options for SUI or stress predominant MUI with prolapse.

### Acknowledgments

Nil

### Declaration of patient consent

Patient's consent not required as patients identity is not disclosed or compromised.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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APPENDIX

Queensland Female Pelvic Floor Questionnaire

Patient:

Date:

Primary Problem:

Secondary:

Duration:

Bladder section

Q 1-14

Score / 42 =

Urinary frequency	Nocturia	Nocturnal enuresis
How many times do you pass urine in the day?	How many times do you get up at night to pass urine?	Do you wet the bed before you wake up?
0 Up to 7	0 0-1	0 Never
1 Between 8 and 10	1 1 2	1 Occasionally – <1/week
2 Between 11 and 15	2 2 3	2 Frequently – Once or more/week
3 More than 15	3 More than 3 times	3 Always – Every night
Urgency	Urge incontinence	Stress incontinence
Do you need to rush/hurry to pass urine	Does urine leak when you	Do you leak with
When you get the urge?	Rush/hurry to the toilet/Can you make it in time?	Coughing, sneezing, laughing, exercising?
0 Never	0 Never	0 Never
1 Occasionally – <1/week	1 Occasionally – < 1/week	1 Occasionally – < 1/week
2 Frequently – >1/week	2 Frequently – >1/week	2 Frequently – >1/week
3 Daily	3 Daily	3 Daily
Weak stream	Incomplete bladder emptying	Strain to empty
Is your urinary stream/flow weak/prolonged/slow?	Do you have a feeling of incomplete bladder emptying?	Do you need to strain to empty your bladder?
0 Never	0 Never	0 Never
1 Occasionally – <1/week	1 Occasionally – <1/week	1 Occasionally – <1/week
2 Frequently – >1/week	2 Frequently – >1/week	2 Frequently – >1/week
3 Daily	3 Daily	3 Daily
Pad usage	Reduced fluid intake	Recurrent UTI
Do you have to wear pads?	Do you limit your fluid intake to decrease leakage?	Do have frequent bladder infections?
0 None - Never	0 Never	0 No
1 As a precaution	1 Before going out/socially	1 1-3/year
2 With exercise/during a cold	2 Moderately	2 4-12/year
3 Daily	3 Daily	3 >1/month
Dysuria Do you have pain in your bladder/urethra	Impact on social life does urine leakage	How much of a bother
When you empty your bladder?	Affect your routine activities (recreation, shopping etc.)	Is your bladder problem to you?
0 Never	0 Not at all	0 No problem
1 Occasionally – <1/week	1 Slightly	1 Slightly
2 Frequently – >1/week	2 Moderately	2 Moderately
3 Daily	3 Greatly	3 Greatly
Other symptoms (hematuria, pain, etc.)		

**Bowel Section Q15–26**

**Score / 36 =**

Defecation frequency How often do you usually open your bowels? 0 <1/week 1 <Every 3 days 2 >3/week or daily 0 > more than 1/day	Consistency of bowel motion How is the consistency of your usual stool? 0 Soft 0 firm 1 Hard/pebbles 2 watery 1 variable	Defecation straining Do you have to strain a lot to empty your bowels? 0 Never 1 Occasionally – <1/week 2 Frequently – >1/week 3 Daily
Laxative use: Do you use laxatives to empty your bowels? 0 Never 1 Occasionally – <1/week 2 Frequently – >1/week 3 Daily	Do you feel constipated? 0 Never 1 Occasionally – <1/week 2 Frequently – >1/week 3 Daily	Flatus incontinence When you get wind/ flatus, can you control it or does wind leak? 0 Never 1 Occasionally – <1/week 2 Frequently – >1/week 3 Daily
Fecal urgency Do you get an overwhelming sense of urgency to empty bowels? 0 Never 1 Occasionally – <1/week 2 Frequently – >1/week 3 Daily	Fecal incontinence with diarrhea Do you leak watery stool when you don't mean to? 0 Never 1 Occasionally – <1/week 2 Frequently – >1/week 3 Daily	Fecal inc. with normal stool Do you leak normal stool when you don't mean to? 0 Never 1 Occasionally – <1/week 2 Frequently – >1/week 3 Daily

Incomplete bowel evacuation Do have the feeling of incomplete bowel emptying? 0 Never 1 Occasionally – <1/week 2 Frequently ->1/week 3 Daily	Obstructed defecation Do you use finger pressure to help empty your bowel? 0 Never 1 occasionally – <1/week 2 Frequently ->1/week 3 Daily	How much of a bother Is your bowel problem to you? 0 No problem 1 Slightly 2 Moderately 3 Greatly
Other symptoms (pain, mucous discharge, rectal prolapse, etc.)		

**Prolapse section Q27 –31**

**Score / 15 =**

Prolapse sensation Do you get a sensation of tissue protrusion in your vagina/lump/bulging? 0 Never 1 Occasionally – <1/week 2 Frequently ->1/week 3 Daily	Vaginal pressure or heaviness Do you experience vag. pressure/heaviness/dragging sensation? 0 Never 1 Occasionally – <1/week 2 Frequently ->1/week 3 Daily	Prolapse reduction to void Do you have to push back your prolapse to void? 0 Never 1 Occasionally – <1/week 2 Frequently ->1/week 3 Daily
Prolapse reduction to defecate Do you have to push back your prolapse to empty your bowels? 0 Never 1 Occasionally – <1/week 2 Frequently – >1/week 3 Daily	How much of a bother is the prolapse to you? 0 No problem 1 Slightly 2 Moderately 3 Greatly	
Other symptoms (problems sitting/walking, pain, vag. bleeding)		

**Sexual function Section Q 32**

**Score / 19 =**

Sexually active? Are you sexually active? no < 1/week > 1/week most days/daily	If NOT, why not: no partner unable vaginal dryness too painful Prolapse 19 embarrassment Prolapse other	Sufficient lubrication Do you have sufficient lubrication during intercourse? 1 no 0 yes
During intercourse vaginal sensation is: 0 None 1 Painful 2 Minimal 3 Normal/pleasant	Vaginal laxity Do you feel that your vagina is too loose or lax? 0 Never 1 Occasionally 2 Frequently 3 Always	Vaginal tightness/vaginismus Do you feel that your vagina is too tight? 0 Never 1 Occasionally 2 Frequently 3 Always
Dyspareunia Do you experience pain with intercourse: 0 Never 1 Occasionally 2 Frequently 3 Always	Dyspareunia where Where does the pain occur 0 No pain 1 At the entrance of the vagina deep inside/ in the pelvis 2 Both	Coital incontinence Do you leak urine during sex? 0 Never 1 Occasionally 2 Frequently 3 Always
How much of a bother are these sexual issues to you? Not applicable 0 No problem at all 1 Slight problem 2 Moderate problem 3 Great	Other symptoms (coital flatus or fecal incontinence, vaginismus, etc.)	

**TOTAL Pelvic floor Dysfunction SCORE:** \_\_\_\_\_

**Appendix 1:** Australian Pelvic floor questionnaire.



## Patient Global Impression of Improvement (PGI-I)

Check the number that best describes how your post-operative condition is now, compared with how it was before you had the surgery:	
Very much better	1
Much better	2
A little better	3
No change	4
A little worse	5
Much worse	6
Very much worse	7

Patient last name: .....

Date of birth: .../.../.....

Patient first name: .....

Date: .../.../.....

Appendix 2: PGI-I score.