Bladder neck placement of a synthetic polypropylene sling for the treatment of stress urinary incontinence

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Abstract

Introduction: Pubo-vaginal sling placed at the bladder neck is the gold standard treatment for stress urinary incontinence (SUI). The synthetic mid-urethral sling (MUS) is now widely used, as morbidity rates with this technique are substantially reduced. This is an initial report on long-term outcomes of a polypropylene sling (PPS) placed in the traditional bladder neck location.
Methods: A retrospective analysis of all patients who underwent PPS insertion at our institution between 2006 and 2014 was conducted. Patient and urodynamic demographics were recorded. Subjective and objective measures of success were determined by postoperative pad usage and validated incontinence questionnaires.
Results: A total of 170 patients were followed for a median of four years (range 1–8). The mean age was 51 years (±10). Subjective response was assessed in 57% of patients; the overall subjective cure rate was 85.3% (n=145), subjective improvement rate was 4.1% (n=7), and the subjective failure rate was 10.6% (n=18). The mean Urogenital Distress Inventory (UDI)-6 score was 6.5 (±5.6) out of a maximum score of 24 and the Incontinence Impact Questionnaire (IIQ)-7 score was 5.5 (±6.3) out of a maximum score of 28. There was no significant difference in objective outcome measures in those with an abdominal leak-point pressure (ALPP) < or >60 cmH$_2$O.
Conclusions: Bladder neck placement of a PPS resulted in cure rates of 85% in this series. SUI secondary to intrinsic sphincter deficiency (ISD) and urethral hypermobility were treated with equal success. Bladder neck PPS placement has a role in the treatment of SUI. Our data may well reassure rectus fascia sling (RFS) surgeons who wish to take advantage of faster postoperative recovery using the less invasive PPS placed at the bladder neck.

Introduction

Stress urinary incontinence (SUI) is the involuntary leakage of urine on effort or exertion, with a reported prevalence of 12–46%.[1-3] Urodynamic SUI is involuntary leakage observed during filling cystometry; it is associated with increased intra-abdominal pressure in the absence of a detrusor contraction.[4] Two mechanisms for SUI are recognized; hypermobility of the urethra or bladder neck during exertion, and intrinsic sphincter deficiency (ISD).[5] Abdominal leak-point pressure (ALPP) is measured on preoperative urodynamics, which can indicate the presence of ISD. Surgical treatment for SUI aims to improve the support and reduce mobility of the urethro-vesical junction with the use of a sub-urethral sling, which is now used to treat SUI secondary to urethral hypermobility and ISD.

Giordano[6] initially introduced the concept of sub-urethral support in 1907 using pedicled gracilis muscle graft as a retropubic sling at the bladder neck. Several procedures for SUI treatment have since been described. In the early 1900s, Stoeckel hypothesized that a proximal urethral position at the bladder neck, and attachment of the sling to the abdominal muscles, were the critical factors for success, rather than the sling material used.[7] The Aldridge pedicled RFS was introduced in 1942;[8] further modification was undertaken by McGuire and Lytton in 1978,[9] who placed the rectus fascia sling (RFS) proximally at the bladder neck, to achieve continence in 80% of patients with ISD. In 1991, Blaivas and Jacobs pioneered the placement of loose RFS and found a significant reduction in the incidence of postoperative urinary retention and requirement for self-intermittent catheterization (SIC).[10] These sling procedures all involved proximal placement of the sling at the bladder neck. Following this, the clinical indications for use of this type of loose sling were extended to include SUI due to urethral hypermobility, as well as ISD.[11,12]

Synthetic polypropylene (PPS) was then introduced as a sling material.[13] This new procedure involved placement of a tension-free vaginal tape (TVT) at the mid-urethra rather than the bladder neck, with the intention of reinforcing the weakened pubo-urethral ligaments and recreating the "hammock" support of the lax anterior vaginal wall and endopelvic fascia. Results published by Ulmsten et al[14] demonstrated decreased operative time, decreased recovery

time, and good outcomes due to the less invasive nature of the procedure. The Ulmsten needle was passed from below upward, rather than the reverse, as is usually the case with RFS. Initial concerns by RFS surgeons about excessive risk of erosion and infection secondary to synthetic sling material proved unfounded, with long-term data from experienced surgeons.[15-18] From 2006 onward, we offered PPS (instead of RFS) as our first choice for the treatment of uncomplicated SUI, but continued to use the long-established McGuire technique of sling placement at the bladder neck. While we recognize that use of the sling in this way is technically off-label, we believe this method is in keeping with the principles of bladder neck support and closure, which have been well-described.

Herein, we report outcomes of bladder neck placement of PPS in a single-surgeon series. This is the first report of PPS placement at the bladder neck.

Methods

A retrospective analysis of all patients who underwent PPS for SUI at our institution between 2006 and 2014 was conducted. We use the SPARC™ self-fixating sling system (AMS, Endo International PLC, Dublin, Ireland), incorporating an AMS macroporous, monofilament, sheath-protected PPS. Patients were fully consented for bladder neck placement of the sling at time of surgery. Data were collected from the hospital inpatient enquiry system and from urodynamic records. We recorded patient demographics and preoperative urodynamic data: ALPP and bladder capacity (volume) at ALLP. Methods, definitions, and units used conform to the standards recommended by the International Continence Society.[19] A postoperative telephone survey was conducted to evaluate success rates. Subjective success, improvement, and failure were defined as "pad free," "reduced pad usage," and "recurrence of incontinence postoperatively with no reduction in pad usage," respectively. Objective measures of success were determined using the Urogenital Distress Inventory (UDI-6) and the Incontinence Impact Questionnaire (IIQ-7), short forms of the original UDI and IIQ. Both are validated questionnaires for assessing symptom distress and quality of life in both men and women.[20,21] IBM® SPSS® v23 was used to perform statistical analysis. Categorical data were analyzed using Fischer's exact test; continuous data were analyzed using T-test.

Procedure description

Our approach involved the McGuire bladder neck placement technique using a PPS (SPARC™) instead of RFS. All procedures were carried out under general anesthesia. Bladder neck position was determined by placing gentle traction on a Foley catheter and palpating the balloon; a small midline incision was made in this area. Dissection to the endopelvic fascia was performed in the usual fashion. The endopelvic fascia was penetrated from below to enter the retropubic space in cases where previous surgery or pelvic injury made it difficult to palpate the needle tip above. Trochars were guided from up-down; the sling was attached to the trochars and pulled into position at the bladder neck. The tape was generally placed without tension. In cases with a degree of ISD or failed previous sling procedure, a variable degree of tension was applied. A thorough urethrocystoscopy was performed using a 70° telescope, ensuring perforation had not occurred. The vaginal wall was closed with interrupted 2/0 Vicryl vertical mattress sutures. A Foley catheter and vaginal pack were left in situ. The pack and catheter were removed on the morning of postoperative day 1. If the patient was unable to void by the time of discharge, they were taught SIC to be continued until spontaneous, efficient voiding resumed.

Results

Demographics (Table 1)

A total of 300 patients underwent PPS during the timeframe; 170 (57%) were contactable for telephone survey postoperatively. Results of responders are reported on. One hundred seventy patients were followed for a median of four years (range 1–8). Preoperative urodynamic data were available for analysis on 98 (58%) patients. All demonstrated genuine stress incontinence (GSI) and nine (9%) had concomitant detrusor overactivity (DO).

Subjective and objective cure (Table 2)

The overall subjective cure rate was 85.3% (n=145). There was no significant difference in subjective outcomes in patients with preoperative ALPP < or >60 cmH$_2$O. The mean UDI-6 score was 6.5 (±5.6) out of a maximum score of 24 and IIQ-7 score was 5.5 (±6.3) out of a maximum score of 28 at latest followup, indicating good objective outcomes.

Table 1. Patient demographics		
Age	Mean	51
	SD	10
BMI (kg/m^2)	Mean	26.7
	SD	5.7
ALPP (cmH$_2$O)	Mean	107
	Range	40–200
Bladder volume at ALPP (mls)	Mean	277
	Range	99–470

ALPP: abdominal leak point pressure; BMI: body mass index; SD: standard deviation.

There was no significant difference in the UDI-6 or IIQ7 scores between those with ALPP < or >60 cmH$_2$O.

Subjective failure

The overall subjective failure rate was 10.6% (n=18) (Table 2). Postoperative urodynamic data were available on six of 18 patients. Five of these patients had residual GSI, with a mean ALPP of 111 cmH$_2$O. Two of five underwent a second PPS. The first patient had an ALPP of 82 cmH$_2$O and a poor outcome with objective scores of 19 and 20. The ALPP was 145 cmH$_2$0 in the second patient, with excellent outcome scores of 4 and 0. RFS was performed in two of five patients (ALPP of 140 cmH$_2$O and 70 cmH$_2$O, respectively). Both had poor outcome scores, with UDI-6 of 20 and 23 and IIQ-7 of 22 and 22, respectively. The fifth patient elected for no further anti-SUI treatment and was instead treated for storage symptoms with anti-muscarinics and intravesical botulinum toxin. The sixth patient had no urodynamic abnormality, but had additional anti-incontinence procedures, including intra-urethral bulking agents and a RFS, with good objective outcome scores of 7 and 9.

Postoperative urodynamic data were unavailable in 12 of 18 with subjective failure. Two of these patients were treated with a second PPS and intra-urethral bulking agents, with mean objective outcome scores of 15 and 14. A combination of RFS and urethral bulking agents was used in four of these patients, and five were treated with intra-urethral bulking agents alone. The twelfth patient elected for no further treatment.

Postoperative events (Table 3)

De novo urgency/urge urinary incontinence (U/UUI) was treated with anti-muscarinics in five patients, three received intravesical botulinum toxin, and three were treated with combined anti-muscarinics and botulinum toxin. The vaginal

sling exposure developed after 1.5 years and was managed by local excision of the exposed sling. Bladder perforation was immediately recognized at cystoscopy and managed by removing and repositioning the needle. Urethrolysis was performed in one patient who had a long-term (>4 week) requirement for self-catheterization.

Discussion

We report objective and subjective outcomes following bladder neck PPS placement for all types of SUI. We have now replaced RFS with PPS as the first choice surgical treatment. PPS results in significantly shorter hospital stay, decreased catheterization time, use of analgesics, and loss of days of work when compared to RFS.[22] Minimal vaginal dissection, the application of a specific PP tape, tension-free, under the mid-urethra, and no bony fixation of the tape, all result in a technically more straightforward procedure with increased efficacy and safety.[16] The tension-free insertion of PPS is standard practice, however, certain patient factors, namely ISD or failed previous sling surgery, influenced us to insert the tape under a variable degree of tension. We believe this modification is necessary to obtain good outcomes in these specific clinical scenarios. PPS use was initially recommended as a primary operation for GSI; it is now used in complex cases, such as failure after traditional anti-incontinence surgery.[16] Re-do surgery with PPS was performed in four patients in our series, with initial failure of PPS with mixed results.

A Cochrane review of mid-urethral sling (MUS) for SUI reported short (<1 year) and long (>5 year) subjective cure rates of 71–97% and 51–88%, respectively. Subjective cure was assessed by self-reporting of participants and responses to symptom-based questionnaires.[15] Deval et al[23] and Ulmsten et al[18] reported subjective cure rates of 70% and 85%, respectively in large studies on TVT for SUI, and cure rates of 74% have been reported on mid-urethral TVT for ISD.[17] A recent systematic review of surgical treatments of SUI demonstrated similar cure rates in the MUS and RFS group and a trend towards a higher re-operation rate in the MUS group.[24] Our subjective cure rate of 85% with bladder neck placement, after a median four-year followup, compares favourably with the literature (Table 4).

We, therefore, offer a PPS as first choice for the treatment of uncomplicated SUI, but continue to use the long-established McGuire technique of sling placement at the

Table 2. Comparison of cure rates between patients with ALPP < and >60 mmH$_2$0

Patients n=98 (%)	ALPP <60 mmH$_2$0	ALPP >60 mmH$_2$O	p
	15 (15%)	83 (85%)	<0.0001
Subjective outcomes			
Cured n=85 (%)	14 (93%)	71 (86%)	0.6846
Improved n=6 (%)	0 (0%)	6 (7%)	0.5863
Failed n=7 (%)	1 (7%)	6 (7%)	1.0
Objective outcomes			
UDI-6	7	7.2	0.9007
IIQ-7	5	7.2	0.2468

ALPP: abdominal leak point pressure; IIQ: Incontinence Impact Questionnaire; UDI: Urogenital Distress Inventory.

Table 3. Postoperative events

De novo U/UUI, n (%)	15 (8.8)
Urosepsis, n (%)	1(0.5)
Pelvic hematoma, n (%)	2 (1.2)
Vaginal sling exposure, n (%)	1 (0.5)
Persistent (>4 weeks) voiding obstruction, n (%)	1 (0.5)

U: urgency; UUI: urge urinary incontinence.

bladder neck. Bladder neck placement, instead of the now traditional method of mid-urethral placement, is in keeping with the principles of bladder neck support and closure, which have been describe by autologous sling surgeons since the early 1900s. The technique of mid-urethral sling placement was introduced, as it lends to the "hammock" theory of mid-urethral support, but the traditional teaching is that proximal urethral placement is an important factor for success in SUI surgery.

Malposition of MUS at the bladder neck has been associated with adverse outcomes in the literature.[25-27] These reports describe an excessive proximal location of the urethral tape relative to the mid-urethra, resulting in recurrent SUI postoperatively. In our series, the tape has been deliberately placed at the bladder neck, with results equaling large MUS studies (Table 4). We, therefore, hypothesize that it is the malposition of the tape relative to its intended location, the mid-urethra, that resulted in failure, rather than the bladder neck location.

De novo U/UUI rates

Overactive bladder symptoms, such as U/UUI, can be associated with SUI, the precise mechanism of which is poorly understood.[28] An average de novo UUI rate of 8.35% for synthetic MUS has been reported.[15] Persistent UUI rates of 11–67% and de novo UUI rates of 0–30% have been reported in RFS studies.[29] Our rate of 8.8% after bladder neck PPS placement is, therefore, similar or better than that reported for MUS and RFS.

Voiding dysfunction/tape erosion rates

Urethral obstruction requiring surgery or long-term SIC has been reported in 1–7% of patients undergoing RFS.[29] We attribute our low urethral obstruction rate of 0.5% to surgeon technical experience and careful patient selection to identify those with poor detrusor contractility on preoperative urodynamics; 0.5% of our patients developed a vaginal sling exposure, comparing favourably with the reported rate of 1.5%.[15] None of our patients developed a urethral/bladder neck erosion and we hypothesize this is due to its bladder neck location, where there is additional tissue support when compared to the mid-urethra.

Bladder perforation

The bladder perforation rate after synthetic MUS insertion is 2.5%,[15] comparable to our rate of 2.9%. This is lower than generally reported for top-down needle placement, such as the SPARC procedure (10.5%)[30] and is likely attributable to surgeon experience and technique. A postoperative pelvic hematoma was seen in 1.2% of our patients. This is in keeping with the reported rate of 0.7–1.9%.[15]

SUI can be classified on the basis of urethral hypermobility and/or ISD, determined by measuring the ALPP level and by direct or flurourodynamic observation of urethral motion. There is no strict definition, but it is thought to occur in those with a urethral resting pressure of ≤20 cmH$_2$0.[16] McGuire's methodology to evaluate urethral sphincteric function was to measure the abdominal or valsalva LPP on urodynamics.[31] An ALPP of <60 cmH$_2$0 indicates ISD, while an ALPP >90 cmH$_2$0 indicates urethral hypermobility primarily.[11] Both entities have been successfully treated with PPS. However, the incidence of sling failure is greatest in those >70 years, with a low urethral resting pressure (≤10 cmH$_2$0), and in whom the urethra is immobile.[16] As expected, the ALPP was >60 cmH$_2$0 in significantly more patients in our cohort. Interestingly, the subjective outcomes were not significantly different in terms of subjective or objective cure rates, improvement, and failure rates in those with ALPP > and <60 cmH$_2$O.

We accept there are a number of limitations with out study. Due to the retrospective nature of the study design, baseline symptom assessment for comparison with postoperative results is lacking. Our telephone survey received a response rate of 57%, and therefore, we have not captured outcome data on 43%. There is a possibility of bias in that those with poor outcomes may be unwilling to participate in the study and we, therefore, may not be able to extrapolate the subjective and objective outcome results to the 43% of the cohort who remain unsurveyed. We remain confident that we have captured all our complications, as our institutional referral pattern is such that patients with postoperative complications are unlikely to be referred elsewhere. Our data on short-term (<4 weeks) SIC was incomplete and, therefore, not reported. The strengths of the study are its homogeneity as single-surgeon, single-centre study, increasing the validity of the results, and a median followup period of four years, ranging up to eight years.

Table 4. Comparison of outcomes between large TVT studies

	n (patients)	Mean followup (months)	Subjective cure rate	De novo U/UUI	Vaginal tape exposure	Bladder perforation	Retropubic hematoma
McLoughlin et al (2017)	170	48	85%	8.8%	0.5%	2.9%	1.2%
Cochrane review of mid-urethral slings (2015)	n/a	n/a	51–88%	8.35%	1.5%	2.54%	0.7–1.9%
Deval et al (2002)	187	27	70.6%	21.3%	NR	9.6%	NR
Ulmsten et al (2001)	90	56	84.7%	5.9%	0%	1.1%	3.3%

We suggest that our low incidence of vaginal tape exposure and high subjective cure rates are related to accurate placement of the tape at the bladder neck level (as in the classic RFS), where the tape is at a slightly deeper level than at the mid-urethra. We also believe that an interrupted mattress closure of the vagina protects against subsequent exposure.

Conclusion

Bladder neck placement of a PPS is at least as efficacious as mid-urethral placement in our surveryed cohort. We report a lower incidence of vaginal tape exposure than quoted in the literature. In addition, there is significantly reduced postoperative morbidity in comparison to the RFS. We report a very low incidence of persistent (>4 weeks) voiding dysfunction postoperatively. We had no cases of urethral or bladder exposure/erosion in our series. Using both subjective and objective measures of success, our approach is effective for both the treatment of SUI secondary to ISD and urethral hypermobility. Bladder neck PPS placement may have an important role in the surgical treatment of SUI.

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