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TITLE PAGE

Optimising the tension of an autologous fascia pubovaginal sling to minimise retentive complications

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ETHICS

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ABSTRACT

AIM

To determine the optimal degree of PVS tension, measured by lax sling dimensions to minimise the risk of urinary retention.

METHODS

This prospective study analysed female patients undergoing PVS for stress urinary incontinence (SUI) by two surgeons over 24 months from January 2016.

Intra-operative measurements of lax sling dimensions tented over rectus fascia were recorded. Logistic regression was used to analyse the likelihood of urinary retention (more than 3 months of intermittent self-catheterisation (ISC) or surgical revision) for given PVS dimensions. Secondary analysis assessed for an association between PVS measurements and persistent SUI.

RESULTS

51 patients were recruited with median age of 53 (34-78) and follow up of 11 (3-20) months. All but 1 patient reported improvement of SUI. 10 (19.6%) patients developed post-operative urinary retention. 5 (9.8%) resolved after a temporary period of ISC. The other 5 (9.8%) required ongoing ISC or sling division. A strong association existed between short sling height and prolonged urinary retention (p=0.00). ROC curve analysis showed a sling height of 40mm had a sensitivity of 100% and specificity of 51% for retentive complications (AUC= 0.90). Lax sling height up to 60mm was not associated with persistent SUI.

CONCLUSIONS

Stretching the sling suspension sutures at least 40mm above the rectus fascia was associated with a lower risk of urinary retention than less than 40mm. This simple technique would appear to be worth evaluating in a larger sample. A looser sling did not compromise the cure of SUI at a mean follow-up of 11 months.

INTRODUCTION

SUI in women impacts greatly on physical, sexual and psychosocial health. It is an undeniably common problem with prevalence estimates in Australia ranging between 13 and 46%[1], increasing with age. Only 53%[2] achieve subjective cure with conservative treatments, with many subsequently choosing to opt for surgical correction.

Debate exists over the gold-standard surgical treatment: autologous fascia pubovaginal slings (PVS) versus synthetic mid-urethral slings (MUS). A recently updated meta-analysis[3] failed to prove superiority of one sub-urethral sling over the other; comparing both effectiveness and complication rates.

MUS has a successful dry/ cure rate of 81-84%[4]. This however is offset by 6% risk of bladder perforation, as well as up to an 8% incidence of mesh related complications (extrusion, infection, scarring, dyspareunia, chronic pain and erosion)[4]. Due to the comparative simplicity and speed of MUS insertion, it has become the procedure of choice for treating uncomplicated SUI by most incontinence surgeons.

By comparison, PVS utilises native tissues and is thus spared from mesh specific complications. A meta-analysis found the SUI cure rate with PVS was 82-90% in patients with more than 4 year-follow up[4]. Nonetheless, it is a longer and more complex procedure with a slower recovery, requires both vaginal and abdominal incisions with inherent wound complications (8%), and has higher rates of obstructive voiding patterns. However, since the FDA issued a warning on transvaginal mesh use for pelvic organ prolapse (2008 – 2011), MUS slings have also come under the spotlight. As a result, more PVS surgery is now being done, with a corresponding decrease in MUS surgery[5].

Historically, PVS was used for intrinsic sphincter deficiency (ISD - more severe urinary incontinence), associated with greater leakage and tendency to urethral fixation. Given the increasing awareness of complex long-term mesh complications, indications for PVS have broadened to include “index” SUI. PVS remains the preferred treatment for complicated SUI (following failed prior incontinence surgery, to support a urethral diverticulum repair or fistula repair).

There is little randomised controlled data comparing MUS to PVS. Non-randomised comparisons without controlling for risk factors, show that the rates of sustained voiding dysfunction (lasting more than one month or requiring intervention) occur in 8% (4-15%) of women undergoing PVS, compared with 3% (2-4%) for MUS[4].

The goal of PVS is to restore the proximal urethral support to address urethral hypermobility and intrinsic sphincter deficiency elements. Historical slings involved tunnelling of attached and mobilised rectus fascia with high rates of voiding dysfunction. Once it became evident that a free graft of fascia suspended on monofilament sutures could provide long term cure rates, that has become the standard. The method by which the suspension sutures are tied together so that slings do not result in urinary retention or voiding dysfunction is in evolution. Mid-urethral placement of a sling of any fabric is less likely to cause voiding dysfunction. Proximal urethral placement may however be preferable in cases where the proximal urethra is wide open at rest – a condition that may be diagnosed on fluoroscopy. Such pre-operative characterisation is rarely available. Where urethral re-supporting is required rather than correction of ISD, a loose sling only may suffice.

Over the years multiple attempts have been made to develop a reliable way to appropriately tension a PVS. These include intra-operative rectal ultrasound to measure the urethrovesical angle, using a per-urethral cotton bud to maintain a specific urethrovesical angle and using a spring scale to measure the sling tension[6-8]. However, these methods have not become standard practice. As such, it is now commonplace for incontinence surgeons to tension a PVS according to a simple heuristic rule: tie the suspension suture knot 2 or 3 fingers breadth above the rectus fascia[9] (not too tight, not too loose, and lacking reproducibility).

The purpose of this study is to analyse sling suture dimensions with a view to improving the technique of tensioning PVS. We aimed to develop a reliable approach to objective measurement of sling height (rather than subjective tensioning) which would minimise retentive complications and still achieve excellent continence rates.

PATIENTS AND METHODS

A prospective study was performed, analysing clinical outcomes of all female patients undergoing autologous fascia sling for stress urinary incontinence (SUI) by two Melbourne-based primary operators (HOC, JG) over a 24-month period commencing January 2016. Both surgeons were experienced with PVS, and used an agreed standardised surgical technique. All eligible women aged over 18 years were recruited from both the surgeons' private and public practices. Institutional ethics approval was obtained for this study (HREC/16/WH/201).

SUI was defined as the involuntary leakage of urine with physical activity, coughing or sneezing. Only women who voided with detrusor contractions were included; pre-existing urinary retention or those who voided with abdominal straining were excluded. Women with mixed incontinence (i.e. both SUI and urge incontinence) and women with a previous failed SUI surgery or previous bulking procedure performed for SUI were eligible for study inclusion. Patients with concomitant prolapse were excluded, as were women who underwent an autologous fascia sling procedure for a primary reason other than SUI. Our study excluded patients with an acontractile bladder and those who strained to void (unknown PdetQmax). All patients had urodynamic studies (UDS) prior to surgery. Women who demonstrated bladder contractility (any rise in Pdet) during the voiding phase were classified as those with detrusor contractions and were included in the study.

Both primary surgeons used a consistent operative technique. Initial technique was developed with collaboration of both surgeons (the first 12 cases) to confirm uniform technique prior to separate independent implementation.

The procedure was performed through a combined abdominal and vaginal approach. With the patient in a dorsal lithotomy position, a 6-8 cm transverse abdominal incision is made about 3cm above the pubic bone. Autologous tissue was harvested from the anterior rectus sheath (8 x 1.5 cm), and placed transvaginally as a suburethral sling at the bladder neck without causing upward distortion or hyper-suspension. The sling length and width of 8 x 1.5 cm was chosen because of the surgeons' familiarity and previous experience. The current literature describes different fascial sizes and variation in certain steps of the surgical technique.[10] There is also a paucity of data in the literature if the sling length or width can alter the clinical outcome. The sling was placed at the level of the bladder neck in all cases: the proximal border of the sling was placed at the level where the catheter balloon started (indicating the level of the bladder neck).

Monofilament, polypropylene Prolene® sutures were secured to each end of the harvested fascia when the fascia was still not fully removed from the patient, as the authors found that this partial attachment stabilised the fascia for easy placement of the Prolene® sutures, as compared to placing them after the fascia was fully removed and on the nurse's instrument table. The Prolene® sling arms were then passed through retropubic tunnels and delivered just lateral to the rectus muscles, through the inferior leaf of the rectus fascia.

The operation then proceeded to tie the ends of the fascia sling via the traditional method of '2-3 fingerbreadths' above the fascia. The fascia sling was lifted upwards by its knot, so that its greatest height was achieved without resistance from, or causing distortion to, the abdominal wall tissue. Based on the traditional tensioning method and forming an isosceles triangle, the base and height of this tented sling were recorded in millimetres (Figure 1). These measurements were used to reflect the laxity of the PVS. During the measurement of the sling height, a 14F Foley catheter was in place. The urethra and bladder neck were observed at this time as the vaginal incision was still not closed. Measurement of the sling height did not cause distortion of the urethra in all cases.

It is important that the sling was not hyper-suspending the bladder neck prior to tying the knot as this may cause the knot to retract back later. The vaginal incision was not closed until after the knot was tied. This allowed the surgeons to check that the sling arms had not been pulled up too tight inadvertently, just prior to the final tensioning. If the bladder neck was observed to be hyper-suspended, the sling arms could be re-adjusted via the vaginal incision, before the final tensioning was done.

Cystoscopy was then done after tensioning to ensure no bladder injury, but was not routinely used as an aid for sling tensioning.

The measurement technique was found to have good inter-rater reliability during the initial collaborative cases and can be easily passed on to other surgeons. After independent implementation, the primary surgeon who did the tensioning measured the sling height. Potential bias and variability can occur here but this was reduced with ensuring that the sling arms were not pulled upwards when tying the knot.

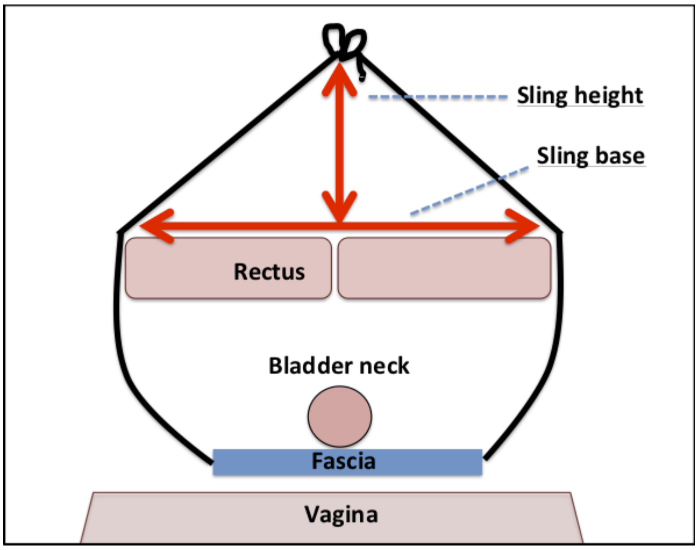

Figure 1: Measured sling height and base dimensions

Routine post-operative management was trial-of-void (TOV) at day 2. All women were routinely reviewed at 6 weeks and 3 months with a uroflow study, UDI-6 (short form urogenital distress inventory) and PGI-I (Patient Global Impression of Improvement) questionnaire. These surveys provided a component based 'symptom severity score' and an overall appraisal of the clinical outcome, both validated for use in incontinence research[11,12].

Long-term voiding dysfunction was the primary clinical endpoint, defined as prolonged intermittent self-catheterisation (ISC) beyond 3 months or division/ revision of autologous fascia sling.

The collected dataset also included: Age, BMI, pre and post-operative self-reported pad usage, valsalva leak point pressure (VLPP) from pre-operative urodynamic studies (UDS), post-operative post-void residual volumes (PVR) and encountered complications.

Categorical variables are presented as percentage number of patients, and continuous variables as median with range. Logistical regression was used to analyse the likelihood of a sling being 'too tight' for different supra-rectus sling height and base lengths measured intra-op. Subjective outcomes were assessed via UDI-6 and PGI-I.

RESULTS

5 patients were lost to complete follow up (9%). 3 patients declined to be part of the study. A total of 10 patients were excluded from the study: 2 patients were excluded as they were already doing clean intermittent catheterisation (CIC) prior to the sling surgery for neurogenic reasons. 8 other patients were also excluded as their sling was placed not for the primary reason of treating stress urinary incontinence (2 had

urethral diverticulectomy, 6 had re-inforcement of cystocele repair with a fascial sling).

51 women that completed the full study had a median follow up of 11 (3-20) months . Median age was 53 (34-78), median VLPP 60 (25-145) cmH_2O and median BMI of 28 (18.4-43). The surgeons had a split caseload of 20:31.11 (21.6%) women had pre-existing DO with mixed LUTS, 5 (9.8%) underwent PVS as a salvage procedure following failed SUI surgery (4 tension-free vaginal tapes (TVT), 1 Burch colposuspension) and 4 (7.8%) had PVS surgery for recurrent SUI post division of a tight TVT.

Table 1: Demographics

Retentive complications	No (n=41)	Yes (n=10)	p value
Age (yr)	53 (34-74)	54 (41-78)	0.86
BMI (kg/m2)	29.4 (18.4-43)	25 (20.6-32)	0.08
VLPP (cm H2O)	70 (25-145)	43 (30-65)	0.08
Pre-existing DO/ Mixed LUTS (n)	10	1	0.43
Recurrent SUI after previous divided sling (n)	2	2	0.17
Previous failed MUS/SUI surgery (n)	5	0	0.57
Primary Operator ratio	17:24	3:7	0.72
Duration of follow up (mo)	9 (3-20)	14 (3-19)	0.19

10 (19.6%) patients developed post-operative urinary retention. 5 (9.8%) self resolved after a temporary period of ISC less than 3 months. The remaining 5 (9.8%) women had persistent long-term retentive complications requiring indefinite ISC or revision surgery (division or loosening of the sling). Out of the 5 patients who had revision surgery, only 1 (the first one) was noted to have a change in the height of the knot (from 3.5cm to 3.0cm), discovered during the revision surgery. The tensioning during the initial surgery may have been done with the sling arms inadvertently pulled up prior to the tying of the knot which then retracted back down when the wound was closed, to a lower height. As this case was seen very early on during the study, the surgeons had been particularly careful not to accidentally pull up on the sling arms or hypersuspend the bladder neck, before the knot was tied in subsequent cases. The vaginal incision was not closed prior to sling tensioning for this reason, to allow for assessment and readjustment of the sling if needed. The

following 4 patients who needed revision surgery did not have a change in height of the knot.

Acknowledging the UDI-6 questionnaire's limitation for assessing OAB, in our study, 8 patients had worse/new urge incontinence post-op, so potentially 8/51 (15.7%) patients experienced de novo or worsening OAB.

The range of PdetQmax for the population was 9 - 41 cmH2O (median 22cmH2O). Pre-op PdetQmax was not associated with retentive complications in our study (p = 0.85, Table 1).

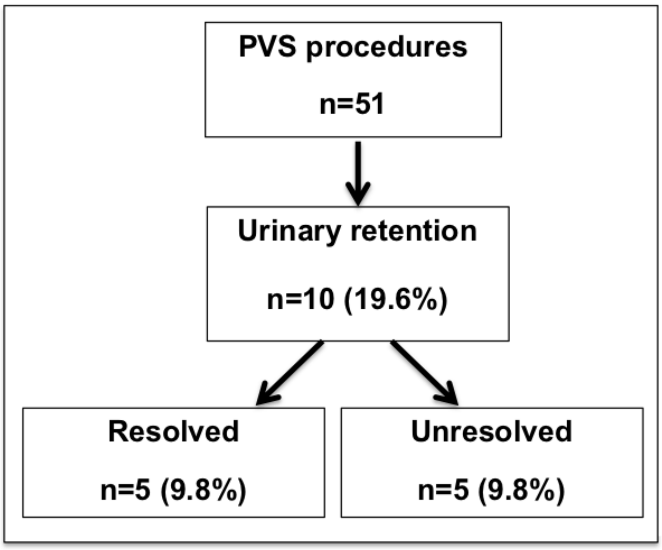

Figure 2: Study endpoints

On logistic regression (Table 2), short lax sling height was associated with post-operative urinary retention (OR 0.74 [95%CI 0.60-0.91], p=0.004) and unresolved voiding dysfunction and eventual sling revision (OR 0.74 [95%CI 0.61-0.90], p=0.003). Sling base length was not associated with post-operative retention (p=0.22) or long-term retention (p=0.15).

Table 2: Logistic regression of lax sling height and base measurements (Odds Ratios)

	Post-operative Urinary Retention	**Unresolved Voiding Dysfunction**
Sling Height (mm)	0.74 (**p=0.004**)	0.74 (**p=0.003)**
Sling Base (mm)	1.05 (p=0.22)	1.07 (p=0.15)

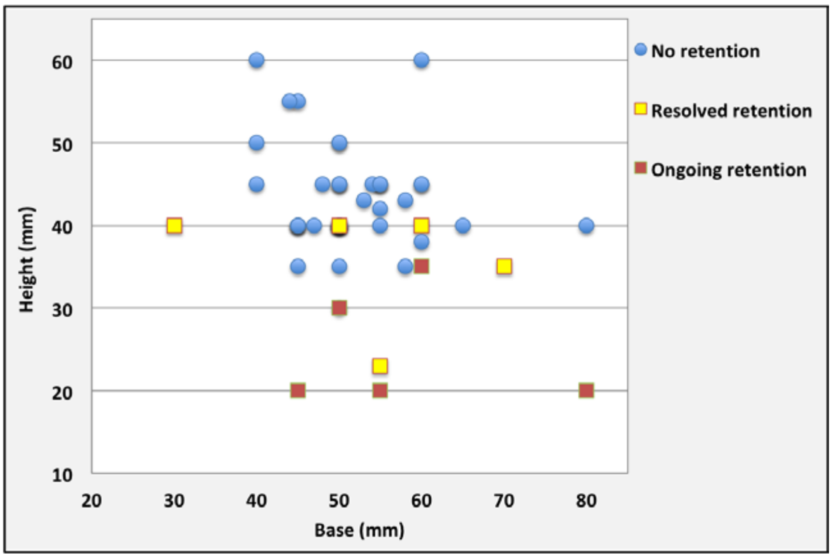

Figure 3: Distribution of measured sling dimensions

Age (p=0.72), duration of follow up (p=0.20) and BMI (p=0.10) were not confounders for urinary retention on univariate logistic regression. Nor was operator (p=0.51), VLPP (greater versus 60cmH2O or less, p=0.34), pre-existing DO (p=0.43), previous divided sling/TVT (p=0.17) or previous failed SUI surgery (p=0.57) using Fisher's exact test.

A sling height of 40mm on ROC curve analysis (Figure 4) had a sensitivity of 100% and specificity of 51% for retentive complications (AUC= 0.90). 33% of those with a sling height of 40mm or less encountered retentive complications, compared to 0% of those with a sling height greater than 40mm (Fishers Exact p=0.003).

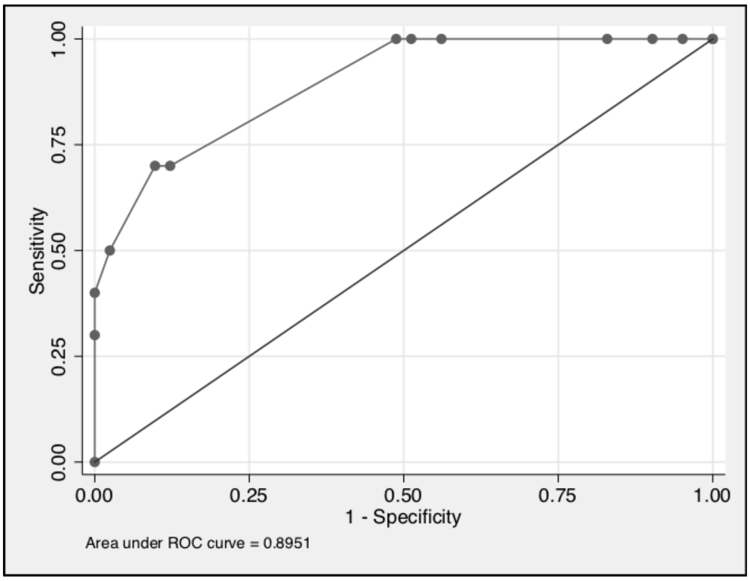

Figure 4: ROC Curve of Lax Sling Height and Urinary Retention

Other encountered post-op complications were: 3 (6%) with urinary tract infection, 4 (8%) with wound issues (haematoma, seroma and superficial wound dehiscence), 1 (2%) with unsatisfactory cosmetic result and 1 (2%) with sexual dysfunction.

Overall the PVS success rate was high, with subjective resolution of exertion related leakage in 82% (42/51), improvement in a further 16% (8/51) of women, and a failure rate of 2% (1/51). Of the 8 women who had a mild degree of residual SUI, only 2 needed to use a safety liner throughout a 24-hour period. One patient underwent transurethral bulking injection (Bulkamid®) with good effect. A secondary analysis was performed on this subgroup to see if measured lax sling lengths also demonstrated predictive ability for procedure failure and persistent SUI. Logistic regression compared sling height to the binary outcome of any SUI reported via UDI-6 question 3 ("Do you experience urine leakage related to physical activity, coughing or sneezing?"). Sling height was also compared to self-reported need for ongoing pad usage post-operatively. Neither definition was statistically significant (p=0.51 and 0.62 respectively). However, univariate analysis (Table 3) demonstrated an association between sling failure/ persistent SUI and BMI (p=0.045). No other variable (Table 2) was statistically significant including lax sling height (p=0.56), VLPP (60cmH2O or less, 0.51), pre-existing DO (p=0.34), salvage PVS after previous failed SUI surgery (p=0.08) and re-do procedure after previous divided MUS (p=0.48).

Table 3: Univariate analysis of persistent post-operative SUI subgroup

Continuous Variable	Log Regression	Dichotomous Variable	Fishers Test
Sling height (mm)	0.56	VLPP <60cmH2O	0.51
Sling base (mm)	0.85	Pre-existing DO/ Mixed LUTS	0.34
Age (yrs)	0.32	Recurrent SUI after previous divided sling	0.48
BMI (kg/m2)	**0.05**	Previous failed MUS/SUI surgery	0.08
Follow up (months)	0.41	Operator	0.98

Regarding overall satisfaction with the procedure (assessed by PGI-I), 87% of women described their condition as being either "very much better" or "much better". 11% said it was "a little better" whereas only 2% stated their overall condition had worsened. In assessing the main determinants of global satisfaction, a positive correlation was only found between PGI-I score and responses from the retention domain question from UDI-6 (Spearman's ρ=0.34, p=0.02); indicating that patients' dissatisfaction was related to voiding dysfunction but not persistent SUI.

DISCUSSION

Recognition that synthetic MUS are associated with low but very significant foreign body morbidity and chronic pain has redeveloped interest in alternatives. Free grafts of autologous rectus fascia (PVS) became a standardised procedure in the 1980s and popularised in the 1990s at a similar time to the rising popularity of synthetic MUS. Whilst the majority of surgeons had been offering the relatively ineffective anterior colporrhaphy and colposuspension, a major conversion to synthetic MUS occurred across the globe. The rise was related to relatively low operative morbidity and greatly improved success relative to colposuspension and colporrhaphy, boosted by industry support for education and operative training opportunities. Relatively low growth occurred in the number of PVS which were generally reserved for complex urethral disorders rather than “index” SUI.

Position of any sling in the proximal urethra is associated with greater voiding dysfunction than when placed in the mid urethra. Curing or at worst, significantly improving severe sphincter dysfunction is the goal of PVS and any tensioning technique would not want to thwart that primary goal. Notwithstanding, if it is possible to reduce voiding dysfunction rates without compromising SUI cure, that would be desirable.

This pilot study of 51 patients demonstrated that a standardised approach to measuring intra-operative sling height during autologous rectus fascia PVS insertion may reduce voiding dysfunction. A wide range of sling heights (20 to 60mm) were observed using the traditional method of tying the knot a couple of fingerbreadths above rectus; thus demonstrating the inherent difficulty in reproducing consistent tension from this method. The ROC curve analysis found a sling height greater than 40mm was associated with a reduced incidence of voiding dysfunction. The significance of sling height is explained by the relative obstruction of the sling pulling the proximal urethra and bladder neck anteriorly, increasing the vesical pressure required to effect voiding.

Unlike sling height however, sling base measurements (ranging from 40 to 80mm), did not influence the incidence of post-operative urinary voiding dysfunction. Formed by the upward piercing sling through the lateral borders of the rectus muscle, sling base differences were attributed to normal anatomical variation of rectus width. Quadratic modelling (assuming fixed points where PVS traverses the lower leaf of the rectus fascia), demonstrated that the base dimension negligibly contributes to laxity; doubling the base of a sling, affects its mobility by only 1 to 2 millimetres.

Higher rates of voiding dysfunction have been demonstrated in autologous fascia PVS patients who were dependent on Valsalva manoeuvre to void pre-operatively by Iglesia et al[13]. Therefore, our study only included women who voided from detrusor contractions confirmed on UDS. Subgroup analyses were performed on enrolled patients with a history of previous incontinence surgery and those with pre-existing mixed incontinence. Neither of these factors appeared to affect clinical outcomes in this modest sized cohort ($p>0.05$).

PVS is now used for correction of both urethral hypermobility and ISD. In our series, the incidence of ISD on the basis of VLPP measurement was relatively high (51.4%). Although other studies have demonstrated that ISD has slightly poorer cure rates than hypermobility[14], VLPP (with <60cmH_2O indicative of probable ISD) was not associated with higher rates of voiding dysfunction nor procedure failure/ persistent SUI in our study. Continuing the study with larger numbers and a cohort with less severe SUI (more cases of ‘index” SUI) may help determine whether this technique could have greater application.

Modifications in traditional autologous fascia PVS technique have been described in an effort to minimise the inherent risk of urinary retention with PVS surgery. Linder et al published a series of 33 women who underwent a transobturator approach to autologous fascia sling placement[15]. 9% of patients required short term ISC and nil required release of sling for ongoing voiding dysfunction. Notably however, 15% of patients required a salvage operation within the 14.9 months of average follow up for ongoing SUI. Khan et al[16] published results of mid-urethrally placed autologous fascia slings, with improvement rates of 90% and 75.4%, and dry rates of 48% and 50.8% at 1 and 10 years respectively. ISC was performed by 6.5% of patients and division of sling occurred in 3.3% of cases comparable to synthetic MUS slings.

Assessed through secondary analysis, PVS laxity was not found to predict sling failure (persistent SUI) with heights up to 60mm. Subjective rather than objective cure rates were chosen for this analysis as self-reporting of improvement/ cure must be considered of primary importance to patients. Despite subjective cure rates being typically lower than objective cure rates, an inability to detect a small correlation could readily be explained by the study being underpowered. Nonetheless, this study at least suggests that any correlation between a ‘loose’ sling (40 to 60mm height) and persistent SUI is insignificant compared to the correlation between a ‘tight’ sling (<40mm height) and voiding dysfunction; both statistically and in terms of clinical consequence. Patients reported worse PGI-I score because of voiding dysfunction complications and not because of mild residual SUI. For this reason, this study supports a prudent approach to tensioning fascia slings.

Consistent with other contemporary research, this study demonstrated that age does not appear to be a factor in cure or complication rates with sub-urethral slings[17], an important factor worthy of further study in an ageing population. Obesity was the only variable found to have an association with persistent SUI. This highlights the importance of emphasising relevant conservative measures in holistic SUI treatment: weight loss, minimising alcoholic and caffeinated beverages, pelvic floor exercises and treating constipation[18].

Given the recent controversy in both academic and lay literature about mesh use in reconstructive pelvic surgery, patients are increasingly looking to alternatives[19]. With a median follow up of 11 months, this study is limited by duration of follow-up and being a consecutive series of only 51 patients. The value of the study is the effort to standardise sling tension to decrease voiding dysfunction which may prove to be of significance as patients move to robust native alternatives.

Although we used the UDI-6 survey, another questionnaire such as OAB-q SF could also be used to assess for OAB, as UDI-6 did not ask about urgency. However, we chose to use UDI-6 because of its ease and incorporation of questions pertaining to urge incontinence, stress incontinence and urinary retention, all in one questionnaire. Additionally, cough stress test was only done during the UDS pre-operatively but not post-operatively. Ideally this would be included for a more objective measure of SUI rather than just relying on the UDI-6 questionnaire.

Other limits of this study include its heterogenous nature (mixed incontinence and previous failed SUI surgery), although subgroup analyses failed to demonstrate any statistical impact. Furthermore, any conclusions drawn from this study must be tempered by the modest cohort size and low event rate (10/51). Potential confounders include the health of periurethral tissues, nature of vaginal closure, position of the sling along the urethra and degree of fibrosis that occurred during healing. Admittedly these factors may impact on final sling tension, but they are hard to control for and measure objectively. Unfortunately, menopausal and smoking status were not obtained as part of the study protocol. These are potentially useful data for any future study, as they may affect the fascia quality and the healing ability of the patient.

We also note that sling tension has to be adjusted according to each individual patient's degree of leakage. In this study, the exact sling height was not pre-planned prior to the surgery, but rather we looked at the variability one can get from the traditional '2-3 fingerbreadths' method. A further study in the future should certainly look at randomizing the lax sling height to patients with different VLPP, and then correlated with outcomes such as success rate and urinary retention.

We demonstrated the presence of a strong association between lax sling height and reduced voiding dysfunction. Height less than 40mm on ROC curve analysis had a sensitivity of 100% and specificity of 51% for retentive complications. Additionally, a height of 40 to 60mm was not found to be associated with poorer SUI cure rates. Given there was no observable detriment, we are encouraged to continue this standardized approach to sling tensioning. This serves as a proof-of-concept study to guide a larger, more detailed experimental study on the topic.

CONCLUSIONS

A higher lax sling height of greater than 40mm above rectus fascia may reduce the risk of voiding dysfunction and the need for sling revision.

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