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In-Situ Anterior Vaginal Wall Flap for Treatment of Stress Urinary Incontinence due to Urethral Hypermobility (Five Years Follow Up)

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ABSTRACT

Introduction: Stress urinary incontinence can be attributed to various factors, including the weakening of the supportive layer resembling a hammock. While tension-free vaginal tape has been employed as a minimally invasive solution, it has many delayed complications. The objective of this study was to assess a novel minimally invasive approach utilizing autologous tissue flap to address stress urinary incontinence stemming from urethral hypermobility.

Patients and Methods: A prospective cohort study encompassing fifty patients afflicted by stress urinary incontinence due to urethral hypermobility. The patients underwent surgical intervention involving the application of an in-situ anterior vaginal wall flap as a sling. The primary outcome measure was the objective cure rate at the five-year mark. Secondary outcomes encompassed operative complications, the emergence of voiding problems postoperatively, urge symptoms, and urinary tract infections.

Results: The study yielded an objective cure rate for stress urinary incontinence of 80%, which slightly declined to 74% after a five-year follow-up period. Notably, 8% of patients exhibited de novo detrusor over-activity. Urinary tract infections were observed in 4% of cases, suprapubic wound infections in 2%, recurrent stress urinary incontinence in 4%, and extended time required to initiate voiding in 4% of cases.

Conclusion: The employment of an in-situ anterior vaginal wall flap proved to be an efficacious and cost-effective modality for addressing stress urinary incontinence linked to urethral hypermobility.

Keywords:
Stress incontinence; Urethral hypermobility; Surgical treatment; Vaginal flap.

INTRODUCTION

The International Continence Society defines stress urinary incontinence as "the complaint of any involuntary loss of urine on effort or physical exertion (e.g., sports) or on sneezing or coughing" [(1)]. Its prevalence ranges between 12 and 55% according to the patient's age [(2)].

One of the causes of stress urinary incontinence is the loss of the hammock-like supportive layer that compresses the urethra during the increase in the intra-abdominal pressure such as during cough [(3)], leading to urethral hypermobility and stress incontinence. Colposuspension consisted of lifting the areas adjacent to the proximal urethra and bladder neck to the level of the retropubic space and is used to treat stress incontinence. This technique has undergone many modifications over the years until the development of Burch colposuspension in 1961[(4)], which was considered the gold standard for years with an initial success rate of 90 %, dropping down to 65% after 10 years [(5)]**.** However, it is not without complications as procedure failure, urinary retention, wound infection, osteitis pubis, suture break, suture erosion, enterocele, suprapubic pain, urinary tract infection, hemorrhage, and detrusor instability [(6)].

This lead to the development of minimally invasive dynamic slings as the tension-free vaginal tape (TVT) by **Ulmsten *et al*.**[(7)] as a minimally invasive procedure in order to decrease the risks of complications associated with colposuspension procedures; however, as long-term follow-up data became available, several delayed complications started to appear as tape erosion, which usually presents about 18 months after the operation, which may be caused by atrophic tissues, tape tension and poor vascularity[(8)]. Up to the extent that The National Institute of Clinical Excellence in its guideline in 2019 recommended autologous rectus fascial slings as one of the options of the surgical treatment of stress incontinence [(9)].

The technique of correction of urinary incontinence over the years proved to be adequate and gold-standard treatment [(9)]. However, the materials used may deserve innovation, which the focus should be on the patient. Based on that idea, the aim of the current study is to test a minimally invasive procedure using autologous tissue flap for the treatment of stress urinary incontinence due to urethral hypermobility in a trial to provide another technique, with autologous tissue, reliable and easily reproducible in practice, for correction of stress urinary incontinence.

PATIENTS AND METHODS

This prospective cohort study was conducted in As-Salam International Hospital, Al Safwa Hospital, Al Gabry Hospital, between March 2015 and March 2018. Fifty patients were prepared in this study for surgical management of stress urinary incontinence (SUI) type 2 due to urethral hypermobility.

All the patients performed full medical history, clinical examination (general and local), urine analysis, Q-tip test (to determine urethral hypermobility), and stress provocation test with a partially filled bladder (250 cc) in both supine and standing positions to detect stress incontinence. Urodynamic evaluation with

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cystometry and uroflowmetry were performed in patients who were not diagnosed with stress urinary incontinence. Stress urinary incontinence (SUI) was defined by the International Continence Society [(1)] as the involuntary loss of urine during increased intra-abdominal pressure (cough or staining) during filling cystometry, in the absence of detrusor contraction. However, the complaint of urge incontinence was defined as the involuntary leakage accompanied by or immediately preceded by urgency due to overactive bladder (OAB) or detrusor overactivity.

Inclusion criteria encompassed the following parameters:

Patients exhibiting stress urinary incontinence (SUI) attributable to urethral hypermobility, as indicated by a Valsalva leak point pressure exceeding 90 cm H_2O, devoid of detrusor overactivity and/or urge incontinence, as substantiated by urodynamic study results. Additionally, patients should not present intrinsic sphincteric deficiency (ISD), maintain a normal voiding cystometry pattern (defined by a maximum flow rate surpassing 15 ml/s for a voided volume exceeding 200 ml), and possess voiding detrusor pressure beneath 40 cm H_2O, accompanied by a urinary residual volume not exceeding 50 ml. Neurological disorders were required to be absent.

The surgical technique adopted for this procedure involved the use of regional anesthesia for all patients. Spinal or epidural anesthesia facilitated the precise adjustment of vaginal sling sutures by prompting the patient to cough during surgery following the instillation of 250 ml of warmed saline into the urinary bladder. Patients were positioned in the dorsal lithotomy stance, and both the vaginal and lower abdominal areas underwent preparation through an iodine scrub. To expose the anterior vaginal wall sling, a weighted vaginal speculum and silk labial retraction sutures were employed. Furthermore, infiltration of the anterior vaginal mucosa with normal saline was conducted, enhancing the dissection of the vaginal sling from the surrounding tissue. The surgical procedure entailed creating a rectangular incision in the anterior vaginal wall (Figure 1).

The incisions were extended from the mid-urethral level to beyond the bladder neck level, maintaining a 1 cm distance medially from the folded edge of the anterior vaginal wall (vaginal fornix). A sharp dissection was conducted over the shining surface of the peri-urethral fascia using Metzenbaum scissors. The attachment point of the urethro-pelvic fascia to the tendinous arc of the obturator was identified. The urethro-pelvic ligaments were dissected using a combination of blunt and sharp techniques, without completely separating them from the tendinous arc at the pelvic sidewall. Curved Mayo scissors was used to enter the retropubic space at the tendinous arc level, exposing the urethro-pelvic ligament. The urethra and overlying mucosa were detached from any remaining attachments, ensuring that the rectangular sling lay over the urethra distally and the bladder neck proximally (Figure 2).

For the creation of the bladder neck and urethral support "hammock," two pairs of stay sutures composed of No. 1 polypropylene sutures were placed at the four corner angles of the rectangular flap in the sagittal plane. The initial pair of sutures was positioned at the bladder neck level, involving the vesico-pelvic fascia, urethro-pelvic ligament, and anterior vaginal wall. The second pair of No. 1 polypropylene sutures encompassed the levator ani musculature as it inserts near the mid-urethral segment, the medial edge of the urethro-pelvic ligament, and the anterior vaginal wall (Figures 3 and 4). To transfer the polypropylene sutures, a double-pronged needle was advanced into the vagina near the symphysis pubis through a 1 cm suprapubic incision, with manual control. Cystoscopy was conducted to ensure the absence of bladder or urethral injury. The bladder neck remained in constant view during the process of tying each polypropylene stay suture, initially to itself and subsequently to the corresponding suture on the same side.

The final configuration of the vaginal flap assumes a U shape, resembling that of a TVT (tension-free vaginal tape); however, the distinction lies in attaching the middle section of the U to the upper urethra, with the bladder neck not remaining free as in the case of TVT. Consequently, it takes on the form of a flap. This maneuver was meticulously executed to ensure the unobstructed openness of the bladder neck, with the overarching objective of furnishing support to the urethra and bladder neck while circumventing any hindrance. Typically, a gap of 1 to 2 fingers can be comfortably accommodated between each polypropylene suture knot and the underlying rectus fascia. Assessment of continence involved the infusion of the bladder with 250 ml of warm saline, followed by requesting the patient to cough. Subsequently, the sutures were meticulously adjusted by manipulation, either tightening or loosening, until any leakage was eradicated, all the while refraining from exerting pressure on the bladder neck or urethra, thus minimizing the likelihood of postoperative voiding complications. The closure of the vagina was accomplished using continuous 2-0 polyglactin sutures, while the suprapubic incisions were sutured as well (Figure 5). A vaginal pack was positioned, and an 18 F urethral catheter was retained for a period of 3 days. Patients were kept under observation overnight, and the vaginal pack was removed within the first 24 hours.

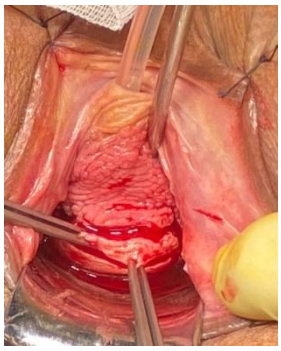

Figure 1
Rectangular incision in the anterior vagina

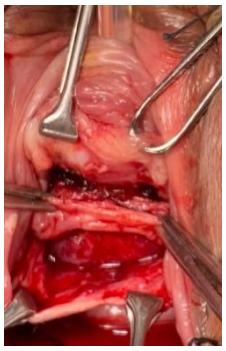

Figure 2
Dissection of urethra

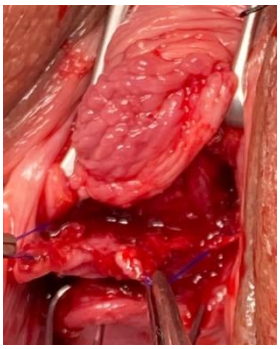

Figure 3
Stay sutures

Figure 4
Stay sutures

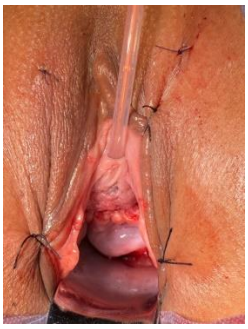

Figure 5
Closure of the vagina

Follow-up: Subsequent to discharge on the second day, catheters were extracted on the 3rd or 4th day. Post-catheter removal, the assurance of proper voiding devoid of substantial residual urine, as detected through ultrasound, was ascertained. Patients were advised to promptly report any voiding difficulties or complications within the ensuing 2 weeks. A sequence of outpatient follow-ups were scheduled at 2 weeks, 1 month, 3 months, followed by intervals of every 6 months over the course of five years to gauge the cure rate. The follow-up assessment encompassed a quality of life (QOL) questionnaire[10], originally outlined by Kelleher, designed to evaluate symptoms and patient contentment. Moreover, the evaluation involved a provocative physical examination, cystometry, uroflowmetry, and meticulous documentation of any transient or persistent complications. In instances where patients encountered voiding issues, a repeat urodynamic study was administered.

Outcome measures: Neutral investigators were responsible for collecting outcome measures. The primary outcome measure hinged on the objective cure rate after a span of 5 years, established through stress testing. A patient was deemed cured if she attested to the absence of leakage and expressed contentment with the surgical outcome, an assessment substantiated by the analysis of the questionnaire. Furthermore, there should be no urinary loss during provocative physical examination and cystometry performed with a full bladder. A patient was categorized as significantly improved if she reported sporadic mild leakages (a few drops), expressed overall satisfaction with the surgical outcome based on questionnaire assessment, and exhibited no urinary loss during both provocative stress testing and cystometry conducted with a comfortably filled bladder (200-250 ml). Patients, even if improved, who failed to meet the aforementioned criteria were classified as treatment failures. The secondary outcome measures encompassed operative complications, the emergence of postoperative voiding difficulties, urge symptoms, and urinary tract infections.

Ethical approval: The Ethical Committee of Al-Salam International Hospital, Al Safwa Hospital, and Al Gabry Hospital, approved the study and written informed consent was obtained from all patients after clarification of the procedure. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

Quantitative parameters were presented as range, mean and standard deviation. Qualitative parameters were presented as frequency and percentage.
Data analysis was performed using SPSS (IBM corporation Armonk NY) V 27 software.

RESULTS

Patient age ranged from 32 to 71 years. Mean parity was 4.1 ± 1.8, and 18 patients were menopausal. Mean body mass index (BMI) in kg/m^2 was 30.4 ± 2.2.

Baseline detrusor pressure was 10.3 ± 3.2 cm H_2O, baseline Valsalva leak point pressure was 107 ± 9.4 cm H_2O, and mean preoperative urethral closing pressure was 16.9 ± 1.8 cm H_2O.

Operating time and length of hospital stay were 41.5 ± 5.6 minutes and 5.6 ± 1.4 days, respectively. Mean intraoperative blood loss was 210 ± 42 ml and no cases required blood transfusion. All patients voided spontaneously after removing the catheter except in 6 patients who experienced voiding difficulties with a significant amount of residual urine and required reinsertion of the catheter for additional 5 days. The patients resumed normal voiding after the removal of the second catheter.

During the initial two weeks following surgery, postoperative complications were generally minor. These included urinary tract infections in 2 patients (4%), suprapubic wound infections that resolved with oral antibiotics in 1 patient (2%), persistent suprapubic pain in 1 patient (2%), recurrent stress urinary incontinence in 2 patients (4%), and prolonged time required to initiate voiding in 2 patients (4%). Prolonged urinary retention did not occur. Notably, there were no instances of bladder perforation, vesicovaginal fistula, bowel injury, nerve injury, or vascular injuries.

Using the defined categories of surgical outcomes, the results were as follows: 40 patients (80%) were deemed cured of stress urinary incontinence, 7 patients (14%) experienced significant improvement, and 2 patients (4%) were considered to have undergone an unsuccessful procedure. Only one patient was lost to follow-up. Among the 7 patients classified as having achieved improvement, they reported occasional leakage, primarily when sneezing, occurring less than twice weekly, and expressed satisfaction with their outcomes. The 2 cases classified as failures manifested six months after the procedure. No substantial changes were observed in postoperative outcomes over time. De novo detrusor overactivity and urge incontinence emerged in 4 patients (8%). These contractions occurred exclusively while standing, with no contractions evident during supine cystometrography. All patients exhibiting detrusor overactivity were aged 60 and above, received medical treatment, and did not necessitate additional surgical intervention.

A postoperative urodynamic examination was administered to 7 patients who reported one or more symptoms suggestive of voiding disorders (e.g., hesitancy, prolonged stream, weak flow, or sensation of incomplete bladder emptying). These evaluations unveiled flow rates and voiding pressures indicating changes indicative of obstruction, characterized by heightened urethral closure pressures that, nonetheless, remained within the realm of normal values. The mean maximum flow rate observed was 18 ml/sec, spanning a range of 16 to 20 ml/sec, accompanied by an average voiding pressure of 38 cm H_2O, fluctuating between 30 and 45 cm H_2O. Residual urine volumes did not surpass 100 cc. These patients were subsequently monitored for any signs of increasing post-void residual urine volumes.

Notably, no significant bladder outlet obstruction was identified in the pressure flow study. Although flow rates and voiding pressures exhibited indications of changes towards obstruction, no patient displayed abnormal flow, pressure, or residual urine exceeding 100 cc subsequent to the vaginal sling procedure. Maximum urinary flow indicated either no decline or a slight decrease (< 4 ml per second) in 38 patients, and a decrease exceeding 4 ml per second, while remaining within the normal range, in 12 patients. Throughout the entire five-year follow-up period, there were no reported instances of urethral erosion, likely due to the fact that the vagina was not separated from the urethra. Overall the subjective success rate was 94% (47 patients were either cured or satisfied), while the objective success rate was 80% (40 patients that were cured), dropped to 72% (36 patients) after 5 years.

DISCUSSION

The current study showed an initial objective cure rate from stress urinary incontinence of 80%, dropping down to 72% after 5 years, while de novo detrusor overactivity was 8%, early postoperative urinary tract infection was 4%, suprapubic wound infection was 2%, recurrent stress urinary incontinence 4%, and prolonged time to initiate voiding 4%. However, as time passes, the objective and subjective cure rate of operations for stress incontinence decrease, but still the current operation had an objective success rate after 5 years compared to that of TVT, which was 76.8% in a study involving 138 patients who underwent TVT and followed up for five years[11]. Still, it was lower than the objective five years cure rate of TVT and TVT-O in another study multicenter open-labeled randomized controlled study involving 260 patients conducted in Finland (84.7% for TVT vs. 86.2% in TVT-O) [12]; however, the Finnish study excluded cases with BMI over 35, unlike the current study, which had no limitation to the BMI of the cases. In general, success rates for retropubic and trans obturator slings varied widely, ranging between 51 and 99%[13,14,15], while single incision mini-slings had lower success rates[16].

The commonest reported complications of tapes are tape exposure followed by pain, then urinary problems as urgency, recurrent urinary incontinence, voiding dysfunction, and recurrent urinary tract infection[17]. The long-term complication reached 10.9%[18]. Infection due to the tape can interfere with the successful integration of the tape into host tissues leading to exposure of the tape in some patients[19]. While tape erosion was reported in 15% in a multi-institutional review[20], which may be vaginal erosion

presenting by non-specific symptoms as dyspareunia, vaginal discharge, and pelvic pain, while bladder and urethral erosions usually present with voiding symptoms, hematuria, and recurrent infections and are usually a result of an unidentified perforation at the time of surgery[21]. The current operation has the advantage of not separating the vaginal mucosa from the upper urethra and bladder neck, thus minimizing the risk of both bladder and urethral injury. It is estimated that about 1 in 30 cases require a second procedure for removal or revision of the tape[22]. In the first 9 years of mid-urethral sling placement, about 3.3% removed their mid-urethral slings[23], which bring into light the use of autologous slings in the surgical treatment of stress urinary incontinence.

In their study, **Brubaker *et al***.[24] reported that 42% of patients who did mid-urethral slings in the TOMUS had at least one adverse event (30% minor vs. 12 % major). The current study reported 4% urinary tract infection and 2% wound infection vs. 4.1% and 0.8% in TVT[25] vs. 10.7 and 17.1% [26]. Voiding difficulties were more or less similar between the current study and other studies (4% in the current study vs. 2.3% [25] and 3% [26]). Similarly, pain and neurological symptoms were less in the current study (2%) as compared to 5.4-9.7% in another study [26].

The recurrence rate of the current study was 4% (2 cases); both of them had previous failed surgery for stress urinary incontinence, which is expected as recurrent cases tend to have a lower success rate in general. **Lin *et al.*** [27] compared the recurrence rates of both TVT and TOT in cases of vaginal mesh surgery and found a 12 % recurrence rate following TVT vs. 40% in TOT. **Schimpf *et al.*** [28] also reported a higher recurrence rate following TOT than following TVT in their meta-analysis of 21 studies. As the current operation is more similar to TVT than TOT, we had a low recurrence rate in our study.

The current study had the advantages of avoiding the complication associated with tape rejection and tape erosion found in synthetic urinary tapes and less cost of the operation as it depends on autologous tissue, thus, saving the cost of the tape in low-resource settings. On the other hand, the limitations of the current study are the lack of tension-free operation as this is a vaginal flap, in addition to, depending on the experience of the urologist, which is subjective, in the visualization of the bladder neck during the tying of the sutures as the operation is done at the level of the bladder neck, unlike the tapes which are done at mid-urethral levels.

CONCLUSION

In-situ anterior vaginal wall flap is an effective and cheap treatment modality for stress urinary incontinence due to urethral hypermobility avoiding the complications of tape erosion and rejection with acceptable results after five years of follow-up. A large randomized controlled trial is needed to compare this operation with TVT.

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