ORIGINAL RESEARCH

A Comparative Study of Polypropylene Mid-urethral Slings and Autologous Pubovaginal slings in the Treatment of Female Stress Urinary Incontinence at a Tertiary Care Hospital

[1]Dr. Venkata Pradeep Kumar N, [2]Dr. Maddala Sudarsana Rao, [3]Dr. Mahesh M, [4]Dr. Venkata Ranga Swamy A, [5]Dr. Subba Rao Chodisetti

[1]Assistant Professor, Department of Urology, Alluri Sitaramaraju Academy of Medical Sciences, Eluru, Andhra Pradesh, India
[2]Assistant Professor, [5]Professor & Head of the Department, Department of Urology, Andhra Medical College, Visakhapatnam, Andhra Pradesh, India
[3]Associate Professor, Department of Urology, Sri Devaraj Urs Medical College and RL Jalappa Hospital & Research CentreKolar, Karnataka, India
[4]Associate Professor, Department of Urology, Super Speciality Hospital, Government Medical College, Anantapur, Andhra Pradesh, India

Corresponding author
Dr. Venkata Ranga Swamy A
Associate Professor, Department of Urology, Super Speciality Hospital, Government Medical College, Anantapur, Andhra Pradesh, India
Email: drrangasuro@gmail.com

Received: 19 March, 2024 Accepted: 23 April, 2024

ABSTRACT

Background: Urinary incontinence poses a significant health concern globally, with stress urinary incontinence (SUI) being a prevalent subtype. Despite its impact on quality of life, many affected individuals do not seek medical attention, and treatment options vary, including surgical interventions such as synthetic mid-urethral slings and autologous pubovaginal slings. **Methods:** A randomized prospective comparative study was conducted at a tertiary care center over a 23-month period, involving 30 female patients with stress urinary incontinence. Patients were divided into two groups: Group A underwent polypropylene transobturator mid-urethral sling surgery, while Group B underwent autologous rectus fascia pubovaginal sling surgery. Demographic characteristics, preoperative, intraoperative, and postoperative assessments were recorded. Follow-up evaluations were conducted at one, three, and six months postoperatively. **Results:** Baseline characteristics were comparable between the two groups ($p>0.05$). Intraoperative assessment revealed a longer operating time in Group B compared to Group A (130.20 vs. 38.67 minutes, $p<0.001$). Postoperative outcomes showed a shorter catheter duration (2.20 vs. 3.40 days, $p=0.0012$) and hospital stay (3.33 vs. 4.47 days, $p=0.0004$) in Group A compared to Group B. Subjective resolution of urinary incontinence was comparable in both groups. Minor complications were reported in patients from Group A, irritating voiding symptoms (n=3), MESH erosion (n=1) and groin pain (n=1), while in both the groups a total of 3 patients reported transient urinary retention. **Conclusion:** Both polypropylene mid-urethral sling and autologous pubovaginal sling surgeries effectively treated stress urinary incontinence. While subjective resolution was high, polypropylene sling had shorter catheterization and hospitalization time. Minor complications occurred in both groups.

Keywords: stress urinary incontinence, trans-obturator sling,pubovaginal sling, complications, outcomes

INTRODUCTION

Urinary incontinence (UI), according to the International Uro-gynecological Association (IUGA) and the International Continence Society (ICS), refers to the reported experience of involuntary urine loss. In developing countries, an estimated 26% of women contend with urinary incontinence. Among these, stress urinary incontinence (SUI) is notably more prevalent, with a rate of 12.6%, surpassing mixed urinary incontinence (MUI) at 9.1% and urgent

urinary incontinenceat 5.3% [1]. Most women have not been seen seeking medical attention for this condition. UI can have a significant impact on an individual's quality of life, including disruptions in social relationships, psychological distress, and hospitalizations due to skin breakdown and urinary tract infections [2,3]. Studies have shown that UI is associated with depression, stress, and low self-esteem, which can worsen the symptoms of UI and lead to social restriction and isolation [4,5]. SUI can affect intimate relationships and may limit sexual interaction [6].

Treatment for SUI includes initial conservative therapies and then surgery if conservative therapies outcome are not satisfactory. There are a variety of surgical treatments offered for SUI including different sling placement techniques, sling positioning, and synthetic or autologous material. The autologous sling, obtained from the fascia Lata, was first described in the 1930s 6. The use of a strip of rectus fascia beneath the bladder neck by vaginal route and anchoring it superiorly in the abdominal wall was proposed by Aldridge AH [7] in 1942. The autologous fascia pubovaginal sling was popularized by McGuire and Lytton [8] in 1978, who reported 80% success rate in patients with intrinsic sphincter defect. However, autologous sling use, declined due to the initial success of soft polypropylene slings. The year 1998 marked the rise in popularity of transvaginal tape, composed of a soft polypropylene mesh material, following a multicenter study that documented a remarkable 98% cure rate[9]. The surgical gold standard for SUI treatment is currently placement of a synthetic mid-urethral sling [10]. With the increasing adoption of synthetic slings, there has been a concurrent rise in reported complications associated with their use. The growing apprehension surrounding the use of synthetic transvaginal meshes in organ prolapse surgery has intensified the scrutiny on synthetic slings as well [11]. However, due to the recent scare about mesh erosion due to artificial tapes, there is great reluctance in their use and they are no longer available in many countries like United Kingdom causing renaissance of autologous rectus fascia sling for SUI [13]. However, the re- adoption of autologous PVS has been slow due to the surgery's technical difficulty and perceived higher morbidity rates Autologous slings. Therefore, the purpose of this study is to compare outcomes and complications of sling placement using polypropylene mid-urethral sling and autologous pubovaginal sling.

MATERIALS AND METHODS

Study design

This randomized, prospective, comparative study was conducted at the Department of Urology, King George Hospital, Andhra Medical College, Visakhapatnam, Andhra Pradeshbetween January 2020 to December 2021. The study was ethically approved by institutional ethical committee and study protocol was in accordance with the principles of declaration of Helsinki. Written informed consent was taken from the study participants.

Study population

Inclusion and exclusion criteria

Adult females (≥18 years) with a complaint of involuntary urinary leak on physical exertion, sneezing, coughing and who failed conservative therapy were included in the study. Patients with positive ICS-UCT (International Continence Society-Uniform Cough Stress)/ standing cough stress test, with normal voiding habits, a pliable and compliant vaginal wall with adequate vaginal capacity, having normal postvoid residual volume were included in the study.The patients with prolapse (uterine, cystocele, rectocele), urgency and urge incontinence, history of continuous urinary leak, with genito-urinary fistulae, urinary tract infection , renal insufficiency and neurological history were excluded from the study. Also, females with history of anti-incontinence or radical pelvic surgery, pregnancy within the last 12 months or currently lactating, postvoid residual volume ≥150ml and those who were not willing to undergo surgical interventions were excluded from the study.

Sampling procedure

All 30 female patients (18-65 years) with history of clinical stress urinary incontinence were randomly assigned to two groups. Group A (15 females): Polypropylene trans-obturator mid urethral sling; Group B (15 females): Autologous rectus fascia pubovaginal sling surgery.Cephalosporin was administered to patients prior to surgery. Dorsal lithotomy position was selected and spinal anesthesia was given during surgery.

Surgical interventions

Group A transobturator sling (TOT)

Technique used in the study for TOT repair was outside-in procedure. Asepsis of operating area was done using betadine (5% W/V) solution followed by A16 F foley's catheter insertion to empty the bladder. Normal saline (10cc of 0.9%) was injected into the anterior vaginal wall, and a vertical incision (2cm) was made at the mid-urethral level. Vaginal flaps were raised, and dissection was performed. The mesh was inserted with the help of needle passer at both sides and was adjusted at the level of mid urethra. The tape was cut at the level of skin followed by closing of vaginal.The skin incision was made using 2-0 Vicryl sutures with a single stitch. *Post-operative care:* Catheter was removed after 48 hours. Antibiotics were given for three days followed by two days analgesics.

Group B pubovaginal sling procedure

The patients positioned in dorsal lithotomy underwent Pfannenstiel incision (6-7 cm) above pubic

symphysis,extending to the marked rectus fascia (2 × 8 cm).The marked portion of rectus fascia was elevated and then closed in tension-free manner using Vicryl suture.The graft was placed in 0.9% normal saline after harvest and cleaned thoroughly. One polypropylene suture was used across full length of sling and tied down, leaving the sutures long, while graft was place in saline solution until needed. Catheterization was performed using an A 16 F Foley catheter. Normal saline injection (10cc of 0.9%) was given into vaginal epithelium and vertical incision (4 cm at the junction of bladder neck to proximal urethra) was performed, vaginal flaps were raised. With the help of cystoscopy, extravesical passage was confirmed.Using a Stamey needle, the graft was fixed, and the distal aspect of the graft was sutured to the periurethral tissue using 4-0 Vicryl sutures. Vaginal incision was closed (2-0 Vicryl suture) after achieving homeostasis. The ends of graft sutures were tied down above rectus fascia and subcutaneous suction kept drain, followed by closing of abdominal incision using 3-0 nylon suture. All women were given Inj. piperacillin-tazobactam and Inj. metronidazole for 72 hours, drain was kept for 72 hrs, followed by catheter removal on 3rd day. Catheter was reinserted in case of no passage of urine, and patients were discharged on 5th or 6th day once they able to pass urine by their own.

Post-operative care: Patients were kept on a soft diet the night of surgery. Analgesics were administered for two days, followed by oral paracetamol for next three days and intravenous antibiotics for three days. Patients were discharged with an indwelling foley's catheter, if they were unable to urinate or with high PVR volume and de-catheterization trial was done on 4th or 5thpost-operative day.

Data collection

The data was recorded as demographic characteristics (age, body mass index, menopausal status, parity).Pre, intra or post-operative assessment (stamey grading, duration of symptoms, VLPP (Valsalva leak-point pressure)), operating time, post-operative catheter days, total hospital stay days, and urinary retention status) was recorded. Assessment of resolution of stress incontinence was measured in terms of different parameters as cured and dry,improved, and failed. Immediate post-operative complications were recorded in the patients such as urinary retention, groin pain, hematuria, irritative lower tract symptoms, fever, major post-operative bleed, and surgical site infection.

Follow-up

Follow-up done at urology OPD after six months for the assessment of new urinary symptoms, surgical site infection (graft site and vagina). ICF-uniform cough stress test was performed if necessary.

Statistical methodology

Data analysis was carried out using statistical package of social sciences version 23.0.Qualitative/descriptive data was represented as numbers and percentage while quantitative data was represented as mean and standard deviation. For all statistical analysis $p<0.005$ was considered as statistically significant.

RESULTS

A total 30 female patients with stress urinary incontinence were randomized into two groups, group A and group B, 15 patients each.

Baseline characteristics were summarized in table 1. The mean age group of patients in group A and group B were 42.47and 43.20 years respectively. Majority of the patients from group A (60.00%) and group B (66.67%) were aged between 41-50 years. Body mass index of patients was comparable in both the groups ($p>0.05$). Most of the patients (73.33% each) from both groups were overweight. Menopausal status comparison revealed that the majority of patients in both Group A and Group B were premenopausal (66.67% and 60.00%, respectively), followed by postmenopausal individuals in both groups (26.67% and 40.00%, respectively). Most of the patients from group A (60.00%) and group B (53.33%) had parity of two.The mean duration of symptoms among group A and group B were 1.73 years and 1.83 years respectively.

Pre-operative assessment

Among group A, Stamey grade was one in 46.67% and two in 53.33% patients, and vice versa among group B. The mean VLPPamong group A and group B were82.47 and 85.93 cm H_2O respectively (Table 2).

Intra-operative assessment

The mean of operating time for group B was higher (130.20 min) as compared to group A (38.67 min).

Post-operative assessment

The mean post-operative catheter duration for Group A and Group B were 2.20 days and 3.40 days. Additionally, the mean total hospital stay for Group A was 3.33 days, while for Group B, it was 4.47 days.

Assessment of subjective incontinence

Subjective resolution of urinary incontinence was assessed between two groups (Figure1). The majority of patients among group A (87.67%) and group B (100%) reported complete resolution of symptoms with no residual leakage. However, 13.33% patients from group A reportedurine leak occasionally on exertion but less as compared to pre-operative status. None of the patients from both the groups reported failure of the surgery subjected to the resolution of incontinence.

All the patients in their follow-up visits showed negative ICS UCST.

Complications

Over the period of 23 months, 7 out of 15 patients experiencedcomplications (Table 3). Minor complications were recorded among group A patients, where 3 patients had irritating voiding symptoms. One patient from group A reported groin pain after five days of surgery who was advised for oral analgesic for next five days. However, one patient from group A developed mesh erosion after six months follow up, where surgical removal of mesh was carried out followed by autologous pubovaginal sling placed.

One patient among group A developed urinary retention. Two cases among group B had transient urinary retention, however, none of the patients from group B had reported any other complications after treatment.Patients who reported urinary retention on first decatheterization trial were again catheterized and called for follow up on 4th and 5th post-operative day. One patient from group A who developed urinary retention during 1stdecatheterizationwas successfully decatheterized on subsequent follow up visit on the 4th post-operative day.However, amongst the two patients from group B who reported urinary retention during 1stdecatheterization trial, one patient was successfully decatheterized on subsequent follow up visit on the 5th post-operative day and second patient was successfully decatheterized on 6th post-operative day. Interestingly, no case had reported permanent urinary retention.

Table 1: **Baseline characteristics**

Parameters	Group A (TOT) [N=15]	Group B (PVS) [N=15]
Age (years)		
<40	5 (33.33)	4 (26.67)
41-50	9 (60.00)	10 (66.67)
>50	1 (6.67)	1 (6.67)
Body mass index (kg/m^2)		
Overweight	11 (73.33)	11 (73.33)
Obesity	4 (26.67)	4 (26.67)
Menopausal status		
Postmenopausal	4 (26.67)	6 (40.00)
Perimenopausal	1 (6.67)	0
Premenopausal	10 (66.67)	9 (60.00)
Parity		
One	1 (6.67)	2 (13.33)
Two	9 (60.00)	8 (53.33)
Three	4 (26.67)	4 (26.67)
Four	1 (6.67)	1 (6.67)
Duration of symptoms	1.73 (0.65)	1.83 (0.65)
Data presented as n (%), unless otherwise specified. PVS, pubovaginal sling; TOT, trans-obturator sling.		

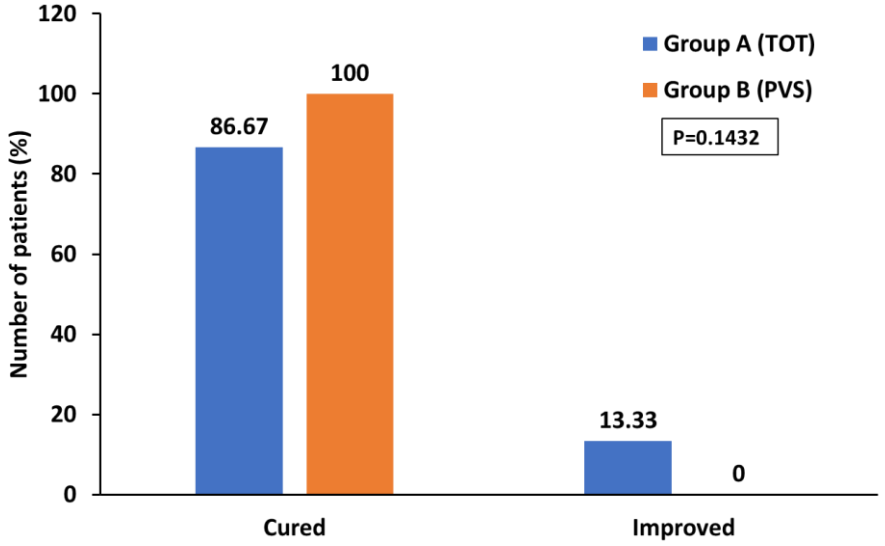
Table 2: Pre-, intra-, and post-operative outcomes.

Parameters	Group A (TOT) [N=15]	Group B (PVS) [N=15]	p-value
Pre-operative factors			
Stamey grading, n (%)			0.7151
One	7 (46.67)	8 (53.33)	
Two	8 (53.33)	7 (46.67)	
VLPP (cm H_2O)	82.47 (7.90)	85.93 (5.01)	0.1622
Intra-operative factors			
Operating time (minutes)	38.67 (9.15)	130.20(13.82)	<0.001
Post-operative outcomes			
Catheter duration (days)	2.20 (0.56)	3.40 (0.91)	0.0012
Total hospital stay(days)	3.33 (0.62)	4.47 (0.92)	0.0004
Data presented as mean (SD), unless otherwise specified. PVS, pubovaginal sling; TOT, trans-obturator sling; VLPP, Valsalva leak-point pressure.			

Table 3: Complications

Complications	Group A (TOT) [N=15]	Group B (PVS) [N=15]	p-value
Irritating voiding symptoms	3 (20.00)	0	0.0672
MESH erosion	1 (6.67)	0	0.3091
Groin pain	1 (6.67)	0	0.3091
Urinary retention			0.5452
Transient	1 (6.67)	2 (13.33)	
Permanent	0	0	
Data presented as n (%). PVS, pubovaginal sling; TOT, trans-obturator sling.			

Figure 1: Comparison between two studied groups by subjective resolution of incontinence



DISCUSSION

Stress urinary incontinence (SUI) significantly impacts the psychosocial well-being, interpersonal relationships, quality of life, productivity, and overall health of affected women. It stands as a prevalent condition among middle-aged women.All sling procedures increase outlet resistance and provide mechanical support, rendering the outcomes potentially independent of the sling material utilized. While autologous tapes were once endorsed, their popularity has waned due to the availability of simpler and quicker tension-free tapes.The transobturator tape (TOT) was developed to reduce the risk of bladder injury and has been described in both "out-to-in" and "in-to-out" approaches, with an autologous fascial TOT also being documented. TOT midurethral slings have gained acceptance and popularity, emerging as a leading option in SUI surgery. They have become the new gold standard for surgical treatment due to their simplicity for both surgeons and patients, as well as their excellent surgical outcomes and low morbidity rates [13-15].While mesh slings continue to be regarded as the gold standard for surgical treatment of SUI, there has been a resurgence of interest in autologous slings due to concerns regarding the safety of mesh.The key findings of this study were: i) comparable baseline characteristics between group A (TOT) and group B (autologous pubovaginal sling), indicating proper randomization; ii) significantly shorter mean operating time in group A compared to group B; iii) higher subjective and objective cure rates in group B, although the difference was not statistically significant; iv) longer mean postoperative catheterization duration and hospital stay in group B compared to group A, both of which were statistically significant; v) similar rates of intraoperative and postoperative complications between the two groups, with no statistically significant differences observed.

In the present study, the mean age of patients in Group A (TOT) was 42.47 years, while in Group B (PVS), it was 43.20 years. Comparing to more recent studies, Sharma JB et al. [16]found a mean age of 46.8 years for Group A and 42.33 years for Group B, showing a slight divergence from our study's results. However, Elsersy MA et al. [17]reported mean ages of 45.2 years for Group A and 46.2 years for Group B, closely aligning with our findings. Mourad S et al. [18]recorded higher mean ages of 54.6 years for Group A and 56.8 years for Group B.

In the present study, the mean duration of surgery for Group A (TOT) was 38.67 minutes, while for Group B (PVS), it was 130.20 minutes, both showing statistically significant differences ($p < 0.001$). Similarly, in an prior study, it was revealed that the mean operational time was significantly longer in the autologous rectus fascia group compared to the

synthetic mesh group (p=0.029) [19].Comparing to previous studies, the mean durations for Group A ranged from 17 to 52 minutes, while for Group B, they ranged from 55.60 to 109 minutes [16-18,20].

In the present study, the mean postoperative catheterization duration for Group A (TOT) was 2.20 days, while for Group B (PVS), it was 3.40 days (p = 0.0012). Comparing to previous studies, durations ranged from 0.8 to 2.5 days for Group A and from 2 to 5.8 days for Group B across different studies [16-18,20].

In the present study, the outcome assessment revealed that 86.6% of patients in Group A (TOT) were cured, while 13.3% showed improvement. In contrast, all patients in Group B (PVS) were categorized as cured. Comparing to a study conducted by J.B. Sharma et al. [16] reported a similar outcome, with 100% of patients in both Group A and Group B achieving cure. Prior studies have shown high success rates in both groups, with 95% of Group A and 98% of Group B achieving cure in the study, indicating parallel outcomes [17]. Another earlier study demonstrated comparable results, with 89.7% of Group A and 85.4% of Group B achieving cure [20]. Additionally, a previous study reported slightly lower cure rates, with 93.75% of Group A and 83.87% of Group B achieving cure.

In a previous study, it was reported that there was no significant difference between the efficacy and complications of using autologous rectus fascia and synthetic mesh in transobturator tape procedures for treating urinary stress incontinence [19].

CONCLUSION

The autologous pubovaginal sling boasts a higher cure rate without mesh-related complications compared to the trans-obturator tape. However, it requires longer operative time and postoperative stay. Conversely, the TOT offers shorter operative time and postoperative stay but has lower cure rates and may lead to mesh-related complications. Overall, the autologous pubovaginal sling appears to be a promising option for stress urinary incontinence treatment due to its superior outcomes and absence of mesh-related issues.

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