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Original Research Article

Outcome Of Autologous Fascial Pubovaginal Sling (Afpvs) Surgery for Stress Urinary Incontinance in Females – A Prospective Clinical Study.

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Abstract

Urinary incontinence (urinary leakage) is a common problem affecting middle aged women. Among the six types of urinary incontinence (stress, urge, overflow, mixed, functional, reflux) stress urinary incontinence is a common variant affecting the quality of life. Stress urinary incontinence (SUI) can be classified into mild, moderate and severe varieties depending upon the severity of symptoms. For mild SUI - lifestyle changes, weight lossin overweight and obese women, pelvic floor exercises , pessaries and medical management with Duloxetine may help. Most patients with moderate to severe SUI not responsive to other interventions usually requires surgical treatment. Various surgical options include kelly's plication, bursch colposuspension, bulking agents and sling surgeries.

In our study 25 cases were treated with pubovaginal autologous fascial slings. Out of 25 patients none had undergone previous operation for SUI. Patients with pelvic organ prolapse, benign uterine pathologies and urge incontinence were excluded from the study. Post-operative urethral pressure measurements indicated that sling increased the urethral pressure but didn't cause obstruction during voiding. Since

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there was a measurable decrease in the urethral pressure during detrusor contraction.

A satisfactory result with good urinary control was obtained in 23 cases and moderate improvement in 2 cases.

Keywords: Stress urinary incontinence, Autologous rectus fascia, pubo vaginal sling surgery, TOT vaginal tape, urodynamic study

Introduction

Stress urinary incontinence (SUI) is an under-diagnosed problem affecting up to 50% of women worldwide.[1] SUI has a significant impact on the quality of life for many women and also imposes a financial burden to the individual and the health care system. Treatment for this problem includes initial conservative therapies and then surgery if outcome of conservative therapies is not satisfactory. More than 200 surgical procedures have been described in the literature for the treatment of stress incontinence. The role of surgery in the treatment in SUI has evolved steadily in the last two decades. The synthetic mid-urethral sling and its different insertion methods have gained widespread popularity and are now the most frequently used surgical interventions for women with SUI.[2]

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. Traditional autologous pubovaginal slings (PVS) have re-emerged as a viable alternative to synthetic slings in light of the issues with synthetic slings.The re-adoption of autologous PVS has however, been slow due to the technical difficulty of the surgery and perceived higher morbidity rates.[(3-6)]

In our study, we will discuss the various aspects of autologous PVS and its indications as an alternative to synthetic slings.

AIMS AND OBJECTIVE

The aim of the present series was to report the outcome and complications of autologous pubo vaginal slings (AFPVS) as a versatile procedure for SUI in female carrying a high risk of mesh related complications.

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MATERIAL AND METHODOLOGY

This is a Prospective clinical study in the department of urology, K.G.H. Visakhapatnam conducted between September 2019 to august 2021. The sample size was 25. The data will be compiled and subjected to statistical analysis using Statistical Package for Social Sciences (SPSS) package [Stata, version 23.0 SPSS INC, Chicago, IL, USA]. For quantitative data, percentage, mean and standard deviations will be computed. For significance of difference of means, t-test for independent samples will be used. Data will be summarized as proportions for categorical variables and Chi-square will be performed to judge independence of attributes. The tests will be applied at 95% confidence interval that is, p value less than 0.05 will be taken as significant.

Study population: Inclusion criteria

1. Adult females with a complaint of involuntary urinary leak on physical exertion, sneezing or coughing; who failed conservative therapy.
1. Only patients with positive ICS- uniform cough stress test or positive standing cough stress test .
2. Only patients with normal voiding habits (fewer than eight episodes per day and fewer than two episodes per night).
3. Pelvic examination documents pliable and compliant vaginal wall, and adequate vaginal capacity.
4. Postvoid residual volume is normal were included in the study
5. Those who gave a valid informed consent

Exclusion criteria :

1. Pelvic organ Prolapse (uterine, cystocele, rectocele)
2. Complain of Urgency and urge incontinence
3. Genitourinary Fistulae
4. Presence of urinary tract infection.
5. Renal insufficiency

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6. Presence of any Neurological history and neurological findings

7. Patient with a history of anti-incontinence surgery

8. Pregnant female

9.Those who have not given consent

SURGICAL PROCEDURE

Patient in lithotomy position spinal anesthesia, Foley's catheter inserted. Transverse suprapubic incision --A graft of rectus fascia 8cm x 2cm was cut from rectus sheath and No.1- 0 prolene sutures were taken on both ends and it was dipped in solution of normal saline with 80 mg Gentamycin. Midline vertical incision was given on anterior vaginal wall and vaginal mucosa was separated from urethra and up to inferior pubic rami. At the abdominal end, space of Retzius was dissected,each side of bladder neck and urethra into dissected space on vagina avoiding injury to bladder and urethra and the two ends of rectus fascia sling with prolene threads were pulled up in the space of Retzius and the threads were then brought anterior to the rectus muscle and rectus sheath by perforating them and the prolene threads were tied anterior to the rectus sheath keeping a clamp underneath to avoid too tight knot after adjusting the rectus fascia sling in the mid urethra in the dissected space and ensuring that equal amount of tape went on each side. Another clamp was kept between urethra and the tape to avoid making it too tight . The vaginal mucosa was closed over the tape using 3-0 Vicryl suture.Abdomen was closed without tension after releasing rectus sheath and putting subcutaneous drain for 48 hrs. Foley's catheter was kept for 2 days. All women were given Inj. Piperacillintazobactam and Inj. Metronidazole for 48 hrs. In case of non- passage of urine, catheter was reinserted. Patients were discharged on 5th or 6th day after they passed urine of their own.

Assessment of resolution of Stress Incontinence

Subjective evaluation of continence:

• **Cured and dry -** Complete resolution of symptoms with no residual leakage under normal and abdominal stress situations.

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• **Improved** - Still, sometimes urine leak occurs on exertion but significantly less as compared to preoperative status.

• **Failed** - Complain of SUI same or more than previous to surgery.

Objective evaluation of continence

• ICS- uniform cough stress test

FOLLOW-UP

Follow-up was done at urology OPD after one month, three months and six months.An inquiry was made regarding any new urinary symptoms. If present, a detailed history was taken regarding the same. The graft site and vagina were examined for the status of healing and to rule out any surgical site infection.ICS-uniform cough stress test was performed. If no complaint of urinary leakage, then this is done only on the first follow-up visit and not repeated if found negative.

• Ultrasound-KUB was done, and PVR volume was measured. (If no complaint of urinary leakage, then this USG was done only after a 3month follow-up visit).

Factors studied • Clinical features and voiding dairy before and after surgery • Operating time • Post op urgency • Post of urinary retention • Post of voiding difficulty requiring CIC • Post of chronic pelvic pain • Post-op healing of graft harvesting site • Post of significant UTI • Post of success rate - women reporting being completely “dry” or “improved” at follow-up.

Results

In our study we have taken a sample size of 25 patients, most of them were of the age group of 46-50, around 8 were in age group of 41-45, 3 ppl were in age group of 51-55, 1 was in age group of 36-40. Out of the 25 patients none were nulliparous, 2 patients had one children while majority around 15 had 2 children and 7 had 3 children and 1 lady had 4 children. 6 ladies had attended their menopause, 9 were pre menopausal and 10 were peri menopausal.

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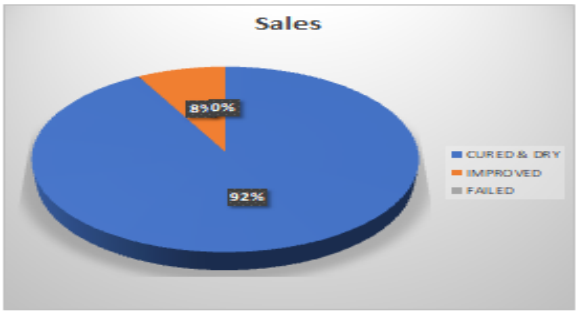
Most of the patients had their symptoms lasting less than 2 years , 10 had symptoms lasting 2 to 3 years and 1 patient had symptom lasting for 3 to 4 years and 1 had persisting more than 4 years.

The Stamey incontinence score (grade 0, continent; grade 1, loss of urine with sudden increase in abdominal pressure such as from coughing, sneezing, or laughing; grade 2, leaks with lesser degrees of physical stress such as walking, standing erect from a sitting position, or sitting up in bed; grade 3, total incontinence, urine is lost without any relation to physical activity or position) was checked to represent SUI severity in all enrolled patients. Table 1 shows the stamey incontinence score for our patients. 11 had score of 1, 14 patients had score of 2. None had total incontinence.

Post op outcome



Post op outcome Subjective continence	No of pts
Cured/dry	23
Improved	2
failed	0
total	25

TABLE 1 : POST OP OUTCOME

As can be seen from the above table out of the 25 patients taken for the study 23 were cured, with 2 patients showing improvement with incontinence score and subjective improvement. None of our patients had total incontinence or status quo after the surgery.

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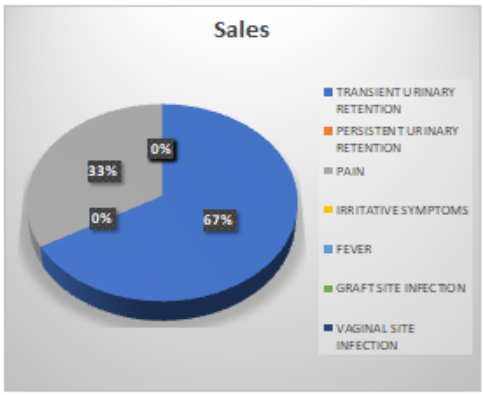
POST OP COMPLICATIONS



complications	NO OF PTS
Transient Urinary Retention	2
Persistent Urinary Retention	0
Pain	1
Irritative symptoms	0
Fever	0
Graft site infection	0
Vaginal site infection	0

TABLE 2 : POST OP COMPLICATIONS

As seen from the above table we had 2 patient who had transient urinary retention. There were no persistent urinary retention. 2 patients had pain post operatively which was managed with analgesics for short term. No patients reported any irritative symptoms post surgery. No patient had any post operative fever or graft site infection or any vaginal site infection.

Discussion

Our is a Prospective clinical study to report the outcomes and complications of autologous pubo vaginal slings. Our study included 25 patients, which was comparatively less than other studies like habb et al , morgan et al, khan et al. In our study, the mean age of the patients was 47 years, which was less but not much different from the mean age of patients in other studies, which was from a minimum of 52.3 years to a maximum of 65.7 years.[9,10,11,12]

Most of the studies used subjective assessment of continence like validated questionnaire and some also did objective evaluation by pad test or stress test. In our study, we did both subjective assessments by follow-up history of incontinence, bladder diary and objective assessment by ICI-USCT. [9,10,11,12]

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The cure rate was highest in our study compared to other above-mentioned studies, but this may be due to difference in inclusion and exclusion criteria and comparatively shorter follow-up in our study than the other studies. In other studies, the percentage of patients complaining of de-novo urgency or UUI after PVS varied from 0% to 10.8% which was 0% in our study which was followed till 6 months. [9,10,11,12]

In the above-mentioned studies, the percentage of patients who went into persistent urinary retention after PVS varied from 2.40% to 7.50%. In our study however only 2 patients went into transient urinary retention managed by per urethral foley catheter, and none of the patients went into persistent urinary retention. [9,10,11,12]

If we compare the outcomes of our study with retro pubic mid urethral slings(MUS) and transobturator(TOT) mid urethral slings we see that many of the studies have de novo urgency in rate of 5 % to 25% with the maxiumum rate of 26% in study conducted by urich at al,2016 and the minimum of 5.9% in study conducted by al-zahrani et al ,2016. Our study had 0% denovo urgency rate. 2 patients in our study had urinary retention, which was more than the other above-mentioned studies. But all these cases of urinary retention were transient in nature. There were no cases of persistent urinary retention. The outcome of autologous PVS in our study was non-inferior to all the above-mentioned studies on MUS for SUI[13,14,15,16]

Limitations

The study will be done in a limited number of subjects and for a shorter duration of follow up(6 months) . The results may vary if done in a large number of subjects.

Conclusion

Autologous PVS is a safe and effective treatment option for patients with stress urinary incontinence. Although direct comparison with other series was hindered by a difference in inclusion and exclusion criteria, our study outcome was non-inferior to the outcome of other published studies on PVS and MUS surgeries for SUI. Rectus fascia sling was free of cost while synthetic tape was expensive.

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We also observed that putting the rectus fascia sling at the level of mid urethra and putting a subcutaneous drain can reduce the complication rate.So in comparison to MUS using synthetic mesh and thus mesh-related complication, **autologous PVS seems to be a promising versatile option with no limitation on indications for use in the treatment of SUI**, with a similar outcome and no mesh-related complications.Thus autologous PVS is an age-old effective procedure for SUI in females, and it is imperative that we continue to educate our residents on the indications and surgical technique of the PVS.

ETHICAL JUSTIFICATION

This study involves clinical evaluation of the urinary incontinence patients and all patients diagnosed with it will be offered standard therapy to choose from. Patients who will opt for autologous PVS will be included in the study.Patients will be included in the study after an informed consent and will have the right to opt out of the study at any time without giving any reason.

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