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CLINICAL STUDY OF SURGICAL MODALITIES IN THE MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE-PROSPECTIVE STUDY

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ABSTRACT

AIMS OF THE STUDY: 1.To determine the efficacy of different surgical modalities that are performed in our institute for genuine stress incontinence namely 1.pubovaginal sling(PVS),2.tension free vaginal tape(TVT)3.transobturator tape (TOT)and to analyse the various clinical parameters that may influence their outcome.
2.To compare the results of our study with those of similar studies in literature.

METHODOLOGY: A total of 32 patients with symptoms of genuine stress incontinence between June 2014 and June 2017, who underwent 3 different surgical procedures are analysed for various outcomes. All the patients were initially evaluated by taking detailed history, physical examination, Stamey grading, pad test, uroflow, valsalva leak point pressure, cystoscopy and Bonney's test

RESULTS: Out of the 32 patients, 30 patients are cured of their symptoms and in 2patients , the symptoms improved. There is no failure rate. Of the 3 types of surgical procedures performed, there is 100% success rate (6 patients) for Pubovaginal sling (PVS), 92.8%(13 patients) for Tension-free vaginal tape (TVT) and 90% success rate for Transobturator tape(TOT) procedures. Complications are minimal and minor.

KEYWORDS : stress urinary incontinence, pubovaginal sling, tension free vaginal tape, transobturator tape

INTRODUCTION

Stress urinary incontinence (SUI) as defined by the international continence society is the involuntary leakage of urine on effort or exertion, or on sneezing or coughing. It has substantial impact on the quality of life for many women. Treatment includes initial conservative therapies and then surgery is an option for women whose quality of life is still impaired. Advances in surgical techniques have led to availability of a number of different procedures to treat SUI. The choice of sling material to use and the method of fixation are controversial.

An evolution in sling procedures has occurred , from bladder neck slings to slings located at mid urethral level. Urethral slings are currently the procedure of choice for the surgical correction of female stress urinary incontinence.

Historically , surgeons used the rectus fascia pubovaginal sling for complex SUI after a failed anti –incontinence operation. In addition , surgeons performed this operation extensively for treatment of primary intrinsic sphincter deficiency(ISD).

Despite originating as autologous procedure, many different types of materials have been used as sling substitutions, including various sources of autologous tissue, allograft tissue, xenograft tissue and synthetic material. Almost all these substitutions have been made in an attempt to limit patient morbidity by alleviating the additional morbidity created by the harvesting of the sling material.

Tension-free vaginal tape(TVT) is one of the minimally invasive devices invented, based on the suburethral sling theory. It is a logical extention of the ideology of supporting the vesicourethral junction at the sub urethral level in cases of SUI due to both urethral hypermobility and intrinsic sphincter deficiency. Synthetic mesh instead of biological material is used in the procedure.

Most important point about TVT is that, it is effective in both the types of SUI, i.e, urethral hypermobility and intrinsic sphinter deficiency.

Retropubic midurethral slings require blind passage of trocar through the retropubic space. Inadvertent bladder injury occurs in 3-5% of cases. Vascular and bowel injuries although very rare, were reported that result in significant morbidity and mortality. In the hope of avoiding these complications, Delorme designed the Transobturator technique for midurethral sling placement in 2001.

Transobturator tape(TOT) sling uses the basic concept of midurethral support with sling placed underneath the urethra. Resistance against the urethra is generated when intraabdominal pressure increases outlet resistance and prevents SUI.

METHODOLOGY

The study was a prospective randomized study to analyse the various outcomes of SUI managed, using pubovaginal slings using autologous grafts(rectus abdominis fascia ,fascia lata) TVT and TOT.

Our study population includes 32 patients with symptoms of genuine stress incontinence who attended the urology outpatient department, government general hospital between June 2014 and June 2017.

INCLUSION CRITERIA: All the patients with

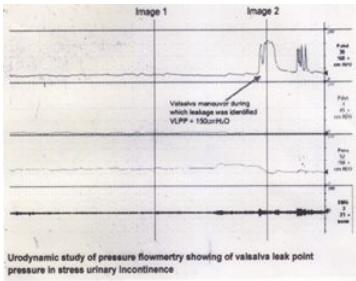
1. History of urine loss with physical exertion only(history and stress test)
2. Normal voiding habits (fewer than 8 episodes during daytime and fewer than 2 episodes during night time)
3. Pliable and compliant vaginal wall and adequate vaginal capacity on pelvic examination.
4. Normal postvoid residual volume, were included in the study

EXCLUSION CRITERIA:

The following patients were excluded from the study.Patients with

1. Uterine prolapse,cystocele,rectocele
2. urgency and urge incontinence
3. fistulae
4. UTI
5. renal insufficiency
6. neurological history and neurological findings
7. history of anti-incontinence or radical pelvic surgery
8. pregnancy

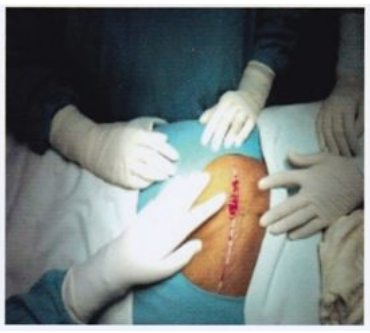
Initially, all patients were evaluated by using a proforma which includes detailed history, physical examination,stamy grading, pad test, uroflow, valsalva's leak point pressure(VLPP),cystoscopy and Bonney's test



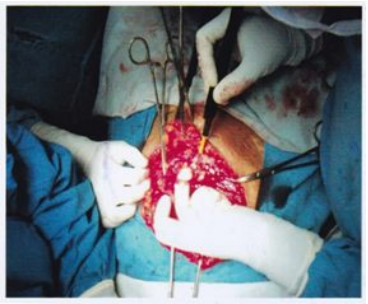
All patients were managed randomly for SUI using one of the procedures (PVS,TVT,TOT) under spinal anaesthesia . Mean followup was 12 months.

PUBO VAGINAL SLING PHOTOS

Abdominal incision



Rectus fascia harvesting



TVT PHOTOS

TOT PHOTOS
OUTSIDE-IN TECHNIQUE

RESOLUTION OF STRESS INCONTINENCE:

Cured and dry was defined as the complete resolution of symptoms with no residual leakage under normal and stress situations. Patients having incomplete resolution of symptoms were considered improved.

Followup for 12 months. Monthly for 3 months followed by at 6 months and 12 months postop.

Median cure/Dry or Improved Rate **subjective** -12 months median
Median cure/ Dry or Improved Rate **objective** -6 months median

Subjective assessment
Questionnaire

During the last 4 weeks. How much urine did you leak?
Never ……1
A little bit……..…..2
A moderate amount……...3
A lot……4
Constantly ……5

During the last 4 weeks ,how much urine did you leak?
I used no pads in my underwear….1
I used 1 pad per day……..……2
I used 2-3 pads per day……3
I used 4-5 pads per day……4
I used 7 or more pads per day……5

Objective assessment: physical examination and stress test
Voiding diary
Pad test

The results and postoprerative complications like pain , obstructive symptoms, bleeding and mesh related complications are tabulated in the form of master chart to analyse the results. These results are compared with other similar studies and certain conclusions are obtained .

Data is processed and analyzed using SPSS 16.0(Statistical Package for Social Sciences) software. The test statistics used to analyze the data are descriptive statistics, Chi –square test, and Student's t-Test. For all analytical tests ,the level of significance was set at 0.05 and $p<0.05$ was considered significant.

OBSERVATIONS AND RESULTS

In our series ,total number of patients studied were 32. Detailed analysis of parameters of these patients

TABLE 1 TYPE OF PROCEDURE AND NO. OF PATIENTS

PROCEDURE	NO. OF PATIENTS
Pubo vaginal sling	6
Tension free vaginal tape	14
Transobturator tape	12

TABLE 2 AGE GROUP

AGE(Yrs)	No. of patients	%
30-35	2	6.25
36-40	5	15.625
41-45	14	43.75
46-50	8	28.125
51-55	4	12.5

Out of 32 patients, 14 patients in our study fall in 41-45 yrs age group, 8 patients are between 46-50 age , 5 patients are between 36-40 yrs,4 patients are between 51-55 yrs, 2 patients are between 30-35 yrs, with mean age of 45.65 yrs.

TABLE 3 STAMEY Grading

GRADING	NO. OF PATIENTS	%
0	0	0%
1	16	50%
2	16	50%
3	0	0%

In our study, 50% of patients had Grade 1 and 50% had Grade 2 SUI.

TABLE 4 PAD TEST-Pre op

Weight of the pad in grams	No.	%
2-3	10	31.25
3.1-5	20	62.5
5.1-6	4	12.5
>6	2	6.25

In our study, 20 patients had a pad test weighing between 3.1-5 gm , 10 patients between 2-3 gm, 4 patients between 5.1-6 and 2 patients with pad weight more than 6 gm.

TABLE 5 VLPP

PRESSURE (cm of H2O	No. of patients	%
>120	0	0
80-120	18	56.25
60-80	14	43.75
<60	0	0

In our study, 43.75% of patients had 60-80 cms of H2O and 56.25% had 80-120 cms of VLPP.

TABLE 6 : Preoperative characteristics of patients who underwent pubovaginal sling, Tension free vaginal tape and Transobturator tape

Characteristics	PVS	TVT	TOT
Age (mean±SD)	44.5± 1.95	45.2± 1.89	46.5±2.10
SUI grading(mean±SD)	1.6±0.5	1.5±0.7	1.5±0.7
VLPP(mean±SD)	92.2± 10.1	92.1± 8.29	92.0±9.46
Pad test(mean±SD)	5.2±0.9	4.7±1.1	4.8±1.0

Outcome results

TABLE 7 :CONTINENCE

7A.Subjective

	No of patients	%
Total	32	100
Cured	30	93.75
Improved	2	6.25

Majority of patients in our study(93.75%) were cured for SUI managed by PVS and mid urethral slings and 6.25% of patients were improved of symptoms . No failures were noted.

7B. TYPE OF PROCEDURE AND RESULT

	PVS	TVT	TOT
Cured/Dry	6(100%)	13(92.8%)	9(90%)
Improved	--	1(7.14%)	1(10%)
Failed	--	--	--

TABLE 8 :Pad test (post op)

No. of pads (weight in grams)	No. of patients	%
0/dry	30	93.75
<1gm	2	6.25

Maximum number of patients were pad free. Few patients used < 1pad/day.

TABLE 9:POST OP COMPLICATIONS

COMPLICATION	NO. OF PATIENTS	%
Total no.	5	15.65
Presented with retention	2	6.25
Irritative symptoms	3	9.4
Major bleeding	Nil	--
Infection	Nil	--
Mesh extrusion/erosion	Nil	--
Bladder injury	Nil	--
Mortality	Nil	--

Only 15.65% of patients presented with postop complications , those were retention of urine and irritative voiding symptoms.

TABLE 10:Type of procedure and complication

TYPE OF COMPLICATION	PROCEDURE DONE	NO. OF PATIENTS
Irritative voiding symptoms	PVS	1
	TVT	2
Retention of urine	TVT	2

SUMMARY:
Out of 32 patients , 30 patients were cured of their symptoms and 2 patients were improved of their symptoms . 5 patients developed complications. 2 patients developed acute urinary retention , which were managed by perurethral Foley's catheterization which was normalized on 5th postoperative day after removal of catheter.

Three patients complained of irritative voiding symptoms of urgency and frequency whose urine culture was sterile and urine microscopy was unremarkable, they were managed by anticholinergics for 5 days, symptoms were improved.

DISCUSSION

Stress urinary incontinence(SUI) is a condition that affects the psychosocial welfare, interpersonal relationships, quality of life, productivity and general health of affected women. It is one of the common diseases in middleaged women(1)

Despite the significant prevalence, due to invasive nature and associated significantly prolonged recovery from surgery, many women did not undergo surgical treatment. Since the introduction of tension free mid urethral sling procedures(MUS), there remained only few indications for combined transabdominal and transvaginal placement of pubovaginal slings at the bladder neck. It has been suggested that only autologous fascia has longterm results(21,22), but no reliable, long term, prospective trials, have judged the success rate of traditional pubovaginal slings(23).

Table 11: Comparison of our study on pubovaginal slings with studies in literature

TABLE 11A

Study	Follow-up	Cured /improved/failed
Albo et al,2007	24 months	66%success 34% improved
Mitsui et al,2007	25 months (5-91)	80%cured 10% improved 10% failed
Onur et al,2008	18 months(5-28)	84% cured/improved
Present study	14 months(6-24)	100% cured

TABLE 11B

Study	No. of patients	Age	Pure SUI
Albo et al,2007	326	51.6±10.1	247(76%)
Mitsui et al,2007	29	64(43-79)	6(21%)
Onur et al,2008	25	57(39-85)	NA
Present study	6	46(37-50)	100%

TABLE 11C

Study	Assesment of outcome	urgency or UUI	Persistent urinary retention
Albo et al,2007	Padtest,cough test,voiding diary	3%	6%
Mitsui et al,2007	Questionnaire,subjective, UDS	1	8(26%)
Onur et al,2008	Questionaaire	2	0
Present study	Questionnaire, pad test, cough stress test	1	0

In a study by Onur et al,2008 where 25 patients underwent rectus fascia pubovaginal sling surgery for stress urinary incontinence 80% of patients were labelled as cured, and 10% of patients as improved , and 10% of patients as failed based upon postoperative questionnaire. In our study all 6 patients were labelled as 100% cured based upon post operative questionnaire and objective assessment (P value 0.0006,which is significant at P<0.05)

In a study by Albo et al 2007(24) where 326 patients underwent rectus fascia pubovaginal sling surgery for SUI with a success rate of 66% and a mean followup of 24 months, 6% of patients had postoperative persistent urinary retention. In our study of 6 patients there were no cases of postoperative urinary retention (Pvalue=0.57 which is not significant at P<0.05)

In a study by Mitsui et al 2007 where 29 patients were managed by rectus fascia pubo vaginal sling with a mean follow up of 64 months. 1 patient had denovo urinary urgency and urge urinary incontinence(UUI), postoperatively. In our study we had 1 patient with postoperative UUI(P value =0.20 which is not significant at P<0.05)

We performed pubovaginal sling surgery in only 6 patients and assessed the outcome and postoperative compliations .The sample size being small we could only get significant results in terms of patient outcome (100% cure rates). In terms of post operative complications our results were statistically not significant.

The TVT sling introduced by Ulmsten et al.(25) in 1996 has gained widespread popularity supported by long-term prospective data. Delorme (16) in 2001 then described the TOT procedure, which involved the tension free insertion of a polypropylene tape via a tunneler in a horizontal plane under the midurethra between the two obturator foramina in an outside-in orientation. A variation to this technique has been described in 2003 by de Leval in intrinsic sphincter deficiency(26) termed the TOT vaginal tape inside out technique which directs the needles in the opposite orientation.

These mid urethral slings have grown in acceptance and popularity to gain a leading position in SUI surgery .It became the new gold standard for the surgical treatment of SUI, not only because of their simplicity for both surgeon and patient, but also because of excellent surgical outcomes and low morbidity.

The transobturator slings appear to have reproducible short term continence results similar to those seen with the TVT procedure , yet seemingly less voiding dysfunction.

Midurethral slings appear to mimic the suprapubic approach by stabilizing the midurethra, recapitulating the "hammock"support or U support that is thought to be responsible for continence.

TABLE 12: Comparison of cure rates between TVT in our study and studies in literature

STUDY	NO. OF PATIENTS	FOLLOW-UP	CURE RATES
Ward and Hilton,2002	175	6months	66%
Ward and Hilton,2004	175	24 months	63%
Ward and Hilton,2008	175	5months	75%
Present study	14	12months	92.8%

In 3 different studies conducted by Ward and Hilton(27) they studied the clinical outcomes of 175 patients in each study managed by TVT. They noticed a cure rate of 66%at a mean followup of 6 months in first group, 63% at a mean followup of 24 months in second group , 75% at a mean followup of 5months in third group. In our study which comprised of 14 patients with SUI managed by TVT we noticed a cure rate of 92.8% at a mean follow up of 12 months. (p=0.012, which is statistically significant at p<0.05).

TABLE 13: Comparison of complications in patients who underwent TVT between our study and studies done in literature

STUDY	NO. OF PATIE-NTS	BLADDER INJURY	URGE INCONTINE-NCE	VOIDING DIFFICULTY
Aboussaly et al,2004	241	5.8%	0.4%	19.7%
Tamussino et al,2001	2795	2.7%	Not reported	Not reported
Doo et al,2006	134	3.7%	3.8%	8.2%
Present study	14	0%	14.2%	14.2%

In a study by Aboussaly et al ,2004(26) which was done on 241 patients with SUI managed by TVT, they reported complication rates of 5.8% bladder injuries, 0.4% urge incontinence and 19.7% of voiding difficulty.

In our study which was done on 14 patients we noticed 14.2% of urge incontinence and 14.2 %of voiding dysfunction.

TABLE 14: Comparison of our study on TOT with studies in literature

TABLE 14 A

STUDY	NO.	FOLLOW-UP	CURED/IMPROVED /FAILED
Delorme et al,2003	15	17 months	90.6% 9.4% 0%
De tayrac	30	12 months	90%3.3%6.7%
Neuman ,2007	30	15 months(4-24)	97.3% cure 2.7% improved
Present study	12	12 months	90% cure 10% improved

TABLE 14B

STUDY	ASSESSME-NT OF OUTCOME	PATIENT'S AGE	COMPLI-CATIONS
Delorme et al,2003	Cough stress test, uroflow	64(50-81)	None reported
De tayrac	Cough stress test, Questionna-ire	54.7	6 uncomplicated UTI, 1 obturator hematoma
Neuman ,2007	Questionnaire	55(29-83)	0.7%vaginal erosion, 1.3%dyspareunia
Present study	Questionnaire	43(34-53)	None

In a study done by Delorme et al,(16) 15 patients underwent SUI management by TOT there were no complications reported in his study. In our study carried on 12 patients, there were no complications when SUI was managed by TOT.

De Tayrac et al in their study which was done on 30 patients, they reported a complete cure from SUI in 90% , and improvement of symptoms in 3.3% of patients, and failure in 6.7%.

Outcomes were assessed by de Tayracet al based on questionnaire and cough stress test, our study was also based upon questionnaire and cough stress test to assess the post operative outcome .

In our study which was carried on 12 patients we noticed 90% cure rate, and improvement in 10% of patients, there were no failures in our study.

CONCLUSIONS

- Considering the findings of the study, we can conclude that SUI can be effectively managed by Pubovaginal sling using rectus fascia and by midurethral sling using Tension free vaginal tape and Transobturator tape.
- These methods may be used in all cases of SUI.
- Traditional autologous pubovaginal slings (PVS) have re-emerged as a viable alternative to synthetic slings in light of the issues with synthetic slings.
- In this contemporary cohort of women considered suitable candidates for either a PVS or an MUS, both the procedures have comparable efficacy and complication rates.PVS may be safely offered to patients who would otherwise be good candidates for MUS if they are concerned with the implantation of mesh.
- The re-adoption of autologous PVS has however ,been slow due to the technical difficulty of the surgery and perceived higher morbidity rates.
- The concept of the midurethral sling has revolutionized surgical treatment of SUI.Its minimally invasive approach and success rates have led to an increasing acceptance of the technique.
- While TVT have proven to have longterm efficacy, their introduction via a retropubic route has been associated with a number of perioperative or postoperative complications resulting from penetration of the tape or supporting needle in to the bladder, urethra, bowel,nerves and vessels.
- In short term followup, TOT appears to be as effective as TVT, shorter operating time than TVT and has fewer complicati ons. TOT is safe and effective in women with SUI.
- Longterm followup is necessary prospectively to further evaluate these procedures.

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