

SAFETY AND EFFICACY OF RETROPUBIC MID-URETHRAL SLING IN FEMALE STRESS URINARY INCONTINENCE**Gopalam Padmaja Rani¹, Vijayabhaskar Reddy Gouru², Surya Prakash Vaddi³, Supraja Gundala⁴, Gugulothu Anusha⁵**Received : 10/05/2024
Received in revised form : 03/07/2024
Accepted : 19/07/2024

Keywords: stress urinary incontinence, retropubic mid-urethral sling, tension free vaginal tape

Corresponding Author:
Dr. Gopalam Padmaja Rani,
Email: padmajarani064@gmail.com

DOI: 10.47009/jamp.2024.6.4.54

Source of Support: Nil,
Conflict of Interest: None declaredInt J Acad Med Pharm
2024; 6 (4); 262-267^{1,4,5}Department of General Surgery, Sri Venkateswara Medical College, Tirupathi, India.²Department of Urology, Sri Venkateswara Medical College, Tirupathi, India.³Department of Urology, Narayana Medical College, Nellore, India.**Abstract**

Background: The Aim was to study prospectively the safety and efficacy of retropubic mid-urethral slings in female patients with stress urinary incontinence using local slings and to study complications (early and late). **Materials and Methods:** This is a prospective observational study of women requiring surgical treatment for stress urinary incontinence. 25 female patients with SUI attending Narayana General Hospital, Nellore were enrolled in the study. The period of study was from May 2010 to April 2012. **Results:** Retropubic mid-urethral sling surgery is a safe and effective procedure in female patients with stress urinary incontinence. The use of a locally made sling with reusable trocar needles (Centilene mesh sling of Centenial surgical sutures Ltd; Thane, India) reduced the cost of the procedure. Results were similar with the usage of local slings, in comparison to literature using standard imported slings. **Conclusion:** We conclude that the retropubic mid-urethral sling procedure with a locally made sling is both a safe and effective method for the treatment of female Stress urinary incontinence.

INTRODUCTION

Stress urinary incontinence is a significant health problem worldwide with considerable social and economic impact on individuals and society. It also has an important negative impact on the quality of life and social, physical, psychological, occupational, and sexual aspects of the patient's life¹. Stress urinary incontinence is defined as involuntary leakage of urine on effort like exertion, sneezing, or coughing². Urinary incontinence is more prevalent in women than men, making gender itself a risk factor³. Advancing age, high parity, vaginal deliveries, obesity and menopause are associated with increased risk of urinary incontinence. In all age groups with incontinence, stress incontinence is most common (49%) followed by mixed incontinence (29%) and pure urge incontinence (21%). SUI is categorized into three grades. Grade I: Urine leak with rise in intraabdominal pressure like cough or sneeze. Grade II: Urine leak with mild exercise like walking, or climbing steps. Grade III: Urine leak even with change of posture.

Among all the surgical procedures for treating SUI, the mid-urethral slings provide patients with a less invasive and safe therapeutic option compared to traditional sling and Burch procedures without compromising efficacy. The concept of the mid-

urethral sling was first introduced by "Ulmsten" in 1996 as the tension-free vaginal tape (TVT) procedure and it has become one of the predominant surgical procedures for treating SUI⁴. The results of TVT implantation are very encouraging, with cure rates of more than 80% being reported in all studies, with minimal morbidity and a quick postoperative recovery. Retropubic mid-urethral slings made of synthetic polypropylene mesh are placed at the level of mid-urethra via a minimal vaginal incision in a tension-free manner by a retropubic approach. The mid urethral sling can also be placed by trans-obturator approach avoiding entry into retropubic space, and the results of this procedure are similar to the retropubic approach. However, accumulated experience has demonstrated that significant complications are possible with both techniques and long-term outcome data are pending with the trans-obturator approach⁵. Thus the best sling procedure is the one, that works best in the hands of the individual surgeon, based upon accumulated experience and familiarity with anatomy such that complications can be avoided. In this study, we report our experience with 25 consecutive women with stress urinary incontinence treated with a retropubic mid-urethral sling. We concentrated on doing the procedure with minimum cost using locally made sling (Centilene mesh sling, Centenial Surgical Suture Ltd, Thane,

India) with less hospital stay and with satisfactory continence rates.

Aims & Objectives

1. To study the clinical pattern and presentation of female patients with stress urinary incontinence.
2. To assess the risk factors of age, BMI, obstetric history, prior pelvic surgeries, and co-morbid conditions like chronic cough, constipation, and diabetes mellitus predisposing to stress urinary incontinence.
3. To study prospectively the safety and efficacy of retro pubic mid-urethral sling surgery using locally made sling and to study the complications (early and late).

MATERIALS AND METHODS

This was a prospective observational study of women requiring surgical treatment for urinary stress incontinence. 25 female patients with SUI who attended Narayana General Hospital, Nellore were enrolled in the study. The period of study was from May 2010 to April 2012. The age group ranged from 30-70 years with a mean age of 43 years. All grades of SUI, diagnosed clinically were considered. Preoperative urodynamic evaluation was done in selective patients. In all the 25 female patients, various risk factors for stress incontinence like age, obesity, parity, and route of delivery were studied.

Inclusion Criteria

1. Females with self-reported stress urinary incontinence symptoms of duration > 3 months.
2. Observation of leakage by cough and Valsalva stress test at a bladder volume < 300 ml.

Exclusion Criteria

1. Patients with pure urge incontinence.
2. Patients with significant genitourinary prolapse.
3. Pregnancy
4. Current chemotherapy or h/o pelvic irradiation therapy.
5. Systemic diseases known to affect bladder function like Parkinson's, Multiple sclerosis, and Spinal cord injury.
6. Prior augmentation cystoplasty.

The patients in the proposed study were subjected to

1. Detailed history
2. Thorough physical examination including pelvic examination.
3. Urine analysis and haematological investigations like haemoglobin, blood sugar and serum creatinine estimation.
4. Radiological investigations like USG abdomen and PVR urine volume.
5. Cystoscopy and in selected patients, urodynamic studies were done.

All the patients were treated with Retropubic mid-urethral sling placement and followed from 6 months to 24 months

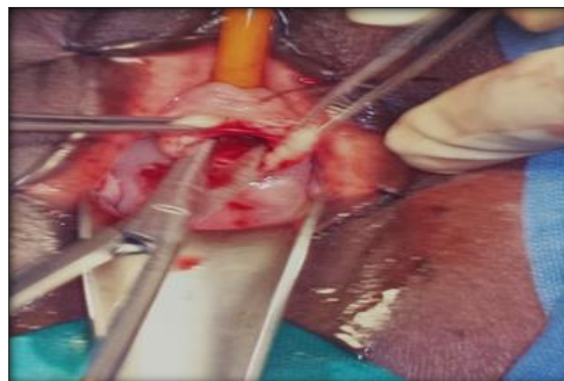


Figure 1: Sharp dissection of para urethral spaces



Figure 2: Trocar being passed retropublically into paraurethral space

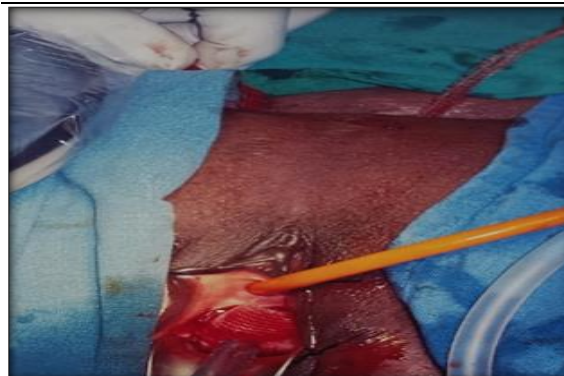


Figure 3: Polypropylene mesh retrieved through suprapubic incisions and placed around mid-urethra



Figure 4: Centelene mesh placed around mid-urethra as tension-free

We studied the operative time, intra-operative and postoperative complications, fit for discharge time from the hospital and outcome of the surgery. All the details were noted in proforma case sheets.

RESULTS

From May 2010 to April 2012, 25 patients were diagnosed to be suffering from stress urinary incontinence and treated with Retropubic mid-urethral sling surgery, were evaluated.

Incidence in different age groups: The incidence of SUI is high in the 41-50 years age group. The lowest age is 24 years, the maximum age is 66 years and the mean age is 43 years. In our study we had an equal number of 5 patients in the 20-30, 31-40, and 51-60 age groups, suggesting the difficult vaginal route of deliveries and multiparity as risk factors even at a young age.

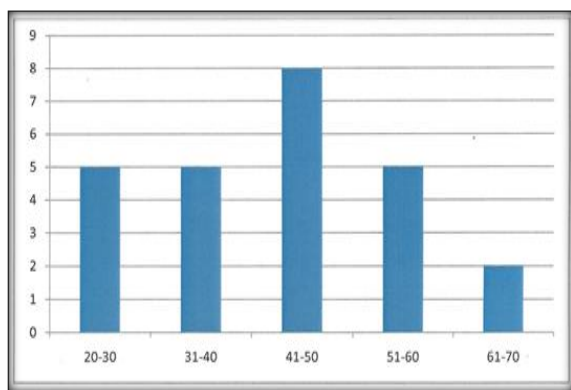


Figure 5: Incidence in different age groups in our study

Incidence according to BMI

In 3 patients BMI was between 18-25, in 11 patients between 25-30 and in 10 patients BMI was more than 30. Mean BMI of the study group is 29.84.

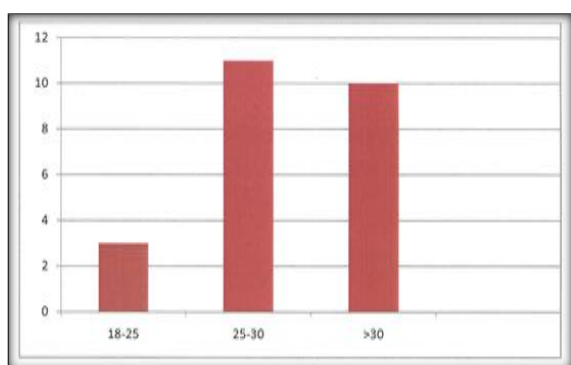


Figure 6: Incidence according to BMI

Incidence according to the route of delivery

Out of 25 patients, 20 were multiparous with 2 or more deliveries. In our study, 23 out of 25 patients (92%) delivered normally and in 4 patients, there was a clear history of obstructed labour. Only 2 patients underwent Caesarean section.

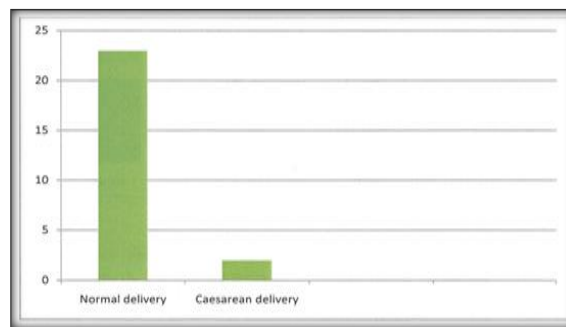


Figure 7: Incidence according to route of delivery

Of 25 patients, 4 patients were with grade 1 SUI, 10 patients were with grade II SUI and 11 patients were with grade III SUI.

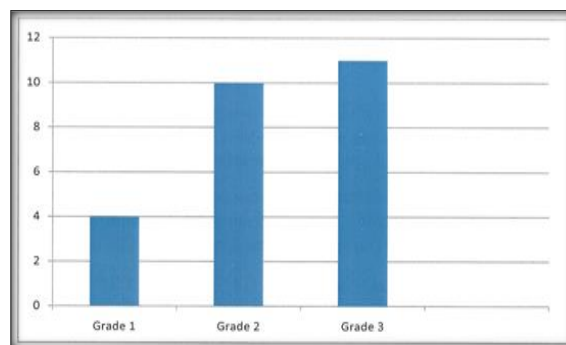


Figure 8: Incidence according to grade of incontinence

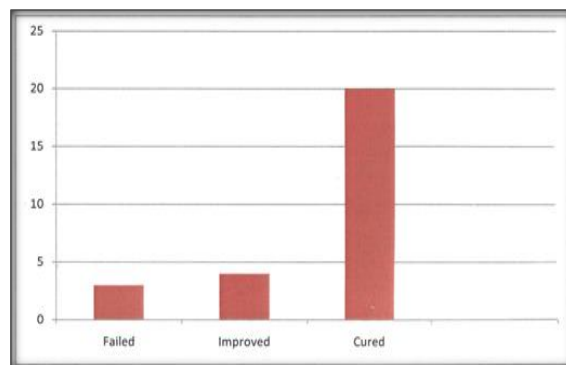


Figure 9: Outcome after a mean follow-up of 15.88 months

All patients received a retropubic mid-urethral sling with Centilene (polypropylene) mesh. 82% of patients were fit for discharge on the next day of surgery. One patient underwent Burch colposuspension for the same stress incontinence problem 1 year prior, but it was a failure and now she is cured with RPMUS. There were no major complications and 80% of patients had no complications at all. In 2 patients (8%) intra-operational bladder perforation with trocar needles occurred, which was recognized by intraoperative cystoscopy. In both patients, needles were retrieved and passed again. 3 patients (12%) had post-operative voiding difficulty. Out of them, after the adjustment of the sling, 2 patients voided & uneventful thereafter, but 1 patient didn't void and was again

catheterized & lost for follow-up. 4(16%) patients had urge component along with stress incontinence, which was cured in 3 (12%) patients. The remaining 1 (4%) patient along with 1(4%) more patient who developed de-novo urge symptoms were kept on anticholinergics. One patient (4%) developed postoperative UTI. One patient (4%) had a poor stream postoperatively for which urethral dilatation was done and she was uneventful thereafter. 1 patient (4%) had suprapubic hematoma which resolved

spontaneously. None of the patients needed a blood transfusion. In our study, none of the patients developed urethral mesh erosions but 2 patients (8%) developed vaginal mesh erosion. In one patient the vaginal erosion was asymptomatic. No patient had wound infection. With a mean follow-up period of 15.88 months (max follow-up time-24 months and min follow-up time of 6 months), 88% of treated patients were completely cured (72%) or significantly improved (16%).

Table 1: Correlation between grade of SUI & risk factors

GRADE OF SUI	I	II	III
NO OF PATIENTS	4	10	11
MEAN AGE	45.17	42.34	43.25
MEAN PARITY	2	3	3
BMI	23.34	27.62	28.13

Table 2: Correlation between grade of SUI & Complications

GRADE OF SUI	I	II	III
POSTOP URINARY RETENTION	0	1	2
MESH EROSION	0	0	2
RECURRENCE	0	0	0

Table 3: Correlation between grade of SUI & outcome

GRADE OF SUI	I	II	III
CURED	6	8	4
SIGNIFICANTLY IMPROVED	2	2	0
FAILED	0	1	2

DISCUSSION

In developing countries like India, women do not complain about their urine leakage symptoms to the doctor, due to embarrassment. They used to live with this condition for years. The majority of women with SUI consult a doctor only when the problem is severe and/or causing discomfort to family members. The peak age of incidence in our study was in 40-50 years age group and found to be on par with contemporary studies like Ulmsten et al in which their mean age was 57 years. Obesity has often been invoked as a risk factor for urinary incontinence. Evidence suggests that the prevalence of both urge and stress incontinence increases proportionately to a rising BMI. In Our study mean BMI was 29.84 proving the association of increased BMI with female SUI. Subak and co-workers showed that in overweight women randomly assigned to a weight reduction program, weight loss reduced the number of stress and urge incontinence episodes.¹

Both parity and mode of delivery, particularly vaginal delivery and obstructed labour have been implicated as a risk factor for the development of incontinence. According to Moran PA7 et al, the study of 40 patients with SUI who received TVT, the mean age of the women was 51.1 years. the mean parity was 2, the mean BMI was 25. Epidemiological studies showed an increased risk of SUI among women who had vaginal delivery compared to caesarean section. In our study 20 out of 25 patients (80%) were multiparous and 23 (92%) were delivered vaginally thereby suggesting the relationship of

multiparity and vaginal route of delivery with female SUI. Data suggest that pregnancy and delivery contribute to pelvic floor injury due to compression, stretching, nerve injury, muscle tear, and connective tissue disruption⁹.

Midurethral slings have grown in acceptance and popularity to gain a foremost position in SUI surgery¹⁰. Numerous studies provide a large amount of Level 1 and Level 2 evidence that supports the concept of a sling placed at the mid-urethra. Long-term follow-up studies have been published for the original TVT procedure, with the most recent publication providing level 2 evidence with a mean follow-up of 11.5 years. There was an objective cure rate of 90% & 77% of subjective cure.

The proposed mechanism by which the TVT procedure restores continence revolves around the theory that in stress incontinence, there is inadequate urethral support from deficient pubourethrovaginal ligaments and the suburethral vaginal wall. The TVT procedure is thought to correct this defect and create a new mid-urethral suspension continence mechanism, which creates a dynamic urethral resistance under stress but causes no disturbance to urethral function at rest.

In Ulmsten et al,¹¹ the study of 3 year follow-up of TVT, 86% of treated patients were completely cured and 11% were significantly improved. In Rezapour M et al,⁶ the study of TVT in mixed incontinence patients, 85% were completely cured and 4% were significantly improved and in 11% the operation failed. In the present study with a mean follow-up of 15.88 months, we found cure rates of 88%

(completely cured in 72%, significantly improved in 16% of treated patients) and failed in 12% of patients, suggesting the efficacy of RPMUS. Our cure rates were comparable to standard studies in the literature. Moreover, the results of this study were approximately equivalent to the best results reported using other techniques such as the Burch operation, which is a more invasive procedure. So Retropubic midurethral sling surgery can be used for the treatment of female stress urinary incontinence and mixed urinary incontinence.

The other advantages of the technique are: the short duration of the procedure and the procedure is done under regional anaesthesia. Our mean operating time was 31.96 minutes in our present study, comparable to the mean operating time of 29 minutes in the Ulmsten et al study. Patients were fit for discharge on the first postoperative day without a Foley catheter. The sling used in our study (Centilene sling, Centinel surgical sutures Ltd, Thane, India), was cost-effective compared to the marketed TVT slings. As the trocars were reusable after sterilization, the cost of the procedure was further reduced. The most encouraging finding was that there was no defective healing or rejection of the tape even with a local sling. The introduction of 5 mm diameter trocar needles is relatively blind and no visual control is possible for the retropubic part of the introduction. This is a possible risk factor for complications such as vascular, neurogenic, urethral, bladder, or gastrointestinal tract injury.

We have not encountered any major vascular complications except suprapubic hematoma in 1 patient, which resolved spontaneously. Primicero et al,¹² reported hemorrhage from the external iliac vein in a patient with TVT which had to be repaired through laparotomy. Abouassaly et al¹³ reported major bleeding of 500 ml in 16 women (2.5%) (16/421) with TVT. Kristensen et al¹⁴ in a study of 778 patients with TVT, reported hemorrhage that needed a transfusion in 5 patients (0.6%). The intraoperative complications of the TVT procedure were mainly associated with the risk of bladder perforation. We had bladder perforations with TVT During the first year of follow-up, Rajendra et al,¹⁸ reported vaginal erosion in 2.4% (10/419). Ortega et al,¹⁹ reported 1 case of erosion/extrusion of the mesh towards the urethra, the mesh was resected transvaginally with a good outcome. We thought that we may overcome the problem of mesh erosion by proper dissection of tissues, by keeping proper vaginal flaps, and by placing the mesh without twists. On analysing the data and on follow-up of patients, we found satisfactory outcomes with retropubic mid-urethral slings. The primary outcome measures are the

needles in 8%, which were detected intraoperatively with cystoscopy, and needles were retrieved immediately and passed again sparing the bladder. This is comparable with Meschia et al,¹⁵ studies of 440 women with SUI who received RPMUS and had uneventful bladder perforations of 6%. Kristensen et al¹⁴ in a study, reported a 6.6% of bladder perforation rate in 778 patients. Lee et al,¹⁶ also reported a bladder perforation rate of 6.4%. We had postoperative voiding difficulty of 12% which is comparable with other studies. Abouassaly et al,¹³ reported urinary retention (>24 hours later) in 47 patients (19.7%). Of the 40 patients, retention was managed with clean intermittent catheterization. To resolve retention in 7 patients, the mesh had to be released and in 3 patients the mesh had to be cut. Kristensen et al¹⁴ reported difficulty in voiding in 56% and 16.6% had urinary retention. They concluded that patients who had voiding dysfunction before surgery had a risk of presenting with urinary retention post-surgery. Lee et al¹⁶ reported that out of 10 patients with TVT surgery, 7.1% had urinary retention after surgery.

In our study, 4 patients had urge component along with stress incontinence preoperatively, which was cured in 3 patients (75%), one patient (25%) was put on anticholinergics along with one more patient who developed de novo urge incontinence. Abouassaly et al¹³ reported de novo urgency in 36 patients (15%), Sabadell et al reported that 23 patients failed to TOT and a TVT was placed in a second surgery; de novo urgency occurred in 5 cases (21.7%) and it was treated with oral anticholinergics with a good clinical response. We did not encounter urethral mesh erosions but 2 patients had vaginal mesh erosions. One patient is asymptomatic and found only during follow-up examination and in the other patient, the partner found difficulty during intercourse due to mesh erosion. Abouassaly et al,¹³ reported one patient with mesh erosion intravaginally (0.4%) (1/241). Andonian et al¹⁷ reported a single case of erosion in the SPARC group (1/41) and none in the TVT group (0/43).

resolution of stress urinary incontinence based on subjective and objective assessments.

Retropubic mid-urethral sling surgery using a locally made sling (Centilene sling) for our female patients with stress incontinence was found to be effective with low morbidity and satisfactory cure rates. It was associated with shorter operating time, short hospital stays, and early recovery when compared to invasive abdominal procedures, leading to less cost. The use of local slings, with reusable trocars which cost about Rs.2000/- in comparison to imported slings which cost about Rs. 15000/- further reduced the cost.

Table 4: Complications after RPMUS in our study in comparison with other studies

Author	N	Bladder perforations (%)	Postopvoiding difficult	Post purge (%)	Vascular injuries (%)	Urethral erosion (%)	Vaginal erosion (%)	Postop infection (%)	Nerve damage (%)
Huang et al ²⁰	106	2	11	10	-	-	-	-	-

Azam et al ²¹	67	19	5	-	-	-	-	-	-
Neuman et al ²²	75	8	-	-	4(intra op)	-	-	2.7	-
Karram et al ²³	350	4.9	4.9	-	0.9 (major bleed)	0.9	10.9	0.9	1.7
Present Study	25	8	12	4	-	-	8	4	-

CONCLUSION

Stress urinary incontinence is the most common form of urinary incontinence in women, reducing their quality of life. SUI is found to be more common in the perimenopausal age group, multiparous with the vaginal route of deliveries, and in patients with increased BMI.

Retropubic mid-urethral sling surgery is a safe and effective procedure in female patients with stress urinary incontinence. The use of a locally made sling with reusable trocar needles (Centilene mesh sling of Centennial surgical sutures Ltd; Thane, India) reduced the cost of the procedure. Results were similar with the usage of local slings, in comparison to literature using standard imported slings.

We conclude that the retropubic mid-urethral sling procedure with a locally made sling is both a safe and effective method for the treatment of female Stress urinary incontinence.

REFERENCES

- Serati M, Salvatore S, Uccella S, Artibani W, Novara G, Cardozo L, Bolis P (2009) Surgical treatment for female stress urinary incontinence: what is the gold-standard procedure? *Int Urogynecol J* 20:619-621.
- Coyne KS, Zhou Z, Thompson C, Versi E (2003) The impact on health-related quality of life of stress, urge and mixed urinary incontinence. *BJU Int* 92:731-735.
- MacLennan AH, Taylor AW, Wilson DH, Wilson D. The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery. *BJOG* 2000; 107: 1460-70.
- Ulmsten U, Henriksson L, Johnson P, Varhos G: An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol* 7: 81, 1996.
- Rezapour M, Ulmsten U. Tension-free vaginal tape (TVT) in women with recurrent stress urinary incontinence-a long-term follow-up. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;12 (Suppl 2): S9-S11.
- Rezapour M, Ulmsten U. Tension free vaginal tape (TVT) in women with mixed urinary incontinence-a long-term follow-up. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;12 Suppl 2: S15-12. 15.
- Moran PA, Ward KL, Johnson D, Simirni WE, Hilton P, Bibby J. Tension-free vaginal tape for primary genuine stress incontinence: a two-centre follow-up study. *BJU Int* 2000; 86:39-42.
- Petros PE, Ulmsten UI. An integral theory of female urinary incontinence. Experimental and clinical considerations. *Acta Obstet Gynecol scand Suppl* 1990; 153: 7-31.
- Ashton-Miller JA, Howard D, Delancey JO (2001) The functional anatomy of the female pelvic floor and stress continence control system. *Scand J Urol Nephrol* 207(Suppl):1-7.
- Fong ED, Nitti VW (2010) Review article: mid-urethral synthetic slings for female stress urinary incontinence. *BJU Int* 106:596-608.
- Ulmsten U, Johnson P, Rezapour M. A three-year follow-up of tension-free vaginal tape for surgical treatment of female stress urinary incontinence. *BrJ Obstet Gynaecol* 1999; 106:345-50.
- Primicerio M, De Matteis G, Montanino OM, Marceca M, Alessandrini A, et al (1999) Use of the TUT (Tension-free Vaginal Tape) in the treatment of female urinary stress incontinence. Preliminary results. *Minerva Ginecol* 51(9):355-8.
- Abouassaly R, Steinberg JR, Lemieux M, Marois C, Gilchrist LI, et al, (2004) Complications of tension-free vaginal tape surgery: a multi-institutional review. *BJU Int*. 94(1):110-3.
- Kristensen I, Eldoma M, Williamson T, Wood S, Mainprize T, (2010). Complications of the tension-free vaginal tape procedure for stress urinary incontinence. *Int Urogynecol J*. 21(11):1353-7.
- M. Meschia, P. Pifarotti, F. Bernasconi, E. Guercio, M. Maffioli, F. Magatti, L. Spreafico Tension-Free Vaginal Tape: Analysis of Outcomes and Complications in 404 Stress Incontinent Women *International Urogynecology Journal* June 2001, Volume 12, Issue 2 Supplement, pp S24-S27.
- Lee JH, Cho MC, Oh SJ, et al, Long term outcome of the Tension free vaginal tape procedure in female urinary incontinence: a 6-yr follow-up. *Korean J Urol* 2010; 51: 409-15.
- Andonian S, Chen T, St Denis B and Corcos J. (2005). Randomized clinical trial comparing suprapubic arc (SPARC) and tension-free vaginal tape (TVT): one year results. *Eur Urol* 47(4):537-41.
- Rajendra M, Han HC, Lee LC, Tseng LA, Wong HF. (2011) Retrospective study on tensionfree vaginal tape obturator (TVT-O). *Int Urogynecol J*. Sep 3. [Epub ahead of print]
- Ortega C, Velázquez S, Kunhardt R. (2009) Urethral erosion secondary to the placing of tension-free vaginal tape. A case report. *Ginecol Obstet Mex*; 77(8):393-5.
- Huang KH, Kung FT, Liang HM, Huang LY, Chang SY. Concomitant surgery with tension-free vaginal tape. *Acta Obstet Gynecol Scand* 2003; 81:948-53.
- Azam U, Frazer M, Kozman E, Ward K, Hilton P, Rane A. The tension-free vaginal tape procedure in women with previous failed stress incontinence surgery. *Urology* 2001; 166:554-6.
- Neuman M. Transvaginal suture placement for bleeding control with the tension-free vaginal tape procedure. *Int Urogynecol J Pelvic Floor Dysfunct* 2006 Feb;17(2):176-7. Epub 2005 Feb 24.
- Karram MM, Segal JL, Vassallo BJ, Kleeman SD. Complications and untoward effects of the tension-free vaginal tape procedure. *Obstet Gynecol* 2003 May; 101(5 Pt 1):929-32.