



A PROSPECTIVE STUDY ON OUTCOME OF TENSION FREE TRANS OBTURATOR TAPE FOR FEMALE STRESS URINARY INCONTINENCE

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ABSTRACT Stress urinary incontinence (SUI) is a common problem seen in women, can be a cause for social embarrassment and poor hygiene. Sixty female patients with SUI, who underwent Trans-obturator surgery (TOT) procedure from Sept 2015 to March 2017 were included in this prospective study conducted at the Institute of Urology, Rajiv Gandhi Government General Hospital. They were assessed and underwent TOT and were followed up for a minimum period of 12 months. Cure was defined as the disappearance of both subjective and objective SUI by using Urogenital Distress Inventory and Negative cough test on physical examination. The results showed success rates of 93.33% and 80% at the end of 1st month and 1st year respectively which are comparable with several studies. TOT is a simple, effective and safe procedure for treatment of female SUI proven after 1 year of follow up and has a simple and easy learning curve.

KEYWORDS : stress urinary incontinence, trans obturator surgery, urinary retention

INTRODUCTION:

The International Continence Society (ICS) defines the symptom of urinary incontinence as the complaint of involuntary loss of urine. Stress urinary incontinence (SUI) is defined as the involuntary loss of urine on effort or physical exertion (e.g. sporting activities) or on sneezing or coughing (Abrams P, 2003) (Taweel, 2010). SUI can develop via 2 mechanisms: hyper mobility, where there is significant displacement of the urethra and bladder neck during exertion and other being intrinsic sphincter deficiency (ISD). Sling procedures in the past were far from standardized. Multiple different descriptions have been given regarding the different types of materials used, anchoring points and methods to adjust the tension of the sling. Many underwent the procedure under general anesthesia and had subsequent complications associated with the procedure. With the advent of the tension free vaginal tape procedures in the USA in the late 90s, the treatment for SUI underwent a revolution, where the procedure could be safely completed under local anesthesia within 20 minutes. Three very small incisions with minimal dissection is seen to be adequate for the procedure and is associated with excellent cure rates and satisfactory patient outcomes.

MATERIALS AND METHODS:

This was a prospective study conducted in the Institute of Urology, Rajiv Gandhi Government General Hospital, where 60 patients with SUI who underwent TOT procedure from September 2015 to March 2017 were included and followed up for a period of 12 months at the least.

All patients were evaluated with detailed history including a bladder diary pre-operatively. International Consultation on continence questionnaire and Urogenital Stress Inventory were used for this purpose. Age, parity (including their mode of delivery) and menopausal status were taken into consideration. Complete physical examination including pelvic examination, urine analysis and urodynamic studies were done. Patients with pure urge incontinence were excluded. Of the 60 patients, 35 underwent the outside to inside technique of TOT, while the remaining had the inside to outside TOT procedure. Simultaneous repair of 4 cystocele and a rectocele were done. Trial vaginal hysterectomy was performed for 2 patients with uterine fibroids and 2 for those with uterine prolapse. Bilateral sacrospinous colposuspension was performed in 3 patients for vault prolapse.

The definition for cure of SUI was the disappearance of subjective and objective SUI using Urological Distress Inventory and negative cough test on physical examination at week one, 6 months and one year. Assessment for immediate and late complications was done and the results noted.

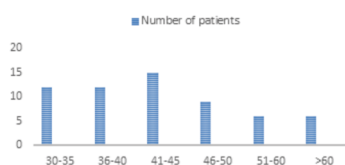


Figure 1 : Age distribution

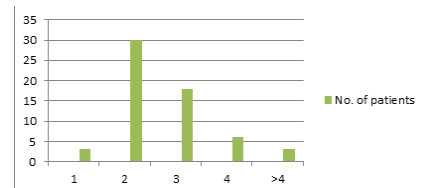


Figure 2 : Parity distribution

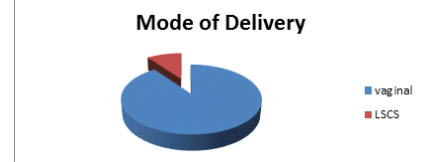


Figure 3 : Mode of delivery

PROCEDURE:

The device consisting of two specially curved 5mm diameter insertion needles that are attached to a 40cm segment of polypropylene tape which is 11mm wide. The tape is covered with a clear plastic sheath which is to protect the tape from contamination and allows easy passage through the tissues. The bladder is catheterized using a rigid catheter guide with a 18Fr Foley's catheter, so that the bladder is taken out of harm's way in the path of the needle. A handle is attached to the insertion needle, which is ergonomic and reusable with sterilization.

Trans-obturator tape (TOT) operative techniques varies with the insertion methods; the inside to outside and outside to inside TOT approaches. Patient is placed under dorsal lithotomy position for both techniques. In the inside to outside approach, stab incisions are created approximately 2cm above the horizontal line level with the urethra and 2cm lateral to the labial folds. 2cm mid urethral incision vertically begins 1cm from external urethral meatus. The introducer is passed at 45 degrees and perforates the obturator membrane. It then exits via the stab incision. Similar procedure is done on the opposite side. All plastic sheaths are removed, excess material cut and ensuring that there is no excess tension on the sling the incisions on the skin and vaginal are then closed. In the outside to inside approach, a small vertical incision is created over the mid urethra following which a puncture incision is made at the level of the clitoris in the obturator foramen. The needle is then passed via the stab incision and then turned in a medial orientation and advanced on the tip of the index finger and brought out through the vaginal incision. An intra operative cystoscopy is performed to ensure there is no bladder perforation, though, currently less commonly done, we used it for the study purpose. Following this the synthetic material attached is brought out through the stab wound. The procedure is then repeated on the opposite side. No tension must be maintained on the tape by passing a curved scissor between the tape and urethra. The rest is then as per the inside to outside TOT technique.

RESULTS:

Of the 60 patients, 50 underwent TOT surgery under sub-arachnoid block and 10 under IV sedation. Mean operative time was noted to be 12 minutes, ranging from 6 to 30 minutes and catheterization time was 0.9days. Outcomes were noted at the end of the 1st month and 1-year period. At 1 month, 93.33 percent (56/60) of patients were found to be cured and 3.33 percent (2/60) had persistent voiding dysfunction with de novo urgency or urge incontinence, who just needed follow up. Perineal pain was noted in one patient (2.5%), which lasted for 3 months and subsided. Post-operative leg pain was observed in 6.67% i.e. 4 patients. Vaginal erosions or peri-operative complications were not seen. Two patients developed urinary retention; one patient recovered after 15days, while the second did not recover and was taught self-intermittent catheterization. Immediate post-operative period, 2 patients developed lower urinary tract infections. At the end of the 1st year, 48 of the 60 patients, i.e. 80 percent were clinically cured from their stress incontinence symptoms. An additional 12% had an improvement in their symptoms.

COMPLICATIONS	NUMBER	PERCENTAGE
Bladder injury	Nil	0
Vaginal erosion	Nil	0
Voiding dysfunction		
Irritative symptoms	2	3.3%
Obstructive symptoms	2	3.3%
Post-operative perineal pain	1	1.67%
Post-operative leg pain	4	6.67%
Infection:		
Thigh Abscess	Nil	0
Infected obturator hematoma	Nil	0
Lower urinary tract infections	2	3.3%
Vascular injury	Nil	0
Nerve injury	Nil	0

DISCUSSION:

The definition of urinary incontinence has undergone a sea of change of the decades, based on an increased understanding of the pathophysiology of the condition. The two methods of performing sling surgeries, tension free vaginal tape and trans-obturator tension free surgeries helped to overcome the symptoms of stress. Of the two, TVT is noted to have certain areas of morbidity which is decreased in the case of TOT surgeries. Hence, since its advent TOT surgeries have noted to have gained popularity where there is minimal morbidity associated (Delorme E, 2001; V, 2010). There is some controversy involved with regards to the effect on sexual function, where it seems to swing on both sides of the spectrum with view to various authors. But, it little seems to affect the popularity of the procedure in comparison to TVT surgery (Raziye Narin, 2013). As per Tarek Soliman et al, cure was found in 84.1 percent and an improvement of symptoms in 13.1 percent of patients. (Tarek Soliman, 2017) Şükrü Kumsar et al divided the patients as per their BMI and concluded cure rates as 96%, 94.4% and 94.7% in the normal weight, over weight and obese group categories. (Şükrü Kumsar, 2015)

In our study the mean age in the study was seen to be around 43.67 years. Other studies showed a higher mean age i.e. beyond 50 years. Moore et al showed a mean of 56.8 years and Isabelle et al showed 57.9 years, while Hamal et al a mean age of 51.36 years was noted (Moore RD, 2006). (Incontinence, 2013) (Isabelle Kaelin-Gambirasio, 2009) In our study the mean operative time was found to be 12 minutes; where the surgical time ranged between 6minutes to 30 minutes. The same was found to be around 25.36, 18 and 12.4 minutes in Hamal et al, Taweel et al and Moore et al respectively (Taweel, 2010) (Incontinence, 2013)

Cure which was defined as the absence of both subjective and objective symptoms was seen in 93.33% of patients. 3.33% continued to have voiding dysfunction. 80 % of patients continued to see the success of the procedure and were deemed clinically cured, while another 12% showed an improvement over their symptoms. Failure of any sort of improvement was perceived in 3.33 % and 8% patients at the end of 1st month and 1st year respectively. Cure rates were reported as 90.6% by Delorme in 2001 with improvement in 9.40% of patients (Delorme E, 2001). Similar rates were seen in Spinosa et al and Taweel et al of 92.3% and 92% improvement in symptoms respectively. Also a 24 month follow up seen with the Taweel et al study showed a satisfaction rate of 88% and a cure in 85% of patients (Jean-Pierre Spinosa, 2005) (Taweel, 2010). The highest cure rates at the end of the 1st year were seen in the Mellier et al study achieving 95%, but also showed a 1%

failure unlike Delorme which showed no failure rates (G. Mellier, 2004), (Delorme E, 2001).

Of the various complications noted post-operative leg pain was seen in 6.67% of patients which subsided after 6 months with conservative management. Vaginal erosions were not observed in any of the patients. One patient, i.e. 1.67% had post-operative perineal pain. Lathe et al in 2007 published a meta- analysis that the outside-in TOT was not associated with groin pain (PM Lathe, 2007). The study by Hamal et al also had no incidence of perineal or thigh pain post operatively (Incontinence, 2013)

Mean period of catheterization was seen to be about 0.9days; i.e. between 0 to 2 days. Two patients developed urinary retention due to excessive tension of the tape; amongst which one eventually had to be taught intermittent self-catheterization. The second patient recovered well, and the catheter was removed after 15 days. No other complication was seen in these patients. Hamal et al also showed one patient with urinary retention and 2 with post-operative urinary tract infection (Incontinence, 2013). Also 3 patients out of 20 patients required prolonged catheterization necessary for more than 3 days. Lower urinary tract infections were seen in two patients, i.e. 3.33% of the patients in our study. 5% of patients were found to have UTI in the Taweel et al study along with 4% who had urinary retention (Taweel, 2010).

None of the patients in our study were found to have vaginal erosion or bladder injuries, which was comparable with the Hamal et al and Delorme groups. In contrast the Taweel et al study showed lateral vaginal injury in 1% of patients (Incontinence, 2013) (Delorme E, 2001) (Taweel, 2010).

CONCLUSION

Trans obturator tape is a simple, effective and safe procedure for the treatment of female stress urinary incontinence confirmed after 1 year of follow up and has a simple and easy learning curve. Post-operative morbidity associated with TOT is noted to be minimal and manageable but evaluation of the results with a long term follow up is necessary.

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