

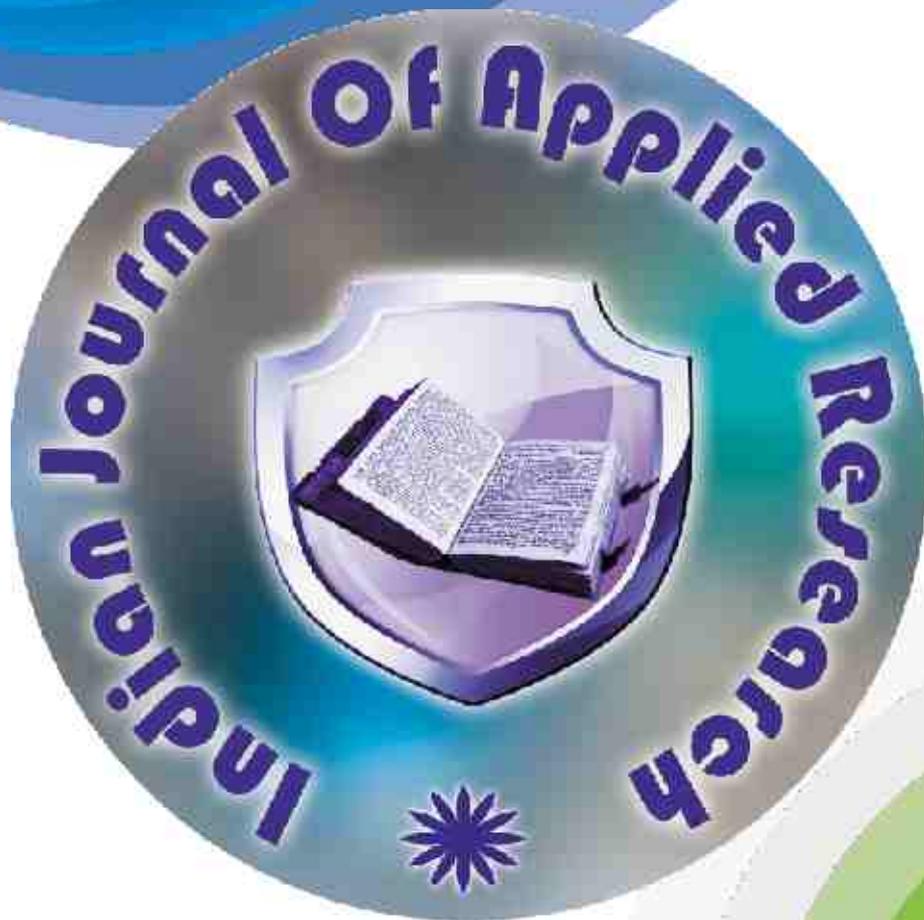
₹ 200

ISSN - 2249-555X

Volume : 1

Issue : 5

February 2012



Journal for All Subjects

www.ijar.in

Listed in International ISSN Directory, Paris.



ISSN - 2249-555X

Indian Journal of Applied Research

Journal for All Subjects

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A Novel Surgical Approach For Treatment Of SUI TVT Obturator Tape

* Dr. Ketaki Junnare ** Dr. Durga Karne
*** Dr Neelesh Risbud

* Lecturer, Smt. Kashibai Navale Medical College & General Hospital, Pune

** Senior Resident, Smt. Kashibai Navale Medical College and General Hospital, Pune

*** Professor. Smt. Kashibai .Navale Medical College and General Hospital , Pune

ABSTRACT

Objectives To objectively and subjectively assess the success rate at 6 months and 12 months after tension-free vaginal tape obturator (TVT-Ob) procedure. Design A prospective observational study of a cohort of 50 consecutive women who underwent the TVT-O procedure between 2007 and 2011. Setting A tertiary referral multispeciality rural general hospital and a medical college. Methods Standardised QOL questionnaires were completed preoperatively and at 6 months. At 6 months, a urogenital history, visual analogue scale score (VAS) for patient satisfaction, ultrasonography(USG), and urinary stress test were performed. Urogenital history and patient satisfaction verbal analogue score (VeAS) were obtained by telephone interview at 1 yr . Results Mean follow up was 18.45 months. Objective success rate was 94%. Subjective success rates were 92 and 84% at 6 and 12 months. Complications included recurrent urinary tract infection (two), voiding difficulty (two), persistent groin discomfort (three), wound infection (one), vaginal tape erosion (one), and urethral irritation (one). Prevalence of de novo urge incontinence was 4.1 and 4.8% at 6 and 12 months. Conclusion The TVT-Ob is a safe and effective treatment for female stress urinary incontinence.

Keywords : Stress urinary incontinence, TVT-Ob procedure , QOL ,patient satisfaction.

Introduction\

The tension-free vaginal tape (obturator approach) is a transobturator suburethral synthetic sling used in the treatment of female stress urinary incontinence(SUI). . The transobturator approach is believed to avoid bowel injuries and reduces the risk of bladder and major vascular injuries. It eliminates the need for routine cystoscopic examination during insertion.

Methods

A prospective analysis was made of 50 consecutive women undergoing the TVT-O procedure. Consent for the procedure and this study was obtained from all the participants. Formal ethics committee approval was not required for this study as it was categorised as a clinical audit.

All the women underwent preoperative clinical examination to demonstrate SUI,USG and urine microscopic examination after a detailed urinary history taking. Thirty-one women (62%) had isolated symptoms of stress urinary incontinence, 19 (38%) had mixed urinary symptoms and no patient with overactive bladder alone was included in the study.

The TVT-Ob procedures were performed in accordance with the technique described by Delorme E(outside- in technique)(3).Participants were evaluated at 6 months postoperatively when a urogenital history and examination, a visual analogue scales (VAS) for patient satisfaction (pertaining to the TVT-O procedure only), a postvoid residual volume and a urinary stress test were performed. The patients were examined with full bladder and asked to perform various

provocative measures like coughing , sneezing , straining. Leakage of urine indicated a positive stress test . A negative stress test was the objective measure of success used in this study.

Patients completed standardised QOL questionnaire devised on the King's college pattern in a local language preoperatively and at 6 months postoperatively .

After 12 months, a further urogenital history and verbal analogue score (VeAS) for patient satisfaction (pertaining to the TVT-O procedure only) were obtained by telephone interview. Participants were specifically asked if they had urinary leakage due to stress incontinence, leakage due to urge incontinence, voiding difficulty, or other urinary symptoms such as frequency, urgency, nocturia or dysuria.

The primary outcome measure was the objective success rate of the TVT-O procedure, as shown by a negative urinary stress test 6 months following surgery. Secondary outcome measures included subjective success rates of the TVT-O procedure 6 and 12 months following surgery, pre- and postoperative comparison of pre and post operative symptomatology , complication rate, QOL analysis, and patient satisfaction.

Tests for significance were conducted using the t test. Statistical analysis pertaining to subjective success rates and prevalence de novo urge urinary incontinence were undertaken using Fisher's exact test.

Results

Mean duration of follow up was 18.45 months (SD 2.34). Onewoman was lost to follow up at 6 months and fourat 12 months. The mean age was 55.5 years (SD 9.43)

and median parity was 3 (range 0-11). Twenty seven (54%) were menopausal. All of the above had clinically demonstrable stress incontinence. Twenty-nine women (58%) had concomitant urge incontinence symptoms. Concomitant surgery was performed in 20 women (40%). These procedures included: anterior vaginal repair (20), posterior vaginal repair (6), vaginal hysterectomy (6). Success rates are detailed in Table 1. These were calculated as a percentage of the 49 women who returned for follow up at 6 months, and a percentage of the 46 women who followed up at 12 months. The objective success rate was 94%, and the subjective success rates (asymptomatic of stress incontinence) were 92 and 84% at 6 and 12 months. The decline in subjective success rate between 6 and 12 months was not statistically significant (P= 0.13). There was also a statistically significant reduction in the prevalence of urge urinary incontinence from 58% preoperatively to 28% (P< 0.001) at 6 months and 36% (P< 0.001) at 12 months postoperatively. The difference in the prevalence of urge urinary incontinence between 6 and 12 months was not statistically significant (P= 0.36). The prevalence of de novo urge urinary incontinence was relatively stable at 4.1% at 6 months and 4.8% at 12 months. There were no significant differences between preoperative and postoperative urinary patterns or postvoiding residual volumes.

Two women had recurrent UTI (urinary tract infections) Refer to Table 2. There were two women (4.8%) with voiding difficulty, which developed between the 6- and 12-month postoperative review. One woman was complicated by recurrent UTIs and required intermittent self-catheterisation, while the other was managed with double/triple voiding techniques. There were no women with injury to bladder, vessels or other viscera. One patient had urethral irritation which resolved on its own. One case had erosion of tape for which resurgery had to be done for excision of tape and suturing back vaginal epithelium.

QOL analysis showed a significant improvement in mean QOL scores at both 6- and 12-month follow up (table 1). Subjects also reported an improved general state of health compared with the previous 12 months in 72.4% at 6 months and 59% at 12 months. This was determined by subjects' response to the last question of the QOL questionnaire: 'Compared with my general level response to the last question of the QOL questionnaire: 'Compared with my general level of health over the past 12 months, my health state today is better/much the same/worse'. In addition, visual analogue scores (VAS) at 6 months and VeAS at 12 months indicated high patient satisfaction (VAS, VeAS ≥ 80%) in 87% of women at 6 months and 77% at 12 months.

Table 1. Comparison of pre- and postoperative outcomes

Variable	Preoperative	6 months postoperative	12 months postoperative	P
(SUI, stress urinary incontinence; UUI, urge urinary incontinence.)				
Number of women	50	49	46	
SUI	50	3(6.01%)	3(6.52%)	<0.001
UUI	29	8(28%)	10(36%)	<0.001
De novo UUI		8(4.1%)	10(4.8%)	
Residual volume		30.8 (SD 35.1)	29.05 (SD 38.9)	0.40
Subjective cure (%)		92	84	0.13

Table 2. Operative and postoperative complications

Complications	6 months postoperative	12 months postoperative
Voiding difficulty	1(2.04%)	2(4.34%)
Wound infection	1(2.04%)	—
Haematoma	0	—
Groin discomfort	6(12%)	3(6.52%)
Urethral irritation	1(2.04%)	—

Discussion

This study indicates that the TVT-Obturator procedure is a safe and effective treatment for female stress urinary incontinence. Our objective success rate of 94% at 6 months and subjective success rates of 92 and 84% at 6 and 12 months were comparable with those reported for the retropubic TVT (81.96%) and Burch colposuspension (80.95%)-(5).

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The prevalence of urge incontinence was significantly reduced from 59% preoperatively to 28% at 6 months and 36% at 12 months. Similar findings have also been reported with the retropubic TVT and Burch colposuspension (5). 8 of the 19 women with urge urinary incontinence in our study were treated with anticholinergic medication, all the above were still symptomatic of urge urinary incontinence at 12 months. Thus, the reduction in the prevalence of urge incontinence was not a result of concomitant anticholinergic therapy. Similarly, concomitant anterior vaginal repair was performed on 19 women symptomatic of urge urinary incontinence. Of those, only 11 had a resolution of their symptoms of urge urinary incontinence. It is therefore reasonable to conclude that any concomitant prolapse surgery performed did not have any significant effect on the reduction of postoperative prevalence of urge urinary incontinence.

While bladder injury is the most common intraoperative complication reported with the retropubic TVT (5), occurring in 3.89.7% of women, there were no such injuries in our series. Juma et al (2007) reported 1.52% incidence of intra-operative bladder perforation with TOT (transobturator tape) series (1).

12 % of women (six) experienced groin discomfort within the first 6 postoperative months, only 3.6% of them (three) had persistent groin pain, which had not resolved by the 12-month review. Similar complication was reported by Lim et al with their TVT O series (2).

There were no women with intraoperative haemorrhage in our series. This is preferable to a 'significant' intraoperative blood loss in 0.95.4% with the retropubic TVT and 38.1% with the Burch colposuspension (1).

There was also one woman (2.04%) with superficial wound infection in our series compared with 0.42% reported for the TVT and 57% for the Burch colposuspension (5). Our 1.1% rate of paraurethral vaginal mesh erosion from the TVT-O is comparable with the 0.44.1% quoted in other series for the retropubic TVT (5).

One patient reported urethral irritation which had resolved spontaneously at twelve months telephonic follow up interview.

Comparisons of the preoperative and postoperative QOL questionnaires showed a significant improvement in QOL both at 6 and 12 months postoperatively. This was reflected in the high levels of patient satisfaction (VAS, VeAS ≥ 80%) achieved at 6 (87%) and 12 months (77%). This is comparable to reports in the study by Lim J et al (2006) (2) who reported 80 % and 70 % patient satisfaction rates at end of six and twelve months respectively.

Conclusion

Our results indicate that the TVT-O procedure is a safe and effective treatment for female stress urinary incontinence. The short and medium-term objective and subjective success rates appear comparable with the traditional Burch colposuspension and the retropubic TVT procedure. There appears to be a reduction in the prevalence of voiding difficulty when compared with the reported rates for the Burch colposuspension and the retropubic TVT procedure. The overall complication rate was low, patient satisfaction was high, and QOL was improved after treatment. The TVT-O appears to have performed favourably as a safe and effective alternative to the other traditional treatments for female stress urinary incontinence.

The TVT Obturator tape has an advantage of being a simple and shorter procedure with less post operative morbidity as compared to TVT or Burch. The learning curve is very short and the fear of bladder injury or an intraoperative haemorrhage since eliminated, makes the procedure very surgeon friendly.



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