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Research Article

A Prospective Study Comparing Continuous Bladder Drainage and Intermittent Self-Catheterization after Tension Free Vaginal Tape (TVT)

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Received: October 17, 2017; **Published:** November 01, 2017

Abstract

Objective: To compare transurethral indwelling catheterization (TIC) with intermittent self-catheterization (ISC) with respect to voiding function, urinary tract infection and quality of life following tension free vaginal tape surgery (TVT) operation.

Design: Single-center prospective intervention study with multiple points of follow-up.

Setting: Urogynecology clinic at a teaching hospital in Ottawa Canada.

Population: All patients undergoing a TVT procedure without any additional pelvic reconstructive surgery. Inclusion Criteria: all patients who have consented to undergo a TVT procedure for stress urinary incontinence and are able to carry out in and out catheterization. Exclusion criteria: any concomitant pelvic reconstructive surgery, inability to follow-up after surgery or patients with recurrent stress urinary incontinence.

Methods: Approval was obtained by the institutional review board (OHSN-REB Protocol # 2006836-01H). Patients were randomized to the TIC or the ISC group. Patients were discharged home on the same day of surgery. They visited the clinic three days after surgery for voiding assessment with uroflowmetry and post-void residual (PVR) measurement. Voiding dysfunction (VD) was defined as PVR more than or equal to 150 ml. A urine specimen was collected for culture and sensitivity. Quality of life questionnaires; Incontinence Impact Questionnaire (IIQ-7) and International Consultation on Incontinence Questionnaire (ICIQ) were completed preoperatively and at six weeks after.

Main Outcome Measure: Voiding dysfunction rate.

Results: A total of 72 patients were included in the study. They were divided equally into 2 groups (TIC and ISC) of thirty-six. The mean PVR postoperatively on day three for TIC vs. ISC group was 22 ml vs. 28 ml (p = 0.65) and at six weeks 34 ml vs. 37 ml (p = 0.84) respectively. The mean IIQ-7 postoperative scores were 12.6 for TIC group vs. 11.98 for ISC group (p = 0.85). The postoperative scores for ICIQ averaged at 3 for the TIC group vs. 3.19 for the ISC group (p = 0.91). The incidence of UTI's showed no significant difference between the groups (38.8% vs 28%, p = 0.32).

Conclusions: Transurethral indwelling catheterization and ISC seem to be equally effective in achieving normal voiding after TVT. PVR was comparable in both groups. VD among the ISC group was two times that among the TIC group, yet normal voiding was re-

sumed in all. Among the TIC group, UTI was 1.4 times that among the ISC group which might be of clinical significance especially in old age.

Keywords: *Tension Free Vaginal Tape; Urinary Retention; Transurethral Indwelling Catheterization; Intermittent Self-Catheterization; Voiding Dysfunction*

Abbreviations

VD: Voiding dysfunction; QoL: Quality of life; (ISC): Intermittent Self-Catheterization; TIC: Transurethral Indwelling Catheterization; TVT: Tension Free Vaginal Tape; PVR: Post-Void Residual; UTI: Urinary Tract Infection; ICIQ: International Consultation on Incontinence Questionnaire

Introduction

Female urinary incontinence is a medical condition that is becoming more and more prevalent with the aging Canadian population. Several studies reported that incontinence is more common with advancing age [1,2]. All anti-incontinence procedures have an obstructive effect on the urethra providing continence, but may also affect voiding [3]. Many theories have been proposed to explain voiding dysfunction (VD) and retention after surgery for stress urinary incontinence. They include periurethral edema, increased contractility or obstruction of the urethral sphincter and suppressed contractility of the detrusor muscle [4].

VD has been defined in several ways including urinary retention, discharge home with a suprapubic catheter, the need for intermittent catheterization for a period longer than 3 days, 2 weeks, 3 weeks, 4 weeks, 3 months, 6 months or more, requiring sling revision or sling release [4]. Tension-free Vaginal Tape (TVT) is quickly becoming one of the most common procedures performed to correct stress urinary incontinence [5]. Several studies have investigated voiding dysfunction after TVT procedure. Due to the differing definitions of voiding dysfunction, studies have found incidence of VD post TVT of 9 to 50% [3,4,6-9]. The mean number of days for postoperative catheter use was found to be 4 - 9 days [3,4]. A low pre-operative peak urinary flow rate, pre-operative vault prolapse concurrent vault suspension surgery and postoperative urinary tract infection have been shown to be correlated with VD after TVT [7,10].

Although subjective function does not change after a TVT procedure, the maximum flow rate significantly decreases and the detrusor pressure at maximum flow significantly increases [3]. However, over time, these parameters showed significant improvement [11]. VD after TVT with concurrent pelvic reconstructive surgery has been studied with the finding of increased transient urinary retention [12]. Patients who underwent a posterior colporrhaphy at the time of TVT or had previous anti-incontinence surgery also took longer to resume normal voiding [13].

Up to our knowledge no study to date has prospectively looked at different catheterization policies after TVT procedure focusing on its impact on voiding dysfunction and the return to a normal continent voiding habit. The purpose of our study was to assess the resolution of short-term voiding dysfunction following TVT procedures using two different types of urodynamic catheters. In addition to determine the incidence of urinary tract infections and the overall subjective improvement in quality of life (QoL).

Materials and Methods

A prospective intervention study comparing TIC vs CIC as tools for bladder drainage following TVT surgery. The study was conducted in the teaching hospital in Ottawa, Canada (OR), from August 2007 till May 2009. Approval was obtained by the institutional review board (OHSN-REB Protocol # 2006836-01H). This study had two points of follow-up 3 days and 6 weeks post operatively. Participants were recruited for this study from the urogynecology clinics at the Riverside campus and Ottawa Hospital. All patients undergoing a TVT procedure without any additional pelvic reconstructive surgery were eligible for enrollment in the study.

Inclusion Criteria were: All patients who consented to undergo a TVT procedure for stress urinary incontinence and are able to carry out in and out catheterization.

Exclusion Criteria were: Patients undergoing concomitant pelvic reconstructive surgery, patients unable to follow-up three days after surgery, patients with recurrent stress urinary incontinence and patients with overactive bladder.

Before surgery, eligible patients were informed about the study protocol including information about TVT and the randomization procedure to determine the type of catheter for each patient. Upon agreement, written informed consent was obtained from each patient.

Consented patients were given appropriate in and out catheterization teaching module by the urogynecology nursing staff as per usual protocol.

All patients received the same routine preoperative care including prophylactic antibiotic. On the operative day, patients were randomly assigned to either TIC or SIC for the assessment of urodynamic function after the TVT procedure. An opaque sealed envelope was opened to determine the allocation group. Surgery was performed by the urogynecologists. Although small variations in surgical technique may have occurred, the surgeons had a similar surgical basis. No additional funds for data collection and clinic staff teaching were required as its part of the usual protocol.

The patients were discharged home the same day of surgery with either an indwelling catheter in place or with supplies to carry out in and out catheterization. Meanwhile, they were asked to return to the clinic 72 hours after surgery. Thereafter, patients were followed-up weekly till the sixth week. Voiding function was assessed with an uroflow device and post-void residual (PVR) was measured with a bladder scanner. We defined abnormal PVR as a post-voiding residual volume exceeding 150 milliliter measured by bladder scanner [14].

If VD persists, with the voided volume less than 200 ml and a PVR more than 150 ml, self-catheterization was continued while recording the voided and residual volumes. One week later and during the next clinic visit, the patient is reassessed in the same manner. This was continued on a weekly basis till resuming normal voiding function.

Quality of life questionnaires: Incontinence Impact Questionnaire (IIQ-7) and International Consultation on Incontinence Questionnaire (ICIQ) were completed by all the patients pre-operatively and six weeks after surgery [15,16]. On day five post-surgery, urine specimens were collected for culture and sensitivity to determine urinary tract infection. Assessment was done by the institutions microbiology lab and significant bacteriuria was defined as 10^5 colony forming units in a culture.

To ensure confidentiality, a unique identification number was allocated to each patient. The master list linking patient names to their identification numbers was kept by the principal investigator and accessed only with a password. Results of the study were presented only in aggregated form, and no study subjects were identified in reports. The data were anonymized till the end of the study, and only the principal investigator has access in the future.

Outcome measurements

The primary outcome of our study was to assess the resolution of short-term voiding dysfunction by measuring the PVR and determining incident cases of VD. The secondary outcomes included: Incidence of urinary tract infection and Qo L scores using IIQ-7 and ICIQ scales.

Sample Size

Sample size was calculated using tests comparing two independent means with 0.05 significance level and 80% power determined that 35 patients would be required to detect a 25% difference in voiding function.

Statistical analysis

Descriptive statistics using mean, median and standard deviation (SD) were used to describe baseline data. Categorical data were compared by Fisher's exact test and Mann-Whitney test was used to compare between continuous data. Incidence of VD was measured and the relative risk was computed. A p-value of < 0.05 was considered to be statistically significant.

Results and Discussion

Results

From August 2007 till May 2009 a total of 117 patients underwent TVT procedure. Of these patients 72 fit the inclusion criteria and were included in the present study. Patients were randomly assigned to either TIC or ISC where each group comprised of 36 individuals. All patients received the allocated intervention and were followed till the end of the study on the sixth week post-surgery. No adverse events occurred.

In table 1, baseline characteristics of both groups are shown. No significant statistical differences between both groups regarding age and QoL. However, the 2 groups of patients had significantly different BMI and parity (P = <0.01). None of the patients were using medication affecting bladder and bladder outlet such as anti-cholinergic or alpha adrenergic agents.

	TIC (n = 36)	ISC (n = 36)	*P*-value
Age (years)	55 (12)	56 (10)	0.70
Body mass index (kg/m^2)	27 (1.8)	24 (1.9)	< 0.01*
Parity: median (range)	3 (1 - 5)	2 (1 - 4)	< 0.01*
IIQ-7	44.5 (23.97)	42.56 (23.76)	0.73
ICIQ	13.55 (3.28)	13.19 (3.45)	0.65

Table 1: *Patients' Characteristics at Study Onset.*

Data are presented as mean ± standard deviation (SD), unless otherwise indicated. Categorical data compared by Fisher's exact test and Mann-Whitney test used to compare continuous data. P-value ≤0.05 is significant. [TIC: Transurethral indwelling catheterization; ISC: Intermittent Self-Catheterization; IIQ-7: Incontinence Impact Questionnaire; ICIQ: International Consultation on Incontinence Questionnaire].

The clinical outcome measures for both interventions are shown in table 2. There was no statistical difference in the rate of VD nor the PVR between both groups on day three and on week six post-surgery. The mean PVR postoperatively on day three for TIC vs. ISC group was 22 ml vs. 28 ml (p = 0.65) and at the sixth week was 34.5 ml vs. 37 ml (p = 0.84) for TIC and ISC, respectively. In total, there were three cases of voiding dysfunction. One patient from the TIC group and two cases from the ISC group. There was no significant difference in VD incidence between the two groups with a P value = 0.56. The complete time to full resolution of the VD for the three cases was as follows: Five weeks for the patient from the TIC group and three and seven weeks for the patients from the ISC group, respectively. None of the three patients developed UTI during the follow-up period.

The risk of UTI was slightly higher in the TIC group (38.9%) compared to the ISC group (28%). However, the difference was not statistically significant (p = 0.32).

In table 3, In reference to the preoperative data, the quality of life scores had improved remarkably in both groups. Yet, there was no significant statistical difference in the postoperative scores of both groups. The mean IIQ-7 scores was12.6 for TIC group vs. 11.98 for ISC group (p = 0.85). Similarly, the postoperative score for ICIQ averaged at 3 for the TIC group vs. 3.19 for the ISC group (p = 0.91).

Parameter	TIC	ISC	Statistical significance
Post-void residual mean (range) 3 days post- surgery 6 weeks post- surgery	22cc (0-260) 34.5 cc (0-160)	28 cc (0-300) 37 cc (0-277)	P = 0.65 P = 0.84
Incidence of VD	2.8%	5.6%	RR = 2 95% CI (0.18 - 1.1) P = 0.56
Incidence of UTI	38 .9%	28%	RR = 0.7 95% CI (0.37 - 1.39) P = 0.32

Table 2: *Impact of Catheterization Procedure on Voiding Dysfunction (VD) and Urinary Tract Infection (UTI) following Tension Free Vaginal Tape (TVT) surgery.*

[RR: Relative Risk; CI: Confidence Interval]. Mann-Whitney test used for continuous data. P-value ≤ 0.05 is considered significant.

Quality of life	TIC Group	ISC Group	P Value
IIQ-7	12.6 ± 23.4	11.98 ± 20.6	0.85
ICIQ	3.00 ± 2.91	3.19 ± 4.42	0.91

Table 3: *Quality of life according to catheterization procedure after Tension free Vaginal Tape (TVT) surgery.*

[IIQ-7: Incontinence Impact Questionnaire; ICIQ; International Consultation on Incontinence Questionnaire; TIC: Transurethral indwelling catheterization; ISC: Intermittent self-catheterization]. Data are presented in mean ± standard deviation. P-value ≤ 0.05 is set as significant.

Discussion

The impact of TVT on QoL has been thoroughly investigated, yet to our knowledge no published data evaluated catheterization policies in the management of voiding following TVT surgery. In this prospective study, we compared between TIC and ISC following TVT operation among a group of Canadian patients by assessing PRV, VD, UTI and QoL. The advantage of ISC is related to shorter duration of catheterization leading to less discomfort and low level of UTI as compared to TIC. On the other hand, ISC might not be suitable under all settings especially among noncompliant patients. Moreover, if patients failed to use the ISC effectively, the rate of VD might be higher as compared to TIC. At baseline, patients were matched for age and QoL. The observed difference in parity and BMI is not expected to affect the outcome of operation. It would rather affect the Qol, however, Qol was comparable for both groups, both at base line and after surgery.

In the present study, there was no significant difference between the TIC and the ISC regarding the PVR. Several studies among both genders have been carried out looking at post-operative voiding dysfunction after total joint arthroplasty comparing indwelling catheterization with in and out catheterization. However, results were inconsistent, while favoring indwelling catheter over intermittent catheterization in one study. The reverse was reported in another study [17-20]. Indwelling Foley catheters reduced the frequency of postoperative urinary retention [20]. In contrast, satisfactory voiding resumed earlier with the use of repeated intermittent catheterization [18]. The variations may be the result of differences in the methodology, patient's characteristics and surgical procedure.

Our study demonstrated that the relative risk of VD among the ISC group was 2 times that among the TIC group, although this is not statistically significant, it still has a clinical implication. In agreement with the present study, published data also supported the assumption of better urinary drainage using indwelling catheter. A randomized trial has been carried out looking at continuous bladder drainage compared with catheterization after total abdominal hysterectomy. 36% of those undergoing in and out catheterization, and only 4% of those receiving an indwelling catheter had urinary retention [21].

As for UTI, it has been estimated that indwelling catheterization has a risk of 5 - 10% per day [22,23]. During catheterization, ascending infection can occur through two mechanisms; either direct inoculation with the catheter insertion and/or by colonization through ascending bacteria from the urethral meatus along the catheter [24-26]. The continuing presence of an indwelling catheter with TIC had a clinically higher risk of UTI which suggests a significant role for colonization in the development of bacteriuria. In support, 29% of the catheterized group and 13% of the intermittent catheterization group had urinary tract bacteriuria.21Additionally, similar results were reported among men, where intermittent catheterization resulted in a lower incidence of postoperative bacteriuria compared with an indwelling catheter [17].

In this study, we report a higher risk of UTI in the TIC group compared to the ISC group, however, it did not reach statistical significance. In accordance with our finding, Indwelling Foley catheters were not associated with an increased risk of urinary infection [19]. The observed variability in UTI data can be explained in view of differences in clinical settings, while infection control is maximized in Canada, USA and European countries, strict infection control measures might not be followed in developing countries. The remarkable improvement in QoL following TVT in both groups coincides with previous studies [27,28]. The limitations of the study are the number of patients and it being carried out in one center. Furthermore, the subjective nature of data about quality of life obtained from the questionnaires.

Conclusion

PVR was comparable between the TIC and the ISC groups. Although VD among the ISC group was twice that among the TIC group. However, normal voiding was resumed in both groups indicating that continuous catheterization and intermittent self-catheterization are equally effective in achieving normal voiding after TVT. The high risk of UTI with TIC might be of clinical significance especially in old age. These results will allow surgeons to consider both options in managing mild VD post TVT; keeping in mind patient preference, inability to learn ISC or if the setup doesn't allow teaching all patients ISC prior to the TVT procedure.

Future research will be directed at identifying high and low risk subgroups, and studying patient preferences to either option of management.

Acknowledgements

The author acknowledge the help of Bella Rowena Magnaye for the administrative works extended during the submission of this article.

Conflict of Interest

The authors declare no conflict of interest.

Bibliography

1. Milsom., *et al*. "The influence of age, parity, oral contraception, hysterectomy and menopause on the prevalence of urinary incontinence in women". *Journal of Urology* 149.6 (1993): 1459-1462.

2. Menezes M., *et al*. "Predictors of female urinary incontinence at midlife and beyond". *Maturitas* 65.2 (2010): 167-171.

3. Lucacz E., *et al*. "The effects of the tension-free vaginal tape on voiding function: a prospective evaluation". *International Urogynecology Journal* 15.1 (2004): 32-38.

4. Minassian VA., *et al*. "Tension-free vaginal tape, Burch, and slings: are there predictors for early postoperative voiding dysfunction". *International Urogynecology Journal* 15.3 (2003): 183-187.

5. Reich A., *et al*. "Voiding dysfunction after the tension-free vaginal tape procedure". *Gynecologic and Obstetric Investigation* 72.2 (2011): 79-84.

6. Abouassaly R., *et al*. "Complications of tension-free vaginal tape surgery: a multi-institutional review". *BJU International* 94.1 (2004): 110-113.

7. Hong B., *et al*. "Factors predictive of urinary retention after a tension-free vaginal tape procedure for female stress urinary incontinence". *Journal of Urology* 170.3 (2003): 852-856.

8. Al-Badr A., *et al*. "Voiding patterns and urodynamics after tension-free vaginal tape procedure". *Journal of Obstetrics and Gynecology Canada* 25.9 (2003): 725-730.

9. Klutke C., *et al*. "Urinary retention after tension-free vaginal tape procedure: incidence and treatment". *Urology* 58.5 (2001): 697-701.

10. Wang KH., *et al*. "Voiding dysfunction following TVT procedure". *International Urogynecology Journal* 13.6 (2002): 353-357.

11. Dietz HP., *et al*. "Voiding function after tension-free vaginal tape: a longitudinal study". *Australian and New Zealand Journal of Obstetrics and Gynaecology* 44.2 (2004): 152-155.

12. Meltomaa S., *et al*. "Concomitant vaginal surgery did not affect outcome of the tension-free vaginal tape operation during a prospective 3-year follow-up study". *Journal of Urology* 172.1 (2004): 222-226.

13. Partoll L. "Efficacy of tension-free vaginal tape with other pelvic reconstructive surgery". *American Journal of Obstetrics and Gynecology* 186.6 (2002): 1292-1298.

14. Hakvoort RA., *et al*. "A nationwide survey to measure practice variation of catheterisation management in patients undergoing vaginal prolapse surgery". *International Urogynecology Journal - and Pelvic Floor Dysfunction* 20.7 (2009): 813-818.

15. Uebersax JS., *et al*. "Short forms to assess life quality and symptom distress for urinary incontinence in women: The incontinence impact questionnaire and the urogenital distress inventory". *Neurourology and Urodynamics* 14.2 (1995): 131-139.

16. Avery K., *et al*. "ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence". *Neurourology and Urodynamics* 23.4 (2004): 322-330.

17. Van den Brand I and Castelein R. "Total joint arthroplasty and incidence of postoperative bacteriuria with an indwelling catheter or intermittent catheterization with one-dose antibiotic prophylaxis". *Journal of Arthroplasty* 16.7 (2001): 850-855.

18. Skelly J., *et al*. "Management of urinary retention after surgical repair of hip fracture". *Canadian Medical Association Journal* 146.7 (1992): 1185-1189.

19. Knight RM and Pellegrini VD. "Bladder management after total joint arthroplasty". *Journal of Arthroplasty* 11.8 (1996): 882-888.

20. Oishi CS., *et al*. "Perioperative bladder management after primary total hip arthroplasty". *Journal of Arthroplasty* 10.6 (1995): 732-736.

21. Dobbs S., *et al*. "A prospective, randomized trial comparing continuous drainage with catheterization at abdominal hysterectomy". *British Journal of Urology* 80.4 (1997): 554-556.

22. Given CD and Wenzel RP. "Catheter associated urinary tract infection in surgical patients: a controlled study on the excess morbidity and costs". *Journal of Urology* 124.5 (1980): 646-648.

23. Elpern E., *et al*. "Reducing Use of Indwelling Urinary Catheters and Associated Urinary Tract Infections". *American Journal of Critical Care* 18.6 (2009): 535-541.

24. Stamm WE. "Catheter-associated urinary tract infections: epidemiology, pathogenesis, and prevention". *American Journal of Medicine* 91.3B (1991): 65S-71S.

25. Maki DG and Tambyah PA. "Engineering out the risk for infection with urinary catheters". *Emerging Infectious Disease* 7.2 (2001): 342-347.

26. Chenoweth C and Saint S. "Preventing Catheter-Associated Urinary Tract Infections in the Intensive Care Unit". *Critical Care Clinics* 29.1 (2013): 19-32.

27. Ulrich D., *et al*. "Objective outcome and quality-of-life assessment in women with repeat incontinence surgery". *Neurourology and Urodynamics* 36.6 (2016): 1543-1549.

28. Lee HN., *et al*. "Tension-Free Vaginal Tape-SECUR Procedure for the Treatment of Female Stress Urinary Incontinence: 3-Year Follow-Up Results". *Lower Urinary Tract Symptoms* 7.1 (2015): 9-16.

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