Published in final edited form as:

Int Urogynecol J Pelvic Floor Dysfunct. 2009 September ; 20(9): 1103–1108. doi:10.1007/s00192-009-0909-7.

One Year Outcomes of Tension-Free Vaginal Tape (TVT) Mid-Urethral Slings in Overweight and Obese Women

Lindsay B. Killingsworth, MD¹, Thomas L. Wheeler II, MD, MSPH², Kathryn L. Burgio, PhD^{3,4}, Tovia E. Martirosian, MD⁵, David T. Redden, PhD^{3,6}, and Holly E. Richter, PhD, MD¹

¹Department of Obstetrics and Gynecology, University of Alabama at Birmingham, Birmingham, AL

²Department of Obstetrics and Gynecology, Greenville Hospital Systems University Medical Center, at Greenville, South Carolina

³Birmingham/Atlanta Geriatric Research, Education and Clinical Center, Department of Veterans Affairs, Birmingham, AL

⁴Department of Medicine, University of Alabama at Birmingham, Birmingham, AL

⁵Department of Obstetrics and Gynecology, University of Virginia, Charlottesville, VA

⁶School of Public Health, Birmingham, University of Alabama at Birmingham, AL

Abstract

Introduction—The purpose of this study was to assess the impact of body mass index (BMI) on tension-free vaginal tape (TVT) success rates, patient satisfaction, and complications one year following surgery.

Methods—Baseline and one-year post-surgery outcomes were abstracted, including Urogenital Distress Inventory (UDI-6) scores, Incontinence Impact Questionnaire (IIQ-7) scores, and patient satisfaction ratings. Multivariable logistic and linear regression analyses were performed to examine relationships between outcomes and BMI.

Results—195 subjects with a mean age of 59.3 ± 12.6 were included. There was significant improvement within each group (all p -values < 0.01) in total UDI-6 and IIQ-7 scores from baseline to one year post-surgery; all groups had high patient satisfaction. No differences in improvement or complications rates were observed among the BMI cohorts (all p -values > 0.05).

Conclusion—Differential counseling of overweight or obese women regarding outcomes of the TVT procedure is not supported by these results; longer follow-up is warranted.

Keywords

obesity; outcomes; TVT sling; urinary incontinence

Introduction

The tension-free vaginal tape (TVT) mid-urethral sling, first introduced in 1996 by Ulmsten, is recognized as a highly effective treatment for stress urinary incontinence[1]. A recent

Corresponding author: Holly E. Richter, PhD, MD, University of Alabama at Birmingham, Department of Obstetrics and Gynecology, 618 South 18th Street, NHB Room 219, Phone number 205-934-1704, Fax 205-975-8893, hrichter@uabmc.edu.

Poster presentation Annual Meeting of the Society of Gynecologic Surgeons, April 2009

The authors have no conflicts of interest.

systematic review confirmed a high subjective and objective cure rate when compared to laparoscopic Burch colposuspension, without increasing costs, complications, voiding dysfunction or irritative voiding symptoms[2].

Obesity (BMI > 30 kg/m²) is now an epidemic among industrialized nations, with rates in US and Europe of almost 30%[3]. Urinary incontinence (UI) continues to be a problem among obese women, with a recent study showing 67% of women presenting for bariatric surgery consultation with some form of urinary incontinence[4]. Higher intrabdominal pressures have been observed in patients with greater body mass index (BMI), with a mean of 4.9 mm Hg observed in non-obese patients compared to a mean of 8.9 mm Hg in morbidly obese patients[5]. Increased intra-abdominal pressure results in increased intravesical pressure, increased pressure at maximum cystometric capacity, and decreased cough pressure transmission from the bladder to the urethra, as well as decreased valsava leak point pressures, which may contribute to the development of stress incontinence in obese patients[5-8]. Obesity-induced neurogenic effects on the pelvic floor may also contribute to urethral dysfunction and resulting UI[6]. Even though the TVT sling is highly effective for the treatment of stress UI, there is some concern that its efficacy may be reduced in overweight or obese patients.

Evidence regarding the impact of obesity on outcomes of Burch urethropexy or needle suspension procedures has been mixed [7-10]. Studies investigating the potential impact of obesity on TVT sling outcomes have not demonstrated a difference in outcome by BMI in the short-term (<1 year)[11-16]. Recently, a study by Hellberg *et al* demonstrated significant failure rates (52%) in the morbidly obese population (BMI >35) compared to healthy weight women (19%) with long-term follow up (mean 68 months) [17]. Thus, there are conflicting reports regarding TVT sling efficacy rates in the obese woman. Furthermore, there is very little data describing satisfaction with the procedure in obese patients. The purpose of this study was to assess the potential impact of obesity on TVT sling success rates, patient satisfaction, and complications one year following surgery.

Materials and Methods

After Institutional Review Board approval was obtained, data were abstracted from the University of Alabama at Birmingham (UAB) Genitourinary Disorders Center (GDC) database on patients who had undergone a TVT sling procedure for stress UI between January 2001 and June 2005. All patients undergoing a TVT procedure including those undergoing concurrent pelvic reconstructive surgery were included in this analysis. Objective evaluation of SUI symptoms was performed in all patients and in those with significant prolapse without *a priori* symptoms of SUI, reduction stress testing was performed, which “unmasked” a potential or occult stress incontinence. All procedures were performed by one of three surgeons in the Women’s Pelvic Medicine and Reconstructive Surgery Division with the participation of residents and fellows as appropriate for training. Patients (N=195) were included if they completed and returned the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) at baseline and one year after surgery, and a validated Patient Satisfaction Question (PSQ) one year after surgery.

The UDI-6 and IIQ-7 are validated symptom distress and quality of life impact questionnaires, respectively[18,19]. Each is scored to a maximum of 100, where higher scores correspond to worse symptoms of bother (UDI-6) and impact on life (IIQ-7) from UI. The validated PSQ queries “How satisfied are you with your progress in this program?” (Completely, Somewhat, or Not at all) [20].

Chart reviews were performed to obtain demographic data, medical comorbidities, previous pelvic surgery history, estrogen use, pelvic organ prolapse quantification (POP-Q)[21], urodynamic parameters (uninstrumented uroflow and complex cystometrogram) and concurrent surgery. Data on the following complications were also collected: bladder perforation, urinary retention or incomplete bladder emptying (defined as the need for bladder drainage beyond 2 weeks following surgery), failed voiding trial on the day of discharge from hospital, TVT excision, TVT exposure, ureteral injury, post surgery transfusion, fever, atelectasis, pneumonia, and thromboembolic event. A successful voiding trial was defined as being able to void two thirds of a 300cc retrograde fill (or maximal capacity if <300).

One-year outcomes on the UDI-6, IIQ-7, and PSQ were compared among three BMI subgroups defined using the World Health Organization definitions (normal 20-24.9, overweight 25-29.9, obese $\geq 30 \text{ kg/m}^2$). The presence of stress UI, at baseline and 1 year follow-up, was defined as answering “moderately” or “greatly” on either item of the UDI-6 stress subscale (questions 3 or 4). In addition, comparisons among BMI subgroups for irritative bladder symptoms (UDI-6 questions 1 and 2), and total UDI-6 and IIQ-7 scores were analyzed at baseline and one year.

Univariate analysis via chi-square and Kruskal Wallis were used to identify any potential baseline confounders, defined as variables associated with both BMI category and the primary outcome of stress UI. Multivariable logistic regression for categorical outcomes and multivariable linear regression for continuous variables were used to control for these potential confounders. A sample size of 195 provided 90% power to detect the trend of 20% of normal weight women reporting stress urinary incontinence at one year follow-up, 35% of overweight women reporting stress urinary incontinence at one year follow-up, and 50% of obese weight women reporting stress UI at one year follow-up using an $\alpha = 0.05$.

Results

Of the 469 TVT slings performed between January 2001 and June 2005, 195 (41.6%) had completed the baseline and one-year questionnaires. There were 68 normal weight women, 65 overweight women and 62 obese women included. Patient demographics and parameters are shown in Table 1. A comparison of characteristics between women who did and did not return the one-year questionnaires found no differences for age, race, parity, BMI, prevalence of diabetes mellitus, maximum cystometric capacity (MCC), valsalva leak point pressure at maximal bladder capacity (VLPP-MCC) or presence of stress UI ($p > 0.05$).

The presence of diabetes mellitus ($p = 0.02$) and increased VLPP-MCC ($p < 0.01$) on preoperative urodynamics were identified as potential confounding variables and were controlled for in the multivariable logistic and linear regression modeling. Analyses indicated significant improvement on all outcome measures within each BMI group, including stress UI, irritative bladder symptoms, total UDI-6 score, and total IIQ-7 score ($p < 0.01$) (Figure 1). There were no differences among the three BMI groups in improvement from baseline to one year post surgery (stress UI $p = 0.91$, irritative symptoms $p = 0.95$, total UDI-6 $p = 0.22$, total IIQ-7 $p = 0.17$).

Patient satisfaction with TVT was not significantly different by BMI group ($p=0.98$) (Table 2). The percentage of patients that were somewhat or completely satisfied was 91% for normal weight women, 89% for overweight women and 92% for obese women.

Complications did not differ by BMI group (Table 3). Two normal weight patients underwent repeat incontinence procedures; one patient had a xenograft pubovaginal sling and the other a repeat TVT. One overweight patient had a repeat TVT; however, none of the

obese patients had a repeat incontinence procedure. At one year after surgery, two patients in the normal weight group continued to perform intermittent self catheterization (ISC); however, one of those women had performed ISC prior to TVT placement due to chronic urinary retention. The other woman had a favorable response to alpha antagonist therapy and only performed ISC as needed. A third normal weight woman had urethrolisis at 7 months after TVT placement. One participant from the obese group performed ISC for over 3 months. The 4 other participants with post-TVT retention, defined as requiring bladder drainage 2 weeks after TVT placement, were not performing ISC at one year.

Discussion

Stress UI symptoms one year after TVT sling placement were improved in all three BMI categories with no differences noted among groups. In addition, rates of irritative bladder symptoms showed significant clinical improvement among the three cohorts. Further, the observed improvements in patient-reported distress (total UDI-6 score) and impact on quality of life (total IIQ-7 score) with UI did not vary between normal, overweight, and obese participants. Patient satisfaction was high overall and did not vary by BMI group. Complication rates were low with the exception of failing a voiding trial after surgery; however, retention rarely persisted. Regardless of BMI category, patients had significant clinical improvement in stress and irritative symptoms, while reporting less bother and impact with UI, with the majority being completely or somewhat satisfied.

Among the relatively few studies that have examined the relationship between BMI and TVT sling outcome, four have reported no significant association. Raffi *et al* published a series with 149 consecutive patients followed for at least 6 months post operation (mean 6-24)[12]. Incontinence severity was measured using the Ingelman-Sundberg scale at baseline and objective cough stress test to determine cure. The study found no significant association with TVT sling failure and obesity; however, only 38 (25.5%) patients had a BMI >30. Lovatsis *et al* published a case series of matched patient pairs (those with BMI <30 versus those with BMI >35), controlling for age and prior continence surgery [13]. Cure was defined by objective cough stress test in the office or subjective cure reported in phone interviews. There was a very high cure rate for both groups; however, this study did not address pre-operative severity of symptoms. Mukherjee *et al* published results from 242 women with stress UI, using a quality of life and bladder symptom-specific questionnaire at baseline and at follow up[14]. All BMI categories had improved quality of life and bladder symptoms; however, patients were only followed for 6 months post-operatively. Ku *et al* published one of the largest series of patients, again demonstrating no difference in outcomes greater than 6 months post operatively [15]. However, obesity was defined by a BMI of 27 or greater in their Korean population, making the study less applicable to American and European populations.

In contrast, a recent study by Hellberg *et al* did show that obesity may have an impact on effectiveness of TVT sling in the longer term[17]. Patients (N=970) who underwent a TVT sling between 1995 and 2001 were sent a questionnaire in 2004, garnering 760 (78%) respondents. The average follow up time was 5.7 years, and groups were organized by age and BMI, controlling for other confounders. A significant difference in failure rate was noted between those subjects with a normal BMI (<25; 81.2% cure rate) and those with significant obesity (BMI>35; 52.1% cure rate). However, this paper did not address pre-operative symptoms, did not control for pre-operative symptom severity, and was not able to assess the overall impact and improvement in incontinence after the procedure. Further, a validated questionnaire was not used, thus decreasing reliability of the study data.

In addition to exploring and controlling for confounders, a strength of our study was the use of the validated UDI-6 and IIQ-7 questionnaires with measurement at baseline and prospective follow-up at one year. Therefore, any potential differences in baseline scores between BMI groups that might influence one year scores were accounted for. Another major strength was the use of a validated question for reporting patient satisfaction. Along with the inherent weaknesses of performing a retrospective chart review, another weakness of this study was the potential bias of excluding patients who did not complete both baseline and one-year questionnaires, which comprised the majority of the women who had a TVT sling in this study period. This potential bias was accepted in favor of the above-described statistical advantage of having both baseline and one-year validated subjective outcomes, and is probably limited, as no differences were found in select patient characteristics (age, race, parity, BMI, diabetes mellitus, MCC, VLPP-MCC, and presence of stress UI). Furthermore, the majority of patients also underwent concurrent surgery, which theoretically could impact on incontinence outcomes. However, there were no differences among the BMI groups in rates or types of concurrent surgery, and our information is more generalizable to practices targeting the care of women with other co-existing pelvic floor issues. Finally, the authors are unable to determine how many participants may have had repeat incontinence surgery elsewhere.

Based on the findings of this study, differential pre-surgical counseling of overweight or obese women regarding one-year outcomes of the TVT procedure is not supported, although longer term follow-up is needed.

Acknowledgments

Partially supported by the National Institute of Diabetes and Digestive and Kidney Diseases DK068389 to HER.

References

1. Ulmstem U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J*. 1996; 7:81–86.
2. Dean N, Herbison P, Ellis G, Wilson D. Laparoscopic colposuspension and tension-free vaginal tape: a systematic review. *BJOG*. 2006; 113:1345–1353. [PubMed: 17176277]
3. NHANES Data On the Prevalence of Overweight and Obesity Among Adults: United States 1976–2005. www.cdc.gov
4. Richter HE, Burgio KL, Clements RH, Goode PS, Redden DT, Varner RE. Urinary and anal incontinence in morbidly obese women considering weight loss surgery. *Obstet Gynecol*. 2005; 106:1272–1277. [PubMed: 16319252]
5. Noblett KL, Jensen JK, Ostergard DR. The relationship of body mass index to intra-abdominal pressure as measured by multichannel cystometry. *Int Urogynecol J Pelvic Floor Dysfunct*. 1997; 8:323–326. [PubMed: 9609328]
6. Cummings JM, Rodning CB. Urinary stress incontinence among obese women: review of pathophysiology therapy. *Int Urogynecol J Pelvic Floor Dysfunct*. 2000; 11:41–44. [PubMed: 10738933]
7. Brieger G, Korda A. The effect of obesity on the outcome of successful surgery for genuine stress incontinence. *Aust N Z J Obstet Gynaecol*. 1992; 32:71–72. [PubMed: 1586341]
8. Dwyer PL, Lee ET, Hay DM. Obesity and urinary incontinence in women. *BJOG*. 1988; 95:91–96.
9. Hutchings A, Griffiths J, Black NA. Surgery for stress incontinence: factors associated with a successful outcome. *Br J Urol*. 1998; 82:634–641. [PubMed: 9839576]
10. Kjolhede P. Long-term efficacy of Burch colposuspension: a 14-year follow-up study. *Acta Obstet Gynecol Scand*. 2005; 84:767–772. [PubMed: 16026403]
11. Zivkovic F, Tamussino K, Pieber D, Haas J. Body mass index and outcome of incontinence surgery. *Obstet Gynecol*. 1999; 93:753–756. [PubMed: 10912980]

12. Raffi A, Darai E, Haab F, Samain E, Levardon M, Deval B. Body Mass Index and Outcome of Tension-Free Vaginal Tape. *European Journal Urology*. 2003; 43:288–292.
13. Lovatsis D, Gupta C, Dean E, Lee F. Tension-free vaginal tape procedure is an ideal treatment for obese patients. *Am J Obstet Gynecol*. 2003; 189:1601–1605. [PubMed: 14710079]
14. Mukherjee K, Constantine G. Urinary stress incontinence in obese women: tension-free vaginal tape is the answer. *BJU Int*. 2001; 88:881–883. [PubMed: 11851607]
15. Ku JH, Oh JG, Shin JW, Kim SW, Paick JS. Outcome of mid-urethral sling procedures in Korean women with stress urinary incontinence according to body mass index. *Int J Urol*. 2006; 13:379–384. [PubMed: 16734854]
16. Kalantzis A, Polozois K, Grammatikas A, Doulas K, Dimitripoulou C, Lykourinas M. The effectiveness of the tension-free vaginal tape (TVT) in obese women with genuine stress incontinence. *BJU Int – Supplement*. 2004; 94:250.
17. Hellberg D, Holmgren C, Lanner L, Nilsson S. The very obese woman and the very old woman: tension-free vaginal tape for the treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*. 2007; 18:423–429. [PubMed: 16868657]
18. Shumaker SA, Wyman JE, Uebersax JS, McClish DK, Fantl JA. Continence Program in Women Research Group. Health Related Quality of Life Measure for Woman with Urinary Incontinence: The Incontinence Impact Questionnaire and the Urogenital Distress Inventory. *Qual Life Res*. 1994; 5:291–306. [PubMed: 7841963]
19. Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Continence Program for Women Research Group. Short forms to Assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. *Neurourol Urodyn*. 1995; 14:131–139. [PubMed: 7780440]
20. Burgio KL, Goode PS, Richter HE, Locher JL, Roth DL. Global ratings of patient satisfaction and perceptions of improvement with treatment for urinary incontinence: validation of three global patient ratings. *Neurourol Urodyn*. 2006; 25:411–417. [PubMed: 16652380]
21. Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P, Shull BL, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol*. 1996; 175:10–17. [PubMed: 8694033]

Figure 1.

A Proportion of subjects with stress urinary incontinence at baseline and 12 months. B. Proportion of subjects with irritative symptoms at baseline and 12 months. C. Total UDI-6 scores at baseline and 12 months. D. Total IIQ-7 scores at baseline and 12 months.

Table 1

Baseline characteristics of normal (BMI 20-24.9), overweight (BMI 25-29.9) and obese (BMI >30.0) women undergoing TVT

	Overall N=195	Normal N=68	Overweight N=65	Obese N=62
Age (Mean $\pm$ SD)	59.3 $\pm$ 12.5	60.8 $\pm$ 13.8	61.1 $\pm$ 11.0	56.7 $\pm$ 12.1
Race, N (%)				
- African American	9 (4.6)	3 (4.1)	0	6 (3.1)
- Hispanic	1 (0.5)	0	1 (1.5)	0
- Caucasian	185 (94.9)	65 (95.6)	64 (98.4)	5 (90.3)
Parity median, (range)	2 (0-8)	2 (0-5)	2 (0-6)	3 (0-8)
ERT use, N (%)	127 (65.1)	43 (63.2)	42 (64.6)	42 (67.7)
Previous Hysterectomy, N (%)	127 (65.1)	44 (64.7)	44 (67.7)	39 (62.9)
Previous Vaginal Repairs, N (%)	78 (40.0)	26 (38.2)	29 (44.6)	23 (37.1)
Asthma or COPD, N (%)	31 (15.9)	11 (16.1)	8 (12.3)	12 (19.4)
Diabetes Mellitus, N (%) [*]	16 (8.2)	2 (2.94)	6 (9.2)	8 (12.9)
Concomitant procedure, N (%)	151 (77.4)	53 (77.9)	53 (81.5)	45 (72.6)
Concomitant TVH, N (%)	29 (14.9)	9 (13.2)	13 (20.0)	7 (11.3)
Concomitant Anterior Repair, N (%)	83 (42.6)	28 (41.2)	35 (53.8)	20 (32.2)
Concomitant Posterior Repair, N (%)	132 (67.7)	43 (58.8)	47 (72.3)	42 (67.7)
Concomitant Apical Repair, N (%)	68 (34.9)	24 (35.3)	26 (40.0)	18 (29.0)
Concomitant Uterosacral Suspension N, (%)	32 (16.4)	15 (22.1)	19 (29.2)	12 (19.3)
Concomitant Sacrospinous Fixation, N, (%)	7 (3.6)	2 (2.9)	3 (4.6)	2 (3.2)
Concomitant ASC, N (%)	4 (2.1)	1 (1.5)	1 (1.5)	2 (3.2)
Concomitant Colpocleisis, N (%)	9 (4.6)	5 (7.4)	2 (3.1)	2 (3.2)
Concomitant TAH, N (%)	5 (2.6)	3 (4.4)	1 (1.5)	1 (1.6)
Urodynamics				
Continuous Uroflow, N (%)	154 (79.0)	55 (80.9)	47 (72.3)	52 (83.9)
Detrusor Overactivity, N (%)	46 (23.6)	9 (13.2)	27 (41.5)	10 (16.1)
First Desire, ml H ₂ O (mean $\pm$ SD)	160.6 $\pm$ 84.4	162.5 $\pm$ 82.5	156.6 $\pm$ 86.0	159.3 $\pm$ 89.1
Strong Desire, ml H ₂ O (mean $\pm$ SD)	287.6 $\pm$ 90.1	285.4 $\pm$ 77.8	290.1 $\pm$ 97.6	277.8 $\pm$ 93.74

	Overall N=195	Normal N=68	Overweight N=65	Obese N=62
Maximum Cystometric Capacity, ml H ₂ O, (mean±SD)	379.2 ± 64.9	380.5 ± 73.0	388.4 ± 60.0	365.2 ± 61.7
VLPP, 200 ml, cm H ₂ O (mean±SD), N=115	87.5 ± 41.1	81.5 ± 32.4	84.4 ± 37.7	97.6 ± 50.0
VLPP, 300 ml, cm H ₂ O (mean±SD), N= 27	96.6 ± 44.2	87.3 ± 45.3	86.6 ± 40.5	109.4 ± 54.2
VLPP, MCC cm H ₂ O (mean±SD) *, N= 135	84.4 ± 40.1	72.1 ± 29.2	82.2 ± 32.9	101.4 ± 51.7
Postvoid residual, mL	33.0 ± 42.3	43.06 ± 56.9	35.6 ± 37.2	26.1 ± 34.2
Maximum Flow, mL/sec	22.4 ± 10.6	22.6 ± 9.6	21.6 ± 11.6	23.1 ± 10.8
POPQ				
Ba (mean±SD)	-0.1 ± 2.6	+0.1 ± 2.7	+0.2 ± 2.8	-0.4 ± 2.7
Bp (mean±SD)	-0.9 ± 2.5	-0.9 ± 2.7	-0.9 ± 2.6	-0.7 ± 2.6
C (mean±SD)	-5.6 ± 5.5	-5.5 ± 6.2	-5.2 ± 5.2	-6.1 ± 5.6

* Diabetes Mellitus and VLPP @ MCC were potential confounders (associated with both BMI group and the primary outcome) and were, therefore, controlled for in the analyses.

Table 2

Patient Satisfaction Ratings One Year After Surgery By BMI Group

	Normal (N=68)	Overweight (N=65)	Obese (N=62)	P Value
Completely Satisfied, N (%)	45 (67.6)	44 (67.7)	42 (67.7)	0.98
Somewhat Satisfied, N (%)	16 (23.5)	14 (21.5)	15 (24.2)	
Not Satisfied, N (%)	6 (8.8)	7 (10.8)	5 (8.1)	

Table 3

Complications by BMI Group

	Normal (N=68)	Overweight (N=65)	Obese (N=62)	<i>p</i> * Value
Trocar perforation, N (%)	2 (2.9)	1 (1.5)	2 (3.2)	0.80
Retention, N (%)	4 (5.9)	1 (1.5)	3 (4.8)	0.38
TVT excision, N (%)	1 (1.47)	0	0	0.35
TVT exposure, N (%)	0	0	0	--
Ureteral Injury, N (%)	0	0	0	--
Transfusion, N (%)	0	0	0	--
Fever, N (%)	2 (2.9)	2 (3.1)	2(3.2)	0.99
Atelectasis, N (%)	0	0	1 (1.6)	0.33
Thromboembolic events, N (%)	0	0	0	--
Pneumonia, N (%)	0	0	0	--

* Fisher's exact test except on Failed Voiding Trial which used chi-square