Effect of Anesthesia on Voiding Function After Tension-Free Vaginal Tape Procedure

M. Murphy, MD, M. H. Heit, MD, MSPH, L. Fouts, MD, C. A. Graham, MD, L. Blackwell, RN, and P. J. Culligan, MD

OBJECTIVE: To determine whether the mode of anesthesia used during the tension-free vaginal tape procedure affects postoperative voiding function.

METHODS: A retrospective cohort study was performed using cases in which tension-free vaginal tape placement was the sole procedure performed. Of the 173 cases reviewed, we were able to use the data from 163. Hierarchal linear regression was used to identify independent predictors of our dependent variable: days to complete voiding. In the first block, established predictors of postoperative voiding dysfunction were entered into the model. In the second block, potential confounders of the relationship between anesthesia type and days to complete voiding identified during univariate analysis ($P < .15$) were entered into the model. In the third block, anesthesia type was entered into the model to determine whether it added any unique variance after controlling for previously established predictors of postoperative voiding dysfunction.

RESULTS: The mean days to complete voiding was similar in our local or regional anesthesia ($n = 90$) and general anesthesia groups ($n = 73$) (2.3 [0–21] versus 2.3 [0–14], $P = .95$). Our final regression model ($F = 2.74$, $P = .011$) included age, prior pelvic organ prolapse surgery, and preoperative urge symptoms and explained 22.2% of the variance in days to complete voiding. Anesthesia type did not add any predictive improvement after controlling for these variables.

CONCLUSION: General anesthesia, and therefore lack of a cough-stress test, does not increase the chance of postoperative voiding dysfunction associated with tension-free vaginal tape. (Obstet Gynecol 2003;101:666–70. © 2003 by The American College of Obstetricians and Gynecologists.)

A recent comprehensive literature review placed the probability of urinary retention after traditional pubovaginal sling procedures at 8%.[1] The tension-free vaginal tape procedure differs from traditional sling procedure in two major ways: Surgeons place the tension-free vaginal tape at the midurethra (as opposed to the urethrovesical junction) and can perform the procedure under local or regional anesthesia. Placing the sling using local anesthesia enables the surgeon to confirm continence with a "cough-stress test" intraoperatively. During this test, the surgeon gradually increases the tension of the tension-free vaginal tape while the patient coughs (and presumably leaks urine) with a moderately full bladder. The surgeon increases tension in small increments until coughing no longer results in urine loss, theoretically decreasing the risk of postoperative voiding dysfunction.[2]

Although Ulmsten[3] initially described the tension-free vaginal tape procedure using local anesthesia, placement under general anesthesia while performing concomitant surgery has since been described.[4,5] Eliminating the cough-stress test during tension-free vaginal tape placement under general anesthesia potentially robs this procedure of one of its advantages over traditional slings. In the limited research evaluating the efficacy of tension-free vaginal tape under general anesthesia with concomitant pelvic reconstructive surgery, short-term cure rates were preserved, but the most common complication was urinary retention.[5] It is unclear whether this high rate of voiding dysfunction was related to the absence of cough-stress testing and/or postoperative changes in pelvic floor function and position due to the reconstructive surgery. There is no literature comparing postoperative voiding function in patients who underwent tension-free vaginal tape procedure alone either with or without the cough-stress test.

The aim of our study was to determine whether general anesthesia (and therefore the inability to perform the cough-stress test) was associated with postoperative voiding dysfunction.

MATERIALS AND METHODS

This retrospective cohort study included 173 women with urodynamically proven genuine stress incontinence who underwent tension-free vaginal tape placement as their sole surgical procedure from April 1999 to January

From the University of Louisville Health Sciences Center, Louisville, Kentucky.

0029-7844/03/$30.00
doi:10.1016/S0029-7844(02)03127-7

2002. Two investigators (MM, LF) entered the data from all charts and also reviewed each other's data collection at intervals to ensure identical recording of information.

Standard preoperative assessment included a general medical history, a detailed urogynecologic history (including history of irritative bladder symptoms [frequency, urgency, and/or urge incontinence], hysterectomy, and prior incontinence or prolapse surgery), an office standing stress test, evaluation of urethral mobility, pelvic organ prolapse quantification,[6] and multichannel urodynamic testing, including pressure flow studies.

Two urogynecologists (PC, MH) performed all the procedures. They chose general, local with sedation, or regional anesthesia, based on their own preference at the time. Placement of the tension-free vaginal tape in patients with local or regional anesthesia was performed as previously described.[7] After filling the bladder with approximately 300 mL of saline, the surgeon asked the patient to cough vigorously while the surgeon adjusted the tape. Tape tension was set precisely to the point where vigorous coughing did not result in urinary leakage. For patients under general anesthesia, the tape was placed in the same fashion without using the cough-stress test. In those cases, the tension-free vaginal tape was adjusted to a position lying loosely under the midurethra. The surgeons did not hydrodissect the space of Retzius, nor did they attempt to simulate a cough-stress test using the Credé maneuver or gag reflex when general anesthesia was employed.

Postoperative evaluation consisted of voiding trial(s), pelvic examination, and continence history taken at follow-up visits by the attending surgeon. The variable, "days to complete voiding," was defined as the difference in time from the day of surgery (day 0) to the day when postvoid residual volumes were less than 100 mL. As this was a retrospective study, Foley catheter management was left to the discretion of the attending surgeon. As a general practice, both surgeons tried to remove the catheters as soon as possible. Postvoid residuals were not determined every day after surgery, however, if the subject failed her first voiding trial. Recorded variables of adverse outcome included failed first voiding trial, patient-reported irritative bladder symptoms or stress incontinence at follow-up office visits, mesh erosion, and tension-free vaginal tape takedown secondary to urinary retention. Outliers were identified by graphing a scatter plot of the variable, days to complete voiding, by subject number.

Univariate analysis was conducted using the Pearson χ^2 statistic for categorical data, the independent-samples t test for continuous parametric data, and the Mann-Whitney U test for continuous nonparametric data. A hierarchical linear regression[8] was then carried out to identify independent predictors of our dependent variable, days to complete voiding. In the first block of the regression analysis, established predictors of postoperative voiding dysfunction, such as patient age, and data from the preoperative pressure flow studies, including Valsalva voiding pattern, postvoid residual, maximum flow rate, and pressure at maximum flow, were entered into the model. In the second block, we entered potential confounders of the relationship between anesthesia type and days to complete voiding identified during univariate analysis ($P < .15$) into the model. These variables included the following: surgeon, prior hysterectomy, prior incontinence surgery, prior pelvic organ prolapse surgery, preoperative irritative bladder symptoms, estimated blood loss, maximum flow on preoperative pressure-flow studies, and maximum preoperative cotton-swab deflection. In the third block, anesthesia type was entered into the model to determine whether it added any unique variance to our dependent variable. Interactions between anesthesia type and potential independent variables entered in the first two blocks were also entered in the third block. Statistical analysis was performed using SPSS 10.0 for Windows (SPSS Inc., Chicago, IL).

Group sample sizes of 63 were required to achieve an 80% power to detect a 3-day difference in days to complete voiding between the null hypothesis that both groups' means were 0.0 and the alternative hypothesis that the mean in our general anesthesia group would be 3.0 with estimated group standard deviations of 6.0 and an α of 0.05. We chose to use a 3-day difference in our power calculation because, in our clinical experience, that interval significantly affects patients' quality of life.

The University of Louisville Human Studies Committee exempted this study from consideration because we used only existing data that could not be traced to an individual patient.

RESULTS

Of the 173 cases reviewed, we were unable to determine the number of days to complete voiding in nine cases. One outlier was removed, based on an analysis of the distribution of our dependent variable and the directional effects on its regressors during multivariable analysis. The outlier was in the general anesthesia group. Although her first postoperative postvoid residual was only 80 mL, she was later diagnosed with urinary retention. She required self-catheterization until she underwent urethrolysis on postoperative day 58. She remained continent and could void to completion after urethrolysis. No other patient in either group experienced a simi-

Table 1. Univariate Analysis Comparing Local and General Anesthesia Groups

Variable	Group		*P*	OR (95% CI)
	Local (n = 90)	General (n = 73)		
Surgeon				
MH	42 (46.7)	69 (94.5)	<.001*	8 (3.1, 21.0)
PC	48 (53.3)	4 (5.5)		
Race				
White	87 (96.7)	71 (97.3)	.827	1.12 (0.38, 3.33)
Other	3 (3.3)	2 (2.7)		
Age (y)	56.4 ± 11.3	58.7 ± 11.6	.204	
Parity	2.6 ± 1.6	2.6 ± 1.5	.985	
BMI	28.5 ± 5.8	28.6 ± 5.4	.928	
Tobacco use	13 (15.5)	10 (14.1)	.808	1.06 (0.64, 1.75)
Prior hysterectomy	47 (52.2)	52 (72.2)	.009*	0.604 (0.40, 0.91)
Prior incontinence surgery	20 (22.2)	25 (34.2)	.088*	0.73 (0.52, 1.03)
Prior prolapse surgery	24 (27.0)	30 (41.1)	.058*	0.72 (0.51, 1.00)
Pre-op irritative symptoms	50 (55.6)	22 (30.6)	.001*	1.8 (1.23, 2.70)
POP-Q stage				
0	40 (45.5)	22 (30.6)	.804	
1	33 (37.5)	30 (41.7)		
2	15 (17.0)	10 (13.9)		
Max cotton swab deflection	37.3 ± 15.8	42.3 ± 22.3	.135*	
Pre-op urodynamics				
Detrusor instability	27 (31.4)	23 (31.5)	.988	1.0 (0.69, 1.43)
Sphincter deficiency	21 (24.1)	22 (30.1)	.394	0.85 (0.60, 1.20)
Valsalva void	9 (10.5)	15 (20.5)	.080*	0.69 (0.48, 1.00)
$P_{det}@Q_{max}$	22.3 ± 14.6	19.1 ± 18.8	.250	
Q_{max}	17.9 ± 8.7	20.4 ± 8.4	.083*	

OR = odds ratio; CI = confidence interval; BMI = body mass index; pre-op = preoperative; POP-Q = pelvic organ prolapse quantification; Max = maximum; $P_{det}@Q_{max}$ = detrusor pressure at maximum flow rate.

Values are presented as n (%) or mean ± standard deviation.

* Variables entered into the second block of the model.

lar "reversal" of voiding function after passing their initial voiding trial. In the 163 patients remaining in the final analysis, one other urethrolysis was necessary. This tension-free vaginal tape was placed under regional anesthesia.

The demographics of the 163 subjects were similar (Table 1). The median stage of pelvic organ prolapse was 1 (range: 0–2). The mean follow-up period was 6.0 months (range: 1–31). Patients who had regional anesthesia (n = 7) were grouped with those who had local anesthesia (n = 83) because of the surgeons' ability to use a cough-stress test in this cohort. The remaining 73 patients had general anesthesia.

The number of complications within the two groups was similar. The local or regional anesthesia group had eight (8.9%), and the general anesthesia group had six (8.2%). In the local or regional anesthesia group there was one retropubic hematoma, one case of postoperative pseudomembranous colitis, and one erosion. The remaining complications in both groups were bladder perforations. All of these bladder perforations healed spontaneously after Foley catheterization for approximately 3 days.

The mean values of days to complete voiding in our local or regional anesthesia and general anesthesia groups were comparable (2.3 [0–21] versus 2.3 [0–14], P = .95). A univariate analysis was performed comparing potential confounding variable values between the two anesthesia groups (Table 1). Given that our two groups exhibited some differences, we performed a hierarchical linear regression to determine whether anesthesia type added any unique variance to our dependent variable and to identify alternative independent predictors of days to complete voiding.

Between the variables in our first model (established predictors of voiding dysfunction) and our second model (variables with P < .15 in univariate analysis), 22.2% of the variance in days to void was explained. When anesthesia type was added to the model, it added no predictive improvement directly or by interaction with variables in the model. In the final model only age, prior reconstructive surgery for pelvic organ prolapse, and preoperative irritative bladder symptoms were independent predictors of postoperative voiding dysfunction as defined in our study (Table 2).

Table 2. Significant Predictors of Post–Tension-Free Vaginal Tape Placement Voiding Dysfunction Determined by Multivariable Analysis

Variable	β	P	95% CI for β
Age	0.06	.03	.01, 0.12
Prior prolapse surgery	2.21	<.01	.83, 3.58
Pre-op irritative symptoms	1.53	.01	.33, 2.72

Abbreviations as in Table 1.
$R^2 = .222$, $F_{7,113} = 2.74$, $P = .011$.

DISCUSSION

Postoperative voiding dysfunction has been reported in 2.8–3.1% of tension-free vaginal tape procedure patients,[9,10] compared with 7.3–20.4% of patients with traditional pubovaginal slings.[11,12] Ulmsten et al[13] hypothesized that the cough-stress test, which can only be performed under local or regional anesthesia, enables surgeons to avoid higher rates of postoperative urinary retention while assuring continence. Nevertheless, many surgeons and patients remain apprehensive about using local anesthesia for this operation. Our data suggest that general anesthesia, and therefore absence of the cough-stress test, is not associated with postoperative voiding dysfunction as defined by our study.

It is important to realize that the cough-stress test is not the only unique feature of the tension-free vaginal tape procedure. Placement at midurethra and the minimal dissection involved with this operation may also contribute to the relatively low rate of postoperative voiding dysfunction. These characteristics may explain our failure to find a difference in voiding function between the two groups.

When considering the external validity of our findings, one should also take into consideration that all tension-free vaginal tapes (including those placed without benefit of the cough-stress test) were placed by urogynecologists previously trained to place traditional slings. The cough-stress test may actually be beneficial to surgeons who have less experience placing slings.

Retrospective studies are always susceptible to bias, and one can never be sure that one has adequately controlled for all confounders. Both surgeons in this study tried to limit the amount of postoperative catheterization time, but the surgeon's individual choice to select a mechanism for catheter removal and the lack of standardization of this critical process may have biased our findings. We tried to minimize this bias by controlling for the variable, surgeon, in our regression analysis.

Alternative end points for voiding dysfunction, such as urethrolysis, could have been used. Although this is probably the most valid marker of symptomatic voiding dysfunction, only two subjects in our cohort needed revision. These subjects were split between the two anesthesia groups. Because analysis of urethrolysis would have been essentially meaningless with these numbers, we used the next best marker available, days to complete voiding. The rate of urethrolysis in our cohort, 2 of 173 (1.2%), is lower than the rate of 2.2% previously reported in a multicenter trial.[14] That study included a significant number of patients who had concomitant prolapse surgery with their tension-free vaginal tape procedure. There may be an association between concomitant prolapse surgery and the need for urethrolysis after tension-free vaginal tape placement. Further investigation into this possible relationship could be helpful in counseling patients before surgery.

Our study does not address the other possible benefit of the cough-stress test, namely excellent stress incontinence cure rates.[2] Although all of the patients in this study returned for follow-up, we do not routinely perform postoperative urodynamic evaluations or issue standardized questionnaires regarding cure. Although we always address the continence status of patients following tension-free vaginal tape placement, we did not do so in a standardized fashion in this cohort. Therefore, we did not feel that we had a well-defined outcome measure for analysis of postoperative continence status. Further work will be necessary to determine whether there is an association between anesthesia type and postoperative urinary continence.

No difference in days to complete voiding was found between local and general anesthesia, but we did identify three preoperative variables associated with post–tension-free vaginal tape procedure voiding dysfunction: age, preoperative irritative bladder symptoms, and prior prolapse surgery. Increasing age was associated with an increase in days to complete void. This finding has also been noted after fascia lata suburethral sling placement.[15] This finding is best explained by the decreased detrusor function seen in older women. The presence of preoperative irritative bladder symptoms was also an independent risk factor. The cause and effect relationship here is difficult to delineate, but bladder storage and voiding functions are clearly interrelated. One study of 134 women with lower urinary tract symptoms showed that 44 (33%) had voiding phase abnormalities.[16] Finally, because pelvic floor surgery involving dissection can produce neuropathy of the pudendal nerve,[17] it is not surprising that prior prolapse surgery is associated with an increased number of days to complete voiding in tension-free vaginal tape procedure patients.

Any studies that suggest a difference in voiding dysfunction between patients undergoing tension-free vaginal tape placement under different types of anesthesia must control for the above variables in their groups.

REFERENCES

1. Leach GE, Dmochowski RR, Appell RA, Blaivas JG, Hadley HR, Luber KM, et al. Female stress urinary incontinence clinical guidelines panel summary report on surgical management of female stress urinary incontinence. J Urol 1997;158:875–80.
2. Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Olsson I. A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. Int Urogynecol J 1998;9:210–3.
3. Ulmsten U, Hendriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J 1996;7:81–6.
4. Vassalo BJ, Kleeman SD, Segal JL, Walsh P, Karram MM. Tension-free vaginal tape: A quality-of-life assessment. Obstet Gynecol 2002;100:518–24.
5. Partoll LM. Efficacy of tension-free vaginal tape with other pelvic reconstructive surgery. Am J Obstet Gynecol 2002; 186:1292–8.
6. Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996;175:10–7.
7. Ulmsten U, Hendriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J 1996;7:81–6.
8. Tabachnick BG, Fidell LS. Using multivariate statistics. 4th ed. Needham Heights, MA: Allyn & Bacon, 2001.
9. Klutke C, Siegel S, Carlin B, Paszkiewicz E, Kirkemo A, Klutke J. Urinary retention after tension-free vaginal tape procedure: Incidence and treatment. Urology 2001;58: 697–701.
10. Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Olsson I. A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. Int Urogynecol J 1998;9:210–3.
11. Cross CA, Cespedes RD, McGuire EJ. Our experience with pubovaginal slings in patients with stress urinary incontinence. J Urol 1998;159:1195–8.
12. Weinberger MW, Ostergard DR. Postoperative catheterization, urinary retention, and permanent voiding dysfunction after polytetrafluoroethylene suburethral sling placement. Obstet Gynecol 1996;87:50–4.
13. Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Olsson I. A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. Int Urogynecol J 1998;9:210–3.
14. Rardin CR, Rosenblatt PL, Kohli N, Miklos JR, Heit M, Lucente VR. Release of tension-free vaginal tape (TVT) for the treatment of refractory postoperative voiding dysfunction. Obstet Gynecol 2002;100:898–902.
15. McLennan MT, Melick CF, Bent AE. Clinical and urodynamic predictors of delayed voiding after fascia lata suburethral sling. Obstet Gynecol 1998;92:608–12.
16. Carlson KV, Fiske J, Nitti VW. Value of routine evaluation of the voiding phase when performing urodynamic testing in women with lower urinary tract symptoms. J Urol 2000;164:1614–8.
17. Benson JT, McClellan E. The effect of vaginal dissection on the pudendal nerve. Obstet Gynecol 1993;82:387–9.

Address reprint requests to: Miles Murphy, MD, University of Louisville HSC, 315 East Broadway, Suite 4002, M-18, Louisville, KY 40202; E-mail: m0murp01@louisville.edu.

Received August 9, 2002. Received in revised form October 10, 2002. Accepted November 24, 2002.