Is the Cough-Stress Test Necessary When Placing the Tension-Free Vaginal Tape?

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OBJECTIVE: To estimate whether the mode of anesthesia (and the resultant ability or inability to perform the cough-stress test) used during the tension-free vaginal tape (TVT) procedure affects postoperative continence.

METHODS: A cohort of 170 women who underwent the TVT procedure without any other concomitant surgery completed the short form of the Urogenital Distress Inventory (UDI-6) to assess their continence status preoperatively and postoperatively. Chi-squared, *t*, and Mann-Whitney *U* tests were used to determine the association between these data and anesthesia type during univariate analysis.

RESULTS: Both anesthesia groups showed significant improvement from their preoperative UDI-6 scores to their postoperative scores. However, when comparing the change from pre- to postoperative UDI-Stress Symptoms subscale scores between the 2 groups, we found a significant difference. Mean improvement in the local group was 58.3 (± 33.8) compared with 41.7 (± 39.4) in the general group ($P = .02$).

CONCLUSION: Women who undergo TVT show significant improvements in incontinence severity regardless of anesthesia type. However, greater improvements in stress incontinence, as measured by the UDI-Stress Symptoms subscale, are seen when the TVT is placed while using the cough-stress test under local analgesia. (Obstet Gynecol 2005;105:319–24. © 2005 by The American College of Obstetricians and Gynecologists.)

LEVEL OF EVIDENCE: II-2

Like many other new minimally invasive suburethral slings, tension-free vaginal tape (TVT) differs from traditional pubovaginal slings in 3 basic ways: surgeons place the TVT at the midurethra (as opposed to the urethrovesical junction), the ends of the sling are not sutured in place, and it can be performed under local analgesia. Placing the sling under local analgesia enables the surgeon to tailor the placement of the tape to each individual patient by using the "cough-stress test" to adjust the sling intraoperatively. The tape is pulled up in small increments until coughing no longer results in urine loss, theoretically assuring continence while decreasing the risk of postoperative urinary retention.[1]

Although Ulmsten et al[2] described the procedure using local analgesia, TVTs are commonly placed during concomitant prolapse surgery under general anesthesia.[3] As surgeons became comfortable placing the TVT under general anesthesia during larger prolapse cases, many adopted the use of general anesthesia even when placing TVT alone. Although this practice saves time, eliminating the cough-stress test during TVT placement potentially robs this procedure of 2 of its theoretical advantages over traditional slings: improved continence and decreased voiding dysfunction.

In a prior study our group demonstrated that general anesthesia (and therefore the lack of a cough-stress test) was not associated with an increase in voiding dysfunction in post-TVT patients.[4] However, that retrospective study did not address the other possible benefit of the cough-stress test: improved postoperative continence.

Only one other study, a case series, has looked at the use of general anesthesia in patients who are undergoing TVT as their sole operative procedure.[5] Although they demonstrated good cure rates (72%) at 6 months, there was no control group with which to compare patient outcomes. Therefore, we designed a cohort study to estimate whether the use of the cough-stress test during TVT placement is associated with postoperative continence.

MATERIALS AND METHODS

We identified a cohort of 170 consecutive women with urodynamic stress urinary incontinence who underwent TVT as their sole operative procedure at our institution from April 1999 to January 2002. Two attending urogynecologists (P.J.C., M.H.H.) performed all the cases. They chose general, local with sedation, or regional anesthesia based on their own preference at the time (most of the general anesthesia cases were done in the latter half of the study period). The 11 subjects who had regional anesthesia were removed from our analysis. Placement of the TVT in patients with local analgesia

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was performed as previously described.[2] The patient was asked to cough vigorously with a full bladder while the surgeon adjusted the tape to minimize leakage. After demonstrating a leak with space clearly visible between the sling and the urethra, the sling was elevated incrementally until no further leakage was seen. In patients with general anesthesia, the procedure was performed in the same way, with the exception of the cough-stress test. In these cases, the TVT was adjusted to a position lying loosely under the midurethra. The surgeons did not attempt to simulate a cough-stress test using the Crede maneuver or gag reflex when general anesthesia was used.

A database was developed to collect preoperative data on these 159 subjects as part of a previous investigation.[4] These data included a general medical history, a detailed urogynecologic history, prior surgical history, an office standing stress test, evaluation of urethral mobility, pelvic organ prolapse quantification,[6] and multichannel urodynamic testing. For the current study, we added to this database the preoperative responses to 3 validated questionnaires: Sandvik's Incontinence Severity Index (ISI),[7] the short form of the Incontinence Impact Questionnaire (IIQ-7), and the short form of the Urogenital Distress Inventory (UDI-6).[8] Our practice routinely mails these questionnaires to patients before their first office visit, and these data were collected retrospectively.

We then prospectively measured subjective surgical outcomes after tension-free vaginal taping by mailing these same 3 questionnaires (the ISI, IIQ-7, and UDI-6) to our subjects. If we received no response, an investigator (C.M.A.) who was blinded to anesthesia type attempted to contact the subjects by phone. We chose to use multiple instruments to measure our outcome of interest because this approach is recommended by the National Institute of Diabetes and Digestive Kidney Diseases.[9] This group also notes that the Second International World Health Organization Consultation on Incontinence recommends the ISI for studies of incontinence.

The ISI is a questionnaire composed of 2 items that assess the frequency (4 levels) and amount (3 levels) of urine leakage. The index value (0–12) is reached by multiplying the 2 items. The criterion validity of the ISI has been demonstrated by its high correlation with pad-weight tests ($r = 0.54$, $P < .01$).[7] The UDI-6 is a 6-item questionnaire used to assess the distress caused by various urogenital symptoms, and the IIQ-7 is used to measure the psychosocial impact of urinary incontinence on activities of daily living. The long forms of the UDI and IIQ are significantly correlated with both the number of incontinent episodes per week and the pad-weight test ($r = 0.22–0.32$, $P < .01$), and short-form scores on these instruments are highly correlated with those of the long forms (UDI-6, $r = 0.93$; IIQ-7, $r = 0.97$, $P < .001$).[10] The UDI-6 can be divided into 3 subscales that assess Irritative, Obstructive/Discomfort, and Stress Symptoms. Our primary outcome of interest was change in the UDI-Stress Symptoms subscale score. Other questionnaires measure symptoms of overall incontinence (stress and/or urge), but we chose this instrument because it was the only available validated measure of, specifically, stress urinary incontinence, the indication for TVT. By comparing change within subjects over time, we were able to control for potential preoperative differences in incontinence severity.

Our secondary outcomes included the ISI, the IIQ-7, and the remaining subscales of the UDI-6. Finally, we also asked the following question of all subjects: "Since your surgery for urine leakage, have you needed to have a second surgery to loosen or 'take down' the TVT tape because it was too tight?"

Analysis of variance was used to compare demographics between the 3 groups: local, general, and nonresponders. Univariate analysis was conducted with the Pearson χ^2 statistic for categorical data, the independent-samples t test for continuous normal data, the Mann-Whitney U test for continuous nonnormal data, and the Sign test[11] for continuous nonnormal repeated measures. Normality of the sample estimates were evaluated by several methods, including a comparison of the shape of the frequency distribution (histogram) of the sample estimate with a normal curve, comparison of the mean and median values of the sample estimate for similarities, and calculation of the quotient obtained when the skewness statistic for the sample estimate was divided by its standard error (values < 2 suggest normality). Statistical analysis was performed using SPSS 10.0 for Windows (SPSS Inc, Chicago, IL).

We performed a power calculation to determine if we had enough subjects in our cohort to detect a 33-point difference between groups in our dependent variable, change in UDI-Stress Symptoms subscale score. We chose a 33-point difference because this represents the difference in the UDI score between "slight" versus "moderate" bother caused by stress symptoms. Group sample sizes of 33 were required to achieve an 81% power to detect this difference in outcome between anesthesia groups with an α of 0.05 using a 2-tailed test. Written or verbal informed consent was obtained from each subject, and the University of Louisville Human Studies Committee approved the study protocol.

RESULTS

Three members of our cohort had suffered non–surgically related deaths by the time of follow-up. We contacted 142 (89.3%) of the remaining 156 subjects. Of

Table 1. Comparison of Nonrespondent, Local, and General Anesthesia Groups

	Local (n = 56)	General (n = 48)	Nonrespondent (n = 55)	*P*
Age (y)	57.0 ± 10.8	59.3 ± 11.8	55.9 ± 12.1	.33
Body mass index (kg/m^2)	27.8 ± 5.1	28.4 ± 5.0	29.6 ± 6.1	.20
Parity	2.3 ± 1.4	2.5 ± 1.6	2.7 ± 1.6	.38
Maximum cotton swab deflection (xx)	35.6 ± 14.2	42.9 ± 25.0	42.0 ± 18.3	.17
Follow-up interval (mo)	30.8 ± 8.2	29.2 ± 6.3	31.4 ± 8.4	.34
Race				
White	54 (96.4)	46 (97.9)	52 (94.5)	.54
Nonwhite	2 (3.6)	1 (2.1)	3 (5.5)	
Tobacco use	8 (14.3)	7 (14.6)	11 (20.0)	.19
Surgeon				
M.H.H.	22 (39.3)	47 (97.9)	36 (65.5)	< .01
P.J.C.	34 (60.7)	1 (2.1)	19 (35.5)	
Prior surgery for:				
Prolapse	16 (28.6)	18 (38.3)	18 (37.7)	.58
Incontinence	13 (23.2)	18 (37.5)	12 (21.8)	.15
Hysterectomy	30 (53.6)	35 (72.9)	35 (64.8)	.12
Preoperative urodynamics				
Intrinsic sphincter deficiency	15 (27.8)	11 (23.4)	17 (30.9)	.70
Detrusor instability	14 (25.9)	16 (33.3)	18 (33.3)	.64
Valsalva void	5 (9.3)	9 (18.8)	6 (11.1)	.32

Data are presented as mean ± standard deviation for continuous data and number (%) of positive responses for categorical data.

these, 132 (84.6%) consented to be in the study. The median follow-up period was 32 months (range 18–48). Seventy-four (46.5%) women had the TVT placed under general anesthesia, and the 85 (53.5%) remaining subjects had local analgesia. Only subjects who completed pre- and postoperative questionnaires (responders) were included in our final analysis. The demographics of the nonresponders and the 2 anesthesia groups were similar (Table 1).

Responders in both the local and the general anesthesia groups showed significant improvements in all but one of their questionnaire scores (Table 2). The only instrument in which subjects did not show significant change was the UDI-Obstructive/Discomfort Symptoms subscale.

Table 2. Within-Group Comparison of Preoperative and Postoperative Questionnaire Scores

Questionnaire (n)	Preoperative Score	Postoperative Score	Mean Change	*P*
IIQ-7				
Local (56)	39.9 ± 24.6	10.8 ± 23.3	29.1 ± 35.2	< .001
General (46)	50.7 ± 34.6	22.9 ± 34.6	27.8 ± 35.7	< .001
UDI-6				
Local (56)	55.2 ± 18.9	21.4 ± 20.2	33.8 ± 25.7	< .001
General (48)	62.9 ± 20.5	32.9 ± 29.1	30.0 ± 30.2	< .001
UDI subscales				
Stress Symptoms				
Local (56)	78.6 ± 19.8	20.3 ± 26.3	58.3 ± 33.8	< .001
General (48)	78.8 ± 23.0	37.1 ± 37.4	41.7 ± 39.4	< .001
Irritative Symptoms				
Local (54)	67.3 ± 30.7	28.9 ± 30.2	37.4 ± 35.9	< .001
General (47)	75.6 ± 25.7	40.8 ± 34.9	34.8 ± 35.6	< .001
Obstructive/Discomfort				
Local (55)	18.8 ± 26.8	14.6 ± 19.5	4.2 ± 32.1	.749
General (44)	36.1 ± 33.1	21.2 ± 26.6	14.9 ± 37.4	.230
Incontinence Severity Index				
Local (36)	9.6 ± 3.1	2.5 ± 3.5	7.1 ± 3.9	< .001
General (28)	10.0 ± 2.8	5.5 ± 4.7	4.5 ± 4.4	< .001

IIQ-7, Incontinence Impact Questionnaire; UDI-6, Urogenital Distress Inventory.
Data are presented as mean ± standard deviation; the Sign test was used for comparison of continuous, nonnormal repeated measures.

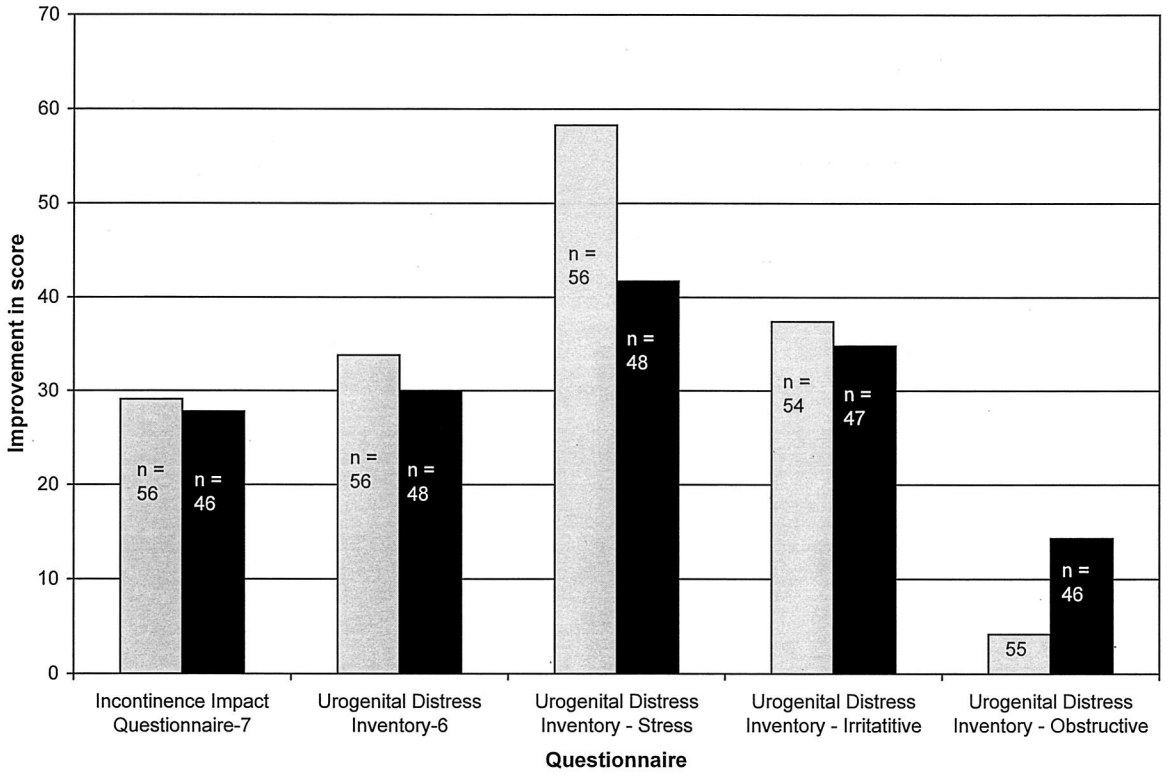

Fig. 1. Between-group comparison of mean improvement in scores of subjects who completed both the pre- and postoperative Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6) questionnaires. The light bars represent the local subjects and the dark bars represent the general anesthesia subjects.
Murphy. The Cough Test and TVT Success. Obstet Gynecol 2005.

Although both anesthesia groups showed significant improvement in continence-related quality of life, the local group showed greater improvement on certain measures. We found a significant difference in the pre- to postoperative improvement between groups in our primary outcome measure: the UDI-Stress Symptoms subscale (Fig. 1). Mean (± standard deviation) improvement of this measure in the local group was 16.6 points higher than in the general anesthesia group (58.3 ± 33.8 points versus 41.7 ± 39.4, $P = .02$). The comparison of improvement in ISI score is not shown in Figure 1 because of its different measurement scale (possible range 0–12), but we also found a greater improvement in incontinence severity in the local group with this instrument. The mean improvement in ISI score was 7.1 ± 3.9 in the local group versus 4.5 ± 4.4 in the general group ($P = .02$). Finally, although we knew that 2 (1.2%) of our subjects (one in each group) needed a "takedown" while under our care, no subjects responded that they had undergone a "takedown" of their TVT since their last office visit.

Most of the general anesthesia cases were performed by one surgeon. When his results were analyzed independently the difference in mean improvement in the Stress Symptoms subscale between anesthesia groups, 17.4 points, was greater than the difference found between groups in the total population, but in this smaller population the difference was not statistically significant (local: 56.1 ± 38.7; general: 38.7 ± 38.6, $P = .12$). When this surgeon's results in local patients alone were compared with the other surgeon's local patients, no difference was found in mean improvement (M.H.H.: 56.1 ± 38.7; P.J.C.: 59.8 ± 30.7, $P = .69$).

DISCUSSION

Our study demonstrates that local analgesia with use of the cough-stress test is associated with greater improvements in stress incontinence than is general anesthesia. Patients whose TVTs are placed under general anesthesia did well, but the fine tuning allowed with the cough-stress test afforded better outcomes in continence, as measured by the UDI-Stress Symptoms subscale. This is accomplished without sacrificing future voiding function. No significant difference was found in UDI-Obstructive Symptoms subscale, and only one subject in

each group needed TVT takedown during more than 2 1/2 years of follow-up. In simple terms, it allows placement that is neither too tight nor too loose. Although this outcome may seem obvious and expected, it has never been demonstrated. In fact, prior studies comparing varying types of anesthesia have not shown any difference in the efficacy of TVT.[12,13]

Our investigation confirms the findings of another large study that demonstrated significant improvements in patient quality of life and symptoms of incontinence following TVT.[14] In that paper, 37 subjects (24.5%) had TVT without concomitant surgery. Like the subjects in our study, these patients had improvement on the IIQ-7 and the Urge and Stress subscales of the UDI-6, but not on the Obstructive/Discomfort subscale. We expected this, because it would be illogical to expect a less obstructive voiding pattern following a sling procedure in patients without prolapse. This speaks to the divergent validity of the UDI-6.

We used only subjective outcome measures in this study. Objective measures of success would have certainly strengthened this investigation, but both subjective and objective measures have limitations. Objective measures may be a poor reflection of how patients perceive they have done following incontinence surgery.[15] Patient perceptions are best measured with validated questionnaires, but even incontinence-specific subjective measures, such as those used in our study, are susceptible to confounding bias from other general health quality-of-life issues. If a subject's perception of her general health is not measured, it is difficult to assess this threat to validity. Unfortunately, we did not include a measure of general health, such as the generic Short-Form 36 (SF-36).[16]

This was a cohort study, not a randomized trial. Despite a lack of randomization, there were no demographic differences between the 2 anesthesia groups. There was, however, a statistically significant difference between groups with regard to the operating surgeon. The fact that almost all the general anesthesia cases were done by one of the two surgeons is a serious study limitation. To better understand what impact this had on our results, we stratified the results by surgeon. When only M.H.H.'s subjects were analyzed, the mean difference in postoperative improvement between anesthesia groups was very similar to the difference between groups seen in the total population. Unfortunately, group size in this stratified analysis did not meet that of our power calculation, and, as might be expected, this difference between anesthesia groups was no longer statistically significant. To see if there was an inherent difference in technique (apart from anesthesia used) between surgeons, we also compared the results of just the local group between the two surgeons. We found no difference in outcomes between the two surgeons in this analysis.

Another potential weakness of this study is that some subjects did not receive all of the preoperative questionnaires. For instance, no subjects from the first year of this cohort received the ISI, because the description of this instrument had not yet been published. Furthermore, every subject who completed the preoperative questionnaires did not necessarily complete the postoperative questionnaires and vice versa. We minimized this shortcoming by including only those subjects who completed both pre- and postoperative questionnaires in our analysis. Although this decreased the number of subjects in our study population, we still found significant differences in the outcomes between groups.

The risk of response bias is always a fear in survey studies with a response rate that is less than 100%. We are confident, however, that response bias in this analysis was minimal. First of all, more than 80% of our cohort consented to be included in the study. Secondly, responders and nonresponders were overwhelming similar. No demographic differences were seen between the nonresponders and the local and general anesthesia groups.

Finally, there may be some uncertainty regarding the clinical relevance of the difference between anesthesia groups that we found in this study. Although it is clear that there was a statistically significant difference in questionnaire response, this difference was not as large as the value we stipulated a priori in our power calculation. Again, we stress that the general anesthesia group showed a large, significant improvement from their pre- to postoperative scores. But the fact that the difference in improvement between groups was found on 2 independent measures of incontinence (one measuring bother from stress incontinence symptoms and the other incontinence severity) bolsters our assertion that this is a clinical, as well as statistical, difference. Nonetheless, when pertinent factors favor the use of general anesthesia over local analgesia, its use can be justified with proper patient counseling.

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