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Can Urethral Retroresistance Pressures Predict Midurethral Sling Outcomes?

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OBJECTIVE: To determine whether preoperative urethral resistance pressure (URP) measurements could predict success or failure of a tension-free vaginal tape (TVT) sling.

METHODS: Subjects came from a previously published study comparing URP measurements to a validated urinary incontinence symptom survey (UISS). We contacted patients from that study to determine whether they had subsequently undergone TVT surgery. Within that cohort, we determined the "current" (i.e., postoperative) UISS and Sandvik urinary incontinence severity score. Success of a TVT sling in this group was defined in 4 ways: (1) postoperative UISS score < 3, (2) postoperative UISS score < 75% of the preoperative score, (3) postoperative Sandvik score < 6, and (4) postoperative Sandvik score < 2. These definitions of "success" were compared across demographic and treatment variables using the Student's t test, ANOVA, χ^2 and ROC curves.

RESULTS: We contacted 69 women who had in fact received a TVT sling after their participation in the previously published study mentioned above. Among these 69 women, mean preoperative urethral retroresistance pressure values were not predictive of surgical success.

CONCLUSION: Preoperative urethral retroresistance pressure measurements did not reliably predict surgical success or failure; therefore, this urodynamic test is of little value to the clinician. (J Reprod Med 2010;55: 103–107)

Preoperative URP measurements did not reliably predict surgical success or failure.

Keywords: urethral retroresistance pressure, urinary stress incontinence, urodynamics.

Due to the effectiveness and minimally invasive nature of midurethral sling systems such as tension-free vaginal tape (TVT), these devices are widely thought of as the "gold standard" surgical treatment for stress urinary incontinence.[1] In fact, these slings are so effective that any surgical failures are typically quite surprising and disappointing to both the patient and her surgeon. In an attempt to counsel patients about their risk of experiencing such a failure, many surgeons perform a series of preoperative urodynamic studies. The most commonly

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used urodynamic tests are maximum urethral closure pressure (MUCP) and leak point pressure (LPP). MUCP assesses the passive resistance (or resting tone) of the urethral sphincter, while LPP assesses the active resistance (or dynamic response) of the urethral sphincter under stress.[2] Unfortunately, there exists a modest overlap between the results of MUCP and LPP testing among symptomatic and asymptomatic patients, which limits the clinical usefulness of both tests.

It is highly unlikely that any such predictive preoperative URP value could be identified, even in a much larger group.

In 2004, Slack et al[3] described a urodynamic measurement called urethral retroresistance pressure (URP). The URP is defined as the pressure required to achieve and maintain an open urethral sphincter while infusing saline solution through the urethra toward the bladder at a constant rate. These measurements are obtained using a proprietary urodynamic machine (Monitorr, Ethicon Women's Health & Urology, Somerville, New Jersey). Since hitting the marketplace in 2003, the Monitorr device has been quite popular among gynecologists, presumably due to its ease of use, portability and affordable price.

While Slack's initial publication clearly demonstrated a statistically significant inverse correlation between URP values and severity of urinary incontinence (i.e., lower scores predicting more severe incontinence), the usefulness of URP values for actually predicting success or failure of continence surgery has not been established. Therefore, the aim of our study was to determine whether preoperative URP measurements could predict success or failure of a TVT sling.

Materials and Methods

Our work was approved by the Atlantic Health Institutional Review Board (study number R04-10-001). This was a retrospective cohort study made up of patients who had previously participated in the above-mentioned original study by Slack et al,[3] which compared URP measurements to validated urinary incontinence severity scores obtained from 258 stress incontinent women at 22 international centers. That study included 161 patients from the United States, and those 161 women made up the potential study group for our work. In other words, we did not attempt to include subjects from outside the United States.

We began with one basic assumption—namely, that a large proportion of those 161 women from the original study had probably gone on to receive surgical treatment for stress incontinence. Due to the fact that all of the investigators in the index study tended to use the TVT device as their primary anti-incontinence operation, we further assumed that women in our cohort of interest were likely to have received that particular type of sling. Based on these assumptions, an independent clinical research nurse (L.B.) attempted to contact all 161 patients to identify the subset who had, in fact, received a TVT sling.

All of the patient contact information was housed at the respective 18 US centers where these patients had completed the original study. Therefore, we first contacted all of those study sites in an attempt to retrieve patient contact information. Of those 18 centers, only 14 were willing to divulge this information, which made our best possible sample size 117 patients. Descriptive statistics, including age, body mass index, duration of urinary incontinence, number of vaginal deliveries and preoperative URP and urinary incontinence symptom score (UISS) values, were determined using information from the original study database.

After identifying the women who had received a TVT sling, we sought to determine whether the clinical outcomes of those operations were somehow correlated with the preoperative URP values recorded by Slack et al.[3] Due to the fact that our study design called for the data to be collected via mailings or phone calls, we based our outcome measures entirely on validated subjective surveys. Specifically, we ascertained each patient's postoperative continence status based on 2 data points: UISS and Sandvik index score.

The UISS, first described by Stach-Lempinen et al,[4] was completed by all patients in the original URP study; therefore, we chose to use that score as our main postoperative end point. The UISS is a 10-question, validated survey designed to assess the impact of any type of urinary incontinence (i.e., not just stress incontinence) on patients' quality of life. The highest possible score on the UISS is 30 (indicating the most severe incontinence), and the lowest

possible score is 0 (indicating no incontinence). We arbitrarily defined surgical cure of incontinence as a function of the UISS in 2 ways: (1) postoperative UISS score ≤3, and (2) a postoperative UISS score ≥75% lower than the preoperative UISS score. We decided on these definitions prior to collecting any data for this study.

We also administered the Sandvik index of urinary incontinence severity.[5] The Sandvik index is derived from two simple questions: (1) "How often do you leak urine?" and (2) "How much urine do you leak each time?" For the first question there are five possible answers: "never," "less than once a month," "a few times a month," "a few times a week," "every day and/or night." The values assigned to these answers are 0, 1, 2, 3 and 4, respectively. For the second question, there are 3 possible answers: "drops," "small splashes" and "more than small splashes." The values assigned to these answers are 1, 2 and 3, respectively. To arrive at the Sandvik index, the value for the first answer is multiplied by the value for the second answer. For example, a woman who reports leaking "small splashes" of urine (score of 2) on a "daily basis" (score of 4) would receive a Sandvik score of 8 (i.e., 2 times 3). We chose the Sandvik index because it correlates well with pad-weight tests and is highly sensitive to changes in incontinence severity following mid-urethral sling placement.[6] For the purposes of our study, we arbitrarily defined surgical cure of incontinence in terms of the Sandvik index in 2 ways, a value ≤6 and a value ≤2.

As all patients in the original URP study completed the UISS, we chose to use the UISS as our main postoperative end point.

Based on the 4 definitions of surgical cure, receiver operating characteristics (ROC) curves were generated for each predictor variable. We chose ROC curves because they provide a visualization of the percentage of true positive predictions relative to the percentage of false positive predictions for each treatment variable across the range of possible values for that treatment variable.[7] When the variable under study cannot distinguish between the 2 groups, in this case "cured" or "not cured," the area will be equal to 50%. (The ROC curve will coincide with the 45° diagonal.) When there is a perfect separation of the values of the 2 groups, the area under the ROC curve would equal 100%, and the ROC "curve" would form a right angle in the upper left corner of the plot. Descriptive statistics were calculated for all available variables. All statistical analyses were conducted using SAS 9.1 (SAS Institute Inc., Cary, North Carolina) and Medcalc 8.1 (Medcalc Software, Mariakerke, Belgium).

Results

We successfully contacted 100 out of the possible 117 patients (86%). No patients we contacted refused participation. Of the 100 patients contacted, 69 had received a TVT since the original study (Figure 1). Those 69 patients made up our study group, and all of them completed the questionnaires. The mean time between a given patient's surgery and her participation in this study was 23.9 months (range, 12–36). There were no significant differences between the TVT group (n = 69) and the "no sling" group (n = 31) for any of the descriptive demographic charistics (Table I).

Using the different cure definitions, a logistic regression model was developed using mean URP as the single predictor. The predictions of this model could yield 1 of 4 outcomes: a true positive (a cured patient was predicted as cured), a false positive (a not-cured patient was predicted as cured), a true negative (a not-cured patient was predicted as not cured) and a false negative (a cured patient was predicted as not cured). The ROC curve plots the percent of true positives (also known as the "sensitivity" of the model) vs. the percent of false positives (also known as "specificity" of the model) across the entire range of mean URP scores. The "optimal" mean URP score was represented at the point on the curve that generated the greatest percentage of true positives while minimizing the percentage of false positives.

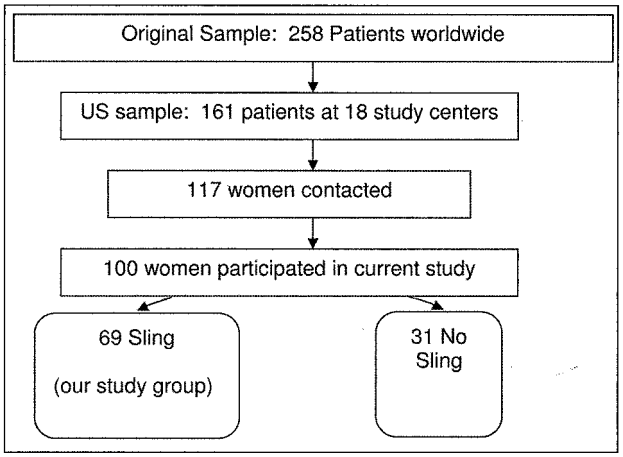

Figure 1 Study flow chart.

Table I *Comparison of Study Participants Who Had and Had Not Received a TVT Sling*

Variable	Study group (TVT group) (n = 69) Mean (SD)	No-sling group (n = 31) Mean (SD)	p Value
Age (yr)	60.3 (10.7)	57.1 (12.7)	0.20
Body mass index	28.8 (4.7)	30.9 (6.4)	0.07
URP value at baseline	66.7 (24.8)	70.1 (29.5)	0.56
Duration of incontinence prior to our study	6.7 (7.2)	7.1 (7.5)	0.81
No. of vaginal deliveries	2.7 (1.5)	2.2 (1.7)	0.10
Baseline UISS	10.1 (3.8)	9.3 (4.3)	0.33
Current UISS	3.2 (4.0)	9.7 (4.5)	<0.0001

Mean preoperative URP values were not predictive of surgical "cure" as defined in any of the 4 above-mentioned ways. Specifically, the areas under the ROC curves had a higher mean URP value in only 52%, 58%, 51% and 52% of the cases, respectively. In other words, a value of 52% would indicate that a randomly selected individual from the "cured" group would have a mean URP score higher than that for a randomly chosen individual from the "not-cured" group only 52% of the time. In our study, we had 38 false positive results and 10 false negative results per 100 patients, demonstrating sensitivity of 89.7% and specificity of 67.6%.

Discussion

The value of identifying those patients who will most likely have successful surgery for stress urinary incontinence is of obvious importance. Previous research has demonstrated the diagnostic benefits of various urodynamic measurements, but, to date, none of these has proven to be definitive in terms of predicting surgical outcomes.

We developed this study design as an inexpensive alternative to a large prospective trial, and we expected our results to be no more than pilot data that could provide us with a better sample size estimate for a future multicenter URP study designed to predict surgical outcomes. What we found, however, was that our data could be thought of as definitive (assuming our definitions of cure were reasonable), suggesting that a larger prospective trial would very likely yield similar results.

This study is limited by its small sample size and by the possibility that our definitions of cure were not clinically relevant. Our validated assessment tools were not designed to discriminate between various types of incontinence, so one could argue that some of the "not-cured" patients could have been reporting primarily urge incontinence. While that criticism would be valid, one must remember that the original study group was selected because they were complaining of primarily stress incontinence. We designed this study around the assumption that within that group of women who were originally complaining of primarily stress incontinence, those who actually then submitted to TVT placement probably had stress-predominant patterns of incontinence.

There are several important strengths of our study. The follow-up interval between TVT placement and completion of the subjective assessment tools was relatively long. Also, the fact that subjects from 14 U.S. centers were represented in our study group speaks to the external validity of our findings.

Our results are similar to those published by Tunn et al in 2007.[8] In a short-term single-center prospective study of 48 women, those authors found no correlation between preoperative URP values and postoperative objective stress urinary incontinence cure (i.e., negative pad tests).

In conclusion, for these 69 patients who underwent TVT placement, preoperative URP measurements did not reliably predict surgical success or failure. Furthermore, our findings suggest that it is highly unlikely that any such predictive preoperative URP value could be identified, even in a much larger group.

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