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Urogynecology digest

Presented by Aparna Hegde

Comparison of surgical outcomes in patients undergoing the TOT sling procedure using a surgical incision beginning at $^1/_3$ and $^1/_2$ of the sonographically measured urethral length respectively: a randomized controlled trial

Viereck V, Kuszka A, Rautenberg O, Wlazlak E, Surkont G, Hilgers R, Eberhard J, Kociszewski J. Do different vaginal tapes need different suburethral incisions? The one-half rule. Neurourol Urodyn. 2014. doi: 10.1002/nau.22658

This randomized controlled trial compares surgical outcomes in 123 women, with urodynamically proven stress urinary incontinence, undergoing a TOT procedure, who were randomly assigned to one of two tape insertion technique groups: the $^1/_3$ rule (62 women) or the $^1/_2$ rule (61 women). The $^1/_2$ and $^1/_2$ rule techniques involved starting the suburethral incision at $^1/_3$ and $^1/_2$ of the sonographically measured urethral length respectively. The study is based on the hypothesis that since TOT tapes are placed in a more ventrocaudal and horizontal direction and have been sonographically shown to have decreased proximal shift toward the bladder neck compared with the TVT, achieving the desired high pressure zone under pressure may require placing the TOT tape more proximally. The primary outcome assessed at the 6-month follow-up visit was SUI treatment success defined as a patient with negative postoperative cough test, negative 1-h pad test and an improvement in the degree of subjective suffering to a VAS score of 0 or 1. The overall cure rate was found to be higher in the $^1/_2$ rule group than in the $^1/_3$ rule group (83.6 vs 62.9 %; p=0.01), particularly in those patients with normal urethral mobility (85.7 vs 55.2 %; p=0.02).

The authors have not specified whether they excluded patients with concomitant anterior prolapse and it is unclear how many patients underwent concomitant anterior repair. Although the tapes were sonographically found to be in the target location suburethrally in 98.4 and 100 % of women in the $^1/_2$ and $^1/_3$ rule groups respectively, the readers would have been better served if the authors had described how the sonographically determined incision start point was translated into actual practice at the time of surgery. The difference in the incision start point may only be a few millimeters in the two groups; thus, translating the sonographically assessed incision start location to an exact point on the anterior vaginal wall may be difficult in patients with concomitant anterior wall prolapse. Secondly, dynamic assessment of the sling function has shown that sling location, concordance of the urethral movement with the sling, and sling deformability on straining are three important parameters that often work together to compensate for the failure of an individual parameter to ensure successful outcomes [1]. Hence, assessment of only a single factor, namely location, as done in this study, may provide an incomplete picture. Although the authors found that all the patients in whom there was sling deformability from flat to C-shaped during straining were cured, it is not clear whether there is any statistical difference in the number of such patients in the two groups. Also, in 11 patients in the $^1/_3$ group as opposed to only 2 in the $^1/_2$ group, the sling did not deform on straining, which may be a potential confounder accounting for the results. There was also a statistically significant difference in the median tape–urethra distance in the two groups during straining (3.5 mm in the $^1/_3$ group vs 2.9 mm in the $^1/_2$ group; p<0.001) suggesting that increased compression of the urethra in the $^1/_2$ group may be a potential confounder, explaining the results. Lastly, the follow-up period of only 6 months may be too short to assess sliding action or any other long-term developments following sling placement.

Determination of the association between levator hiatal dimensions measured at 12 and 36 weeks' gestation using transperineal ultrasound in women during their first pregnancy and mode of delivery, stratified for the indication for intervention

Van Veelen GA, Schweitzer KJ, van Hoogenhuijze NE, van der Vaart CH. Association between levator hiatal dimensions on ultrasound during first pregnancy and mode of delivery. Ultrasound Obstet Gynecol. 2014. doi: 10.1002/uog.14649.

This study is a secondary analysis of a prospective observational study in which the association between levator hiatal dimensions, measured at 12 and 36 weeks' gestation using transperineal ultrasound, and mode of delivery was determined in 280 nulliparous pregnant women. Levator hiatus dimensions were measured at rest, on pelvic floor contraction, and on Valsalva maneuver. Mode of delivery was classified into five categories: (1) spontaneous vaginal delivery, instrumental vaginal delivery due to (2) fetal distress and (3) failure

to progress, Cesarean section due to (4) fetal distress and (5) failure to progress. Women who delivered by Cesarean section because of failure to progress had a significantly smaller hiatal transverse diameter and a trend toward a smaller hiatal area (Tukey's post hoc test, $p<0.001$ and $p<0.005$ respectively) on pelvic floor contraction at 12 weeks' gestation compared with women who had a spontaneous vaginal delivery. Women who had an instrumental vaginal delivery owing to failure to progress showed a trend toward a smaller hiatal anteroposterior diameter on pelvic floor contraction at 36 weeks' gestation compared with women who had a spontaneous vaginal delivery (Tukey's post hoc test, $p=0.033$).

The study has used 3D/4D transperineal ultrasound, a reliable technique for the measurement of hiatal dimensions, and only included nulliparous women. However, the results need to be interpreted with caution for various reasons: the lack of sample size calculation, owing to the fact that it is a secondary analysis, has resulted in a very small number of cases in some outcome categories, leading to relatively low power. Although Tukey's post hoc test was used when ANOVA indicated a p value<0.05, there is an increased likelihood of type II errors when the Bonferroni method is used, which the authors have acknowledged. There is no credible explanation for the fact that differences in hiatal dimensions were found only during pelvic floor contraction and not at rest and during Valsalva maneuver. It is also difficult to understand why there was no statistical difference in the hiatal transverse diameter and hiatal area at 36 weeks' gestation in the five groups, although it was found at 12 weeks' gestation, and conversely in the hiatal anteroposterior diameter at 12 weeks' gestation, although it was found at 36 weeks. It would have been interesting if the authors had compared the measurements taken at 12 and 36 weeks' gestation of the hiatal transverse diameter and hiatal area in the patients who underwent Cesarean section owing to failure to progress and the hiatal anteroposterior diameter in patients who had had an instrumental vaginal delivery. Lastly, this is a single-center study and as the authors have accepted, indication bias may have occurred, as the decision to perform an intervention for suspected fetal distress or failure to progress varies by center and by country. The authors have also not described their definitions of fetal distress and failure to progress, which would have helped to determine the applicability of their results to individual practices.

Comparison of the surgical outcomes in women with SUI or stress-predominant mixed incontinence based on urodynamic diagnosis compared with diagnosis based on office evaluation without urodynamics

Rachaneni S, Latthe P. Does preoperative urodynamics improve outcomes for women undergoing surgery for stress urinary incontinence? A systematic review and meta-analysis. BJOG. 2014. doi: 10.1111/1471-0528.12954.

This is a systematic review and meta-analysis of randomized controlled trials (RCTs) performed to assess whether preoperative urodynamics altered the outcomes of cure or complications in women undergoing surgery with isolated SUI or stress-predominant mixed incontinence (MUI) symptoms. The clinical questionnaire included four parts: the study population including women with pure SUI or stress-predominant MUI requesting surgical treatment, intervention including baseline office evaluation consisting of clinical history, cough test and PVR on bladder scan, comparison consisting of urodynamics, and outcome consisting of cure or improvement of SUI. Only four RCTs met the inclusion criteria; however, data were available for only three RCTs with 388 women randomized to office evaluation and urodynamics and 387 to office evaluation only. There was no statistical difference in the RR of subjective cure (1.02; 95 % CI 0.90–1.15), objective cure (1.01; 95 % CI 0.93–1.11) or complications such as urgency or voiding dysfunction in the two groups. The authors concluded that in women undergoing primary surgery for SUI or stress-predominant MUI without voiding difficulties, urodynamics does not improve outcomes as long as the women undergo office evaluation.

The systematic review conducted a thorough search and included only non-inferiority RCTs carried out in different countries, two of them multicenter. However, as the authors have acknowledged, the quality of a meta-analysis is only as good as that of the studies included. Only two of the RCTs (VALUE and VUSIS trials) were powered, one of which (VUSIS) was stopped prematurely after randomization of only 59 patients. The review did use a random effects model to accommodate the lack of power, but this is a major limitation. Blinding of the outcome assessors was carried out in only one study. The primary outcome in both the VALUE [2] and VUSIS [3] trials was subjective, primarily UDI-6, which focusses mainly on irritative bladder symptoms and includes only one question about the presence and impact of SUI. Tests that assess the severity of SUI such as the cough stress test was used as a primary outcome in only one RCT [4], which is available only as a conference abstract. The fourth study was a pilot to study the feasibility of a future definitive RCT, but the results are not yet available [5]. The majority of the women included had a midurethral sling. However, in the VALUE trial, a single sling approach was not adopted (retropubic and transobturator slings were both used), which may be a possible confounder of the results. As the authors themselves have concluded, methodologically robust RCTs with long-term follow-up and adequate power need to be carried out to ensure that the results are consistent with short-term outcomes.

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