



# Variability of Urethral Length Evaluated Using Introital Ultrasonography and Its Value a Priori in Mid-Urethral Tape Positioning

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## Abstract

**Purpose:** The aim was to evaluate the variability of urethral length and determine if this variability may have a clinical relevance for mid-urethral tape positioning using the classic vaginal incision.

**Methods:** This is an observational study on 205 patients undergoing transvaginal ultrasonography. The length of the hypoechoic core of the urethra was measured from the bladder neck to the distal part in the median sagittal plane. Age, parity, menopausal status and presence of SUI were recorded.

**Results:** 144 patients were enrolled in the study. Overall, mean age was  $45.2 \pm 11.4$  years, and median parity was 0 (range 0-5). Forty-one subjects (30.6%) were post-menopausal, while 47 (32.6%) reported SUI. Mean urethral length of the sample studied was  $33.5 \pm 3.4$  mm, with a median of 33 mm. No differences were observed between subjects with and without SUI. The mean mid-urethral point was  $16.8 \pm 1.7$  mm, with a median of 16.5 mm. Again, no differences were observed between subjects with and without SUI.

**Conclusion:** Urethral length variability in the population evaluated in this study is limited, thus a standard vaginal incision for mid-urethral tape positioning may be used. Nevertheless, the analysis of mid-urethra points shows that the standard vaginal incision seems to increase the risk of incorrectly positioning the tape in some women. Either a pre-operative perineal ultrasound should be performed to identify the correct mid-urethra point for each patient or, alternatively, the vaginal incision should start between 10 and 15 mm from the external urethral meatus (precisely 12.5 mm).

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## Introduction

The International Urogynecological Association (IUGA) and the International Continence Society (ICS) defined Stress Urinary Incontinence (SUI) as the complaint of involuntary loss of urine in effort or physical exertion, or on sneezing or coughing [1]. The incidence ranges from 12.8% to 46.0% and is more common among Caucasian and Hispanic women. SUI can also have a significant negative impact on economic status and quality of life [2,3].

Tension-Free Vaginal Tape (TVT) techniques, both retropubic and trans-obturator, are now the gold standards for the surgical treatment of female SUI [3]. They yield high success rates at long-term follow-up, ranging from 81% to 95%, minimal surgical trauma, shorter postoperative stay, and limited complications [4,5].

Nevertheless, failures and complications, such as urinary retention and de novo urgency, may be due to an incorrect tape positioning [6-9], since the tape must be positioned at the middle third of the urethra, also known as the high pressure zone [10].

The original descriptions of the TVT techniques (retropubic and trans-obturator) indicate specific landmarks for vaginal incision. Ulmsten et al. [11], describing the procedure for retropubic TVT, suggests performing a vaginal incision  $\sim 1.5$  cm long in the midline of the suburethral vaginal wall, starting approximately 0.5 cm from the outer urethral meatus. de Leval [12], on the other hand, suggests performing a midline incision, 1 cm proximally to the urethral meatus and to continue it proximally (towards the vaginal pouches) over a 1 cm distance for the positioning of inside-out Trans-Obturator Tape (TVT-O). Finally, Delorme [13] does not specify height or length of the

vaginal incision for the outside-in Trans-Obturator Tape (TOT).

These landmarks do not take into account patient-to-patient variability of urethral length and adopting the same vaginal incision for all patients may induce incorrect tape positioning and, thus, increase failure and complication rates [7].

Perineal ultrasound, both trans-labial and introital, proved to be an easy, accessible and reproducible method for the study of the urethra and perineal structures [14-17].

The aim of this study was to evaluate the variability of urethral length in a population from Italy. This evaluation might help in determining if urethral length variability may have a clinical relevance for mid-urethral tape positioning using the classic vaginal incision and if ultrasonography can be useful preoperatively. Furthermore, we wanted to quantify the percentage of women from this population in which mid-urethral tape implants would be correctly positioned should the surgical procedure be accomplished using the standard vaginal incision technique. This secondary endpoint was evaluated determining if the mid-urethral point would be included in the boundaries of the vaginal incision proposed by the technique description of TVT.

## Materials and Methods

In this observational study, data from 205 patients undergoing transvaginal ultrasonography for benign gynecologic conditions or for routine check-up were prospectively collected from September 2012 to July 2013.

All patients agreed to be included in the study, allowing the collection of data. Since the study was observational and no intervention other than ultrasonography was performed for other reasons, IRB approval was not requested.

All subjects underwent transvaginal ultrasonography with a 3.5 MHz probe (Esaote MyLab, Esaote, Genoa, Italy) for benign conditions or for routine check-up. All subjects presenting a leiomyoma of the inferior third of the uterine anterior wall or with a cystocele  $\geq$  POP-Q stage II were excluded.

After having completed trans-vaginal ultrasonography, an introital ultrasound examination of the urethra was carried out by a single observer (G.A.T.). With the subject in the semi-sitting position and a bladder-filling volume of  $200 \pm 20$  mL, the probe was placed in the area of the vaginal introitus at the level of the external urethral orifice. The length of the hypoechoic core of the urethra was measured from the bladder neck to the distal part in the median sagittal plane. For each patient, two measurements were taken with the mean of these data points reported as the final urethral length. The mid-urethra point was defined as the urethral length/2.

Age, parity, menopausal status and presence of SUI of all subjects were recorded. The presence of SUI was assessed by direct questioning of the subjects.

A secondary outcome of the study was to calculate the percentage of women whose mid-urethra point evaluated with introital ultrasonography would be located within the boundaries of the vaginal incision, if patients were to undergo mid-urethral tape positioning. We chose to consider the landmarks suggested by de Level [12], since they are the most widely used in clinical practice. Taking into consideration a 10 mm long incision, we approximated tape positioning between the 25° (12.5 mm from the urethral meatus)

and 75° (17.5 mm from the urethral meatus) percentile of the incision length. We then calculated the rate of subjects whose mid-urethral point fell in the interval between the 25° to 75° percentile interval, within the boundaries of the vaginal incision but either below the 25° percentile or above the 75° percentile, and outside the boundaries of the vaginal incision.

Statistical analysis was performed using the Scientific Package for Social Science program (SPSS ver. 15.0, Chicago, Ill., USA). Data distribution was evaluated using the Shapiro-Wilk's test and the descriptive statistics presented accordingly. Differences between subjects with or without SUI were evaluated using the Student's t test for unpaired data for age and with the Mann-Whitney test for parity, urethral length, and mid-urethra point. Intervals of confidence and quartiles were constructed. 95% confidence intervals, variance and interquartile distance were used to evaluate urethral length variability. Differences in the rates of subjects with a mid-urethra point within the boundaries of the vaginal incision were assessed in subjects with and without SUI using the  $\chi^2$  test. Statistical significance was set for a p value  $<0.05$ .

## Results

Data from 205 subjects were recorded. Sixty-one subjects were excluded from the analysis: 39 subjects had a  $\geq$  POP-Q stage II cystocele and 22 subjects had a leiomyoma of the inferior third of the uterine anterior wall. Thus, 144 patients were enrolled in the study.

Overall, mean age was  $45.2 \pm 11.4$  years, and median parity was 0 (range 0 to 5). Forty-one subjects (30.6%) were post-menopausal,

**Table 1:** Characteristics of the subjects included in the study. Values are reported as mean  $\pm$  SD, median [range] or n (%), as appropriate.

	Overall (n=144)	No SUI (n=97)	SUI (n=47)
Age (years)	45.2 $\pm$ 11.4	42.9 $\pm$ 11.1	49.8 $\pm$ 10.5
Parity	0 [0-5]	0 [0-4]	2 [0-5] <sup>a</sup>
Menopause	41 (30.6)		
SUI	47 (32.6)		

SUI: stress urinary incontinence

<sup>a</sup>: p<0.001 vs. non SUI patients

**Table 2:** Descriptive statistics of ultrasonographic urethral findings. Values are reported as mean  $\pm$  SD or absolute number, as appropriate.

	Overall (n = 144)	No SUI (n =97)	SUI (n =47)
Urethral length			
Mean (mm)	33.5 $\pm$ 3.4	33.8 $\pm$ 3.5	33.2 $\pm$ 3.3
Median (mm)	33	33.2	32.9
Range (mm)	26.1-45.8	28.4-45.8	26.1-44.6
95% CI (mm)	33-34.1	33.1-34.5	32.2-34.2
Variance (mm)	11.6	12.1	10.9
IQ distance (mm)	4.05	4.5	3.7
Mid-urethra point			
Mean (mm)	16.8 $\pm$ 1.7	16.9 $\pm$ 1.7	16.6 $\pm$ 1.6
Median (mm)	16.5	16.6	16.4
Range (mm)	13.1-22.9	14.2-22.9	13-22.3
95% CI (mm)	16.5-17.1	16.5-17.2	16.1-17.1
Variance (mm)	2.9	3	2.7
IQ distance (mm)	2	2.25	1.85

SUI: Stress Urinary Incontinence; 95% CI: 95% Confidence Interval; IQ distance: Interquartile distance

**Table 3:** Localization of mid-urethra point in relation to the vaginal incision for tape positioning. Values are reported as *n* (%).

	Within 25° to 75° centile	Within vaginal incision	Outside vaginal incision	RR [95% CI]	p
Total (n=144)	104 (72.2)	31 (21.5)	9 (6.3)		
Pre-menopause (n=103)	78 (75.7)	18 (17.5)	7 (6.8)		
Post-menopause (n=41)	26 (63.4)	13 (31.7)	2 (4.9)	1.2 [0.9-1.6]	0.1
No SUI (n=97)	71 (73.2)	19 (19.6)	7 (7.2)		
SUI (n=47)	33 (70)	12 (25.5)	2 (4.5)	1.0 [0.5-2.7]	0.7

RR: Relative Risk; 95% CI: 95% Confidence Interval; SUI: Stress Urinary Incontinence

while 47 (32.6%) reported SUI. The mean age was significantly higher in women reporting SUI in comparison with women not reporting SUI ( $49.8 \pm 10.5$  vs.  $42.9 \pm 11.1$  years;  $p < 0.001$ ). Median parity was significantly higher in subjects reporting SUI compared to woman without SUI (2 [0 to 5] vs. 0 [0-4]  $p < 0.001$ ) (Table 1).

Descriptive statistics of ultrasonographic characteristics of the urethra are reported in Table 2. Mean urethral length of the sample studied was  $33.5 \pm 3.4$  mm, with a median of 33 mm, a range of 26.1 mm to 45.8 mm, a 95% CI of 33 mm to 34.1 mm, a variance of 11.6 and an interquartile range of 4.05 (Table 2, Figure 1A). No differences were observed between subjects with and without SUI (Table 2). The mean mid-urethral point was  $16.8 \pm 1.7$  mm, with a median of 16.5 mm, a range of 13.1 mm to 22.9 mm, a 95% CI of 16.5 mm to 17.1 mm, a variance of 2.9 mm and an interquartile range of 2 mm (Table 2, Figure 1B). Again, no differences were observed between subjects with and without SUI (Table 2).

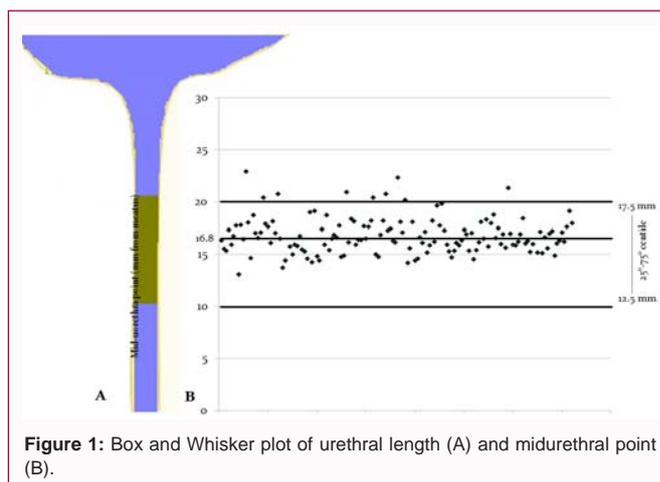
Overall, nine women (6.3%) showed a mid-urethral point outside the boundaries of the vaginal incision limits according to the vaginal incision suggested by de Leval, while 104 subjects (72.2%) had a mid-urethral point within the 25° to 75° percentile boundaries of the vaginal incision limits (Table 3, Figure 2). Thirty-one subjects (21.5%) showed a mid-urethral point within the vaginal incision boundaries, but outside the 25° to 75° percentile range (Table 3, Figure 2). All subjects with a mid-urethral point outside of this range showed a mid-urethral point closer to the bladder neck in relation to the boundaries of the hypothetical vaginal incision.

The sub-analysis of subjects reporting and not reporting SUI did not show differences among these percentages (Table 3).

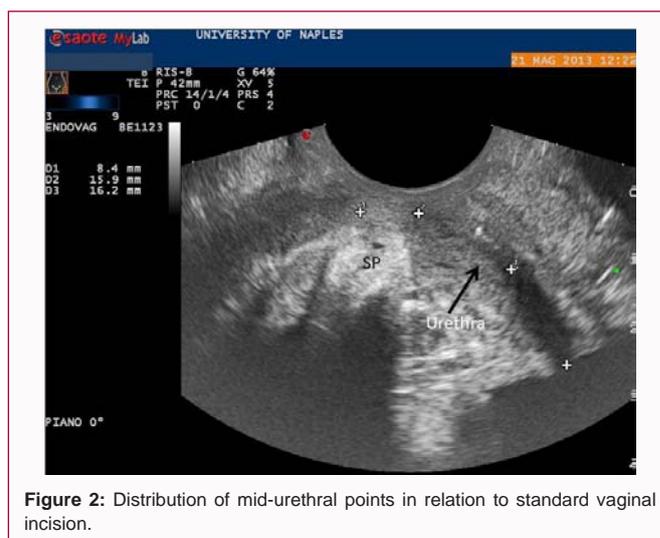
The mean value of the mid-urethral point fell between the 60° and 65° centile of the vaginal incision limits.

## Discussion

In this study, we assessed the variability of the urethral length and its significance for mid-urethral tape positioning when using the standard vaginal incision proposed by de Level and found that urethral length in our population showed a mild variability with a 95% CI of approximately 1 cm. These measurements showed a limited variability of the mid-urethral point (95% CI approximately 0.5 cm) from patient-to-patient. These data seem to indicate that, at least in our population, a standardized vaginal incision can be used for mid-urethra tape positioning without negatively impacting efficacy. On the other hand, the correlation between the distributions of mid-urethra points of our population with the vaginal incision proposed by de Level [12] suggests that a proportion of women (more than 6%) would theoretically have an incorrect tape positioning using that vaginal incision. Moreover, all these patients would have a tape too close to the urethral meatus, providing inadequate support of the urethra, urinary retention or de novo urgency. Instead, if we consider



**Figure 1:** Box and Whisker plot of urethral length (A) and midurethral point (B).



**Figure 2:** Distribution of mid-urethral points in relation to standard vaginal incision.

starting the vaginal incision 1.5 cm from the urethral meatus, as suggested by some experts [18], 11.8% of patients would have the tape positioned too close to the bladder neck, providing inadequate support of the urethra or additional lower urinary tract symptoms. In our population, starting the vaginal incision between 1 and 1.5 cm (precisely 1.25 cm) could allow a correct tape positioning in almost all cases.

Mid-urethral tapes are widely used for the surgical treatment of female stress urinary incontinence. They yield high, long-term cure rates with very limited complications and are relatively easy to perform, due to standardized techniques [11-13].

These techniques involve a vaginal incision, with fixed anatomical landmarks, that do not take into account any anatomical patient-to-

patient variability of urethral length. Indeed, the original description of retropubic tension-free vaginal tape made by Ulmsten states that the vaginal incision should start approximately 0.5 cm from the urethral meatus and be 1.5 cm long [11]. The author later modified this recommendation, suggesting to start the incision 1 cm from the urethral meatus [19-20], a recommendation also made by de Leval for TVT-O [12]. Moreover, different descriptions of the vaginal incision suggest starting the incision 1.5 cm from the urethral meatus [18].

This standardized technique could cause an incorrect positioning of the tape potentially reducing the effectiveness of these devices. A number of studies evaluated the correlation between tape positioning and clinical outcome using an ultrasonography exam [21]. Kociszewski et al. suggests an optimal outcome if the tape is positioned at least 2 cm from the urethra at the junction of the middle and distal thirds and that, to achieve this positioning; the suburethral incision should start at one-third of the sonographically measured urethral length [7,22,23]. On the other hand, Dietz et al. did not find significant effects of mid-urethral tape placement on post-operative outcomes [24,25]. Nevertheless, based on Ulmsten's studies on urethral physiology, mid-urethral tapes should lie in the middle third of the urethra to be effective. In his view, tape positioning may be important for clinical outcome.

We found no differences in urethral length between women affected or not by SUI. It seems that urethral length is not involved in the mechanism inducing SUI, since SUI patients did not show differences in urethral length, as confirmed by other authors [26].

A limitation of our study is that it relies on a limited population, so that generalization of our results may be questionable. Moreover, it also includes young subjects and women not affected by SUI. Nevertheless, our aim was to evaluate urethral length variability in a general population and for this reason we did not exclude young subjects and non-SUI patients. Since the mean urethral length observed in our study is in accordance with previous studies [26-28] we believe that our findings may be transferred to other populations, even though our data need to be confirmed in patients who underwent mid-urethral tape procedures.

## Conclusion

Urethral length variability in the population evaluated in this study is limited, thus a standard vaginal incision for mid-urethral tape positioning may be used. Nevertheless, the analysis of mid-urethra points shows that the standard vaginal incision seems to increase the risk of incorrectly positioning the tape in some women. Either a pre-operative perineal ultrasound should be performed to identify the correct mid-urethra point for each patient or, alternatively, the vaginal incision should start between 10 mm and 15 mm from the external urethral meatus (precisely 12.5 mm).

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