## Perineal Color Doppler Ultrasound of Periurethral

# Vascularization In Women Affected By Urinary Stress

### Incontinence

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#### ABSTRACT

This study aimed to assess the vascular parameters of the urethra through an ultrasound assessment using the trans-labial convex probe (Voluson E8 GE) in women affected by stress incontinence and compare them with women who do not have the disorder.

Patients with USI recruited for the group of cases were 12, and the women not affected by USI were 12. The study compares patients with a disease (cases) with patients who do not have the disease (controls). The design of the study is a controlled case-control observational trial. Thus, the data gathered were the resistance index (RI) and the color score of the studied area to quantify the degree of vascularization. The semi-quantitative parameter identified through the power doppler was the resistance index (RI). The qualitative parameter was the color score of the studied area, obtained through the color doppler assessment; these data were used to quantify each patient's vascularization degree.

The ANOVA test showed a significant difference between the RI values in group 0 (NO USI) and group 1 (USI). The ROC curve analysis was used, demonstrating that the diagnostic test is adequate and has a high discriminating value for identifying the true positives and the true negatives.

The Doppler, therefore, is an important instrument that helps diagnose the more common vascular disorders in climacteric and menopause.

Keywords: Perineal ultrasound, doppler ultrasonography, urinary incontinence

#### Introduction

Stress incontinence is defined as the unintentional loss of urine when endoabdominal pressure increases following coughing, sneezing, sports activity, changing position (1, 2). It is a disorder affects that many women, especially postmenopausal women when there is a significant reduction in circulating estrogens. Besides age, other risk factors are obesity with a BMI>30, diabetes mellitus, vaginal delivery (length of the second stage of labor, Caesarean section, sudden pushing, Kristeller manoeuvre, radical and nonradical surgery (3-6). In the United States, some 25% of women are affected by this dysfunction, and in Italy the incidence is almost the same (7). All urethra layers contribute to the continence

mechanism and act both during stress and at rest. Defects in the smooth and striated muscle fibers, in the connective and elastic tissue and in the submucosal vascular plexus of the urethra, are responsible for the pressure changes in stress incontinence. The vascularization of the urethra, consisting of periurethral vessels and a submucosal vascular plexus, is exuberant and disproportionate compared to the anatomic sizes of this organ (8). The periurethral venous plexus and the intravascular pressure at the level of the urethra are critical factors in the continence mechanism. In agreement with this, the number of periurethral vessels and their systolic and diastolic pressure are found to be reduced in menopausal women with urinary incontinence (9). Estrogens act at this level by increasing the blood supply to

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the urethral epithelial cells and increasing the intravascular pressure (10).Therefore. continence's intrinsic mechanism is based on the so-called "sealing effect" of the urethra, on a competent bladder neck, and an integral urethral sphincter. The sealing effect of the urethral mucosa determines, throughout the length of the urethra, an occluding effect guaranteed by a submucosal vascular plexus of the continence mechanism that entails variations in the systolic and diastolic pressure of the many vessels that surround the urethra (11). In the literature, many studies have attributed to the periurethral blood supply a significant role in ensuring continence (9, 12, 13). Indeed, the submucosal plexus vessels seem to be responsible for the trophism of the urethra and, together with the surrounding connective tissue, they are capable of forming a cancellous erectile tissue that ensures continence under stress. Some studies have examined the relationship between the periurethral vessels and stress incontinence using 2D color Doppler velocimetry (9, 13). The literature shows significant differences between premenopausal incontinent women and postmenopausal incontinent women regarding the number of periurethral vessels, pulsatility and resistance indexes, and the ratio between systolic and diastolic phase (9, 13).

This study aimed to assess the vascular parameters of the urethra through an ultrasound assessment using the trans-labial convex probe (Voluson E8 GE) in women affected by stress incontinence and compare them with women who do not have the disorder. Even though various studies have analyzed these parameters in the literature, there still is not a standard method for introducing this type of assessment into clinical practice. In this connection, we decided through our case series, to produce a standardized method to be applied in the urogynaecological examination of patients who come to our specialized centre. Moreover, we wanted to illustrate the predictive value of stress incontinence in women with altered vascular parameters who report sporadic stress incontinence episodes.

#### Materials and Methods

Patients who came to the Pelvic outpatient clinic of the [omissis for peer review] from July 2016 to December 2018 were included in the group of cases reporting stress incontinence symptoms. Our institutional review board approved the research protocol dated February 2, 2016, with the number 3633.

Patients with stress incontinence recruited for the group of cases were 12. The women not affected by USI were 12. The inclusion criteria, for the group of cases (12 patients), besides the presence of the disorder, were the absence of urinary urgency incontinence, absence of urinary tract infection and inflammation, negative patient history for previous surgery for the correction of genital prolapse and/or stress incontinence, absence of genital prolapse. The inclusion criteria, for the control group (12 patients), besides the absence of the USI, were the absence of urinary urgency incontinence, absence of urinary tract infection and inflammation, negative patient history for previous surgery for the correction of genital prolapse and/or stress incontinence, absence of genital prolapse. The sample that was studied was informed on the assessment modalities and was given detailed informed consent. In the group of cases, a complete pelvic examination was performed to check for prolapse, pelvic floor muscle tone, and the presence of surgical scars to suggest a prior sling surgery. A cough or Valsalva stress test with a full bladder was carried out to confirm the presence of SUI. Urodynamic studies evaluated the anatomy and function of the bladder and urethra, reproducing symptoms in the group of cases. In order to obtain a proper diagnosis, all patients of the case group underwent a urodynamic study. Uroflowmetry demonstrated, in patients of case group, a normal flow curve without postvoid residual. The urine leakage occurred in the presence of either increase in abdominal pressure (cough) in all patients of case group without involuntary bladder contraction. The patients in the group of cases were subjected to a translabial ultrasound. Once the diagnostic phase was over, the patients who were found to have USI through specific tests, micturition diary, and a urodynamic test were offered surgery to correct incontinence with the application of a mid-urethral sling. The control group was made up of women who came to our attention voluntarily, it included 12 healthy women who, after having understood the aims of the study and agreed to take part in the assessment and signed an ad hoc informed consent form. The patients were studied only through a translabial ultrasound assessment to gather data on the periurethral vascularization. A single experienced physician performed the ultrasound examination. In order to study the vascularization of the urethra a convex trans-labial probe in sagittal view was used. The image of the urethra was divided into three parts of interest: proximal, mid and distal part, and for each portion the anterior and posterior wall was assessed. The zone of interest was limited to the bladder neck up to the external urethral meatus, and the peripheral zone (5mm) around the urethra was evaluated in the

Table 1. Table o	Demographic Data	(Case Group)
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Variables	n=12	
Age (years)	55 (mean)	
Age at menopause <45	1	
Age at menopause 45-49	5	
Age at menopause 50-55	5	
Regular period	1	
UI type	12 (Stress incontinence)	

ultrasound imaging, to apply the Color Doppler assessment. The semi-quantitative parameter identified through the power Doppler was the resistance index (RI) capable of estimating the district impedance in low resistance territories' arteries. Through the Color Doppler assessment, it was possible to identify, as a qualitative parameter, the color score of the studied area, to quantify the degree of vascularization of each patient.

Statistical Analysis: The resistance index (RI) was evaluated as a semiquantitative index for each patient using the power-doppler, and through the colordoppler it was possible to assess the intensity of the periuretral vascularization from normal to minimal by attributing a color score from 1 to 4 respectively. Having verified that the distribution of RI values thus obtained was normal, the ANOVA (Variance analysis) test was performed that tested the sample's mean values considering the variances. In this way, it was possible to compare the mean values of more than two groups inferentially, i.e. by observing the sample. The possible evidence of a cut-off capable of avoiding false positives and false negatives was assessed through the ROC analysis. The curves obtained enabled us to determine each RI value's specificity and sensitivity for each portion of the periurethral area to confirm the presence or absence of the disease through the ultrasound. Significance was a p-value < 0.001 (considering a p=<0.05 as being significant).

#### Results

In the group of cases, the patients' mean age was 55 years, 10 in menopause for at least three years, and 2 with regular periods. In the control group the mean age was 50 years, 9 in menopause for at least three years, 2 in menopause for a year, and 1 with a regular period. In all patients, the BMI value was <26. (Table 1,2) A group of cases consisted of 12 patients affected by USI and a control group consisting of 12 patients not affected by USI.

Group 0 was the group of patients not affected by USI. Group 1 included all the patients affected by USI. The first statistical analysis compared the RI value in the proximal area at the anterior wall of the urethra with the degree of incontinence broken down into 0=absence of incontinence, 1=incontinence. The result showed a significant difference in the 0 (NO USI) with patients affected by the urinary disorder (group 1). The mean RI value for group 0 was 0.85, and the mean RI value for group 1 was 0.61. The second statistical analysis compared the RI value in the proximal area at the posterior wall of the urethra with the degree of incontinence broken down into 0=absence of incontinence, 1=incontinence. The result showed a significant difference of group 0 (NO USI) versus the group of patients affected by the urinary disease. The significance level was a p-value < 0.001 (considering a p < 0.05 as being significant). The mean RI value was 0.75 for group 0. and 0.60 for group 1. The third statistical analysis compared the RI value in the mid-portion of the urethra at the anterior wall of the urethra with the degree of incontinence broken down into 0=absence of incontinence, 1= incontinence. The result showed a significant difference of group 0 (NO USI) versus the group of patients affected by the urinary disease. The significance level was a p-value < 0.001 (considering a p<0.05 as being significant). The mean RI value was 0.72 for group 0 and 0.52 for group 1. The fourth statistical analysis compared the RI value in the midportion of the urethra at the posterior wall of the urethra with the degree of incontinence broken down into 0=absence of incontinence, 1=incontinence. There was no significant difference between group 0 and group 1. The mean RI value was 0.64 for group 0 and 0.54 for group 1. The fifth statistical analysis compared the RI value in the distal portion at the anterior wall of the urethra, with the degree of incontinence broken down into 0=absence of incontinence, 1= incontinence. The result showed a significant difference between group 0 (NO USI) and patients affected by the urinary disease. The

Variables	n=12
Age (years)	50 (mean)
Age at menopause <45	1
Age at menopause 45-49	8
Age at menopause 50-55	2
Regular period	1
UI type	0

Table 2. Table of Demographic Data (Control Group)

Table 3. The RI Values In The Different Anatomic Portions of The Urethra

Districts	RI (GROUP 0)	RI (GROUP 1)
Ant-prox	0.85	0.61
Post-prox	0.75	0.60
Mid-ant	0.72	0.52
Mid-post	0.64	0.54
Ant-dist	0.60	0.45
Post-dist	0.66	0.4

significance level was a p-value < 0.001 (considering p<0.05 as being significant). The mean RI value was 0.60 for group 0 and 0.45 for group 1. The sixth statistical analysis compared the RI value in the distal portion of the urethra at the posterior wall, with the degree of incontinence broken down into 0=absence of incontinence, 1= incontinence. The result showed a significant difference between group 0 (NO USI) and patients affected by urinary disease. The level of significance was a p value < 0.001 (considering p<0.05 as being significant). The mean RI value was 0.66 for group 0, and 0.47 for group 1. The analysis of the ROC curve was used to evaluate the accuracy of the diagnostic test. The first evaluation correlated the RI value of the proximal portion of the urethra involving the anterior wall with the presence or absence of urinary incontinence. The test evaluated all the possible test values and for each it calculated the proportion of true positives and of false positives. The ROC curve area that was obtained by joining the proportions between true positives and false positives showed a value of 0.907 with a high significance index of p<0.0001. Considering that the greater the area under the curve with a value as close as possible to 1, that is to say a curve that is close to the top of the chart, the curve obtained demonstrated a high discriminating power of the diagnostic test in identifying the true positives with a 91.61% sensitivity for RI values  $\leq 0.75$ . The specificity, namely the ability to discriminate the true negatives, was 61.11%

for the same RI value ( $\leq 0.75$ ) (according to the ROC curve criterion). The second evaluation correlated the RI value of the proximal portion of the urethra involving the posterior wall with the presence or absence of urinary incontinence. The ROC curve obtained as area presented a value of 0.928 with a high significance index of p<0.0001. The curve obtained showed a high discriminating power of the diagnostic test in identifying the true positives with a sensitivity of 91.67 for RI values of  $\leq 0.69$ . Therefore, the specificity, that is to say, the ability to discriminate the true negatives, was 77.78% for the same RI value  $(\leq 0.69)$ . The third evaluation correlated the RI value of the mid portion of the urethra involving the anterior wall with the presence or absence of urinary incontinence. The ROC curve obtained as area presented a value of 0.912 with a high significance index of p<0.0001. The curve obtained shows a high discriminating power of the diagnostic test in identifying the true positives with a sensitivity of 91.67% for RI values of <0.64. Therefore, the specificity, that is to say the ability to discriminate the true negatives, was 61.11% for the same RI value  $(\leq 0.64)$ . The fourth evaluation correlated the RI value of the mid portion of the urethra involving the posterior wall with the presence or absence of urinary incontinence. The ROC curve obtained as area presented a value of 0.771 with a high significance index of p<0.0036. The curve obtained showed a high discriminating power of the diagnostic test in

Urethral anatomic districts	AUC
Prox ant	0.907
Prox post	0.928
Medio ant	0.912
Medio post	0.771
Dist ant	0.847
Dist post	0.926

**Table 4.** AUC=0.5 non informative test; 0.5<AUC≤0.7 not very accurate test; 0.7<AUC≤0.9 moderately accurate test; 0.9<AUC<1 highly accurate test; AUC=1 perfect test

Table 5. The Specificity and Sensitivity Values With The Respective IR Values

Districts	Sensitivity	Specificity	IR value
Ant prox	91.67%	61.11%	IR≤0.75
Post prox	91.67%	77.78%	IR≤0.69
Mid ant	91.67%	61.11%	IR≤0.64
Mid post	75%	61.11%	IR≤0.60
Ant dist	100%	75%	IR≤0.47
Post dist	91.67%	94.44%	IR≤0.59

identifying the true positives with a sensitivity of 75% for RI values of  $\leq 0.60$  Therefore, the specificity, that is to say the ability to discriminate the true negatives, was 61.11% for the same RI value ( $\leq 0.60$ ). The fifth evaluation correlated the RI value of the distal portion of the urethra involving the anterior wall with the presence or absence of urinary incontinence. The ROC curve obtained as area presented a value of 0.847 with a high significance index of p < 0.0001. The curve obtained showed a high discriminating power of the diagnostic test in identifying the true negatives with a sensitivity of 100% for RI values of  $\leq 047$ . Therefore, the specificity, that is to say the ability to discriminate the true positives was 75% for the same RI value ( $\leq 0.47$ ). The sixth evaluation correlated the RI value of the distal portion of the urethra involving the posterior wall with the presence or absence of urinary incontinence. The ROC curve obtained as area presented a value of 0.926 with a high significance index of p<0.0001. The curve obtained showed a high discriminating power of the diagnostic test in identifying the true positives with a high sensitivity of 91.67% and a specificity of 94.44% for RI values ( $\leq 0.59$ ). In the following charts we see the ROC curves of the anterior wall in the three districts and of the posterior wall for the respective anatomical districts. (Chart 1, Chart 2). Finally, the last parameter that was evaluated was the periurethral vascularization through the Color-doppler. The

subjective scale of periurethral vascularization is calculated with a score from 1 to 4. Color-score: 1=minimum, color-score 2=poor; color-score 3=moderate; color-score4=intense. (Figure 1, Figure 2, Figure 3, Figure 4). In the group of incontinent patients, ten had a color score of 1 and two a color score of 2. The healthy patients instead showed a color score of 4 in six cases, a color score of 3 in three cases and a color score of 2 in three cases.

#### Discussion

The analysis of the initial data, concerning the Anova assessment, that envisages a comparison between the RI values recorded in the different anatomic portions of the urethra, with the presence or absence of incontinence, showed a significant difference between the RI values of the 0 group (NO USI) compared to group 1 (USI) in almost all urethral portions except for the mid posterior region. The significance index was p < 0.05 recorded for all the statistical evaluations (Table 3). Considering the results obtained, there is a significant difference in the RI values between the group of patients affected by USI versus the healthy controls. This first analysis leads to the conclusion that for each district, except one, there is an RI value that is capable of discriminating



Fig. 1. ROC Curves of The Anterior Wall



Fig. 2. ROC Curves of The Posterior Wall

whether the disease is present or not. The statistical analysis has shown a significant difference between the group of patients affected from those who did not have urinary incontinence. The first evaluation of results through the ANOVA test made it possible to identify a discriminating value such as to enable a differentiation between presence and absence of disease. In order to establish a cut-off, among the RI values, capable of making the test as accurate as possible the analysis of the ROC curve was used, constructed considering all the possible values of the test and for each of them the proportion of true positives (sensitivity) and the proportion of false positives were calculated. By joining the points that relate the proportion of



Fig. 3. Periurethral Vascularization, Color Doppler=1



Fig. 4. Periurethral Vascularization, Color Doppler=2

true positives and false positives (so-called coordinates), a ROC curve is obtained. The area under the ROC curve (AUC-Area Under the Curve) is a measure of diagnostic accuracy. A test is considered to be adequate when the area under the curve is  $\geq 80\%$ . Such area may take on values between 0.5 and 1.0; the larger the area under the curve, the greater the diagnostic test's discriminating power. According to the Swets classification [14], based on the AUC's value, the degree of accuracy of a test can be determined in distinguishing a non-informative from a perfect test (Table 4). The table shows the AUC values in all the anatomic districts that were assessed. As can be seen, the values obtained make the test moderately accurate to highly accurate. Therefore, according to the ROC analysis, the diagnostic test proved to be adequate with a high discriminating power to identify the true positives (sensitivity) and the true negatives (specificity). The highest AUC value was recorded for the posterior proximal and posterior distal districts; the lowest value was recorded at the mid posterior district. The specificity and sensitivity values are shown in the table below (Table 5). Also, concerning the specificity and sensitivity evaluation, the most significant values were recorded at the posterior



Fig. 5. Periurethral Vascularization, Color Doppler=3

proximal and posterior distal districts. Instead, the values recorded for the mid posterior district were the least discriminating. The values obtained at the mid posterior district diverged most from the uniformity of the sample. Indeed, for all the other districts, very significant values were obtained for the AUC and sensitivity and specificity. As already pointed out in the section dedicated to the ANOVA analysis, this result may likely be due to the small sample size. The most significant values recorded at the posterior proximal and distal districts could instead have a different meaning.

In the former case (posterior proximal district) the values obtained with higher significance could have an anatomical explanation. Indeed, the socalled "sealing effect" is guaranteed above all at the level of the proximal urethra, where the blood vessels, thanks to their tone, are an element that ensures continence. Hence, the reduction of periurethral vascularization and the venous plexuses, located in the urethral submucosa, determine a decrease in the mucosa's thickness with a drop in the closure pressure of the urethral lumen at rest. The reduction in blood supply in all the women with USI is also confirmed through the Color-Doppler examination. Indeed, 11 women with USI out of 12 have a color score of 1. The most significant values at the posterior distal district level could instead find an explanation in the vaginal atrophy found in most patients with USI. Indeed, the atrophy of the vaginal mucosa determines a reduction in the connective tissue with the pelvic floor's ensuing insufficiency in closing the urethra.

The intrinsic urethral mechanism is represented by the urethral mucosa and sub-mucosa, by the vascular bed of the subepithelial tissue of the corpus cavernosum, by the connective tissue and the urethral smooth muscle fibers. These structures depend on estrogens, and this explains the urinary loss in climacteric women. Indeed, all



Fig. 6. Periurethral Vascularization, Color Doppler=4

the patients in the sample with USI have been in menopause for at least one year. The urethral mucosa acts as a seal due to the synergism between the surface and the subepithelial vascularization. The urethral sphincter's activity is more intense in the median and cranial third of the urethra, where the smooth muscles and the periurethral striated muscles are more developed, and the vascular plexus is more abundant. Hence, a reduction in blood supply causes a reduction by one-third of the intraurethral pressure, thus facilitating the loss of urine. According to the above discussions, the evaluation of the vascular parameters through intrahyatal ultrasound has confirmed the presence of urinary disorder also with the ultrasound. Indeed, what proves to be evident is the high discriminating power of the test that can identify the disorder's presence. The first statistical analysis (ANOVA) showed a significant difference in the RI values between the group of patients not affected by USI and those with USI. Once the difference was identified, through the ROC analysis, it was possible to establish a cut-off value of RI that would discriminate the true positives from the true negatives for each individual anatomic district. We can conclude that the Doppler is an important instrument that helps diagnose the more common vascular alterations in climacteric and menopausal women and has a high discriminating power for urinary disorders such as stress urinary incontinence. Hence, intrahyatal ultrasound may be considered a valid diagnostic instrument for assessing patients with urinary disorders. The number of patients represents the main limitation of this study. In the future, it will be interesting to carry out a double-blind random trial where the doctor performing the intrahyatal ultrasound does not know that there is a urinary disorder. This evaluation will make it possible to appropriately

appreciate the diagnostic power of intrahyatal ultrasound by evaluating the Doppler parameters.

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