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Could pelvic floor sonography be a standalone method for excluding genuine stress urinary incontinence in women?

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ABSTRACT

Objectives: Determine whether introital pelvic floor sonography with transvaginal probe (PFS-TV) can be an independent method in the diagnosis of genuine stress urinary incontinence (SUI) and to create a ultrasonographic diagnostic model to objectify diagnostic process.

Material and methods: The study involved 315 patients with a history of urinary incontinence problems. Based on the clinical examination and urodynamic examination, the final diagnosis was made. Patients were divided into two groups. Group I included women with SUI and Group II included patients without SUI (OAB and no-UI). Each patient underwent PFS-TV at rest and during straining. The groups were compared in terms of ultrasound parameters.

Results: Patients from both groups differed statistically in a significant way ($p < 0.05$) in terms of mean distance between the lower edge of the pubic symphysis at rest 19 mm vs 22 mm (Group I vs Group II) and during straining (D1 and D2) 22 mm vs 26 mm, the average value of the γ angle (at rest (γ1) 37.5° vs 40° and during straining (γ2) and 66° vs 58.5°, average difference value of angle γ during straining and at rest (γ2−γ1) 29° vs 14°, and frequency of urethral funneling 89% vs 17%. Two parameters studied during PFS-TV were included in the logistic regression model used to exclude the stress component of urinary incontinence. Diagnostic test parameters of model were sensitivity 86.6%, specificity 90.4%, accuracy 93.1%.

Conclusions: PFS-TV makes it possible to exclude the stress component of urinary incontinence. The developed logistic regression model allows for the objectification of the results of ultrasound examination in patients with urinary incontinence.

Key words: stress urinary incontinence; pelvic floor sonography; predictive models; logistic regression

INTRODUCTION

Urinary incontinence is a problem affecting approximately 40% of women after the age of 40 [1]. Life expectancy increasing in most parts of the world will result in escalation of this problem and its burden on health care systems. [2] Due to differences in the treatment of different types of urinary incontinence, it is especially important to establish an accurate diagnosis of the type of urinary incontinence. Many methods are used in the diagnosis of urinary incontinence, including pelvic floor sonography (PFS), which has become increasingly popular recently. It is a widely available method accepted by patients. In urogynecology, PFS is useful not only in the diagnosis of stress urinary incontinence but also in the qualification of patients for treatment, assessment of the position of the mid-urethral sling after surgery as well as in the diagnosis of complications [3]. Usually, however, PFS is not used as a stand-alone diagnostic method and the PFS result is interpreted after considering clinical symptoms, medical history, voiding diary, cough test, sanitary tests or urodynamic test.

Objectives

The study aimed to determine whether introital pelvic floor sonography with transvaginal probe (PFS-TV) can be an independent method in the diagnosis of genuine stress urinary incontinence and to create a diagnostic logistic regression model using ultrasound parameters objectifying the result of PFS-TV in the diagnosis of the component stress of urinary incontinence.

MATERIAL AND METHODS

The study included 315 patients and took place in the Obstetrics and Gynaecology Clinic of Combined Voivodeship Hospital in Kielce. Patients were diagnosed because of urinary incontinence in the years 2016–2018. The consent for the research was given by the bioethics commission at the Jan Kochanowski University in Kielce (no. 21/2016). Patients after anterior or posterior vaginal wall repair and apical defect repair were excluded from the study. Each patient, after giving her written consent to participate in the study, was subject to a thorough physical examination including a cough test. Urodynamic tests were performed using the DELPHIS IP PRO928 apparatus. The results were interpreted based on units and definitions set by the International Continence Society (ISC). Based on the result of the urodynamic and clinical examination, the type of urinary incontinence was identified: overactive bladder (OAB) (detrusor overactivity in urodynamic study), stress urinary incontinence (SUI), mixed urinary incontinence (MUI) and incontinence (no UI). Patients diagnosed with MUI were excluded from further analysis. The patients were divided into two groups: Group I — patients with stress urinary incontinence (SUI) and Group II — patients without stress incontinence components (OAB and no UI). Patients with mixed incontinence were excluded from the study. Each patient underwent an introital pelvic floor sonography with a transvaginal probe (PFS-TV) using a Voluson E8 (GE) apparatus and a RIC 6-12D (5–13 Mhz) head. The operator was blinded for urodynamic study, cough test and patient history. The study was carried out according to the procedure described in S2k Guideline 2 [3]. During the PFS-TV examination, the ultrasound head was placed in the vaginal vestibule at the height of the external urethral opening, and the bladder was filled to a volume of 200–400 ml. The head was directed parallel to the long axis of the patient in the gynecological position. During the study, a median sagittal cross-section through the urethra, bladder and pubic symphysis was obtained at rest and during straining. The following measurements were taken: the height of the bladder neck at rest and during straining (H1, H2), the distance between the bladder neck and the lower edge of the pubic symphysis at rest (D1, D2) (Fig. 1), the angle between the long axis of pubic symphysis and the urethral axis ($\gamma 1$, $\gamma 2$) (Fig. 2), the length of urethra (L) (Fig. 3) and the occurrence of a sign of urethral funneling during straining (Fig. 4).

The urethral funneling symptom was considered significant when the funnel depth was greater than 30% of the length of the urethra. Both groups of examined patients were compared in terms of the examined ultrasound parameters. The obtained data made it possible to create a logistic regression model estimating the probability of the absence of the stress incontinence component only based on ultrasound examination.

The data's predictive value and diagnostic test parameters were analyzed. The mean values and standard deviations were used to describe the data, and in the case of skewed distributions, the median was calculated as a measure of central tendency, and the 25^{th} and 75^{th} percentiles were presented as a measure of spread. Mann-Whitney U test or Student's t-test was used to compare the groups depending on the values. Qualitative variables were presented as a percentage, and Pearson's chi-squared test was used for comparison. The difference was considered statistically significant in the case of $p < 0.05$. A logistic regression model was created using the progressive stepwise method. The assessment of the quality of the prediction was presented using the ROC (Receiver Operating Characteristic) curve with the determination of the cut-off point using the Youden's index. The diagnostic test parameters for the created model were calculated. The calculations were made using Statistica 13.1 (Stat Soft Poland).

RESULTS

The study included 315 patients: 153 patients (48.6%) with SUI, 58 patients with OAB (18.4%), 54 patients with MUI (17.14%) and 50 patients (15.9%), with no UI (without diagnosed urinary incontinence). After group aggregation, Group I consisted of 153 patients with SUI (59%) and Group II consisted of 108 patients (41%) patients without the stress incontinence component (OAB + no UI) were formed. The demographic characteristics of both groups are presented in Table 1. Anterior vaginal prolapse was defined ultrasonographically when the neck of the bladder during straining was below inferior margin of the pubic symphysis (value of H2 parameter was below 0). Patients with the component of urinary incontinence were different significantly in terms of the examined parameters from the control group in terms of BMI and weight. Measurements of ultrasound parameters are shown in Table 2. The majority of the examined ultrasound parameters were different significantly between the two groups: mean distance between the lower edge of the pubic symphysis at rest 19 mm vs 22 mm (Group I vs Group II) and during straining (D1 and D2) 22 mm vs 26 mm, the average value of the γ angle at rest (γ1) 37.5° vs 40° and during straining (γ2) and 66° vs 58.5°, and the average difference value of angle γ during straining and at rest (γ2−γ1) 29° vs 14°III. The study groups also differed in the frequency of urethral funneling 89% vs 17%.

After analyzing the data, a logistic regression model estimating the probability of excluding genuine SUI (confirmed by a urodynamic and clinical examination) based solely on ultrasound was created. The model is expressed in the form of the following equation:

$$p=\frac{e^{\beta_0+\beta_1 x_1+\beta_2 D1}}{1+e^{\beta_0+\beta_1 x_1+\beta_2 D1}}$$

where p is the probability of not recognizing stress urinary incontinence (it takes the value between 0 and 1), e — basis of natural logarithm (Euler’s number), β0 = −2.41, β1 = 1.89, β2 = 0.11, χ1 = 0 (the presence of the funnel), χ1 = 1 (no urethral funneling), D1 =the distance of the bladder neck from the lower edge of the pubic symphysis at rest in millimeters. The logistic regression equation shows that the occurrence of the urethral funneling symptom increases the chance of recognizing the stress component of stress urinary incontinence by 44 times (OR = 43.97), and each millimeter of the D1 parameter increases the chance of excluding stress urinary incontinence 1.11 times (OR −1.11). Other ultrasonographic parameters were not confirmed as independent predictors in multivariate models. To assess the possibility of using the equation in clinical practice and assess its usefulness as a diagnostic test to exclude the stress component of urinary incontinence, a ROC curve was drawn (Fig. 5). An area under the curve (AUC) = 0.9065 was established. An optimal cut-off point for p = 0.62 was determined using the Youden’s index. Using the designated cut-off point as a classifier (value over cut-off point excluding SUI in patient), diagnostic parameters of the test to exclude the stress component of urinary incontinence component were determined. The parameters are as follow: sensitivity 89.20%, specificity — 90.4%, accuracy — 93.17%, positive predictive value — 87.7%, negative predictive value — 89.5%.

DISCUSSION

The obtained study results have demonstrated great usefulness of PFS-TV in the stratification of patients between patients with stress urinary incontinence and patients without the stress component of urinary incontinence. PFS-TV is a low-invasive method which, compared to a urodynamic test, allows for faster results, is more comfortable and less invasive for patients. The use of PFS-TV in the diagnosis of urinary incontinence in women makes it possible to avoid bladder catheterisation, thereby reducing the risk of urinary tract infections. The most characteristic ultrasound symptom of SUI is the occurrence of the urethral funneling symptom. In our study, 17% of the patients with OAB and without urinary incontinence experienced urethral funneling (false positive ratio). The performed statistical analysis showed 85% sensitivity and 83% specificity of the presence of the urethral funneling symptom in SUI excluding, and the percentage of false positive results at the level of 17% when this symptom was used as the only diagnostic condition. The application of the logistic regression model we developed increased the diagnostic sensitivity in detecting patients without the stress incontinence component to 89.2%, and specificity to 90.4% while reducing the percentage of false positive results to 9.6%. In our cohort, the logistic regression model has proven itself mainly as a tool for reducing the percentage of false positive diagnoses. Results of our study are in compliance with other literature data which confirm that pelvic floor ultrasound is mainly useful in excluding stress component of urinary incontinence [5]. The limitation of the study is the lack of validation of the created model in an external independent patient population, but this is the goal of subsequent ongoing research studies.

The clinical significance of the ultrasound symptom of urethral funneling is not fully understood. Among SUI patients with clinical symptoms, urethral funneling occurs in 20% — 100% of the cases [5, 6]. Many variables can affect both the occurrence of the funnel symptom and its visualisation during an ultrasound examination, including the experience of the person performing the ultrasound, the type of head, the angle of insonation, urine volume in the bladder. A large discrepancy in the occurrence of sick patients may result from the lack of an unequivocal ultrasound definition of urethral funneling. Urethral funneling is a sign that has a three-dimensional structure. The structure is assessed qualitatively. There are no unambiguous, measurable cut-off points in literature which would mean that the urethral funneling sign is positive. In the study, Wlaźlak et al. [6] showed that the ratio of the funnel depth to the length of the urethra plays a particularly important role SUI diagnostic management, and this symptom was considered characteristic for stress urinary incontinence > 0.5. Limitation of our work is, however, the lack of estimation of this value in each case. Furthermore, the symptom of urethral funneling was treated qualitatively by classifying all cases to the occurrence group with a ratio of ≥ 0.3. This cut-off point was chosen arbitrarily due to the ease of visualisation during an ultrasound examination. In the regression model we propose, the second parameter is D1, which is the distance between the lower edge of the pubic symphysis and the perpendicular line drawn to the neck of the bladder. In patients with the stress incontinence component, the D1 segment usually has values lower than in the control group. This may be associated with subclinical pelvic floor static disorders. Rotational descent (cytourethrocele) may increase the ultrasound dimension and at the same time mask the symptoms of stress urinary incontinence (occult SUI) [7, 8]. The measurements of this distance as well as the height of the bladder neck are characterised by high test-retest reliability and low intraobserver variability [9, 10].

Although only two parameters from the ultrasound examination were used in the regression model in our study, both groups of examined patients differed in most measurements. In patients from Group II (control group) the value of parameter D was higher both at rest and during straining. The bladder neck mobility alone expressed as a change in the D (D1–D2) and H (H1–H2) parameters did not differ between the groups, in contrast to the urethral mobility expressed by the change in the angle γ, which was greater in the group of patients with the stress incontinence component (urethral mobility).

In our study, the average length of the urethra in the entire study population was 26.85 mm (+/− 4.97 mm). Compared to the results published by other authors, this length was significantly different ($p < 0.05$) from the average measurement observed in e.g. a study by Pomian and co-authors (30.1 mm +/− 4.2 mm) [11], but in both studies the distribution of the length of urethra in the examined patients was similar to the normal distribution. The difference in the average urethral length of about 3 mm between the studied populations, despite its statistical significance, is not clinically significant in our opinion, and only confirms that the ultrasound length of the urethra in women is about 3 cm. In our cohort, the length of the urethra did not differ between groups, which confirms that it is not a factor predisposing to the occurrence of stress urinary incontinence. Accurate measurement of urethral length is, however, extremely important when qualifying patients for surgery because of urinary incontinence.

In a classic study, Ulmsten et al. recommended making an incision 1 cm from the external opening of the urethra when placing a mid-urethral sling [12]. Considering that a correctly placed mid-urethral sling should be placed halfway up the urethra, this incision site selection will not be effective in all cases. As our study results showed, the length of the urethra of the patients included in the study was in the range of 22–32 mm. Therefore, placing a sling according to the recommendations of Ulmsten et al. [12] would be effective only in 64% of patients. In the remaining 36% of patients, the use of the incision technique proposed by Umstein may result in the procedure being ineffective due to too high or low insertion of the mid-urethral sling. Hence, it is necessary to individualize the surgical procedure depending on the ultrasound measurement of the patient's urethra.

CONCLUSIONS

Pelvic floor ultrasounds (PFS-TV) make it possible to exclude the stress component of urinary incontinence. PFS-TV is a helpful diagnostic method to define the type of urinary incontinence. The logistic regression model we developed allows us to objectify the results of ultrasound examination of the pelvic floor in women with urinary incontinence.

Conflict of interest

All the authors declare no conflict of interest.

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Table 1. Demographic characteristics of both groups

Variable	SUI (n = 153)	OAB + no UI (n = 108)	p
	Median (25^{th}–75^{th} percentile)	Median (25^{th}–75^{th} percentile)	
Age [years]	52 (46–59)	48 (38–60)	ns
Weight [kg]	71 (66–82)	69 (59–80)	< 0.05
Height [cm]	164 (159–168)	163 (159–167)	ns
BMI [kg/m^2]	27.3 (24.5–30.9)	26.3 (22.6–29.7)	ns
Number of deliveries	2 (2–3)	2 (1–3)	ns
Anterior wall prolapse (POPQ > 1)	34.29%	32.67%	ns

BMI — body mass index; no-UI — no urinary incontinence; ns — no significant; OAB — overactive bladder; POPQ — pelvic organ prolapse quantification

Table 2. Ultrasound parameters in both groups. Each parameter is explained in text

Variable	SUI (n = 153)	OAB + no UI (n = 108)	p-value
	Median (25th–75th percentile)	Median (25th–75th percentile)	
D1 [mm]	19 (15.5–22)	22 (18–28)	0.00
D2 [mm]	22 (18–28)	26 (19–36)	0.00
H1 [mm]	14 (10–18.5)	14 (9–20)	0.42
H2 [mm]	4 (−5–8)	5 (−6–8)	0.13
γ1 [degree]	37.5 (31.5–42)	40 (32–50)	0.04
γ2 [degree]	66 (52–80)	58.5 (44.5–70.5)	0.01
D1–D2 [mm]	(−3) (−7–0)	−4 (−6.5–0)	0.35
H1–H2 [mm]	10 (5–16)	9 (4–15)	0.39
γ1– γ2 [degree]	29 (15–43)	14 (7–28)	0.00
	Percent	Percent	
Urethral funneling (positive)	89%	17%	0.00
	Mean [SD]	Mean [SD]	
Urethra length (L) [mm]	26.5 (4.8)	27.5 (5.01)	0.83

mm — millimeters; no UI – no urinary incontinence; OAB — overactive bladder; SD — standard deviation; SUI – stress urinary incontinence

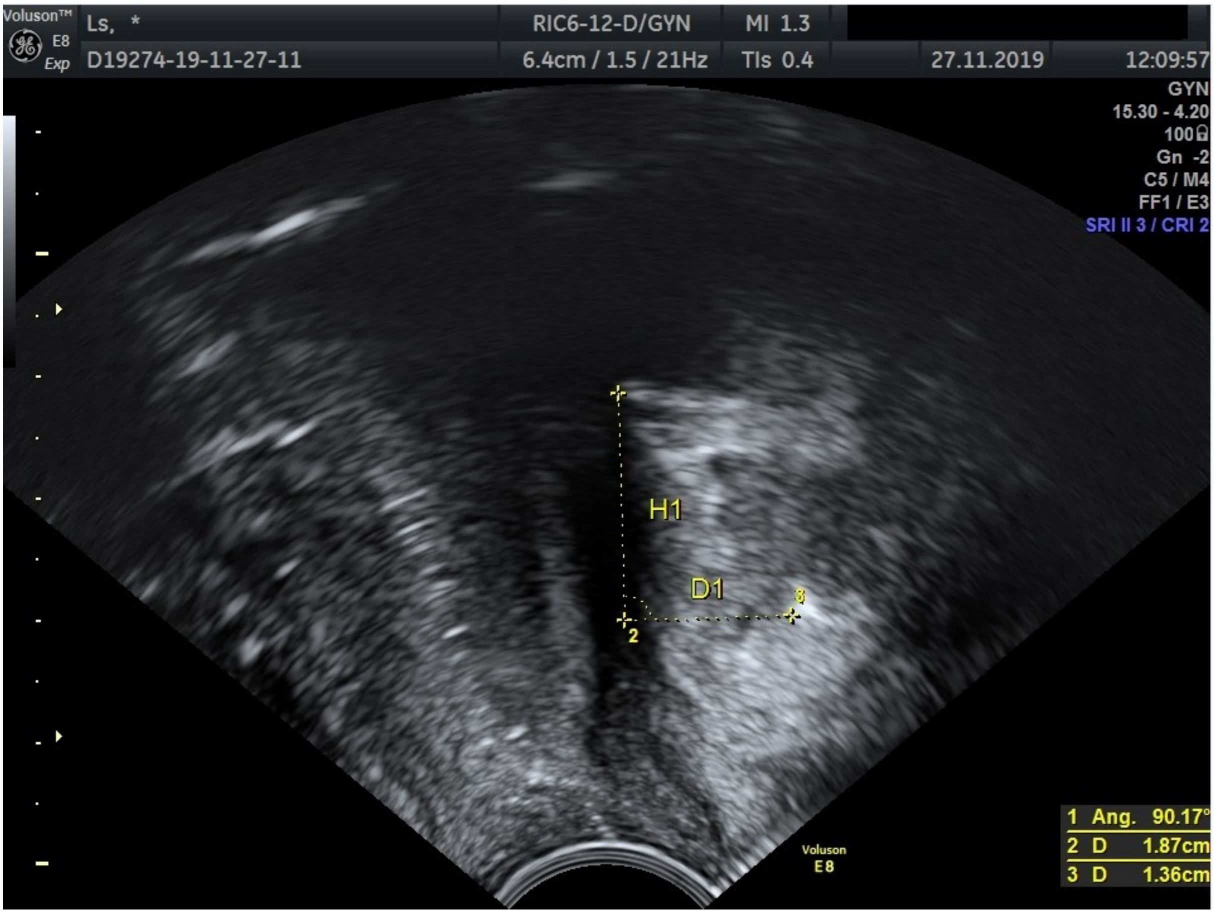

Figure 1. Measurement of D and H at rest

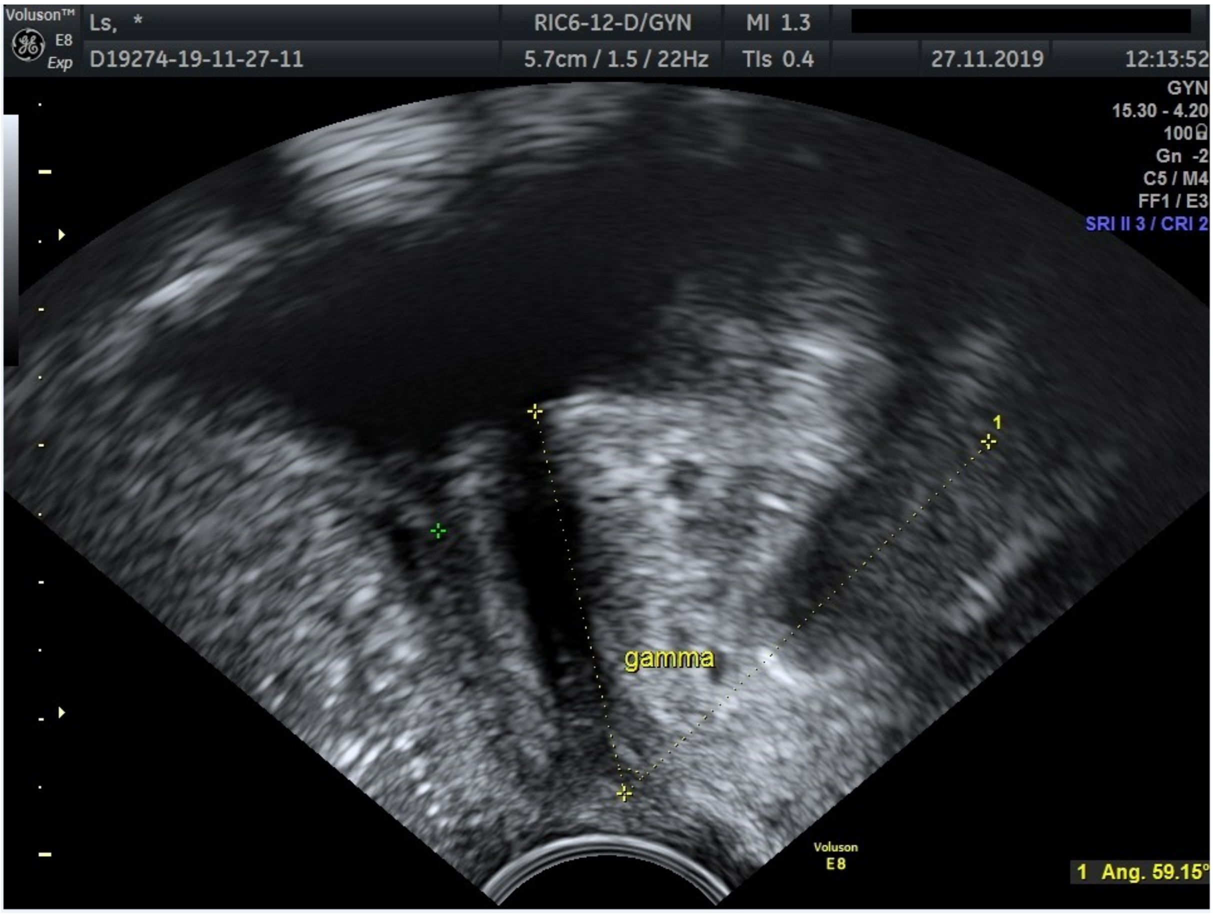

Figure 2. Measurement of gamma angle at rest

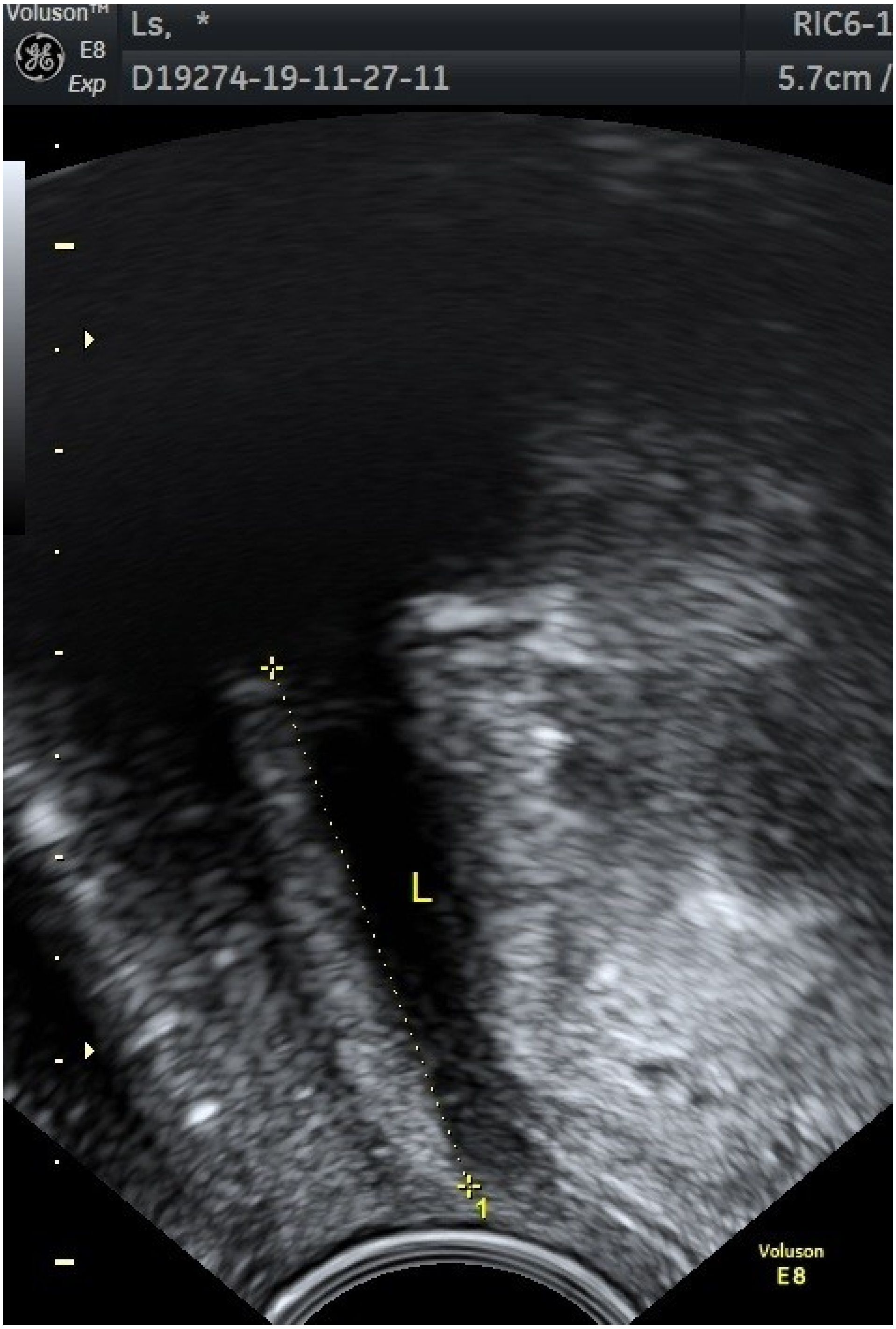

Figure 3. Measurement of urethral length

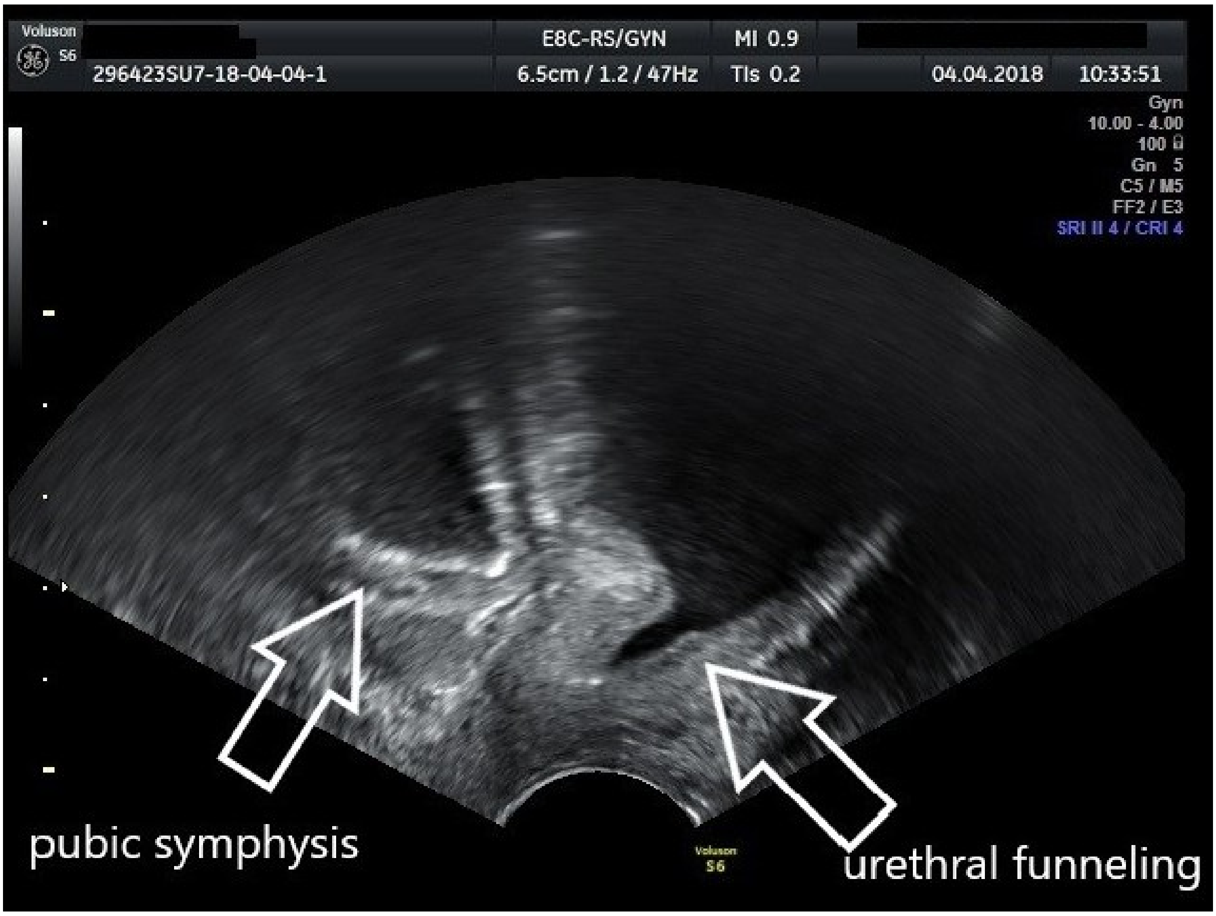

Figure 4. Sign of urethral funneling

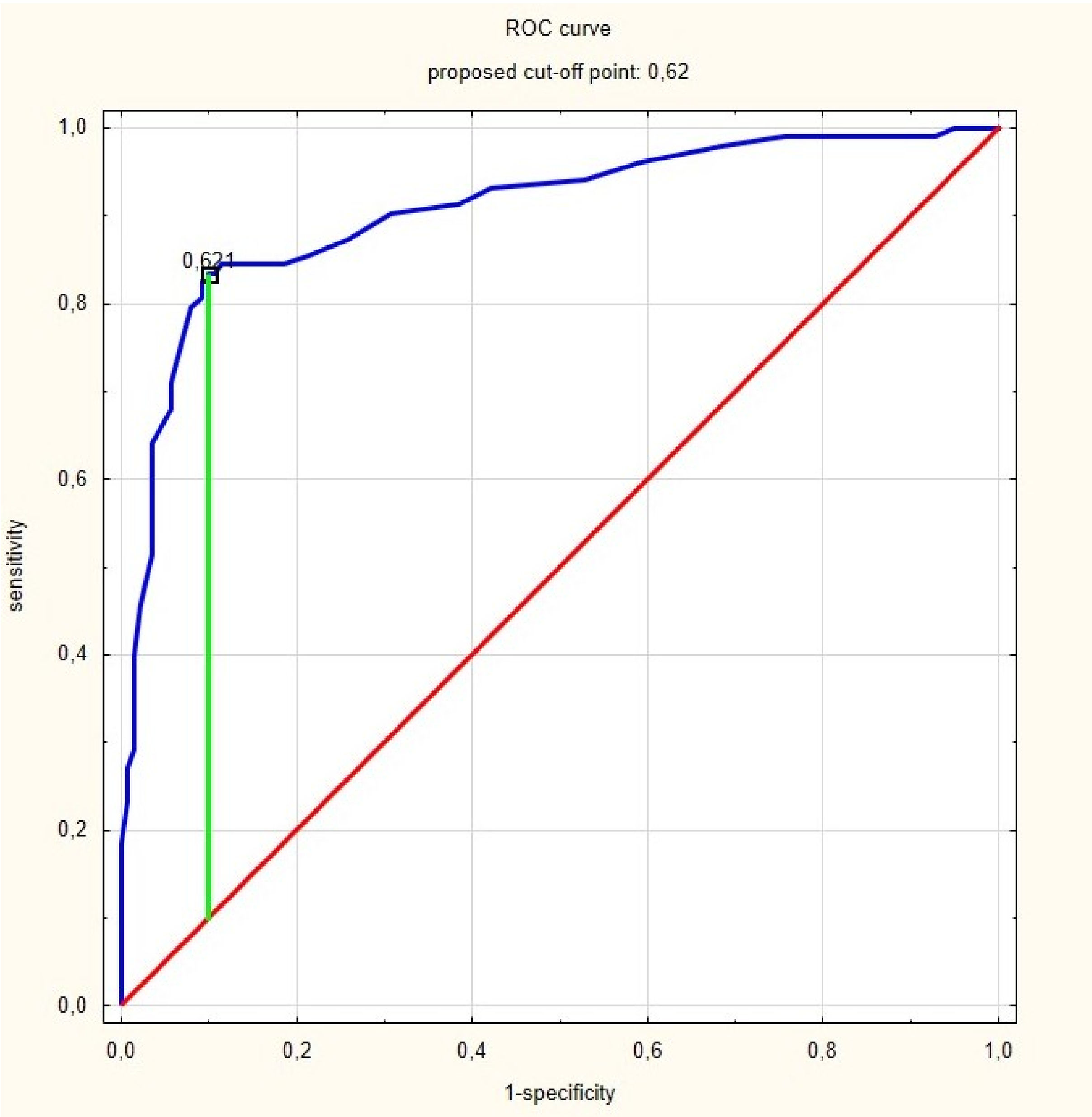

Figure 5. ROC curve. Green line indicates maximal value of Youden index for the curve