

The Effectiveness of Transperineal Ultrasonography in the Diagnosis and Dynamics of Therapy in Women with Stressurinary incontinence.

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ABSTRACT

Aim

Our aim was to explore the effectiveness of transperineal ultrasound in diagnosis and dynamic therapy of SUI.

Methods

Prospective incomparative study of 31 parous women with pelvic floor disorder examined with POP quantification (POP-Q) and 2D transperineal ultrasound before, during and *3 months later* after periurethral injections of hyaluronic acid "Delight G". Statistical analysis was undertaken using Python package SciPy. To check whether the data is normally distributed we used Kolomogorov-Smirnov criteria (scipy.stats.kstest). All background variables (BMI, age and parity) and ultrasound measurements were not normally distributed, hence we used nonparametric statistical criteria. We based on 99 percent confidence level, therefore p-value 0.05 and parameters lower than that were considered to be statistically significant.

Results

Based on the sonography data the most significant parameter was the proximal urethral diameter at rest, which decreased 2.2 times in patients *immediately after surgical treatment* (10.95 ± 1.38 mm vs. 4.98 ± 1.38 mm, $p < 0, 05$). Moreover, this effect continued *3 months after* periurethral injection. In addition, transperineal ultrasound scanning showed that the height of centrum tendineum were 2 times more in patients immediately and *3 months after* surgical treatment (13.53 ± 1.42 mm vs 6.49 ± 1.1 mm and 13.53 ± 1.42 mm vs 7.78 ± 1.17 mm, $P < 0, 05$). Other ultrasound parameters – α -angle at rest and during straining, β -angle at rest and during straining – did not have statistically significant changes after periurethral injection (Figure 3-8).

Conclusion

In the course of our research, it was found that transperineal ultrasound is highly effective not only in diagnosis, but also in assessing the effectiveness of therapy in patients with stress urinary incontinence.

Key words: stress urinary incontinence, pelvic organ prolapse, transperineal ultrasound.

Conflict of interest. All authors declare that there is no potential conflict of interest requiring disclosure in this article.

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Introduction

Urinary incontinence (UI) is a serious social and health issue the frequency of which is increasing [1].

The disease occurs in both sexes, but is much more common in women. The number of women with urinary incontinence in the United States is estimated to grow from 18.3 million in 2010 to 28.4 million in 2050 [2].

Studies show that UI significantly reduces the quality of life for women. UI negatively affects women's sexuality and work life. In addition, women with UI have a higher degree of emotional distress than women with normal micturition.

Stress urinary incontinence (SUI) affects approximately 50% of women who suffer from urinary incontinence (UI) [3].

According to the standard definition of the International Urogynecological Association (IUGA) and the International Continence Society (ICS), SUI is the complaint of urine leakage in combination with coughing, sneezing, or physical exertion [4].

The etiology of UI is multifactorial and its causes are mainly associated with the dysfunction of the bladder, pelvic floor muscles (PFMs), the ligament apparatus, connective tissue including inter alia, endopelvic fascia and/or neural structures. The risk of UI becomes preoccupied with age, but symptoms of UI can occur in postpartum women as well as in young nulliparous women [5].

Other factors associated with urinary incontinence include parity [6,7,9], obesity [7,9,10], previous hysterectomy or pelvic surgery, pulmonary disease [9], diabetes mellitus [7,8,10] and dementia [4].

Treatment options for urinary incontinence range from lifestyle modification to more-invasive surgical interventions.

There are two frequently overlapping mechanisms of stress urinary incontinence: hypermobility of the urethra resulting from loss of support for the bladder neck and urethra, and weakness of the urinary sphincter. If the urinary sphincter is damaged, it leads to the formation of a special subtype of stress urinary incontinence - the so-called internal sphincter deficiency. The cause of urinary sphincter weakness is due to trauma, repeated urogynecological surgeries, neurological diseases, aging, or diseases leading to systemic muscular atrophy.

SUI classification (Blaivas and Olson 1988) based on position of bladder base in relation to the inferior margin of the pubic symphysis (IMPS), and whether or not the bladder neck (BN) is open at rest. Urethral hypermobility is the predominant abnormality in types 1 and 2 in the

Blaivas classification and usually occurs due to weakness of the pelvic floor. This allows rotational descent of the bladder neck and proximal urethra during increased abdominal pressure. Type 3 SUI describes a sphincter mechanism malfunction and has numerous causes [11].

The diagnosis of SUI is based on a targeted medical history, assessment of the quality of life, as well as general and focused physical examinations [12].

The standard method for diagnosing and differentiating various types of SUI is urodynamic study. Other imaging modalities as pelvic floor ultrasonography, cysto-urethrography and magnetic resonance imaging (MRI) have been used to evaluate patients with SUI.

Modern ultrasound examination allows us to adequately assess the dynamics of the bladder neck and the proximal urethra in women with stress urinary incontinence. The technique is simple, non-invasive and does not cause discomfort in women.

Surgical procedures designed to treat urinary incontinence generally can be usually divided into seven main categories:

1. open abdominal retropubic colposuspension,
2. anterior vaginal repair (anterior colporrhaphy),
3. suburethral sling procedure,
4. bladder neck needle suspension,
5. periurethral or transurethral injection of bulking agents,
6. artificial urinary sphincter,
7. laparoscopic colposuspension [13].

Suburethral slings are the main treatment when hypermobility is associated with urinary incontinence. Periurethral injections are generally suitable for patients with internal sphincter insufficiency, no detrusor dysfunction, adequate bladder capacity, and no anatomical abnormalities (eg, hypermobility).

Periurethral injections as a minimally invasive approach have become a new alternative to surgical treatment. Implantation of urethral fillers is associated with minimal pain during treatment and, in addition, the procedure can be performed under local anesthesia on an outpatient basis. The periurethral injection of bulking agents is designed to create artificial urethral cushions that can improve urethral coaptation and hence restore urinary retention.

Therefore, the aim of the present study was to explore the effectiveness of transperineal ultrasound in diagnosis and dynamic therapy of SUI.

METHODS

This was a prospective incomparative study undertaken in 31 women who went in a tertiary gynecological unit for symptoms of SUI between October 1st 2020 and January.

Inclusion criteria were:

- 1) Patients visited the clinics with symptoms consistent with SUI.
- 2) Patients sought help between August 2020 and January 2021.
- 3) Patients with type 3 SUI.
- 4) They received both clinical and ultrasound examinations.

Exclusion criteria were: pregnancy, urinary tract infection, nonparous women, patients with major pelvic surgery (such as hysterectomy, pelvic floor prosthesis). Patients without sonographic data before and after surgical treatment were excluded.

The demographic characteristics of the participants, including age, parity, height, weight, mode of delivery were recorded according to the standard protocol. The body mass index (BMI) was calculated by measuring the weight (in kilograms) divided by the square of the assessed height (in meters). All patients underwent a clinical interview with POP examination performed based on the Pelvic Organ Prolapse Quantification System of the International Continence Society (ICS POP-Q).

All participants were trained on how to appropriately perform the Valsalva maneuver before the examination. First, an expert obstetrician/gynecologist recorded any bulging in the anterior or posterior part of the vagina, and then the physician asked the patients to cough or to do the Valsalva maneuver at least 3 times. All patients with positive cough signs were considered in the study.

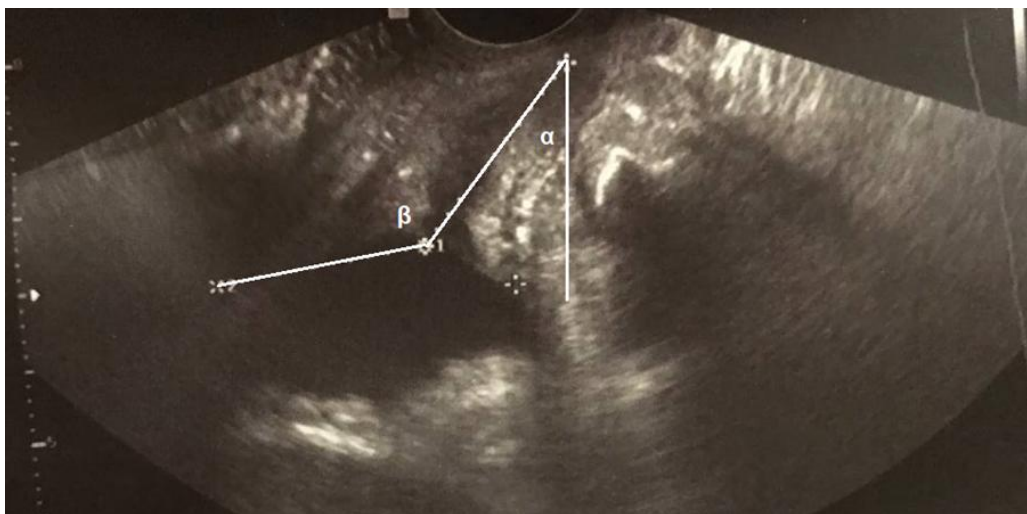
Transperineal ultrasound was performed with the lithotomy position using a Voluson S6 or IC9-RS (GE Healthcare, Milwaukee, WI, USA) a 4–8-MHz transducer that was covered with a condom. The transducer was placed on introitus, vertically in midline with a bladder volume of 250 ± 50 mL. The operator used minimal pressure during the examiner on the pelvic floor.

The US device was set in the dual mode while the symphysis pubis, bladder, uretra, urethrovesical junction, hiatal area, vaginal wall and anal canal were observable. Also were measured:

- The anterior urethropelvic angle α -angle, formed by the urethral axis and the central line of the symphysis pubis, was measured at rest and during straining (Figure 1).
Urethral mobility is calculated as the angle during a Valsalva maneuver minus the angle at rest;
- The posterior urethro-vesical angle β -angle, defined as the angle formed by the urethral axis and a line drawn tangent to the posterior edge of the bladder base near the bladder neck, was measured at rest and during straining (Figure 1);
- The urethral diameter measurement was performed inside the lumen of the two internal

mucous membranes.

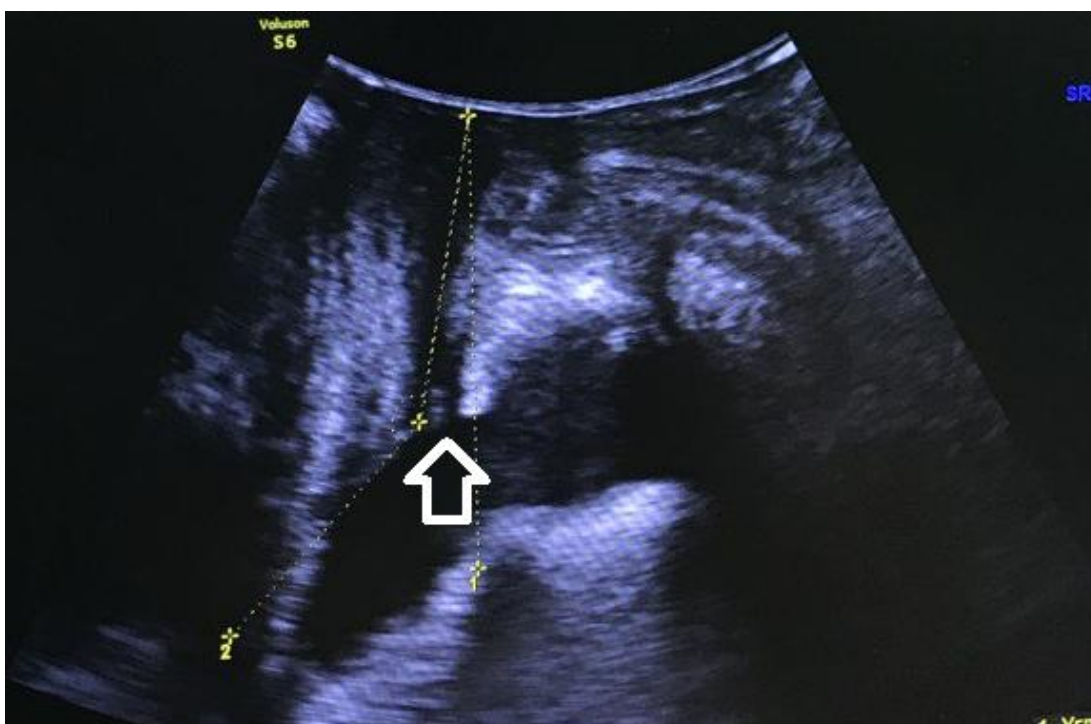
Figure 1. The anterior urethropelvic angle α -angle and the posterior urethro-vesical angle β -angle.



We used the following parameters as markers of the intrinsic sphincter deficiency (ISD) (Figure 2):

- funneling deformation of the urethra at rest with the expansion of urethra more than 1 cm,
- vertical standing of the urethra (angle α at the rest and on straining less 10°),
- expansion of the proximal urethra more than 1 cm [14].

Figure 2. Introital ultrasound measuring urethral diameter 1,26 cm indicating intrinsic sphincter deficiency (marked by white arrow).



The injection implantation was performed transperineal using "Delight G" gel. This is a new generation drug consisting of cross-linked hyaluronic acid with a molecular weight of 3 million daltons. Gel "Delight G", designed specifically and exclusively for the intimate area.

According to the author's methods of professor Orazov M. R. were carried out injections of hyaluronic acid "Delight G» into the myofascial layers periurethral at 3 points at 3, 9, 6 hours in the middle third of the urethra under local anesthesia.

Statistical analysis was undertaken using Python package SciPy. To check whether the data is normally distributed we used Kolomogorov-Smirnov criteria (scipy.stats.kstest). All background variables (BMI, age, period from first birth and parity) and ultrasound measurements were not normally distributed, hence we used nonparametric statistical criteria. To check differences between time series (before, during and after perineoplasty) of ultrasound measurements we applied Mann–Whitney U-test (scipy.stats.mannwhitneyu) women. We based on 99 percent confidence level, therefore p-value 0.05 and parameters lower than that were considered to be statistically significant. The ethical approval for this study was obtained from the Research Ethics Committee of our institution (13-502).

Results

All 31 women were examined with POP-Q (Stage I).

Mean BMI at the time of inclusion was 26.7 kg/m² (range 21.9-31), mean age was 33.6 years (range 27-41). Mean parity 1.39 (range 1-3). Background variables in the group are lined out in Table 1.

Mode of delivery was normal vaginal delivery for 18/31 (58 %), forceps for 1/31 (3,2%), vacuum for 4/31 (12,9 %) and episiotomy for 8/31 (25.8%) of the women.

Table 1. Demographic characteristics of all participants (n = 31).

Abbreviations: BMI, body mass index, POP-Q, pelvic organ prolapse quantification system.

Characteristic	Value
BMI kg/m ² Mean (SD)	26.7 ± 3.1
Age years Mean (SD)	33.6 ± 4.8

Paritynumber Mean (SD)	1.4±0.6
POP-Q stage I n/N (%)	31/31 (100%)
Mode of delivery, n/N (%)	
Normalvaginal	18/31 (58 %)
Vacuum	4/31 (12,9 %)
Forceps	1/31 (3,2%)
Episiotomy	8/31 1(25.8%)

We carried out a comparative analysis of sonographic parameters *before*(A), *immediately after* periurethral injection (B) and *3 months after surgical treatment*(C) (Table 2).

Based on the sonography data the most significant parameter was the proximal urethral diameter at rest, which decreased 2.2 times in patients *immediately after surgical treatment* (10.95 ± 1.38 mm vs. 4.98 ± 1.38 mm , $p < 0, 05$). Moreover, this effect continued *3 months after* periurethral injection (Figure 9).

In addition, transperineal ultrasound scanning showed that the height of centrum tendineum were 2 times more in patients immediately and *3 months after surgical treatment* (13.53 ± 1.42 mm vs 6.49 ± 1.1 mm and 13.53 ± 1.42 mm vs 7.78 ± 1.17 mm, $P < 0, 05$). (Figure 10).

Other ultrasound parameters – α -angle at rest and during straining, β -angle at rest and during straining – did not have statistically significant changes after periurethral injection (Figure 3-8).

Table 2.Time series: A - measurements before periurethral injection, B - immediately after periurethral injection, C - 3 months after periurethral injection.

		A	B	A	C	B	C
α -angle (°) atrest	Mea n (SD)	10.45 ± 1.98	10.35±1. 91	10.45 ± 1.98	10.31±1.2 2	10.35±1. 91	10.31±1.2 2
	p	> 0. 05		> 0. 05		> 0. 05	
α - angle(°)duringstra ining	Mea n (SD)	18.58 ±1.93	18.29±1. 49	18.58 ±1.93	18.42±1.2 9	18.29±1. 49	18.58 ±1.93
	p	> 0. 05		> 0. 05		> 0. 05	
deviation of the α -angle (°)	Mea n (SD)	8.13±1.7 5	7.9±2.16	8.13±1.7 5	8.1±1.16	7.9±2.16	8.1±1.16
	p	> 0. 05		> 0. 05		> 0. 05	
β -angle (°) atrest	Mea n (SD)	93 ±13.2	93±13.18	93.26 ±13.2	93.93±12. 32	93±13.18	93.93±12. 32
	p	> 0. 05		> 0. 05		> 0. 05	

β-angle (°) during straining	Mea n (SD)	96.26 ±12.93	96.87±12 .8	96.26 ±12.93	96.29±12. 33	96.87±12 .8	96.29±12. 33
	p	> 0.05		> 0.05		> 0.05	
deviation of the β-angle (°)	Mea n (SD)	3.26±1.4 8	2.68 ±1.72	3.26±1.4 8	2.65±1.02	2.68 ±1.72	2.65±1.02
	p	> 0.05		> 0.05		> 0.05	
the proximal urethral diameter at rest (mm)	Mea n (SD)	10.95±1. 38	4.98±1.3 8	10.95±1. 38	6 ± 1.12	4.98±1.3 8	6 ± 1.12
	p	< 0.05		< 0.05		> 0.05	
the proximal urethral diameter during straining (mm)	Mea n (SD)	13.53± 1.42	6.49±1.1	13.53± 1.42	7.78 ± 1.17	6.49±1.1	7.78 ± 1.17
	p	< 0.05		< 0.05		> 0.05	

Figure 3. Dynamics of changes of the α -angle at rest before (A), immediately after periurethral injection (B), 3 months after periurethral injection (C). Data are shown for all participants (n =31).

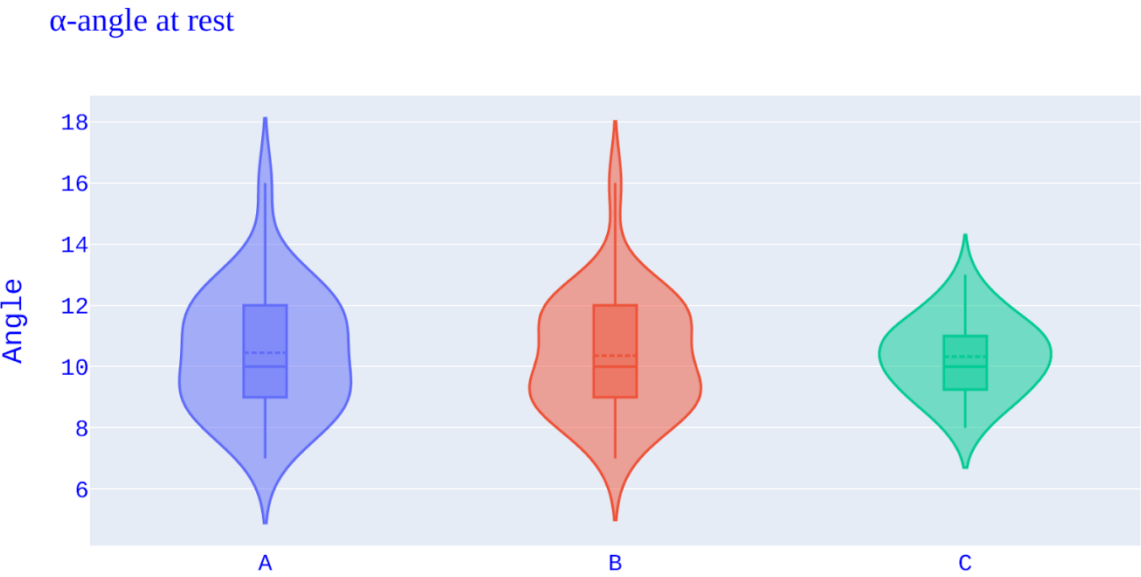


Figure 4. Dynamics of changes of the α -angle during straining before (A), immediately after periurethral injection (B), 3 months after periurethral injection (C). Data are shown for all participants (n = 31).

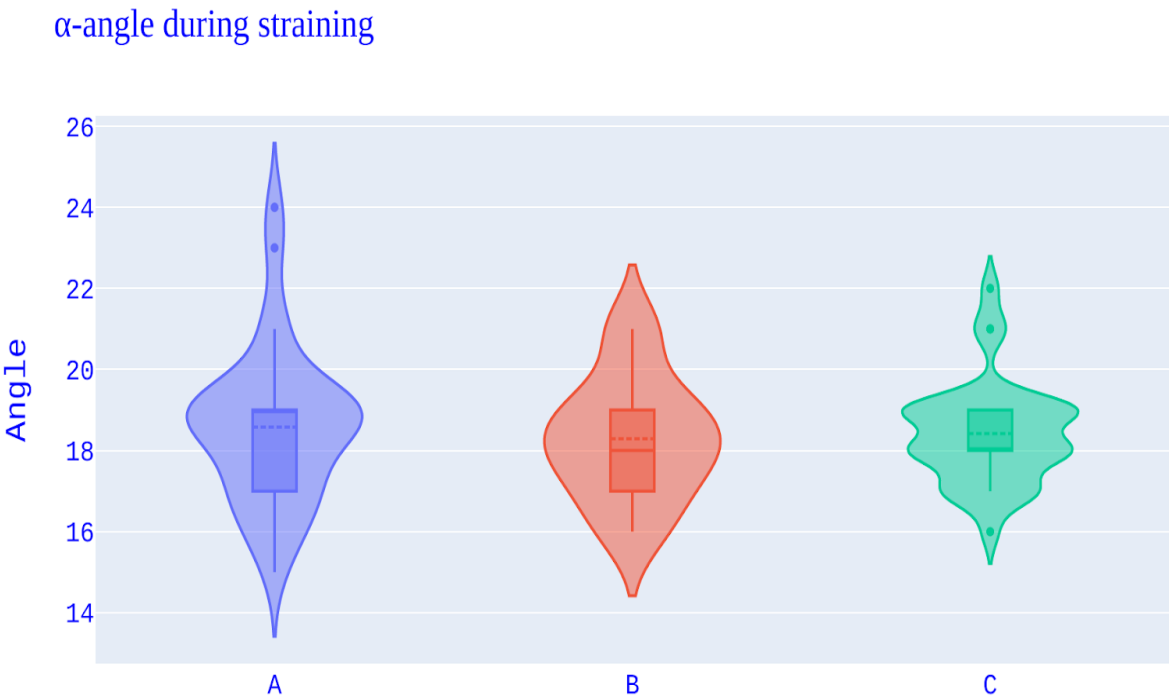


Figure 5. Dynamics of changes deviation of the α -angle before (A), immediately after periurethral injection (B), 3 months after periurethral injection (C). Data are shown for all participants (n = 31).

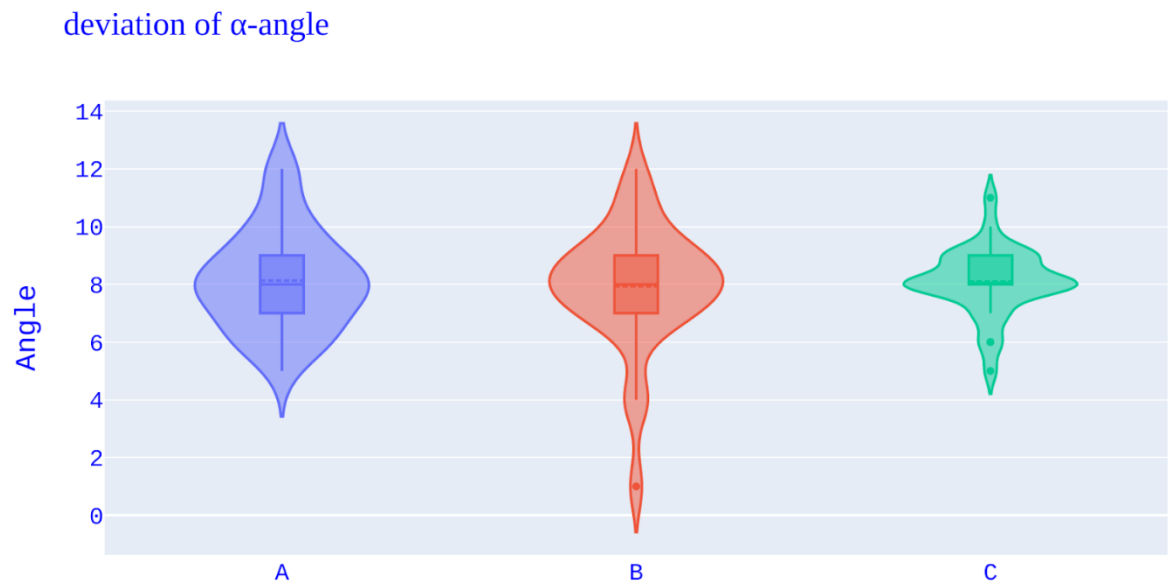


Figure 6. Dynamics of changes of the β -angle at rest before (A), immediately after periurethral injection (B), 3 months after periurethral injection (C). Data are shown for all participants (n = 31).

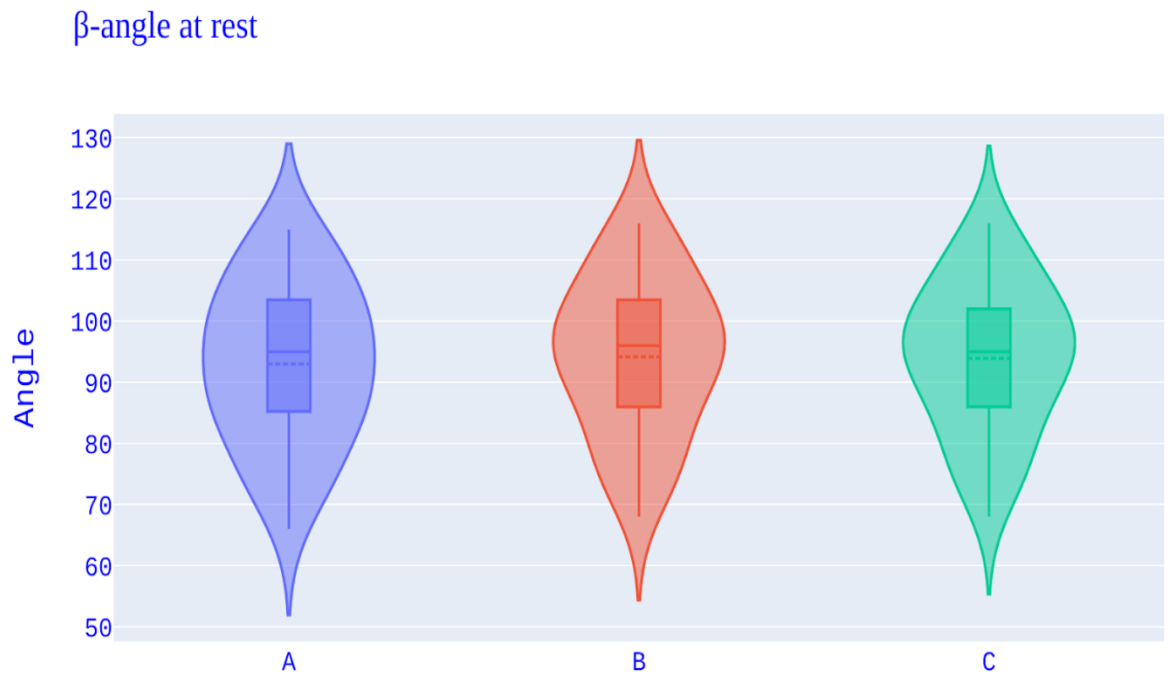


Figure 7. Dynamics of changes of the β -angle during straining before (A), immediately after periurethral injection (B), 3 months after periurethral injection (C). Data are shown for all participants (n = 31).

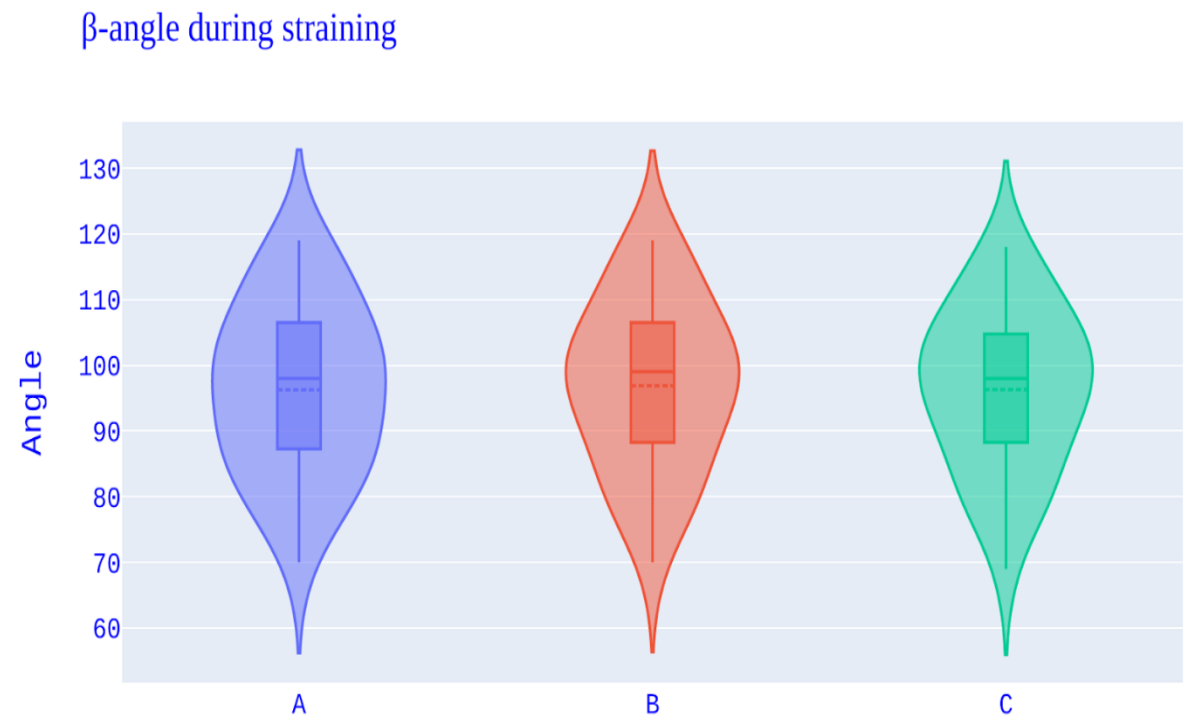


Figure 8. Dynamics of deviation of the α -angle during straining before (A), immediately after periurethral injection (B), 3 months after periurethral injection (C). Data are shown for all participants (n = 31).

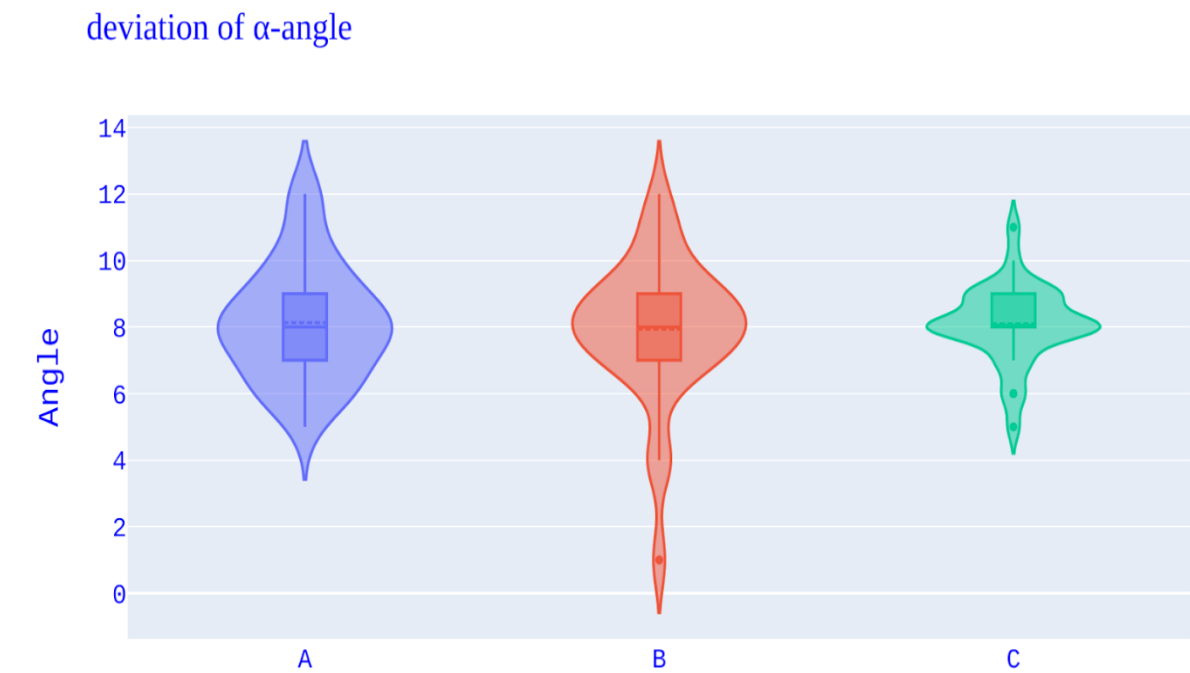


Figure 9. Dynamics of changes of the proximal urethral diameter at rest before (A), immediately after periurethral injection (B), 3 months after periurethral injection (C). Data are shown for all participants (n = 31).

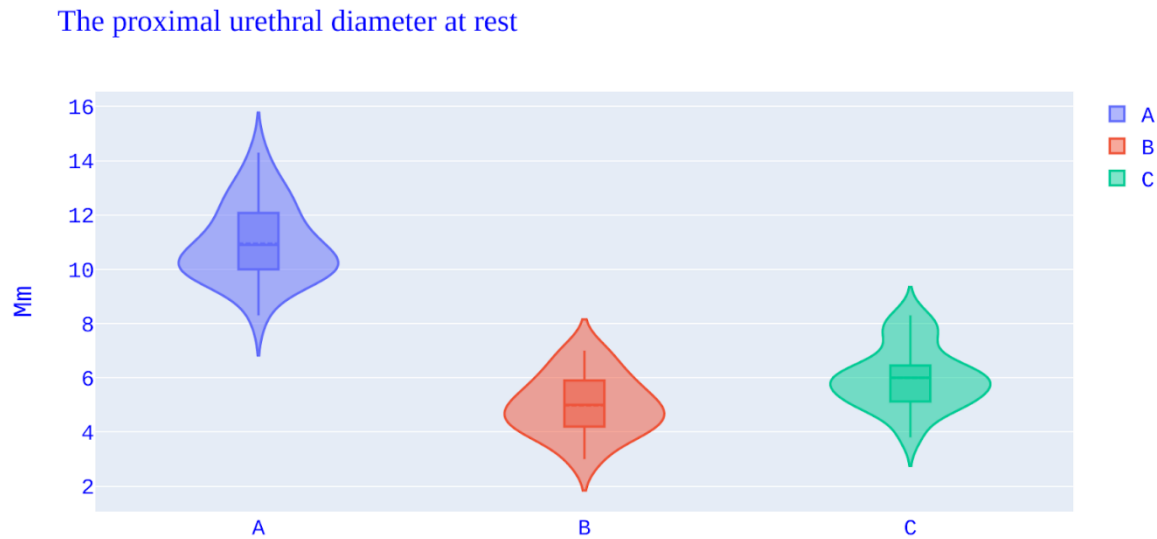
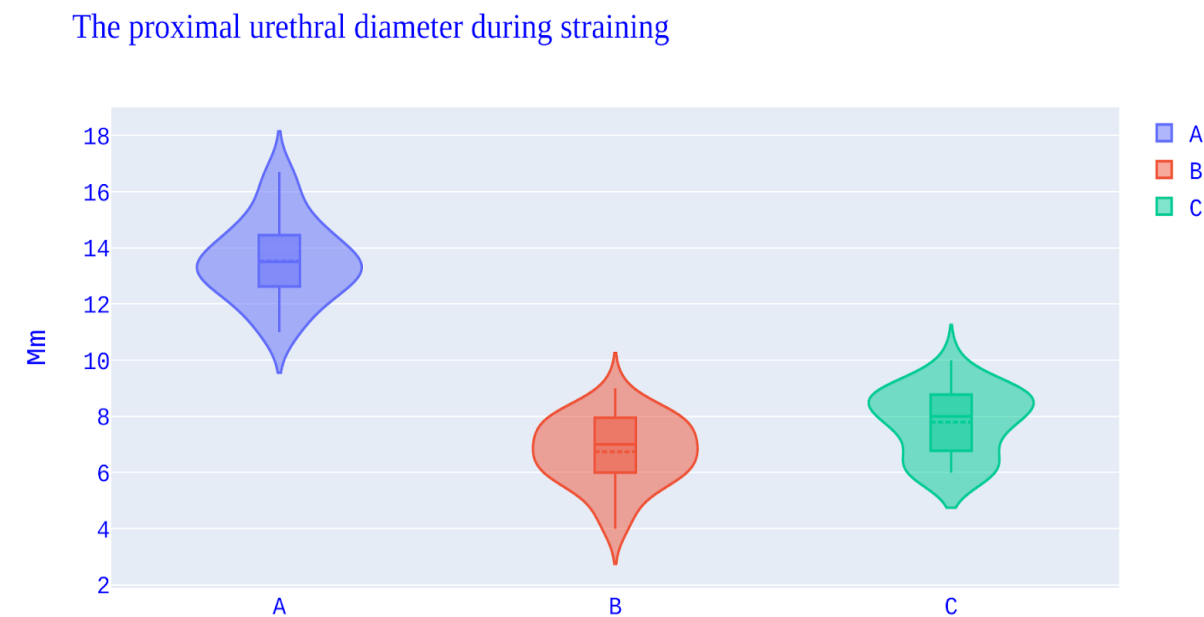


Figure 10. Dynamics of changes of the proximal urethral diameter during straining before (A), immediately after periurethral injection (B), 3 months after periurethral injection (C). Data are shown for all participants (n = 31).



Discussion

It is widely accepted that pre-operative evaluation of women with SUI should also include an assessment of urethrovesical mobility. TPUS allows assessing the mobility of bladder neck and urethral mobility at rest and during coughing, the Valsalva maneuver and pelvic floor contraction.

Sweedat al. evaluated TPUS results in 40 SUI cases compared to 40 controls. Analysis of the results of transperineal ultrasound did not show statistically significant differences in measuring the angles at rest in patients of the study and control groups, but with straining, a statistically significant difference was found in measuring the posterior angle of the urethra and the fronto-urethral distance ($p < 0.001$) [15].

Another study found significant differences between controls and incontinent women regarding alpha, beta angles and bladder neck descent during TPUS. Moreover, urethral angle identified genuine stress incontinence better than urethrovesical mobility (sensitivity 96% vs 87%; specificity 92% vs 68%; positive predictive value 85% vs 55%) [16].

In our study we assess the effectiveness of two-dimensional (2D) transperineal ultrasonography in the diagnosis and dynamics of therapy in women before and after periurethral injection of hyaluronic acid "Delight".

Urethral bulking agents are a valuable alternative to surgical treatment in women with SUI. Although clinical efficacy and durability are not comparable to surgery, increased urethral volume is associated with lower pain and a lower risk of side effects [17].

The most recent Cochrane report on periurethral injection from 2017 showed no difference in the effectiveness of different injection methods. In addition, it was concluded that the results of injection therapy were better than with conservative treatment, but worse than with colposuspension [18].

It is generally accepted that injection therapy is the gentlest method of treatment with a lower risk of complications in comparison with a tension-free vaginal tape [19,20]. Unlike tension-free vaginal tape, injection therapy does not result in any noticeable obstruction, suggesting a lower risk of postoperative bladder emptying problems. This procedure is distinguished by its particular speed, simple technique, and also a minimal recovery period [20].

With proper patient selection and counseling, urethral fillers can be a valuable treatment option for a gynecologist in SUI patients. And ultrasonography can be used as an alternative to traditional radiological methods not only in preoperative diagnosis, but also in assessing the effectiveness of treatment in women with UI in the long term.

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