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Дифференцированный подход к выбору терапии стрессового недержания мочи при дисфункции тазового дна у женщин

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АННОТАЦИЯ

Обоснование. Среди симптомов дисфункции тазового дна у пациенток молодого возраста часто встречается недержание мочи. Стрессовое недержание мочи нарушает психологическое здоровье, сексуальную и социальную жизнь. Исследователи продолжают изучать эффективность современных консервативных методик лечения легких форм стрессового недержания мочи у женщин в репродуктивном и перименопаузальном периодах для предотвращения прогрессирования заболевания и улучшения качества жизни.

Цель исследования — сравнить эффективность тренировок мышц тазового дна с применением лазерного вагинального тренажера «Тюльпан» и парауретральных инъекций гиалуронового биополимера высокой плотности при коррекции стрессового недержания мочи у женщин репродуктивного и перименопаузального возраста с дисфункцией тазового дна.

Материалы и методы. Обследованы 82 пациентки в возрасте 43,35 ± 6,25 лет со стрессовым недержанием мочи легкой и средней степеней тяжести в сочетании с опущением половых органов I–II степеней. После общеклинического и специального исследований, включающих дневники мочеиспускания, оценку степени дискомфорта по визуально-аналоговой шкале, кашлевой тест, ультразвуковое исследование уретровезикального сегмента и тазового дна, 41 женщине был назначен курс дистанционных тренировок мышц тазового дна под контролем врача с применением лазерного тренажера «Тюльпан» (I группа). Во II группе 41 пациентке парауретрально ввели 4,0 мл гиалуронового биополимера высокой плотности, «сшитого» 1,4-бутандиола диглицидиловым эфиром. Изучены результаты эффективности терапии через 1, 6 и 12 мес. после начала лечения.

Результаты. Отсутствие эпизодов стрессового недержания мочи по данным дневников мочеиспускания через 1 мес. установлено в I группе у 29,4 % пациенток, во II группе — у 85,4 % (в 2,9 раза чаще; $p < 0,001$), а через 12 мес. в I группе — у 73,1 % пациенток, во II группе — у 36,4 % (в 2 раза реже; $p = 0,011$). Отрицательный кашлевой тест через 1 мес. выявлен в I группе у 65,0 % женщин, во II группе — у 92,1 % (в 1,4 раза чаще; $p = 0,023$). Через 6 мес. результаты лечения стрессового недержания мочи по данным кашлевого теста статистически не различались и составили в I группе 80,0 %, во II группе — 71,9 % ($p = 0,725$). При оценке силы мышц тазового дна по шкале Оксфорда и по данным перинеометрии в I группе увеличение силы через 1 и 6 мес. выявлено у 100 % пациенток ($p < 0,001$). Обе методики в течение 1 мес. наблюдения одинаково уменьшали мобильность уретры, по данным ультразвукового исследования. Тренировки мышц тазового дна более выраженно улучшали качество жизни женщин через 12 мес. после начала терапии ($p < 0,05$).

Заключение. Введение гиалуронового биополимера высокой плотности приводит к быстрому и выраженному положительному результату лечения стрессового недержания мочи и улучшению качества жизни в ближайшем периоде, оно рекомендовано пациенткам, заинтересованным в быстром достижении результата, информированным об ограниченной длительности эффекта. Регулярные тренировки мышц тазового дна в режиме биологической обратной связи под дистанционным контролем врача способствуют лучшему результату в отдаленном периоде. Данный метод рекомендован женщинам, способным сокращать мышцы тазового дна и готовым к регулярным занятиям.

Ключевые слова: дисфункция тазового дна; стрессовое недержание мочи; объемообразующие вещества; гиалуроновый биополимер; тренировки мышц тазового дна.

Как цитировать

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Differentiated approach to the choice of therapy for stress urinary incontinence in women with pelvic floor dysfunction

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ABSTRACT

BACKGROUND: Among the symptoms of pelvic floor dysfunction, urinary incontinence is common in young patients. Stress urinary incontinence disrupts psychological health, sexual and social life. The effectiveness of modern conservative treatments for mild stress urinary incontinence in women of reproductive and perimenopausal age is being studied to prevent disease progression and improve the quality of life.

AIM: The aim of this study was a comparative assessment of the effectiveness of pelvic floor muscle training using the Tyulpan laser vaginal simulator and paraurethral injections of a high-density hyaluronic biopolymer for the correction of stress urinary incontinence in women of reproductive and perimenopausal age with pelvic floor dysfunction.

MATERIALS AND METHODS: We examined 82 patients aged 43.35 ± 6.25 years with mild to moderate stress urinary incontinence combined with grade I to II genital prolapse. After general clinical and special studies, including voiding diaries, Urgency Bother Visual Analogue Scale, cough test, ultrasound of the urethrovesical junction and pelvic floor, 41 women were prescribed a course of remote pelvic floor muscle training under medical supervision using the Tyulpan laser vaginal simulator (group I). 41 patients underwent paraurethral injection of 4.0 ml of high-density hyaluronic biopolymer crosslinked with 1,4-butanediol diglycidyl ether (group II). The effectiveness of therapy was evaluated one, six and 12 months after the start of treatment.

RESULTS: After one month, the absence of stress urinary incontinence episodes based on voiding diaries was found in 29.4% of patients in group I and in 85.4% of patients in group II (2.9 times more often) ($p < 0.001$); after 12 months, in 73.1% of patients in group I and in 36.4% of patients in group II (half as often) ($p = 0.011$). After one month, a negative cough test was detected in 65.0% of women in group I and in 92.1% of women in group II (1.4 times more often) ($p = 0.023$). After six months, the results of treatment for stress urinary incontinence based on the cough test were not different and amounted to 80.0% in group I and 71.9% in group II ($p = 0.725$). When assessing the pelvic floor muscle strength using the Oxford Scale and perineometry, an increase in strength after one and six months was detected in 100% of patients in group I ($p < 0.001$). Both techniques equally reduced urethral mobility as measured by ultrasound over the one-month follow-up. Pelvic floor muscle training more significantly improved the quality of life of women 12 months after the start of therapy ($p < 0.05$).

CONCLUSIONS: The introduction of high-density hyaluronic biopolymer leads to a rapid and pronounced positive result in the treatment of stress urinary incontinence and an improvement in the quality of life in the short term; it is recommended for patients interested in quickly achieving results, informed about the limited duration of the effect. Regular training of the pelvic floor muscles in biofeedback mode under the remote control of a doctor contributes to better results in the long term. This method is recommended for women who are able to contract the pelvic floor muscles and are ready for regular exercise.

Keywords: pelvic floor dysfunction; stress urinary incontinence; bulking agents; hyaluronic biopolymer; pelvic floor muscle training.

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BACKGROUND

Pelvic floor dysfunction is a multifactorial disease with one or more of the following manifestations: urinary incontinence, pelvic organ prolapse, anal incontinence, and sexual dysfunction. Symptoms of urinary incontinence are observed in 34.6% of patients, genital prolapse in 34.1%, fecal incontinence in 33.6%, and sexual dysfunction in 41.6%. Initially, manifestations typically emerge in young women and gradually progress over time [1]. Among the types of urinary incontinence in women, stress urinary incontinence (SUI) is the most prevalent, occurring in 60.7% of cases [2]. In women of reproductive age, the primary risk factors for the disease are childbirth and perineal trauma. The incidence of SUI increases with increased body weight and heavy physical exertion because these contribute to increased intra-abdominal pressure [3]. Symptoms negatively affect the quality of life and psychological well-being of female patients. Even in mild SUI, urinary loss causes embarrassment, anxiety, physical activity limitations, and impaired sexual and social life [2, 4, 5]. Women are more likely to seek medical attention when the SUI is already severe. The postponement of specialist visits for >10 years after the initial onset of symptoms is attributed to the perceived intimacy of the problem, tendency to view it as a natural consequence of aging and childbirth, and lack of awareness about existing treatment options. Over time, the severity of SUI progresses, significantly worsening the quality of life [6, 7].

Treatment of SUI includes conservative and surgical techniques [8–10]. Pelvic floor muscle (PFM) training (PFMT) is the first-line therapy for mild disease. This method is associated with a low risk of complications [11]. The most effective PFMT is in the biofeedback mode in an outpatient setting under the supervision of medical personnel [9, 12]. In light of the contemporary pace of life, it is not always feasible for women to visit medical institutions. Accordingly, experts are developing a training method at home under the remote supervision of a doctor [13].

The most effective method for treating SUI with long-term maintenance of the result is surgical treatment using synthetic slings (in 92% of cases over a follow-up period of 10 years) [14, 15]. Some patients are not ready for surgical treatment because they intend to become pregnant in the near future or their apprehension regarding potential complications. This makes doctors look for alternative treatment modalities [16–18].

Moreover, 38% of women with urinary incontinence are refractory to PFMT even after meticulous, individualized training, because of trauma or partial muscle denervation [19]. A low treatment efficacy is also associated with a lack of time and motivation for regular exercise. In such cases, other treatment methods may be recommended [13].

The injections of urethral bulking agents (UBAs) into the paraurethral region are the second most commonly performed procedure after surgical treatment; however, they differ in a shorter duration of effect. The injected substances create additional volume in the paraurethral tissues, which helps retain urine when intra-abdominal pressure increases [17, 20].

In recent years, high-molecular hyaluronic acid has been employed extensively as an UBA. After its administration, it is metabolized to form nontoxic byproducts, including carbon dioxide and water. To preserve the substance in tissues for a long time, hyaluronic acid is subjected to chemical stabilization [21, 22]. Hyaluronic acid preparations modified with adjuvants are used in the treatment of SUI in women [23]. These substances are retained in tissues for approximately 12 months. Research on the effectiveness of different preparations of modified hyaluronic acid in the treatment of SUI is ongoing [24, 25]. There is no data in the literature on a comparative assessment of the effectiveness of paraurethral injections of hyaluronic acid and remote PFMT in the biofeedback mode under medical supervision in the treatment of SUI.

The aim of this study was a comparative assessment of the effectiveness of pelvic floor muscle training using the Tyulpan laser vaginal simulator and paraurethral injections of high-density hyaluronic biopolymer in the treatment of SUI in women of reproductive and perimenopausal age with pelvic floor dysfunction.

MATERIALS AND METHODS

A prospective controlled study was conducted at the Consultative and Diagnostic Department of the Research Institute of Obstetrics, Gynecology and Reproductology named after D.O. Ott between October 2020 and March 2024.

The study comprised three stages. At stage I, patients with grade I–II pelvic organ prolapse combined with mild or moderate SUI in the reproductive and perimenopausal period (aged 20–55 years) were selected. This was achieved by questioning 400 women using a specially developed questionnaire, and the selected women were examined [26]. Disease severity was determined based on the complaints, urinary diaries, and classification by D.V. Kan, where mild severity denotes urinary incontinence with marked physical exertion and medium means urinary incontinence with mild physical exertion or during quiet walking [27].

The exclusion criteria for all patients were as follows: mixed urinary incontinence, grade III–IV concomitant pelvic organ prolapse, malignant genitourinary neoplasms, neurological diseases affecting bladder and urethral functions, lower urinary tract anomalies, urinary tract obstruction, acute genitourinary tract infections, pregnancy, previous treatment of SUI within the last month, and refusal to participate in the study. In the group that received paraurethral

Table 1. Comparative analysis of general clinical and special examination data in groups I and II before therapy

Таблица 1. Сравнительный анализ результатов общеклинического и специальных методов обследования пациенток I и II групп до терапии

Indicators		Group I (n = 41)*	Group II (n = 41)*	Statistical confidence
Age, M ± SD (95% confidence interval), years		41.88 ± 7.20 (39.60–44.15)	44.83 ± 4.79 (43.32–46.34)	**p_1 = 0.032**
Age period	Reproductive, n (%)	34 (82.9)	29 (70.7)	p_2 = 0.295
	Perimenopausal, n (%)	7 (17.1)	12 (29.3)	
Duration of stress urinary incontinence, Me (Q_1–Q_3), months		24.00 (12–71)	48.00 (26–108)	p_3 = 0.052
Severity of stress urinary incontinence	Mild, n (%)	32 (78.0)	37 (90.2)	p_2 = 0.226
	Medium, n (%)	9 (22.0)	4 (9.8)	
Sporting activities, n (%)		2 (4.9)	3 (7.3)	p_2 = 1.000
Smoking, n (%)		2 (4.9)	1 (2.4)	p_2 = 1.000
Large fetal delivery, n (%)		5 (12.2)	8 (19.5)	p_2 = 0.547
Perineotomies and ruptures in labor, n (%)		29 (70.7)	30 (73.2)	p_4 = 0.806
High parity, n (%)		22 (53.7)	26 (63.4)	p_4 = 0.370
Premature ovarian failure, n (%)		1 (2.4)	6 (14.6)	p_2 = 0.109
Genitourinary menopausal syndrome, n (%)		4 (9.8)	8 (19.5)	p_2 = 0.349
Uterine myoma, n (%)		11 (26.8)	9 (22.0)	p_4 = 0.607
Endometriosis, n (%)		16 (39.0)	19 (46.3)	p_4 = 0.503
Polycystic ovarian syndrome, n (%)		0 (0.0)	1 (2.4)	p_2 = 1.000
History of endometrial hyperplasia, n (%)		4 (9.8)	1 (2.4)	p_2 = 0.359
Thyroid diseases, n (%)		9 (22.0)	9 (22.0)	p_2 = 1.000
Diabetes mellitus, n (%)		0 (0.0)	2 (4.9)	p_2 = 0.494
Chronic pyelonephritis, n (%)		2 (4.9)	1 (2.4)	p_2 = 1.000
Chronic cystitis, n (%)		3 (7.3)	2 (4.9)	p_2 = 1.000
Gastrointestinal tract diseases, n (%)		7 (17.1)	7 (17.1)	p_2 = 1.000
Increased body weight, n (%)		9 (22.0)	15 (36.6)	p_4 = 0.145
Hysterectomy, n (%)		2 (4.9)	2 (4.9)	p_2 = 1.000
Pelvic floor muscle strength on the Oxford scale, Me (Q_1–Q_3), points		1.00 (1.00–2.00)	0.00 (0.00–0.00)	**p_3 < 0.001**
Vaginal pressure recorded by the perineometer transducer, Me (Q_1–Q_3), mmHg		59.00 (58.00–62.00)	55.00 (55.00–55.00)	**p_3 < 0.001**
Number of episodes of stress urinary incontinence according to urinary diaries, Me (Q_1–Q_3)		4.00 (2.00–12.00)	7.00 (3.00–14.00)	p_3 = 0.212
Degree of discomfort on a visual analog scale, Me (Q_1–Q_3), %		30.00 (30.00–50.00)	52.00 (30.00–70.00)	**p_3 = 0.014**
Ultrasound				
Urethral length, Me (Q_1–Q_3), mm		28.80 (26.50–30.90)	29.55 (26.90–34.80)	p_3 = 0.064
Resting urethral angle α, M ± SD (95% confidence interval), degrees		31.57 ± 10.80 (29.97–35.17)	32.08 ± 9.37 (29.09–35.08)	p_5 = 0.825
Rotation of the urethral angle α, Me (Q_1–Q_3), degrees		27.70 (21.30–42.60)	27.00 (21.85–43.60)	p_3 = 0.959
Interlevator distance, Me (Q_1–Q_3), mm		10.10 (8.50–11.00)	10.00 (7.85–11.40)	p_3 = 0.834

Note: *Ultrasound data are presented for 37 and 40 patients of groups I and II; M ± SD, mean and standard deviation; Me, median; n, absolute number of patients; p_1, Welch's t-test; p_2, Fisher's exact test; p_3, Mann–Whitney U-test; p_4, Pearson's χ^2 test for goodness of fit; p_5, Student's t-test.

administration of UBAs, additional exclusion criteria were lactation, systemic autoimmune diseases, and blood diseases accompanied by hypocoagulation.

A total of 82 women, aged 43.35 ± 6.25 (26–55) years, were selected according to the pre-established criteria.

At stage II, the patients underwent a series of specialized examinations:

- Registration of urinary rhythm and urine volume excreted using urinary diaries for 7 days.
- Gynecologic examination with evaluation of functional tests (cough and Valsalva tests) with average bladder filling and PFM strength according to the Oxford scale.
- Perineometry (with the iEASE XFT device).
- 2D ultrasonography of the pelvic floor and urethrovesical segment with transvaginal transducer using GE Healthcare Voluson E6 and Voluson E10 devices to assess urethral length, resting α angle, Valsalva rotation, interlevator distance, and perineal height [28].
- Assessment of the symptom-related discomfort level using a visual analog scale (VAS) as a percentage (0–100).
- Microscopic examination of genitourinary tract secretions.
- Urinalysis.
- Coagulogram (in the group with paraurethral administration of UBAs).

The results of the examination, based on complaints and urinary diaries, indicated that 84.1% of patients exhibited mild SUI, whereas 15.9% exhibited moderate SUI severity. In addition, 76.8% of women were in the reproductive period, whereas 23.2% were in the perimenopausal period. PFM failure was diagnosed in 50 (61.0%) patients and in combination with grade I and II vaginal wall prolapse in 32 (39.0%). The Oxford scale was used to assess the strength of the PFMs. The results indicated that 35 (42.7%), 22 (26.8%), 20 (24.4%), and 5 (6.1%) women exhibited a strength of 0, 1, 2, and 3 points, respectively.

Following the examination, the patients were divided into two groups. Group I included women (n = 41) who demonstrated the ability to contract the PFMs (Oxford scale score of ⩾1) and expressed motivation to engage in regular training. Group II (n = 41) included women with more severe discomfort, who expressed interest in achieving a prompt treatment result.

The groups were comparable in terms of SUI severity, anatomical abnormalities of the urethrovesical segment, and other anamnestic, clinical, and laboratory data (Table 1). Despite age differences, the groups were comparable by age period (reproductive and perimenopausal).

In group 1, a course of PFMT using the Tulpan laser vaginal simulator following a training session was initiated in 41 women. The device contains a rod, where one end has a drop-shaped sphere and the other end is thickened with a hole for fixing the laser pointer and a hole for hanging a weight to increase the load. The drop-shaped sphere ensures that the trainer can hold it more securely within the vagina and move it freely during training (Fig. 1).

Fig. 1. Tyulpan laser vaginal simulator

Рис. 1. Лазерный вагинальный тренажер «Тюльпан»

When using a laser trainer, the beam from a sensor attached to the vaginal device is reflected on the wall. By its movement and changes in the amplitude of movement during contractions and relaxations of the PFMs, one can judge the effectiveness of the training (Fig. 2).

An advantage of the simulator is that it can differentiate between contractions of pelvic muscles and abdominal muscles. When the PFMs contract, the laser beam reflected on the wall falls below the starting point (with relaxed PFMs), and when the intra-abdominal pressure increases, it rises above the starting point.

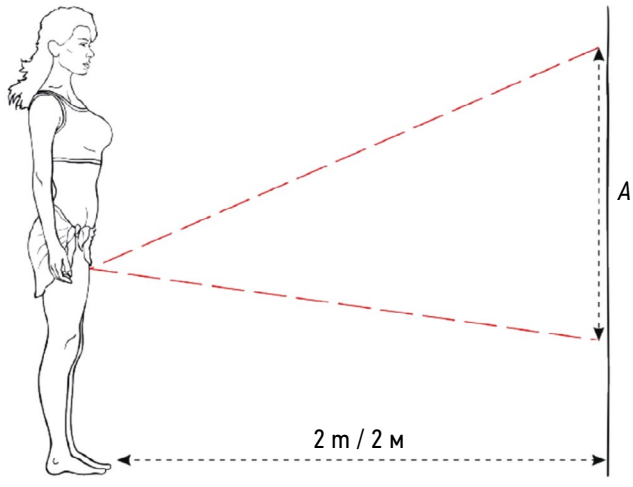

Fig. 2. Changing the position of the laser beam during pelvic floor muscle contraction and measuring the amplitude of the laser beam (*A*). Distance to the wall is 2 m

Рис. 2. Изменение положения лазерного луча во время сокращения мышц тазового дна и измерение амплитуды лазерного луча (*A*). Расстояние до стены — 2 м

A 30-min distance training session was conducted once a week for 12 weeks through videoconference with a group of three individuals under the supervision of a physician. From weeks 8–12 of the training course, the exercises were made more challenging by the weekly addition of weight to the simulator, increasing from 50 to 200–250 g. During the videoconference, the physician evaluated the amplitude of the laser beam and monitored the correct performance of all exercises. For this, the patients periodically showed their abdomen and the reflection of the laser beam on the wall. Between the distance training sessions, the participants were required to perform the tasks daily in accordance with the distance training plan. After the 3-month course, the patients were advised to continue independent training in a supportive capacity 2–3 times a week for 9 months [13].

The distance training course was completed by 33 women (80.5%), whereas 8 (19.5%) discontinued the course because they lacked time for regular exercise (12.2%) and planned treatment of concomitant gynecological diseases (7.3%). After 6 months, 2 (4.9%) patients discontinued PFMT in the maintenance mode.

Group II received paraurethral injections of biodegradable high-density hyaluronic biopolymer (based on hyaluronic acid with a molecular weight of 1.5–3.0 MDa) cross-linked with 1,4-butanediol diglycidyl ether. For the procedure, the woman was placed in a lithotomic position on a gynecologic chair. UBAs were administered under local anesthesia following urethral catheterization with a #14 Foley catheter. The drug was injected under visual control paraurethrally at four points (3, 6, 9, and 12 h after the conventional dial) in the middle urethral area. The injection volume was 1.0 mL at a time [24], with a total volume of 4.0 mL. After the procedure, the urethral catheter was removed, and the result of the cough test was evaluated. The woman then emptied her bladder independently. An ultrasound evaluation of the residual urine volume was conducted.

At stage III, the treatment results in both groups were compared after 1, 6, and 12 months. The examination algorithm is presented in Fig. 3.

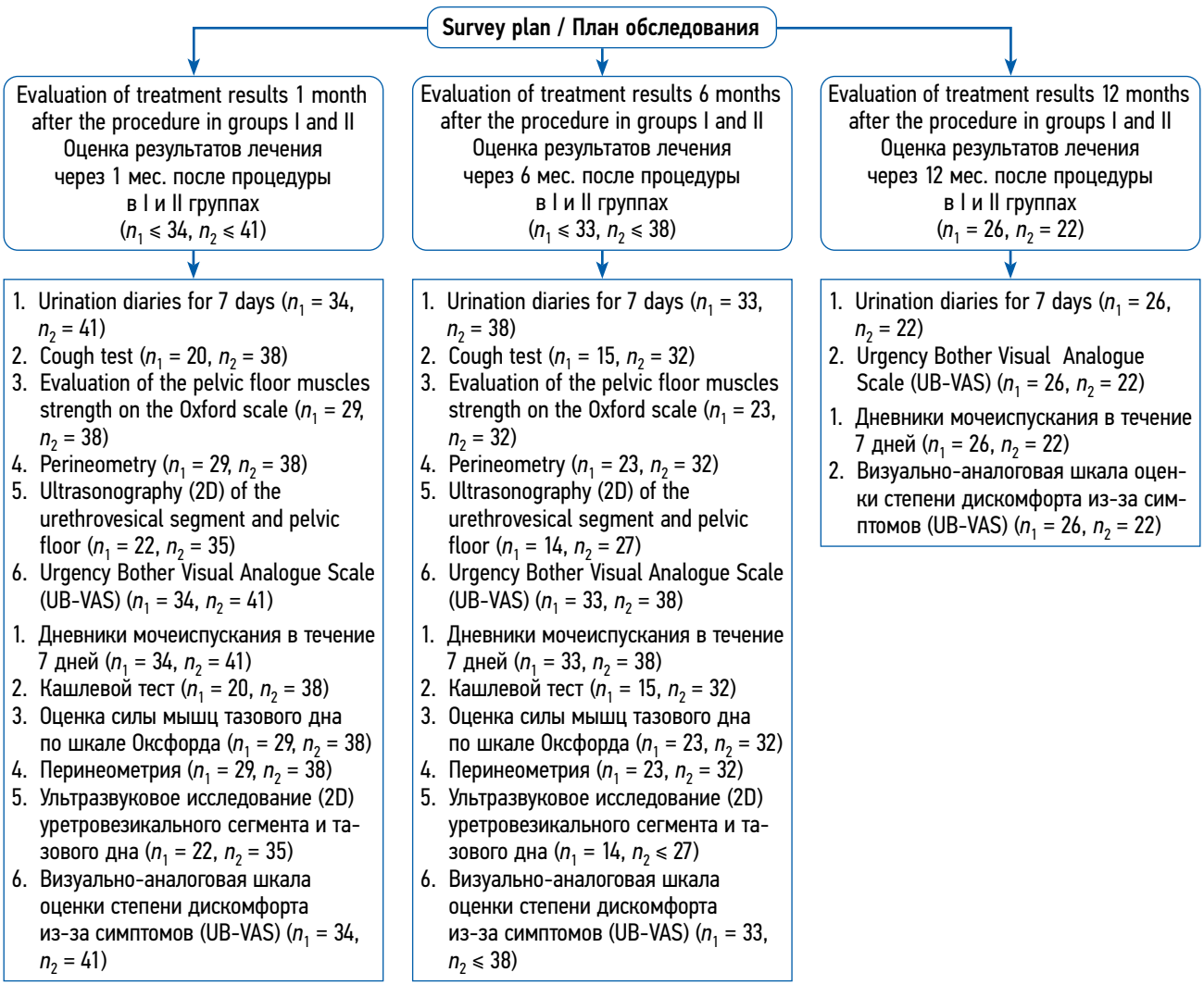

Fig. 3. Patient examination plan

Рис. 3. План обследования пациенток

Table 2. Comparative analysis of urination diary data in groups I and II for 12 months

Таблица 2. Сравнительный анализ данных дневников мочеиспускания в I и II группах в течение 12 месяцев

Indicators		Group I	Group II	Statistical significance (Mann–Whitney *U*-test)
Number of episodes of stress urinary incontinence	After 1 month (n_1 = 34, n_2 = 41)	2.00 (0.00–7.00)	0.00 (0.00–0.00)	**$p < 0.001$**
	After 6 months (n_1 = 33, n_2 = 38)	0.00 (00.00–0.00)	0.00 (0.00–2.00)	$p = 0.104$
	After 12 months (n_1 = 26, n_2 = 22)	0.00 (0.00–1.00)	2.50 (0.00–7.00)	**$p = 0.004$**

Note. Data are presented as median and lower and upper quartiles. n_1, number of patients in group I; n_2, number of patients in group II.

The efficacy of the methodologies was evaluated using a cough test and a urinary diary. The absence of urine leakage was deemed to be indicative of the efficacy of the cough test, whereas the absence of SUI episodes was indicative of the efficacy of the urinary diaries.

Data were processed using SPSS Statistics 27.0.0.0.0 and Microsoft Excel 2019. Quantitative data were evaluated for conformity to a normal distribution using the Shapiro–Wilk and Kolmogorov–Smirnov criteria. Normally distributed data were described using the arithmetic mean (M), standard deviations (SD), and 95% confidence interval (95% CI) limits. For nonnormally distributed data, the values were presented using the median (Me) and lower and upper quartiles (Q_1–Q_3). Categorical data were described in absolute values and percentages. The indicators were analyzed using Student's *t*-test, Welch's *t*-test, Mann–Whitney *U*-test, Wilcoxon's criterion, Pearson's χ^2, and Fisher's exact test. The significance level was set at $p < 0.05$.

RESULTS

The analysis of the effectiveness of SUI treatment according to urinary diary data in groups 1 and 12 months after the initiation of treatment revealed significant differences (Table 2).

At 1 month, 29.4% of patients in group I and 85.4% in group II were free of SUI, which was 2.9 times more ($p < 0.001$). The probability of the absence of urinary leakage 1 month after treatment was 14 times higher in group II than in group I (95% CI, 4.488–43.671). After 6 months, the treatment results were not significantly different ($p = 0.252$). At 12 months, the results were better in group I than in group II: 36.4% of women in group II reported the absence of urinary loss episodes compared with 73.1% in group I, showing a twofold increase ($p = 0.011$). The odds of having no episodes of SUI were 4.75 times higher in group I than in group II (odds ratio 0.211; 95% CI, 0.062–0.718) (Fig. 4).

Urinary diary data indicated that the immediate results (after 1 month) were superior in patients who received a paraurethral injection of hyaluronic biopolymer cross-linked with 1,4-butanediol diglycidyl ether, whereas the long-term results (after 12 months) were better in those who underwent remote PFMT in a biofeedback mode.

The results of the cough test exhibited a comparable trend. A negative cough test was observed in 65% of women in group I compared with 92.1% in group II, representing a 1.4-fold increase ($p = 0.023$). The probability of a negative test in group II was 6.28 times higher than that in group I (95% CI, 1.409–28.009). After 6 months, the results of SUI treatment according to the cough test were not significantly different, which was 80% in group I and 71.9% in group II ($p = 0.725$) (Fig. 5).

The remote training conducted in the biofeedback mode proved to be an effective method for strengthening the PFMs. Upon assessment of the PFM strength according to the Oxford scale in group I, 100% of the patients exhibited an increase in strength after 1 and 6 months ($p < 0.001$). In addition, perineometry revealed that 100% of the patients exhibited an increase in vaginal pressure ($p < 0.001$). Before treatment, 37.9% of women exhibited barely perceptible

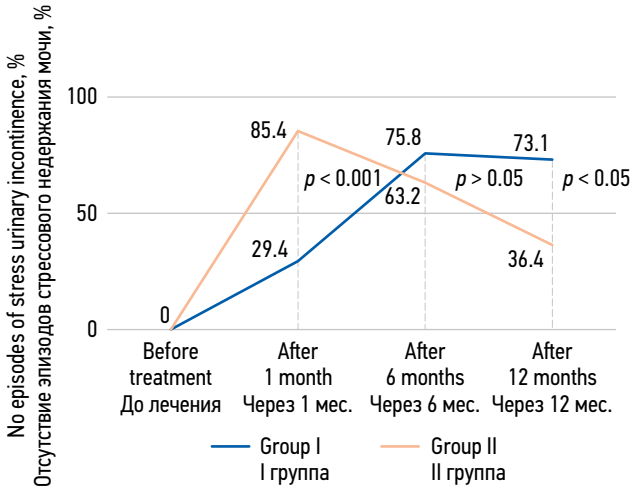

Fig. 4. Comparison of the effectiveness of treatment for stress urinary incontinence based on voiding diaries in groups I and II for 12 months

Рис. 4. Сравнение эффективности лечения стрессового недержания мочи по данным дневников мочеиспускания в I и II группах в течение 12 месяцев

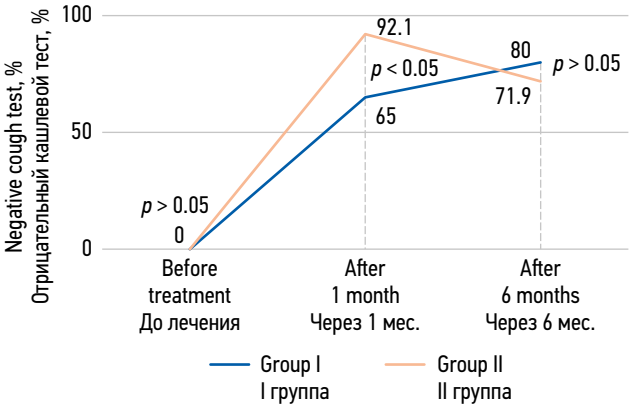

Fig. 5. Comparison of the effectiveness of treatment for stress urinary incontinence based on cough test results in groups I and II for 6 months

Рис. 5. Сравнение эффективности лечения стрессового недержания мочи по результатам кашлевого теста в I и II группах в течение 6 месяцев

contractions of the PFMs (1 point), 51.7% exhibited weak contractions (2 points), and 10.3% exhibited moderate contractions (3 points). After 1 month of PFMT, the number of patients exhibiting moderate contractions (3 points) increased to 82.8%. However, after 6 months, this number decreased to 39.1%. This decline can be attributed to the predominance of women with stronger pelvic muscle contractions (4 and 5 points; 52.2%). The injection of UBAs into the paraurethral region did not affect the strength of muscle contraction. Before treatment with UBAs, 85.4% of patients in group II were unable to contract the PFMs (0 points). No changes were observed during follow-up visits at 1 or 6 months ($p > 0.05$) (Table 3).

Remote PFMT in biofeedback mode and paraurethral injection of the substance equally reduced urethral mobility 1 month after treatment. Thus, according to ultrasound data of the urethrovesical segment and pelvic floor in group II after 1 month, a decrease in urethral angle α rotation was revealed, and in group I after 1 and 6 months there was a decrease in urethral angle α rotation and interlevator distance ($p < 0.05$). A comparative analysis of sonographic data of the pelvic floor and urethrovesical segment of both groups after 1 and 6 months revealed no significant differences ($p > 0.05$) (Table 4).

Both treatments demonstrated a positive effect on women's quality of life at all stages of follow-up. During the study,

Table 3. Comparative analysis of pelvic floor muscle strength assessment data in groups I and II for 12 months

Таблица 3. Сравнительный анализ оценки силы мышц тазового дна в I и II группах в течение 12 месяцев

Indicators		Group I	Group II	Statistical significance (Mann–Whitney *U*-test)
Pelvic floor muscle strength on the Oxford scale	After 1 month (n_1 = 29, n_2 = 38), points	3.00 (3.00–3.00)	0.00 (0.00–0.00)	**$p < 0.001$**
	After 6 months (n_1 = 23, n_2 = 32), points	4.00 (3.00–4.50)	0.00 (0.00–0.00)	**$p < 0.001$**
Vaginal pressure recorded by the perineometer transducer	After 1 month (n_1 = 29, n_2 = 38), mmHg	70.00 (66.00–72.00)	55.00 (55.00–55.00)	**$p < 0.001$**
	After 6 months (n_1 = 23, n_2 = 32), mmHg	80.00 (75.00–85.50)	55.00 (55.00–55.00)	**$p < 0.001$**

Note. Data are presented as median and lower and upper quartiles. n_1, number of patients in group I; n_2, number of patients in group II.

Table 4. Comparative analysis of ultrasound examination data in groups I and II for 12 months

Таблица 4. Сравнительный анализ данных ультразвукового исследования в I и II группах в течение 12 месяцев

Indicators		Group I	Group II	Statistical significance (Mann–Whitney *U*-test)
Rotation of the urethral angle α	After 1 month (n_1 = 22, n_2 = 35), degrees	17.60 (11.00–21.10)	19.00 (14.00–27.2)	$p = 0.238$
	After 6 months (n_1 = 14, n_2 = 27), degrees	18.05 (10.00–25.50)	25.00 (17.90–42.70)	$p = 0.058$
Interlevator distance	After 1 month (n_1 = 22, n_2 = 35), mm	8.90 (7.00–9.70)	9.50 (7.80–12.30)	$p = 0.156$
	After 6 months (n_1 = 14, n_2 = 27), mm	8.20 (7.70–9.30)	10.00 (8.15–12.55)	$p = 0.063$

Note. Data are presented as median and lower and upper quartiles. n_1, number of patients in group I; n_2, number of patients in group II.

the discomfort level due to symptoms of pelvic floor dysfunction as measured by the VAS scale declined significantly ($p < 0.001$). This reduction was more pronounced after 1 month in group II and after 12 months in group I ($p < 0.001$). After 1 month, the final VAS score was reduced by 52 points in group II compared with 17.5 points in group I, which was three times less ($p < 0.001$). After 12 months, significant decreases of 22 points in group II and 35 points in group I were recorded, which was 1.6 times greater ($p < 0.001$). In addition, the VAS score after 12 months in group II was 30 points higher than in group I, indicating a higher discomfort level (Fig. 6).

Consequently, a more rapid decline in discomfort level was observed in the paraurethral injection group, whereas the most favorable long-term outcomes were observed in the remote PFMT group with biofeedback.

Remote training with the Tulpan vaginal simulator did not result in any complications.

During the observation period, no hematoma formation, urgent urge to urinate, or inflammatory processes of the vulva, vagina, and lower urinary tract were observed when the patients were evaluated for complications of paraurethral injections. Four patients (9.8%) exhibited a subfebrile temperature (up to 37.6°C) during the first 24 h after the procedure. One woman (2.4%) experienced pain at the implant site for 24 h. The symptoms were alleviated after a single administration of nonsteroidal anti-inflammatory drugs. One patient (2.4%) experienced urinary retention 5 h after the administration of UBAs. The patient's urine was discharged via catheter, and no further complications were reported.

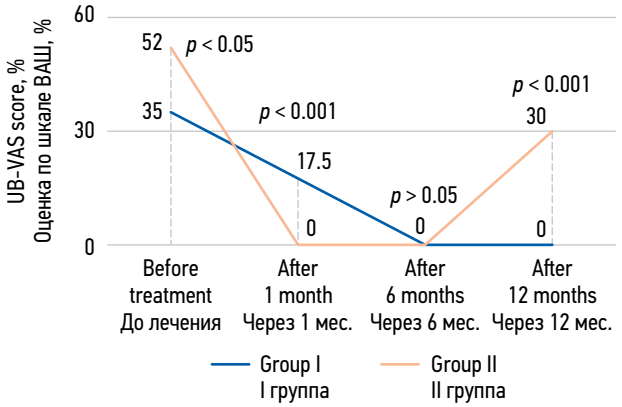

Fig. 6. Comparison of Urgency Bother Visual Analogue Scale (UB-VAS) scores in the treatment of pelvic floor dysfunction in patients in groups I and II for 12 months

Рис. 6. Сравнение оценки степени дискомфорта из-за симптомов по визуально-аналоговой шкале (ВАШ) при лечении дисфункции тазового дна у женщин в I и II группах в течение 12 месяцев

DISCUSSION

PFMT is the initial recommendation for women with SUI [11]. The efficacy of treatment is contingent upon the age of the patient, techniques employed, and type of simulator [29, 30]. Training in the mode of biofeedback is considered the most efficacious approach [12]. With the provision of visual, auditory, or verbal cues, biofeedback enables the assessment of muscle functionality and the maintenance of a high level of motivation throughout the treatment. PFMT in the biofeedback mode can be performed using portable and ambulatory devices [9]. Portable simulators allow performing exercises at home. The perineometer and vaginal cones (Kegel PFMT) are widely used. However, patients reported difficulty and irregularity in performing exercises at home. Approximately 40%–60% of women cannot perform the exercises correctly, and 22% of women try to squeeze their pelvic muscles during contractions, increasing the intra-abdominal pressure (reverse perineal reaction) [12, 31]. To avoid this, patients are advised to exercise under the supervision of specially trained medical personnel using ambulatory devices. With the supervision of medical personnel, women can quickly learn to consciously control the correctness of exercise and achieve better treatment results [13]. D. Chmielewska et al. reported that the effectiveness of SUI treatment by biofeedback therapy under the supervision of a physician in a medical facility for 2 months is 68.5% [32].

A novel approach to conservative therapy is PFMT with biofeedback, which is remotely controlled by a physician. According to E. Hui et al., this method is as effective as biofeedback therapy in outpatient settings [33].

This study of remote PFMT using the Tulpan laser simulator with biofeedback under the control of a physician demonstrated the high efficiency of treatment for mild SUI in women. In 1 month, 29.4% and 65% of women did not experience SUI episodes and had negative cough test, respectively. In the remote period, after 6 months of independent regular training, the treatment efficiency had increased, with 75.8% and 80% of women reporting the absence of SUI episodes and negative cough tests, respectively. After 12 months, 73.1% did not experience SUI episodes. Furthermore, during the 6-month follow-up period, all patients (100%) exhibited an increase in PFM strength.

PFMT is ineffective in the treatment of SUI in women who are not ready for regular exercise and cannot contract their pelvic muscles. In this study, 19.5% of patients interrupted training because they lacked time for exercise and planned treatment of gynecological diseases. Furthermore, 42.7% were unable to contract the pelvic muscles. These changes may be associated with muscle and nerve damage as a result of childbirth. These patients have been offered alternative treatments, including UBA injections. In a systematic review, V. Hoe et al. found that the efficacy of UBAs at a follow-up of <2 years ranged from 30% to 80% [34]. The efficacy of this therapy may vary

depending on the composition of the filler used, method of assessment, severity of urinary incontinence, and age of the woman [14, 18, 34].

Currently, high-molecular hyaluronic acid cross-linked with adjuvants is actively used for the treatment of SUI. It participates in tissue regeneration and repair [22]. Intraurethral injections of high-molecular hyaluronic acid cross-linked with dextranomer have shown high efficiency. According to I.A. Apolikhina, 90.3% of patients showed clinical improvement after 6 weeks of observation when the filler was used; after 12 months, the effectiveness decreased by 40% [35]. The use of high-molecular hyaluronic acid cross-linked with dextranomer has been associated with urethral pseudocysts and urethral obstruction, necessitating surgical correction [36]. Consequently, some countries have ceased the use of this substance.

In this study, the use of paraurethral injections of hyaluronic biopolymer cross-linked with 1,4-butanediol diglycidyl ether is an effective treatment for mild SUI in women of reproductive and perimenopausal age. The effectiveness of injections was maximum 1 month after the procedure, while data from urination diaries and cough test results showed that it was 85.4% and 92.1%, respectively, in the long-term period after 6 months it was 63.2% and 71.9 % respectively. After 12 months, no SUI episodes were recorded in 36.4% of the patients. No serious complications were noted during the paraurethral injection of UBAs. Desirable side effects were observed, which did not necessitate surgical correction and were resolved within a day after the procedure.

The comparison of the two therapeutic approaches revealed that paraurethral injections of UBAs were more efficacious in the treatment of mild and moderate SUI in the immediate period, 1 month after the procedure. However, regular PFMT in the biofeedback mode for 12 months increased the positive effect and demonstrated greater efficiency of the treatment in the remote period. In contrast to UBA injections, remote training also contributed to the strengthening of PFMs during the 6-month follow-up period. The advantages of remote PFMT in the biofeedback mode include the absence of complications and the development of the skill of conscious control of PFM contractions before and during the increase in intra-abdominal pressure.

Both techniques reduced the discomfort level associated with symptoms of pelvic floor dysfunction. However, in the long term, women who underwent remote PFMT with biofeedback under medical supervision were more satisfied with the treatment outcomes.

CONCLUSIONS

Injections of high-density hyaluronic biopolymer yielded rapid and pronounced positive outcomes in the treatment of SUI and improved the quality of life in the immediate period. This treatment is recommended for patients interested in rapid results and who are aware of the limited duration of the effect. Regular biofeedback training of the PFMs under the remote supervision of a doctor contributes to better long-term results. This method is recommended for women who can contract their PFMs and are ready for regular exercise.

ADDITIONAL INFORMATION

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Competing interests. The authors declare that they have no competing interests.

Author contribution. All authors made a substantial contribution to the conception of the study, acquisition, analysis, interpretation of data for the work, drafting and revising the article, final approval of the version to be published and agree to be accountable for all aspects of the study.

Personal contribution of each author: *E.I. Rusina* — study concept and design, collection and processing of material, text writing, editing; *M.M. Zhevlakova* — study concept and design, collection and processing of material, statistical data processing, text writing; *E.V. Shelaeva* — collection and processing of material, text writing, editing; *M.I. Yarmolinskaya* — text writing, editing.

Ethics approval. The present study protocol was approved by the local Ethics Committee of the Research Institute of Obstetrics, Gynecology and Reproductology named after D.O. Ott (No. 104 dated 23.10.2020).

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Конфликт интересов. Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, связанных с публикацией настоящей статьи.

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