LITERATURE REVIEWS

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NEW OPPORTUNITIES IN THE DIAGNOSIS AND TREATMENT OF OVERACTIVE BLADDER AND URGENT URINARY INCONTINENCE ACCORDING TO THE UPDATED CLINICAL GUIDELINES ON URINARY INCONTINENCE (2024)

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The main changes and additions to the clinical guidelines "Urinary Incontinence" (2024) are presented in the review. Certain changes to the guidelines "Urinary Incontinence" developed by the Russian Society of Urologists (RSU) and approved by the Ministry of Health of the Russia became possible thanks to the work of the expert Councils, which include the national leading specialists dealing with the problem of urination disorders. The inclusion of the Russian drug in the clinical guidelines will allow regulating the prescription of bladder polypeptides (Vesusten) in the routine clinical practice of a urologist and will help a wider range of patients receive pathogenetic therapy for OAB/urgent urinary incontinence.

K e y w o r d s: *clinical guidelines, urinary incontinence, overactive bladder, polypeptide drug, Vesusten*

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The aim of clinical guidelines (CG) is to provide informational support for physician decision-making, contributing to improved quality of medical care for patients with various diseases/conditions, taking into account the latest clinical data and principles of evidence-based medicine. The clinical guidelines are revised at least once every three years and not more than once every six months [1].

The updated CG "Urinary Incontinence" in 2024 was developed by All-Russian Public Organization "Russian Society of Urologists", Russian Society of Obstetricians and Gynecologists, and All-Russian Public Organization "Russian Association of Gerontologists and Geriatricians", with simultaneous expansion of the panel, which in addition to urologists (Gazimiev M.A., Gadzhieva Z.K., Kasyan G.R., Krivoborodov G.G.) now includes the Chief External Specialist in Obstetrics and Gynecology of the Ministry of Health of Russia (Adamyan L.V., Ph.D., MD, Academician of the Russian Academy of Sciences) and the Chief External Specialist in Geriatrics of the Ministry of Health of Russia (Tkacheva O.N., Ph.D., MD, Professor, Director of the Pirogov Russian National Research Medical University of the Ministry of Health of Russia - Separate Structural Unit Russian Gerontological Research and Clinical Center, President of the Russian Association of Gerontologists and Geriatricians) [2].

The target audience has been expanded to include specialists with higher medical education in "Gerontology."

The documents related to the Guidelines in the updated version of the "Urinary Incontinence" include only:

- Clinical guguidelines of the Russian Society of Urologists.
- Order of the Ministry of Health of the Russian Federation dated November 12, 2012, No. 907n "On approval of the Procedure for providing medical care to the adult population in the profile of 'urology'."
- Order of the Ministry of Labor and Social Protection of the Russian Federation dated March 14, 2018, No. 137n "On approval of the professional standard 'urologist'" (with amendments and additions).

Various changes or additions to the clinical guidelines "Urinary Incontinence," created by the Russian Society of Urologists (RSU) and approved by the Ministry of Health of the Russian Federation, became possible due to the work of expert councils, which include leading specialists in the country dealing with urination disorders.

One such meeting, the Expert Council on Neurourology and Urodynamics organized by the Neurourology Section of the RSU, took place on October 7-8, 2022. Following the council, a resolution was created and published [3], according to which it was recommended:

- Inclusion in the Guidelines "Urinary Incontinence," "Neurogenic Dysfunctions of the Lower Urinary Tract," and "Benign Prostatic Hyperplasia" of mandatory assessment of the risk of cognitive impairments and other adverse events associated with anticholinergic burden before prescribing M-anticholinergics

(comments may include a recommendation to use the Anticholinergic Cognitive Burden Scale (ACB) calculator, specified in the methodological guidelines of the Ministry of Health of Russia "Pharmacotherapy in elderly and senile people," or the MoCA scale).

- In the relevant Guidelines, recommend that in the presence of risk factors associated with anticholinergic burden (elderly or comorbid patients, those with confirmed cognitive impairments or taking drugs with anticholinergic activity), therapy should be initiated with beta3-adrenomimetics in patients with non-neurogenic urinary disorders [2].

This was subsequently reflected in the updated clinical guidelines in 2024:

– *It is recommended that in the presence of risk factors for cognitive disorders associated with anticholinergic burden (elderly or comorbid patients, those with confirmed cognitive impairments or taking drugs with anticholinergic activity), therapy should be initiated with beta3-adrenomimetics in patients with non-neurogenic urinary disorders (strength of a recommendation A, level of evidence 2) [2, 4-9]. Comments: The choice of treatment for patients with overactive bladder (OAB) in terms of cognitive safety is determined by the age of patients, their cognitive abilities, and the anticholinergic burden of current and planned therapy [8-10].*

Taking the above-mentioned data into account, the appendix to the guidelines "Urinary Incontinence" has been supplemented with the cognitive function assessment questionnaire (Mini-Cog). This methodology allows for a quick assessment of definite cognitive impairments. It may not be sufficiently sensitive to non-dementia cognitive disorders.

Considering the composition of the panel and the target audience of specialists, along with understanding the possible pathogenesis of urinary incontinence, the guidelines has been supplemented with the following recommendations:

– *It is recommended that elderly patients suffering from urinary incontinence and cognitive impairments have a consultation with a geriatrician [11, 12] (strength of a recommendation C, level of evidence 5).*

Comments: Determination of the cognitive status of an elderly patient using the Mini-Cog questionnaire (appendix) is mandatory.

– *It is recommended that women suffering from urinary incontinence and concomitant gynecological disorders have a consultation with a gynecologist [11, 12] (strength of a recommendation C, level of evidence 5).*

The updated guidelines of the Ministry of Health of the Russian Federation "Urinary Incontinence" 2024 has eliminated provisions not specified in the instructions for beta3-adrenomimetics (mirabegron), specifically removing the phrase about its cautious prescription to patients with cardiovascular diseases.

It should be noted that the most important addition to the guidelines "Urinary Incontinence" in 2024 was the expansion of the list of drugs for treating urgent urinary incontinence (and consequently OAB) with a new drug: *"It is recommended for reducing the severity of urgent urinary incontinence (reducing the number of episodes of urinary incontinence, frequency, and urgency of urination) to use bovine urinary bladder polypeptide medications that have a pathogenetic effect and regulatory influence on detrusor contractile activity (G04BD Drugs for urinary frequency and incontinence), intramuscularly at a dose of 5 mg, once daily, three times a week. The course of treatment is 10 injections. The need for repeated courses is determined by the attending physician. Bovine urinary bladder polypeptides can be used as initial therapy, as well as in the presence of limitations to treatment with other drugs for improving frequent urination and urinary incontinence or in case of their insufficient efficiency (strength of a recommendation A (level of evidence 2))*.

Comments: The efficiency of therapy with bovine urinary bladder polypeptide medications should be evaluated three weeks after the completion of the therapy course [5].

The algorithm of physician actions presented at the end of the guidelines has also been supplemented with this new polypeptide preparation.

The inclusion of this preparation in the guidelines became possible due to the outcomes of the Expert Council "Prospects for Pathogenetic Therapy of Overactive Bladder/Urinary Incontinence in Modern Realities. The First Year of Using Vezusten," held on October 15, 2023 [13]. The Expert Council members concluded that Vezusten, in combination with other standard therapies for OAB, including treatment of frequent urination and urinary incontinence, has the potential to be in demand on the Russian market and may offer distinct benefits to both clinicians and patients:

- Substantial symptom control in OAB, with efficacy comparable to standard symptomatic treatments
- High safety profile
- Ease of use

The recommendations of the Expert Council members were:

- To reduce the severity of urge urinary incontinence through pathogenetic therapy involving a course of intramuscular injections of regulatory peptides targeting the urinary bladder (Vezusten)
- To use the Vezusten within the registered instructions as initial therapy for OAB, as well as in combination with symptomatic medications
- Justified use of Vezusten in the presence of limitations to therapy with M-anticholinergics and beta3-adrenoreceptor agonists or in case of their insufficient efficiency
- Assessment of the efficacy of therapy with urinary bladder regulatory peptides is recommended three weeks post-treatment
- Importance of continuing scientific research initiatives to study the features of Vezusten usage in various patient groups, consolidation of scientific and practical data, and further publications

The members of Expert Council unanimously voted for the inclusion of the Russian medication based on urinary bladder polypeptides (Vezusten) in the current versions of the guidelines, noting the importance of determining the correct patient profile [13].

The inclusion of Vezusten® became possible based on the assessment and analysis of experimental and clinical research results.

The organ specificity of the peptide preparation Vezusten® was studied by culturing fragments of various tissues in the presence of this drug. A significant increase in the growth zone of explants of the urinary bladder wall of young and old rats (a total of 890 explants) was demonstrated, proving the organ-specific action of the preparation on urinary bladder tissues. Adding

similar concentrations of preparations based on extracts from cartilage, blood vessels, testes, ovaries, liver, brain, kidneys, and other tissues to the organotypic culture of the urinary bladder wall did not cause a significant change in the growth zone of urinary bladder explants [14].

The regulatory influence of regulatory peptides on the contractile activity of the detrusor in a model of normal and hypertrophied (under obstruction) urinary bladder has been proven [15]. To form OAB in animals (rats), a model of urinary bladder hypertrophy was used. The urethra was ligated for six weeks, leaving a thin catheter. Starting from the fourth week after ligation, a course of therapy with Vezusten was carried out with one intramuscular injection once a day for 10 days, followed by a waiting period (10 days after the end of the course). When obstruction developed, the mass increased almost six times and the volume of the urinary bladder almost seven times, with the residual urine volume constituting 64.6% of the urinary bladder volume. According to the study, Vezusten normalized the indicators of functional activity of the urinary bladder (mass, volume of the urinary bladder, and their ratio). In the Vezusten group, compared to the control group (no treatment), the mass and volume of the urinary bladder were 3.3 to 4.5 times lower, and the postvoid residual urine volume was six times lower, not exceeding 11% of bladder volume (vs. 0% in healthy animals and 64.6% in the control group). The postvoid residual in this model correlated with the severity of detrusor dysfunction; an increase in residual urine volume indicated impaired evacuatory function of the urinary bladder.

The effect of Vezusten on the contractile ability of detrusor cells in vitro was also confirmed. The study was carried out on isolated urinary bladder muscle (detrusor) with measurement of its contraction degree (on normal and hypertrophied urinary bladder). An increase of 82.1% to 167.3% in contractile activity was observed in the muscle tissue of the normal bladder specimen (at different dosages). In specimens of the hypertrophied urinary bladder, the initially elevated contractile activity of detrusor myocytes was reduced by 12.7%, 33.4%, and 43.8% under the influence of Vezusten at concentrations of 8, 16, and 32 μg/ml, respectively. In further experiments, the concentration of 32 μg/ml was accepted as a therapeutically effective dose, which corresponds to 5 mg for human dosage. The greatest effect of the preparation was obtained at a dosage of 32 μg/ml, equivalent to a human dose of 5 mg [15]. It should be noted that at the preclinical stage of Vezusten research, Vezusten reduced the increased contractile activity of the detrusor but did not have a similar effect with its normal contractile ability. This is a distinctive feature of regulatory peptides compared to drugs of other groups.

Clinical studies on the efficiency and safety of Vezusten were carried out with the participation of 290 people, of whom 32 were healthy volunteers and 258 were patients with OAB, in phase I, II, and III studies, which were carried out in accordance with GCP standards. Based on the findings of a phase III placebo-controlled trial, which included 150 patients aged 18 to 70 years with a diagnosis of OAB lasting at least three months (randomization of patients into two groups of 75 people each), Vezusten® reduced symptoms on the Total Urgency and Frequency Score (TUFS) scale: a pronounced decrease in symptoms on the TUFS scale (more than 20%) was noted in 66.7% of patients on Vezusten, and in only 38.73% in the placebo group. Compared to the baseline, patients in the main group showed a significant decrease in the severity of urgency, assessed by the TUFS value, compared to the placebo group. The average reduction in the total score in the Vezusten® group exceeded that in the placebo group by 1.97 times (the average reduction in the total score in the Vezusten® group was 10.02±9.19 points, while in the placebo group it was 5.09±6.43 points), with the differences between the groups being statistically significant (p=0.0007). In 65.3% of patients, there was a decrease in the daily number of episodes of urinary incontinence by 50% or more compared to baseline. The average reduction in the number of urinary incontinence episodes exceeded the indicators of the placebo group by 2.15 times. According to the study, 89.3% of patients showed a decrease in the daily number of urinary incontinence episodes by 20% or more compared to baseline.

An interesting and important feature of Vezusten, which can be considered an advantage, is that its therapeutic effect persists for a long time after the end of the treatment, i.e., after the regulatory peptides enter the body. This suggests a prolonged therapeutic effect. It should be noted that according to research data on medications based on regulatory peptides, there is no risk of overdose, since after reaching a certain concentration of regulatory peptides, their pharmacological action ceases to intensify [16].

A favorable safety profile of the preparation, comparable to placebo, has been demonstrated [5, 17, 18]. There were no adverse events (AEs) that resulted in discontinuation of study participation. The most common AEs were clinically insignificant deviations in laboratory parameters, the connection of which with the use of the preparations was doubtful or absent. During the phase III trial, 12 AEs were registered at the injection site; all AEs were mild (pain at the injection site), did not require additional actions from the personnel and were self-resolving. When assessing the number of patients who had registered AEs, no significant differences were found between the preparation and placebo groups (p=0.253).

Quite interesting data are presented in a prospective single-center comparative placebo-controlled clinical study in parallel groups with sequential change of medication (carried out from 2022 to the present, with Professor Igor Ivanovich Belousov, MD, Associate Professor, Professor of the Department of Urology at Rostov State Medical University, Rostov-on-Don, as the principal investigator). The study includes 41 patients (men and women) aged 18 to 50 years with multiple sclerosis (MS) and lower urinary tract symptoms (LUTS) with urodynamically confirmed detrusor overactivity. The evaluation of treatment efficiency (using the M-anticholinergic solifenacin and the peptide preparation Vezusten) was conducted after four months (five stages), based on data from the EDSS (Expanded Disability Status Scale), NBSS (Neurogenic Bladder Symptom Score), I-QOL (Incontinence Quality of Life Questionnaire), SF-Qualiveen (Short Form-Incontinence Quality of Life Questionnaire) scales, and urination diaries. The study and its clinical protocol were approved by the local scientific ethics committee at Rostov State Medical University, protocols No. 13/22 (09/08/2022) and No. 3/23 (09/02/2023) [19].

According to the study assessing changes in urinary incontinence, nocturia, and urgency during treatment and follow-up, with solifenacin, 56.4% of the subjects no longer met the criteria for OAB, with a return of signs noted in 97.4% of patients one month after discontinuation of therapy. Resolving of urinary incontinence was noted by 33.3% of patients, with a return to baseline level in 100% of patients one month after discontinuation. Nocturia was eliminated in 54.2% of patients, with an increase in the frequency of the sign by 4.2% after discontinuation of therapy.

At the same time, after treatment with Vezusten, 74.4% of the subjects no longer met the criteria for OAB, with a recurrence of symptoms in 33.4% one month after completion of therapy. Regression of urinary incontinence was revealed in 55.6%, with preservation of the effect one month after the end of the course in 44.4% of the total number of patients. Disappearance of nocturia was observed in 95.8% of patients, with the effect persisting one month after the end of the therapy course in 75% of them. The frequency of detection and number of side effects of the studied preparations corresponded to those indicated in the instructions. However, according to the authors of the study, Vezusten proved to be the safer preparation. Also, speaking about the guidelines "Urinary Incontinence," it should be noted that in the updated version, the level of evidence regarding the lack of necessity for routine urodynamic study has changed [2]:

- *Routine performance of urodynamic study, including measurement of urine flow rate (uroflowmetry), filling cystometry, and voiding cystometry, is not recommended for all patients during conservative treatment of urinary incontinence (strength of a recommendation B (level of evidence 3)) [20].*

In the previous version, the level of evidence was 2, which means that "neglecting" the performance of urodynamic study may be an error in making the correct diagnosis and choosing the appropriate treatment for this category of patients, as urodynamic study is the only method that allows determining and characterizing the function of the lower urinary tract in neurogenic patients with urinary incontinence, with separate assessment of detrusor contractility and external urethral sphincter activity, as well as synchronicity of functioning during urination [2].

It is worth reminding that according to the guidelines:

– *It is recommended to perform urodynamic study to assess the degree of lower urinary tract dysfunction in the following cases [21-24] (strength of a recommendation A (level of evidence 1)):*
- *when the results may change the treatment, for example, the choice of a more invasive method of treating urinary incontinence and pelvic organ prolapse;*
- *as part of an initial and long-term follow-up program for some types of neurogenic dysfunction of the lower urinary tract;*
- *in patients with recurrences of urinary incontinence after surgical anti-incontinence procedures;*
- *in the case of complicated urinary incontinence;*
- *in the case of urinary incontinence in men.*

Additionally, it should be noted that all the definitions of diagnostic and therapeutic aids listed in the updated version of the guidelines are presented in accordance with the nomenclature of medical services (according to the order of the Ministry of Health of the Russian Federation No. 804n dated October 13, 2017 (as amended on September 24, 2020)) [25].

From 2025, guidelines have become the basis for the organization and provision of medical care in the Russian Federation [26]. The Ministry of Health of the Russian Federation reminds us that we should adhere to the guidelines in the process of making clinical decisions to provide the patient with the most effective and safe medical care. At the same time, guidelines cannot replace the professional and clinical thinking of medical workers: the physician must assess the potential benefits and risks for the patient of applying interventions specified in the clinical guidelines, taking into account the individual characteristics of the patient [27].

The inclusion of the Russian medication in the clinical guidelines will regulate the prescription of urinary bladder polypeptides (Vezusten) in the routine clinical practice of urologists and will help a wider range of patients receive pathogenetic therapy for OAB/urgent urinary incontinence [13].

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