DOI: https://doi.org/10.17816/uroved56773

Evaluation of the effectiveness of personalized complex therapy in patients with benign prostatic hyperplasia and chronic prostatitis

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PURPOSE OF THE STUDY: to evaluate the effectiveness of personalized complex treatment of patients with benign prostatic hyperplasia (BPH) in combination with chronic prostatitis using a combined physiotherapeutic effect, taking into account the individual chronobiological characteristics of patients.

MATERIALS AND METHODS: We examined 60 patients with benign prostatic hyperplasia and chronic prostatitis who were sent to the TUR of the prostate. Patients were divided into two groups (n = 30). The comparison group (CG) was treated with alpha-blockers and fluoroquinolones for 28 days. In the main group (MG) – personalized complex therapy. The effectiveness of treatment was evaluated at the time of treatment (visit 1), two weeks later (visit 2) and 4 weeks later (visit 3). The severity of lower urinary tract symptoms, prostate volume and residual urine volume, hemodynamic parameters in the gland were evaluated, and a bacterioscopic and bacteriological examination of prostate secretion was performed.

RESULTS: At the end of 4 weeks of therapy, statistically significant differences ($p < 0.05$) were found in the MG for all the studied parameters. In the bacteriological study of prostate secretions at visit 1 *Escherichia coli* prevailed in the crops. At visit 2 in the CG bacteria were detected in 11 (36.7%) crops, and in 10 (33.3%) patients in the MG. At visit 3, no microbial growth was detected in both groups based on the results of a bacteriological examination of prostate secretions. Initially, both groups had low hemodynamic parameters in the prostate. After the treatment, a more pronounced dynamics of improvement of blood flow in the gland by visit 2 was noted in the MG than in the GP. By visit 3, statistically significant differences were found in all the studied indicators ($p < 0.05$).

CONCLUSION: Thus, according to the results, a personalized comprehensive treatment of patients with benign prostatic hyperplasia and chronic prostatitis reduced the severity of lower urinary tract symptoms and manifestations of the inflammatory process in the prostate, improved hemodynamic parameters and increase of efficiency of antibacterial therapy, as evidenced by the results of bacteriological studies.

Keywords: chronic bacterial prostatitis; benign prostatic hyperplasia; BPH; TUR of the prostate; chronotherapy; physiotherapy with the Smart-Prost device; transrectal ultrasonography; Doppler.

To cite this article:
Barannikov II, Kuzmenko AV, Gyaurgiev TA, Kuzmenko VV. Evaluation of the effectiveness of personalized complex therapy in patients with benign prostatic hyperplasia and chronic prostatitis. *Urology reports (St. Petersburg)*. 2021;11(1):39-47. DOI: https://doi.org/10.17816/uroved56773

Received: 24.12.2020 **Accepted:** 28.02.2021 **Published:** 23.03.2021

DOI: https://doi.org/10.17816/uroved56773

Оценка эффективности персонализированной комплексной терапии пациентов с доброкачественной гиперплазией простаты и хроническим простатитом

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Цель исследования: оценить эффективность персонализированного комплексного лечения пациентов с доброкачественной гиперплазией предстательной железы (ДГПЖ) в сочетании с хроническим простатитом (ХП) с использованием комбинированного физиотерапевтического воздействия с учетом индивидуальных хронобиологических особенностей больных

Материалы и методы. Обследовано 60 пациентов с ДГПЖ и ХП, направленных на трансуретральную резекцию (ТУР) простаты. Пациенты распределены в две группы ($n = 30$). В группе сравнения проводили терапию альфа-блокаторами и фторхинолонами в течение 28 дней. В основной группе — персонализированная комплексная терапия. Оценку эффективности лечения проводили при обращении (визит 1), через 2 нед. (визит 2) и через 4 нед. (визит 3). Оценивали выраженность симптомов нижних мочевых путей, объем простаты и объем остаточной мочи, показатели гемодинамики в железе, а также проводили бактериоскопическое и бактериологическое исследование секрета простаты.

Результаты. У пациентов основной группы к концу 4-й недели терапии были выявлены статистически значимые различия ($p < 0,05$) по всем исследуемым показателям. При бактериологическом исследовании секрета предстательной железы на визите 1 в посевах преобладала *Escherichia coli*. На визите 2 у пациентов в группе сравнения бактерии были обнаружены в 11 посевах (36,7 %), в основной группе — у 10 пациентов (33,3 %). На визите 3 по результатам бактериологического исследования секрета простаты в обеих группах не было выявлено роста микроорганизмов. Исходно в обеих группах были низкие показатели гемодинамки в простате. После проведенного лечения более выраженная динамика улучшения кровотока в железе к визиту 2 была отмечена у пациентов основной группы по сравнению с группой сравнения. К визиту 3 были выявлены статистически значимые различия во всех исследуемых показателях ($p < 0,05$).

Заключение. Персонализированная комплексная терапия пациентов с доброкачественной гиперплазией предстательной железы и хроническим простатитом позволила уменьшить выраженность симптомов нижних мочевых путей и проявления воспалительного процесса в простате, способствовала улучшению показателей гемодинамики, а также повышению эффективности антибактериальной терапии, о чем свидетельствуют результаты бактериологических исследований.

Ключевые слова: хронический бактериальный простатит; доброкачественная гиперплазия предстательной железы; ДГПЖ; трансуретральная резекция простаты; ТУР; хронотерапия; физиотерапия аппаратом «Смарт-Прост»; трансректальное ультразвуковое исследование; ТРУЗИ; доплерография.

Как цитировать:
Баранников И.И., Кузьменко А.В., Гяургиев Т.А., Кузьменко В.В. Оценка эффективности персонализированной комплексной терапии пациентов с доброкачественной гиперплазией простаты и хроническим простатитом // Урологические ведомости. 2021. Т. 11. № 1. С. 39–47. DOI: https://doi.org/10.17816/uroved56773

Рукопись получена: 24.12.2020 **Рукопись одобрена:** 28.02.2021 **Опубликована:** 23.03.2021

INTRODUCTION

Benign prostatic hyperplasia (BPH) remains one of the most significant and common diseases in men [1–3]. Despite significant progress in its treatment, which is associated with the emergence of effective drugs with a high safety profile, conservative therapy is successful not in all patients. More than 30% of men aged <80 years undergo surgery for BPH [4–8].

One of the reasons for the failure of conservative therapy is the presence of concomitant pathology, the most common of which is chronic prostatitis (CP). This disease is often recurrent and usually difficult to treat. According to the National Institutes of Health, more than 25% of men with urinary system diseases have symptoms of prostatitis, which accounts for approximately 9% of the total male population [9, 10]. Morphological studies have revealed signs of chronic inflammation of varying severities in the prostate tissue in 96.7% of patients with BPH [11]. BPH is detected in 57.2% of patients with CP, and 38.7% of patients with BPH have CP signs [12, 13].

The significance of BPH and CP is determined not only by their prevalence but also by a significant decrease in the quality of life of this category of patients. In addition, the high incidence of complications such as acute urinary retention, damage to the upper urinary tract, and erectile dysfunction should be taken into account [14, 15].

Currently, transurethral resection (TUR) of the prostate is the gold standard of surgical treatment for BPH [1–3]. This method has the largest evidence base regarding the efficiency in restoring the outflow of urine from the bladder due to prostatic infravesical obstruction [16]. However, despite its advantages, TUR has a rather high frequency of complications, including bleeding (2.9%), bladder tamponade (4.9%), infectious and inflammatory diseases (4.1%), urethral stricture (5%–7%), and bladder neck sclerosis (2%–4%), which are life threatening [17–20].

Given the inadequate efficiency of the known methods of treatment for CP and BPH, alternative therapeutic methods with a proven pathophysiological mechanism of action are used in medicine, including urology, with increasing frequency [21–25]. At present, various physiotherapeutic procedures in combination with other drugs have been used, such as magnetotherapy, electrophoresis, and laser therapy [22, 23].

All processes in animals, and hence in the human body, are known to be subject to certain rhythms [24]. In different phases of the rhythm, physiological processes in the body are at different levels. Personalization of the treatment of patients, taking into account the individual characteristics of their biorhythms (chronotherapy), has become the subject of study in many fields of medicine, including urology, and is widely used in the treatment of several diseases [25]. Chronotherapy is characterized as graphical determination of the time of the maximum chronobiological activity (acrophase) of each patient and performing medical procedures at this particular time [23–25].

This study aimed to evaluate the efficiency of personalized complex treatment of patients with prostate adenoma combined with CP, using a combined physiotherapeutic effect of the Smart-Prost apparatus, taking into account the individual chronobiological characteristics of patients based on the results of clinical laboratory and ultrasound research methods.

MATERIALS AND METHODS

Sixty patients with BPH referred for TUR, who were diagnosed with category II chronic prostatitis (bacterial) according to the classification of the US National Institutes of Health (NIH) (1995), were examined. The average patient age was 60.5 ± 5.5 years. The duration of CP and BPH was 7.5 ± 2.3 years.

The inclusion criteria were a total International Prostate Symptom Score (IPSS) score of >20 points, residual urine volume (V_{ru}) no more than 100 ml, maximum urinary flow rate (Q_{max}) of 14 ml/s or less, prostate gland volume (V_p) no more than 80 cm^3, prostate-specific antigen level of no more than 2.0 ng/ml, absence of sexually transmitted diseases, bacterial nature of inflammation in the prostate gland (microbial count >10^4 colony-forming unit/ml in the prostate secretion), and duration of CP and BPH of 5–10 years.

The exclusion criteria were the presence of bladder and ureteral stones, hematuria, suspected prostate or bladder cancer, allergic reactions to the drugs used, surgical aids on the pelvic organs, urinary tract infections, neurogenic bladder dysfunction, congenital malformations of the genitourinary system, oncological and severe cardiovascular disease, diabetes mellitus, and hypogonadism.

Patients were randomly distributed into two groups of 30 people each. The comparison group (CG) included patients who received standard therapy with alpha blocker drugs (tamsulosin at a dose of 0.4 mg once a day) and fluoroquinolones (levofloxacin at a dose of 500 mg once a day for 28 days). If necessary, the therapy was adjusted in accordance with the sensitivity of microorganisms [1–3].

The main group (MG) consisted of patients who received standard therapy in combination with physiotherapy sessions with the Smart-Prost apparatus, which were performed in the acrophase of the chronorhythm. The chronorhythm was recorded using the Dinamika computer complex every day at 8.00, after which the time corresponding to the maximum peak of the chronobiological activity of the patient's body (acrophase of the chronorhythm) was determined.

DOI: https://doi.org/10.17816/uroved56773

Treatment efficiency was evaluated at admission (visit 1), after 2 weeks (visit 2), and after 4 weeks (visit 3). The frequency of urination, including urination at night (nocturia), mean score on the IPSS, quality of life (QOL), NIH Chronic Prostatitis Symptom Index (NIH-CPSI) scales, maximum urine flow rate (Q_{max}), prostate volume (V_p), and residual urine volume (V_{ru}) were assessed, and bacterioscopic and bacteriological study of the prostate secretion was performed. During transrectal ultrasound examination (TRUS) of the prostate in duplex scanning mode, peak systolic (V_p), end diastolic (V_d), and mean linear (V_m) blood flow velocity were analyzed, as well as the resistance index (RI) and pulsation index (PI) when imaging the urethral and capsular arteries.

After the therapy, TUR of the prostate was performed in all patients, with subsequent bacteriological study of the resected prostate tissue fragments.

The follow-up period for the analysis of long-term results of surgical treatment was 6 months, during which the frequency of complications (such as acute urinary retention, leukocyturia, hematuria, and bacteriuria) was compared in patients of the two groups.

Statistical analysis of data was performed using the MS Excel 11.0 program of the standard MS Office 2013 package, as well as the IBM SPSS Statistics 21.0 software. Statistical hypotheses were tested using Student's *t*-test and x^2 test. When assessing the significance of the differences revealed between the mean values of the samples, the parameter *p* was calculated, and the probability of the null hypothesis validity was taken equal to 5% ($p < 0.05$).

RESULTS

Comparative characteristics of the research results obtained in both groups during 4 weeks of therapy are presented in Table 1.

The bacteriological examination of prostate secretion at visit 1 provided the following results. In CG, *Escherichia coli* was most often detected (16 (53.3%) of 30 patients), *Enterococcus faecalis* was found in 10 (33.3%) patients, *Staphylococcus epidermidis* was found in 3 (10%), and *Staphylococcus aureus was detected* in 1 (3.3%). In MG, the results were comparable, as *E. coli* was detected in 17 (56.7%) of 30 patients, *E. faecalis* was found in 8 (26.7%), and *S. epidermidis* was detected in 5 (16.7%).

At visit 2 in CG, bacteria were detected in 11 (36.7%) cultures with *E. coli* revealed in 6 (20%) patients, *E. faecalis* was found in 3 (10%), and *S. epidermidis* was detected in 1 (3.3%). In MG, microorganisms were isolated in cultures of 10 (33.3%) patients, *E. coli* was found in 7 (23.3%), *E. faecalis* was detected in 2 (6.7%), and *S. epidermidis* was discovered in 1 (3.3%). No significant differences were found between the two groups ($p > 0.05$).

At visit 3, according to the results of the bacteriological examination of prostatic secretion, no growth of microorganisms was detected in the groups. Comparative characteristics of the hemodynamic parameters in the prostatic vessels in both groups following 4 weeks of therapy are presented in Table 2.

Initially, patients of both groups showed deterioration of blood flow in the prostate gland, which was

Table 1. Clinical indicators in patients of the main group and the comparison group after 4 weeks of treatment, $M \pm m$

Таблица 1. Клинические показатели у пациентов основной группы и группы сравнения после 4 недель лечения, $M \pm m$

Indicator	Visit 1 (before treatment)		Visit 2 (2 weeks)		Visit 3 (4 weeks)	
	CG	MG	CG	MG	CG	MG
Frequency of urination per day	13.8 ± 2.1	13.7 ± 2.2	7.2 ± 1.3	7.0 ± 1.1	6.9 ± 1.1	5.5 ± 1.2*
Frequency of urination at night	4.2 ± 1.4	4.3 ± 1.5	3.0 ± 0.9	2.9 ± 0.9	2.9 ± 1.0	2.3 ± 0.6*
IPSS, points	23.6 ± 1.2	23.5 ± 1.2	19.1 ± 1.2	18.7 ± 1.1	19.0 ± 1.0	17.3 ± 1.1*
QOL, points	5.0 ± 0.9	5.1 ± 0.9	4.5 ± 0.8	4.2 ± 0.9	4.3 ± 1.0	3.7 ± 0.7*
NIH-CPSI, points	28.0 ± 1.8	28.1 ± 1.8	18.4 ± 2.5	18.1 ± 2.1	17.1 ± 2.0	12.4 ± 2.6*
Count of leukocytes in prostatic secretion, in the field of view	29.7 ± 4.8	30.1 ± 4.7	17.2 ± 3.1	17.1 ± 2.1	13.1 ± 4.0	8.4 ± 3.6*
Q_{max}, ml/s	7.8 ± 1.7	7.9 ± 1.8	9.8 ± 2.2	10.0 ± 2.4	10.2 ± 1.9	11.9 ± 2.3*
Prostate velocity ($V_п$), cm^3	71.1 ± 8.7	70.7 ± 8.4	64.2 ± 10.6	61.7 ± 12.1	64.6 ± 10.8	57.9 ± 10.4*
Residual urine velocity ($V_{ом}$), cm^3	53.4 ± 12.8	53.9 ± 12.2	36.2 ± 9.1	35.4 ± 8.3	33.3 ± 6.2	25.0 ± 7.2*

* The difference in indicators before and after treatment is significant ($p < 0.05$). *Note*. CG, comparison group; IPSS, International Prostate Symptom Score; MG, main group; NIH-CPSI, NIH Chronic Prostatitis Symptom Index; QOL, quality of life.

Table 2. Hemodynamic parameters in the prostate in patients of the main group and the comparison group after 4 weeks of treatment, $M \pm m$

Таблица 2. Показатели гемодинамики в предстательной железе у пациентов основной группы и группы сравнения после 4 недель лечения, $M \pm m$

Indicator	Visit 1 (before treatment)		Visit 2 (2 weeks)		Visit 3 (4 weeks)	
	CG	MG	CG	MG	CG	MG
Peak systolic velocity (V_p), cm/s	13.8 ± 1.5	13.6 ± 1.7	16.1 ± 3.1	17.2 ± 3.3	23.1 ± 3.1	26.5 ± 3.0*
End diastolic velocity (V_d), cm/s	1.2 ± 0.9	1.1 ± 1.0	2.0 ± 0.9	3.1 ± 1.2*	2.6 ± 0.9	3.6 ± 0.8*
Mean linear velocity (V_m), cm/s	7.5 ± 2.2	7.2 ± 2.5	9.9 ± 2.2	11.3 ± 2.5	11.9 ± 1.9	13.3 ± 1.7*
Pulsation index (PI), cm/s	1.7 ± 0.1	1.8 ± 0.1	1.5 ± 0.2	1.1 ± 0.1*	1.2 ± 0.3	0.9 ± 0.1*
Resistance index (RI), cm/s	1.0 ± 0.1	1.1 ± 0.1	0.9 ± 0.08	0.7 ± 0.06*	0.7 ± 0.08	0.6 ± 0.07*

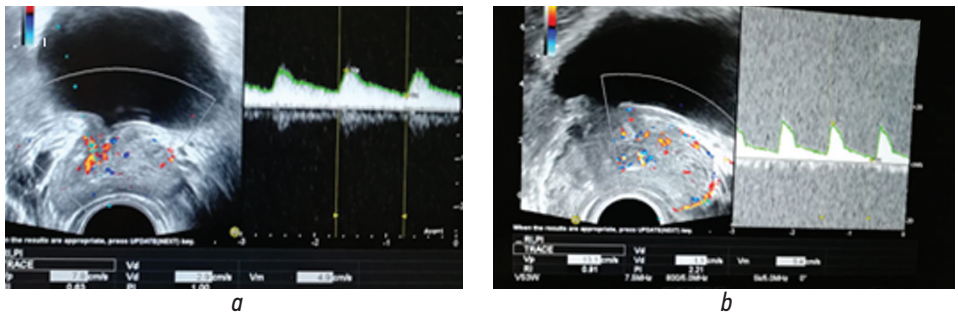
* The difference in indicators before and after treatment is significant ($p < 0.05$). *Note.* CG, comparison group; MG, main group.

manifested by a decrease in the values of the main Doppler parameters (Fig. 1).

After the treatment, compared with CG patients, MG patients showed a more pronounced dynamics of improvement of blood flow in the prostate gland according to Doppler TRUS by visit 2. By visit 3, significant differences were revealed in all studied parameters ($p < 0.05$). An example of Doppler imaging of patient P, made after treatment at visit 3, is presented in Fig. 2.

Bacteriological examination of resected prostate fragments, performed after TUR of the prostate, revealed growth of microorganisms only in 5 (16.7%) of 30 patients in CG, that is, *E. coli* was found in 4 (13.3%) patients and *E. faecalis* was detected in 1 patient. In MG, microorganisms (*E. coli*) were detected only in 1 (3.3%) patient; the differences in CG were significant ($p < 0.05$).

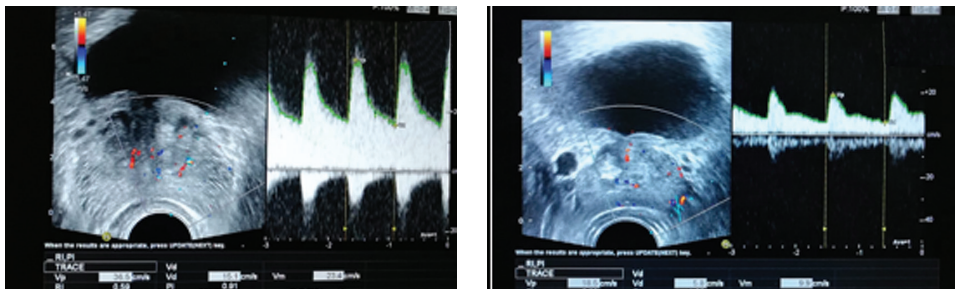
During 6 months of follow-up in the CG, acute urinary retention was detected in 2 (6.7%) patients, leukocyturia was revealed in 18 (60%), hematuria was found in 5 (16.7%), and bacteriuria was detected in 14 (46.7%). In MG, acute urinary retention was detected in 1 (3.3%) patient, leukocyturia was registered in 10 (33.3%), hematuria was found in 2 (6.7%), and bacteriuria was detected in 7 (23.3%) patients.



a *b*

Fig. 1. Patient P. (main group). Doppler TRUS of the prostate before treatment: *a* – urethral branches of the artery of the prostate; *b* – capsular branches of the prostate artery

Рис. 1. Пациент П. (основная группа). Трансректальное ультразвуковое исследование простаты в доплеровском режиме до лечения: *a* — уретральные ветви артерии простаты; *b* — капсулярные ветви артерии простаты



a *b*

Fig. 2. Patient P. (main group). Doppler TRUS of the prostate after treatment at visit 3: *a* – urethral branches of the prostate artery; *b* – capsular branches of the prostate artery

Рис. 2. Пациент П. (основная группа). Трансректальное ультразвуковое исследование простаты в доплеровском режиме после лечения на визите 3: *a* — уретральные ветви артерии простаты; *b* — капсулярные ветви артерии простаты

DISCUSSION

The inflammatory process in the prostate gland deteriorates significantly the clinical manifestations of BPH and increases the probability of postoperative complications. Inflammation also plays an important role in the mechanism of prostate enlargement due to cytokines secreted by macrophages. This, in turn, leads to the formation of HIF-1α, which results in the proliferation of glandular cells and an increase in its size [26].

In addition, tissue hypoxia is an important link in BPH pathogenesis. Vaupel et al. [27] presented 6 mm Hg as the oxygen partial pressure in pathologically altered tissues of the prostate, while it was 26 mm Hg in patients with normal health.

Modern Doppler techniques expand the diagnostic capabilities of TRUS and enable more accurate detection of hemodynamic disturbances in the pathologically altered prostate gland. As regards indicators of the information content of complex TRUS in several studies, the sensitivity, specificity, and accuracy of this method were up to 80%, 93%, and 75%, respectively [28].

The combination of BPH with CP raises many questions when choosing the optimal treatment approach. The predominance of irritative symptoms, absence of a persistent satisfactory effect from the intake of α-adrenergic blockers, and frequent exacerbations of CP necessitate the search for additional methods in the treatment of such patients, aimed at eliminating the inflammatory process and restoring hemodynamics in the prostate [29]. Under these conditions, the use of methods exerting physiotherapeutic effects on tissues and prostate gland, which improve microcirculation and reduce congestion in the prostate, is pathogenetically substantiated [30].

For this purpose, the Smart-Prost apparatus was used in this study, which provides several types of physiotherapeutic effects, namely, infrared radiation with a wavelength of 930–950 nm with a pulse repetition rate of 1–99 Hz and an average radiation intensity of 1.05 W/cm^2, a low-frequency vibration of 2–170 Hz with a maximum amplitude of no more than 2 mm, a constant or low-frequency alternating magnetic field with a strength of 10 ± 3 mTs, a frequency of 1–99 Hz, and a magnetic induction value of up to 3 mTs. These types of effects can improve microcirculation, reduce congestion in the prostate and compression of the acini ducts, as well as enhance local immunity [22, 23]. According to several studies, individual selection of the timing of physiotherapeutic procedures, taking into account the chronobiological rhythms of each patient, also helps increase the efficiency of complex therapy [23–25].

The results obtained in the course of our study are consistent with the data presented in the literature. In a group of patients who received standard therapy in combination with physiotherapy using the Smart-Prost apparatus, significant differences ($p < 0.05$) were revealed in all the studied parameters in the acrophase of the chronorhythm after week 4 of therapy, including lower severity of symptoms in the lower urinary tract; lower mean IPSS, QOL, and NIH-CPSI scores; higher maximum urine flow rate; smaller prostate size; and residual urine volume.

Many studies have shown that patients with prostatitis with pronounced fibrotic changes in the prostate and BPH had a symmetrical, diffuse weakening of vascularization, and with exacerbation of prostatitis, a symmetrical, diffuse increase in vascularization was noted. At the same time, a decrease in hemodynamic parameters in the prostate tissue was noted according to the data of complex TRUS [28]. The study results are consistent with the data available in the literature, as initially, in both groups, low hemodynamic parameters in the prostate gland were revealed. In the group of patients who received standard therapy in combination with physiotherapy sessions using the Smart-Prost apparatus in the acrophase of the chronorhythm, more pronounced improvement of blood flow in the prostate gland according to Doppler TRUS data was noted than in the CG, as evidenced by higher V_p, V_d, and V_m values, as well as lower RI and PI values. By visit 3, significant differences were revealed in all studied parameters ($p < 0.05$).

The results of the bacteriological study of the prostate secretion did not differ significantly between the two groups; however, data of cultures of histological material indicate a more effective elimination of infectious pathogens in the MG. In our opinion, this can be due to the fact that the inflammatory-altered prostate secretion, as well as microorganisms that cause inflammation of the prostate gland, can be found in biofilms on the walls of the ducts of the gland or in obturated acini [31, 32]. The complex physiotherapeutic effect helps increase the efficiency of the antibacterial therapy performed.

CONCLUSION

Thus, personalized complex therapy of patients with BPH combined with CP using a combined physiotherapeutic effect of the Smart-Prost apparatus, taking into account the individual chronobiological characteristics of patients, can reduce the severity of symptoms of the lower urinary tract and manifestations of the inflammatory process in the prostate. It helps improve hemodynamic parameters in the prostate, as well as increase the efficiency of antibiotic therapy, as evidenced by the results of bacteriological studies. In addition, the method of complex therapy used in the study helps improve the results of surgical treatment of patients in this category by reducing the incidence of complications within 6 months after TUR of the prostate.

DOI: https://doi.org/10.17816/uroved56773

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