



РОССИЙСКИЙ ГОСУДАРСТВЕННЫЙ УНИВЕРСИТЕТ ФИЗИЧЕСКОЙ КУЛЬТУРЫ, СПОРТА,  
МОЛОДЕЖИ И ТУРИЗМА

# Report on BAE Mens Pad



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## **Report on Mens Pad**

Chronic and acute inflammation of the prostate is the most common urological disease in men under the age of 50, while in patients over 50 years of age it ranks third in prevalence after benign prostatic hyperplasia and prostate cancer.

According to the recommendations of the European Association of Urology and the Russian Society of Urology, for the treatment of patients with chronic prostatitis and / or chronic pelvic pain syndrome, most urologists prescribe antimicrobial therapy with first-line drugs (fluoroquinolones) for 4 weeks [1].

This is often done empirically, without verifying the primary bacterial agent and determining its sensitivity. Assessing the possibilities of using traditional bacteriological research and PCR diagnostics in the protocol for examining patients with chronic prostatitis, Y.S. Choi et al. [2] showed in 40% of cases the detection of atypical microorganisms (Chlamydia, Mycoplasma and Ureaplasma) in combination with E. coli, Ps. aeruginosa and coccal flora.

Such a comprehensive study of biomaterial for patients with chronic prostatitis in outpatient practice is very rare, and therefore adequate therapy, as a rule, is not carried out, which is considered to be the reason for the inversion of bacterial prostatitis into "abacterial" and, as a result, the patient is becoming incurable.

Dissatisfaction with treatment, frequent relapses of the disease often force patients to go out of control or change doctors, which leads to further chronic inflammation, worsening prognosis and the appearance of such complications.

The above points prompted the need to assess the effectiveness of the use of alternative therapy regimens for chronic prostatitis, affecting, among other things, the "atypical" causative agents of prostatitis.

The article [3], as well as the developers of technology, used in the mentioned article (Bra Pad), reported that the material used in Bra Pad could promote accelerated normalization in the urogenital and endocrine systems.

Therefore, in addition to the use of macrolides, it was decided to also use a combination of macrolides with Mens Pad (the same production and technology as for Bra Pad, but for men), (hereinafter referred to as MPAD) for the treatment of men with chronic prostatitis.

It should be mentioned, the developers of Bra Pad and Mens Pad have extensive experience in the production of biomedical products, with clinical data published in peer-reviewed journals [4-11].

The study group included 20 men with chronic prostatitis, whose demographic, clinical and laboratory data were assessed.

Josamycin was used as a macrolide.

In the case of combination therapy, patients received a combination of macrolide with parallel MPAD wear with duration of therapy from 2 to 5 weeks (according to the decision of the attending physician). All volunteers wore an MPAD in an underwear pocket (the scheme of disposition shown in Figure 1).



Figure 1. Disposition of MPAD in an underwear pocket.

It should be stipulated that the patient was included in the testing after the diagnosis of inflammation of the prostate and the urologist's decision to prescribe macrolide and for the treatment of prostatitis, subject to the signing of an informed consent to participate in the program. The treatment

regimens were determined by the doctor and corresponded to the recommended ones, according to the instructions for medical use: josamycin - 500 mg 3 times a day.

Subsequently, the patients included in the study, according to the statistical analysis plan, were divided into two groups of therapy: macrolides (10 patients) and a group of combination therapy (10 patients). Treatment data for men with chronic prostatitis were collected at baseline (Visit 1) and post-treatment (Visit 2). The scope of examination of patients corresponded to the usual examination in accordance with the Standard of Care for Patients with Prostatitis.

During the first and repeated visits, the following were carried out:

- registration of complaints and anamnesis in accordance with the Chronic Prostatitis Symptom Scale Index (NIH-CPSI);

- digital rectal examination (assessment of the volume, pain and density of the prostate gland);

- ultrasound examination of the kidneys, bladder and prostate gland (with registration of the volume of residual urine and the volume of the prostate gland);

- general analysis of the secretion of the prostate gland (content of bacteria and leukocytes);

Based on the dynamics of changes in the above criteria, the urologist assessed the effectiveness of the patient's treatment.

The physician assessed the efficacy of macrolides and tetracyclines at Visit 2, indicating one of the following treatment outcomes:

- recovery (complete resolution of clinical signs and symptoms);

- improvement (partial resolution of signs and symptoms);

- lack of effect (inadequate response to therapy and the need for additional antibiotic treatment);

- impossible to assess (patient is lost to follow-up).

At the end of the study, statistical analysis was carried out for all groups using the Statistica version 10.0 statistical data processing software package for all analyzed parameters.

The data in the article are presented as mean and standard deviation ( $M \pm m$ ).

The average age of the patients was  $35 \pm 18$  years.

## **Research results**

In the course of the study, dynamics was collected and analyzed in three sections of the NIH-CPSI questionnaire - pain, symptoms of impaired urination and quality of life (Figure 2).

### NIH-Chronic Prostatitis Symptom Index (NIH-CPSI)

Pain or Discomfort

1. In the last week, have you experienced any pain or discomfort in the following areas?

	Yes	No
a. Area between rectum and testicles (perineum)	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>0</sub>
b. Testicles	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>0</sub>
c. Tip of the penis (not related to urination)	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>0</sub>
d. Below your waist, in your pubic or bladder area	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>0</sub>

2. In the last week, have you experienced:

	Yes	No
a. Pain or burning during urination?	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>0</sub>
b. Pain or discomfort during or after sexual climax (ejaculation)?	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>0</sub>

3. How often have you had pain or discomfort in any of these areas over the last week?

<sub>0</sub> Never  
<sub>1</sub> Rarely  
<sub>2</sub> Sometimes  
<sub>3</sub> Often  
<sub>4</sub> Usually  
<sub>5</sub> Always

4. Which number best describes your AVERAGE pain or discomfort on the days that you had it, over the last week?

<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10
NO PAIN										PAIN AS BAD AS YOU CAN IMAGINE

Urination

5. How often have you had a sensation of not emptying your bladder completely after you finished urinating, over the last week?

<sub>0</sub> Not at all  
<sub>1</sub> Less than 1 time in 5  
<sub>2</sub> Less than half the time  
<sub>3</sub> About half the time  
<sub>4</sub> More than half the time  
<sub>5</sub> Almost always

6. How often have you had to urinate again less than two hours after you finished urinating, over the last week?

<sub>0</sub> Not at all  
<sub>1</sub> Less than 1 time in 5  
<sub>2</sub> Less than half the time  
<sub>3</sub> About half the time  
<sub>4</sub> More than half the time  
<sub>5</sub> Almost always

Impact of Symptoms

7. How much have your symptoms kept you from doing the kinds of things you would usually do, over the last week?

<sub>0</sub> None  
<sub>1</sub> Only a little  
<sub>2</sub> Some  
<sub>3</sub> A lot

8. How much did you think about your symptoms, over the last week?

<sub>0</sub> None  
<sub>1</sub> Only a little  
<sub>2</sub> Some  
<sub>3</sub> A lot

Quality of Life

9. If you were to spend the rest of your life with your symptoms just the way they have been during the last week, how would you feel about that?

<sub>0</sub> Delighted  
<sub>1</sub> Pleased  
<sub>2</sub> Mostly satisfied  
<sub>3</sub> Mixed (about equally satisfied and dissatisfied)  
<sub>4</sub> Mostly dissatisfied  
<sub>5</sub> Unhappy  
<sub>6</sub> Terrible

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**Scoring the NIH-Chronic Prostatitis Symptom Index Domains**

*Pain:* Total of items 1a, 1b, 1c, 1d, 2a, 2b, 3, and 4 = \_\_\_\_\_

*Urinary Symptoms:* Total of items 5 and 6 = \_\_\_\_\_

*Quality of Life Impact:* Total of items 7, 8, and 9 = \_\_\_\_\_

Figure 2. NIH-CPSI questionnaire.

In the macrolide therapy group, the baseline value of 25 (21; 29) decreased by visit 2 and became 8 (5; 11) points.

In the combination therapy group, the value at visit 1 was 25 (22; 28) points and changed by visit 2 to the level of 5 (3; 7) points. The differences in the number of points obtained in the dynamics for individual scales in the groups were statistically significant ( $p < 0.05$ ).

Thus, for all groups of the NIH-CPSI questionnaire scale, a decrease in the number of points was observed by the second visit.

Soreness of the prostate during the study significantly decreased in all treatment groups: from 8 (80%) cases to 3 (30%) in the macrolide therapy group and from 9 (90%) cases to 1 (10%) in the combination therapy group.

There was revealed a statistically significant advantage of the combination therapy group compared to the macrolide therapy group in the number of patients without pain.

Laboratory examination of prostate secretion was performed in all patients at visit 1 and at visit 2. The presence of bacteria in the secretion of the prostate gland was detected in 14 (70%) patients (in the total sample of 2 groups) at visits 1 and 2 (10%) at visit 2, leukocytes in the secretion of the prostate gland were detected in 18 (90%) patients at visit 1 and in 10 (50%) at visit 2.

In studies using the PCR method, microorganisms were revealed from 12 (60%) patients at visit 1 and in 2 (10%) at visit 2.

Doctors noted the outcome of the prescribed therapy as "recovery" in 40% in the combination therapy group, in 40% in the macrolide therapy group. "Improvement" was noted in 50% in the combination therapy group and 40% in the macrolide group.

The percentage of effective treatment outcomes ("improvement" and "recovery") was respectively 85% in the entire population, 90% in the combination therapy group, 80% in the macrolide therapy group. In terms of the percentage of effective outcomes, there was a statistically significant superiority of the combination therapy group over the monotherapy group ( $p < 0.05$ ).

## **Discussion and conclusions**

The study demonstrated the high efficacy of a combination of macrolides (Josamycin) and MPAD in men with chronic prostatitis in routine clinical practice. The therapy studied in this program, according to doctors, was effective in 90% of patients.

To assess the effectiveness of therapy, modern and classical methods of assessing the condition of patients were used, as well as methods of statistical data analysis. Among the studied therapeutic groups, according to the research doctors and according to the data of the dynamic assessment of clinical laboratory and instrumental parameters, the most pronounced positive dynamics was noted in the combination therapy group, in which the quality of life significantly increased, the number of bacteria in the secretion of the prostate gland decreased, and the total the rate of recovery and improvement of the patient's condition exceeded that in the macrolide monotherapy group.

Based on the data obtained, it can be concluded that the use of macrolides in combination with the use of MPAD in the treatment of chronic, including “abacterial” prostatitis is promising, however, for more definite conclusions, additional study of the data on large samples is required.

The study confirms the importance of a flexible and individual approach to the treatment of chronic prostatitis, the need for constant evaluation of the effectiveness of treatment, monitoring and a critical approach to existing therapy regimens, the importance of patient adherence to treatment and dynamic follow-up by a urologist in the framework of daily clinical practice.

## Publications

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