

Psychoemotional status and evaluation of preventive measures in patients with postcoital cystitis

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ABSTRACT

BACKGROUND: Chronic somatic diseases can affect a person's psychoemotional state. Few publications are dedicated to assessing the quality of life of patients with recurrent lower urinary tract infections (UTIs). Postcoital cystitis is a distinct form of recurrent lower UTI. Since postcoital cystitis is not considered a life-threatening condition, healthcare providers often fail to give it proper attention, which worsens the psychological state of patients suffering from this condition.

AIM: To analyze the psychoemotional state of patients with postcoital cystitis, as well as their perception of this condition. To evaluate the effectiveness of postcoital antibiotic prophylaxis and women's satisfaction with this method.

MATERIALS AND METHODS: A retrospective analysis was conducted involving 86 female patients who underwent treatment at City Multidisciplinary Hospital No. 2 from 2018 to 2023. The median age was 30 [25–35] years. The psychoemotional status of the patients was assessed using a survey. Methods of prevention and treatment of postcoital cystitis previously used by the patients were analyzed. Parameters were compared between two groups of patients, depending on the duration of antibiotic use after sexual intercourse. Additionally, the patients were invited to answer questions related to this condition in their own words.

RESULTS: Many patients described their experiences in emotionally charged terms. Symptoms of depression or anxiety disorder were reported by 82.6% of the patients. The duration of the condition among the analyzed patients was 6.5 [4–11.25] years. The number of physicians consulted by the patients for postcoital cystitis was 6 [5–10]. Sixty out of 86 women (69.8%) used antibiotic prophylaxis after sexual intercourse. Initially, primary antibiotic prophylaxis was effective in 86.7% of the patients. Among women who used antibiotic prophylaxis for 6 months or longer, the positive effect persisted in 57.6% of cases (p < 0.001).

CONCLUSIONS: Postcoital cystitis has a multifactorial negative impact on women's lives, affecting their physical, psychoemotional, and social well-being, and it may also have a negative effect on their sexual partner. The effectiveness of antibiotic prophylaxis decreases over time, and the patients are not willing to use this method for an extended period.

Keywords: postcoital cystitis; urinary tract infection; antibiotics; urethral transposition; quality of life; prevention.

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15

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Психоэмоциональный статус и оценка предпринятых профилактических мер у пациенток с посткоитальным циститом

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АННОТАЦИЯ

Актуальность. Наличие хронической соматической болезни способно оказывать влияние на психоэмоциональное состояние человека. Немногие публикации посвящены оценке качества жизни пациенток с рецидивирующей инфекцией нижних мочевых путей. Посткоитальный цистит представляет особой разновидность рецидивирующей инфекцией нижних мочевых путей. В связи с тем что посткоитальный цистит не рассматривают как жизнеугрожающее состояние, медицинские работники не относятся должным образом к данному заболеванию, что усугубляет психологическое состояние пациенток.

Цель — проанализировать психоэмоциональное состояние пациенток с посткоитальным циститом, а также их восприятие данного заболевания. Оценить эффективность посткоитальной антибиотикопрофилактики и удовлетворенность женщин этим методом.

Материалы и методы. Выполнен ретроспективный анализ данных 86 пациенток, которые с 2018 по 2023 г. проходили лечение в Городской многопрофильной больнице № 2. Медиана возраста составила 30 [25–35] лет. Психоэмоциональный статус пациенток оценивали с помощью опроса. Проанализированы методы профилактики и лечения посткоитального цистита, которые пациентки применяли ранее. Проводилось сравнение показателей между двумя группами пациенток в зависимости от длительности приема антибиотика после полового акта. Кроме того, пациенткам предлагалось в свободной форме ответить на вопросы, которые касались этого заболевания.

Результаты. Многие пациентки эмоционально описывают те переживания, с которыми им приходится встречаться. Симптомы депрессии или тревожного расстройства отмечали у себя 82,6% пациенток. Длительность заболевания среди анализируемых пациенток составила 6,5 [4–11,25] года. Количество врачей, которых пациентки посетили с проблемой посткоитального цистита, 6 [5–10]. Антибиотикопрофилактику после полового акта использовали 60 из 86 женщин (69,8%). В начале применения первичная антибиотикопрофилактика была эффективна у 86,7 % пациенток. Среди женщин, которые применяли антибиотикопрофилактику в течение 6 мес. и более, положительный эффект сохранялся в 57,6% случаев (*p* <0,001).

Выводы. Посткоитальный цистит оказывает многофакторное негативное влияние на жизнь женщин, затрагивая их физическое, психоэмоциональное и социальное благополучие, а также может оказывать отрицательное воздействие на полового партнера. Эффективность антибиотикопрофилактики со временем снижается, а сами пациентки не готовы к длительному применению данного метода.

Ключевые слова: посткоитальный цистит; инфекция мочевых путей; антибиотики; транспозиция уретры; качество жизни; профилактика.

Как цитировать

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16

BACKGROUND

Chronic somatic diseases may affect a person's psychoemotional state [1]. Urologic diseases are not an exception to this phenomenon. The issue of mental health has been well studied in patients with lower urinary tract symptoms in the older age group, particularly in cases of prostatic hyperplasia and stress urinary incontinence [2, 3]. However, few publications are dedicated to assessing the guality of life of patients with recurrent lower urinary tract infections (UTI), despite the high prevalence of this disease and its economic and social burden. For example, a study conducted in Singapore found that patients with recurrent UTIs had lower quantitative measures of mental health compared with the population norm [4]. The condition of women during exacerbation is not merely physical discomfort. Many women stigmatize their condition by labeling themselves as "dirty" or "unhygienic," similar to conditions associated with sexually transmitted infections [5].

Cystitis is regarded as a condition with a positive prognosis, because it may resolve spontaneously or be managed with non-antibacterial treatments when uncomplicated [6]. Patients who do not suffer from recurrent episodes are amenable to appropriately selected antibacterial therapy with a short course of administration [6, 7]. Studies show that cystitis may have a significant impact on women's quality of life [8].

Postcoital cystitis (PC) is a specific form of recurrent UTI [9]. Episodes of PC exacerbations are associated with sexual intercourse and often manifest with the onset of sexual activity. In this patient population, sexual intercourse (40%–100%) often leads to recurrence of the inflammatory process in the bladder, which inevitably affects the quality of life and psychoemotional state of women suffering from this disease. Women experience psychological discomfort and anxiety about waiting for the next episode of cystitis [10].

Since PC is not considered a life-threatening condition, healthcare providers often fail to give it proper attention, which worsens the psychological state of patients suffering from this condition. Women frequently consult with multiple medical professionals to identify a solution and comprehend their condition [11].

When searching for Russian and foreign studies assessing the impact of PC on psychoemotional health, only isolated publications were found [10]. The data on how women with PC perceive their condition is particularly lacking. In this context, the present study was conducted to gain a better understanding of the level of emotional distress experienced by this patient group.

The study aimed to analyze the psychoemotional state of female patients with PC and their perception of this condition, as well as to evaluate the effectiveness of postcoital antibiotic prophylaxis (AP) and the women's satisfaction with this treatment modality.

METHODS

From 2005 to 2023, 542 patients diagnosed with PC underwent extravaginal urethral transposition using the technique described in patents No. 2408296 dated January 10, 2011, and No. 2686948 dated June 18, 2018. This procedure was performed at the Urological Clinic of the Mechnikov North-Western State Medical University at the St. Petersburg City Multidisciplinary Hospital No. 2. A more detailed assessment of psychoemotional status and previous prophylaxis was performed in 86 patients at the preoperative stage. The median age was 30 [25-35] years. Age, body mass index, disease duration, number of physicians visited for PC, and time of prescription of PC prophylaxis were evaluated. In addition, the study examined women's ratings of the PC importance in their lives and the perceived seriousness with which physicians addressed PC. Ordinal scores ranging from 1, representing the lowest score, to 10, representing the highest score, were used for the analysis.

The psychoemotional status of the patients was assessed using a survey to determine the symptoms of depression or anxiety disorders affecting the subjective view of the women, their referral to specialized physicians, and the need to receive specialized therapy.

Previous methods of PC prophylaxis and treatment were analyzed. The effectiveness of antibiotic use for PC prophylaxis was evaluated at baseline and following six months of treatment. Furthermore, the percentage of patients who refused the proposed prophylactic course, the need to change antibiotics, the number of medications used, the duration of use, and adverse effects were evaluated. Parameters were compared between two groups of patients, depending on the duration of antibiotic use after sexual intercourse. AP for ≤2 months was classified as short-term use, whereas the use for >6 months was classified as longterm. A survey was conducted to assess women's satisfaction with this method of prophylaxis, their willingness to use antibiotics for a long time after sexual intercourse, their concerns about possible harm to their health, and the growth of bacterial resistance with prolonged antibiotic use. In addition, the patients were asked to answer open-ended questions, if they wished, about the psychoemotional aspect of PC, its effect on sexual partners, challenges in communication with healthcare providers, and its influence on physical well-being and functionality. Moreover, the study examined the women's perceptions regarding the use of antibiotics as a preventative measure for PC, as well as perceived challenges to effective management of this condition.

The statistical analysis was conducted using the SPSS Statistica v. 26 software package. Quantitative indices were described as median (*Me*), lower and upper quartiles $[a_1; a_3]$, and interquartile range (IQR). Pearson's chi-squared test or McNemar's test was used to analyze the nominal data. The quantitative data were compared using the Mann–Whitney *U* test, and the Wilcoxon's test was used to examine differences between dependent populations. The correlation analysis using Spearman's method was performed for quantitative indicators. The multiple logistic regression was used to assess the influence of the described quantitative factors on the probability of psychoemotional changes in patients with PC. The Python programming language together with the Pandas and Seaborn libraries were used for data analysis and visualization. The differences were considered statistically significant at p < 0.05.

RESULTS

Psychoemotional Burden

"The pain and hopelessness made me want to take a knife and cut out the painful spot like the eye of a potato. When I was really hurting, I thought about ending my own life." Many patients described their experiences in emotionally charged terms. This quote shows that the disease may lead to extreme despair and even suicidal thoughts.

"My sex life wasn't great. In the end, it was all about nerves and little arguments with my partner. I was always trying to adjust so that the next day would be free if I had an aggravation. I felt a bit off. I often had to turn down sex if I forgot to take my pills with me...". Women report that family life is negatively affected. The quality of personal life of both partners deteriorates, even in the context of an understanding family. Spontaneous sexual activity becomes impossible.

"My condition was even critical, intimacy with a loved one inherently implied payback and pain. A sense of doom and guilt." This quote shows how the disease may destroy sexual life. Instead of pleasure and intimacy, a woman experiences stress and tension, has to be constantly alert to possible exacerbation, which affects her psychoemotional state.

"The worst part was that we couldn't plan a pregnancy because of it." "I put an end to relationships with men, starting a family, and having children." Patients with this disease refuse to have sexual intercourse, which leads to serious problems in family relations and inability to plan pregnancy. This phenomenon may be considered a social problem, especially in view of the priority given to fertility issues in Russia.

"I started avoiding sex, and my relationship with the young man got worse. A lot of inner worries, which turned into depression." Avoidance of sexual contacts becomes a defensive reaction, which leads to a deterioration of the relationship with the partner. Accumulated inner concerns and constant stress often result in depression, a condition that necessitates professional intervention. The presence of symptoms of depression or anxiety disorder in women with PC was assessed using a survey (Fig. 1). The described psychiatric conditions were reported by 71/86 (82.6%) patients, with anxiety disorder in 10/86 (11.6%) patients, depression in 33/86 (38.4%) patients, and the presence of both conditions in 28/86 (32.6%) patients. Of these patients, only 42.3% sought consultation with a specialist. The results of treatment indicated the implementation of specialized therapy in all cases, with 43.3% of women receiving combination therapy comprising psychotherapy and antidepressants or antianxiety medications.

Effect on Physical Activity and Performance

"After a while, I got over it, but I was nervous a lot and constantly listening to my body, which had a negative effect on my productivity throughout the day." PC has a significant impact on several aspects of women's lives, including physical activity and performance. During remission, women can maintain their usual level of activity: "If I don't have a flare-up, it doesn't affect what I do." However, emotional distress and anxiety may lead to a decrease in productivity during the workday.

"First of all, there was a lack of desire and opportunity to play sports, which was a regular part of my life before."

Interaction with Physicians

"Referrals to other specialists (gynecologist refers to urologist, urologist to gynecologist) ..." One of the problems highlighted by patients is the constant referral of patients between different specialists who may not be knowledgeable about the prevention and treatment of PC, which ultimately does not lead to a positive outcome.

The median age was 30 [25–35] years. The body mass index was 20.83 [19.15; 22.56] kg/m². Among the analyzed patients, the disease duration was 6.5 [4–11.25] years. The minimum disease duration was 1 year, and the maximum was 23 years. The age of PC onset was 21 [19; 24] years. The number of physicians to whom patients were referred for treatment of PC was six [5; 10]. However, 32.6% of women reported having consulted with 10 to 30 physicians. Patients were offered preventive strategies only 3 [1; 5] years after the onset of PC exacerbations. The multiple logistic regression analysis indicated that the subsequent prescription of preventive measures increased the likelihood of psychoemotional changes in patients with PC.

A correlation matrix was constructed and displayed as a heat map (Fig. 2) based on the quantitative data. The heat map revealed moderate to strong positive correlations between the quantitative data, except for body mass index. The strongest direct correlation was identified between age and disease duration (r = 0.77), and between prophylaxis initiation and disease duration (r = 0.64), p < 0.001.



Fig. 1. Psychoemotional status of patients. Рис. 1. Психоэмоциональный статус пациентов.

"It's been 12 years since I started having sex, and I've had cystitis ever since. I recently found out that my cystitis is actually a postcoital thing. I already knew that, but earlier urologists didn't really emphasize it or give any special recommendations." It is important to assess the correlation between cystitis and sexual intercourse to determine effective prevention strategies and surgical interventions.

"The doctors at XXX were giving out antibiotics every time I went, or even told me to stop having sex and live without cystitis." In case of recurrent UTIs, it is necessary to prescribe prophylactic methods, which should be discussed with the patient, even during an exacerbation, in order to establish a subsequent algorithm of actions. It is inadmissible to advise patients with PC to avoid sexual activity or "change their husbands," as this only serves to exacerbate the emotional state of women.

Effect on Sexual Partner

"This story has really taken a toll on both of us. My husband has been there for me throughout this difficult time, and now I'm trying to help him deal with the psychological impact of what we've been through. A healthy adult man who, in all other aspects of life, loves me has started avoiding sex." The man's psychoemotional state also suffers in such a couple. The so-called avoidance behavior is a kind of defensive reaction to prevent negative emotions, including erectile dysfunction, in the partner [12]. In addition, even if a woman has an understanding partner, the disease may be a reason for separation. Our patients have repeatedly told us that the presence of PC was a reason for divorce.

Use of Antibiotics as Prophylaxis

"I felt as if I was doomed, like I'd never be able to get pregnant and live a full life since I was on antibiotics all the time." Common concerns among women diagnosed with PC include feelings of doom and fear of infertility due to continuous antibiotic use. In addition, patients expressed concerns regarding the potential adverse effects and decreased effectiveness of antibiotics due to prolonged use, which may complicate the treatment of other infections and exacerbate cystitis in the future. "I wouldn't want to use such a method. I'm afraid that nothing will help at all afterward."

Sixty out of 86 women (69.8%) used AP after sexual intercourse. At baseline, primary AP was effective in 86.7% of patients. However, 22 patients discontinued AP within 1–2 months of use for various reasons. Thirty-eight patients were still receiving prophylactic antibiotics after two months of use; of these, 33 women had been using antibiotics for six months or more.

The effectiveness of primary AP was defined as the absence of cystitis exacerbation along with postcoital antibiotic administration used by the patient at the start of this prophylactic strategy. The effectiveness of AP for six months and longer was 57.6%. For statistical processing of primary AP, the associated data were analyzed according to the duration of antimicrobial treatment (Table 1). The comparison showed a significant difference in effectiveness at the initial period of AP (≤ 2 months) and after ≥ 6 months (p < 0.001). The need to use two or more antibiotics in a short-term prophylaxis occurred in six patients (27.3%), whereas 66.7% of women receiving



Fig. 2. Diagonal: Distribution histograms. Lower triangle: Scatter plots. Upper triangle: Heat map of the correlation matrix (Spearman's method). *** Statistically significant changes in parameters (p < 0.001); * statistically significant changes in parameters (p < 0.05). **Рис. 2.** Диагональ: Гистограммы распределения. Нижний треугольник: Диаграммы рассеяния. Верхний треугольник: Тепловая карта матрицы корреляций (метод Спирмена). ***Изменения показателей статистически значимы (p < 0.001); * изменения показателей статистически значимы (p < 0.001); * изменения показателей статистически значимы (p < 0.05).

prophylactic antibiotics for a long time reported the need to change antibiotics (p = 0.004). In 22/28 (78.6%) cases, the reason for changing antibiotics was a lack of therapeutic effect. Adverse effects were significantly less frequent in women in the two-month group (7/22 [31.8%] vs 21/33 [63.6%], p = 0.021). Among all patients receiving postcoital AP, 48.3% exhibited an adverse reaction to antibiotics. Nevertheless, some women continue to use this strategy, prioritizing their desire to maintain sexual activity over the potential risks associated with therapy. "I had to choose between taking antibiotics and not having sex at all. I took the pills anyway, even though they have some side effects."

Among the patients who had experience of postcoital AP, 14/60 (23.3%) were satisfied with this approach to PC prophylaxis, and only 5% were ready for long-term use

of antibiotics. Most patients expressed concern about the potential adverse impact of this strategy on their health, as well as the development of bacterial resistance to antibiotics resulting from their prolonged use.

Existing Problems

"Only one doctor started prescribing preventative treatment;" "a lot of doctors offered nothing but antibiotics." Patients reported a late initiation of prophylaxis. As previously described, the median duration of prophylaxis prescription was three [1; 5] years. The lack of information from physicians means that patients have to understand the possible causes of the disease and treatment methods on their own, relying on their own conclusions and the experiences of other women with PC. In the studied sample, 90.7% of patients sought solutions

Parameters	Duration of antimicrobial treatment			n voluo
	All cases (group A, <i>n</i> =60)	≼2 months (group B, <i>n</i> =22)	≽6 months (group C, <i>n</i> =33)	<i>p</i> -value (B and C)
Age, years	31 [25; 36]	31 [24.5; 35.3]	33 [25.5; 36.5]	0.519
Body mass index, kg/m ²	21.5 [19.5; 22.5]	22 [20.2; 22.6]	20.8 [19; 22.5]	0.201
Disease duration, years	7.5 [5; 12]	6.5 [4.8; 13.3]	9 [5; 12]	0.535
Age at disease onset, years	21 [19; 25]	22 [18.5; 25]	22 [19.5; 25.5]	0.673
Number of physicians, n	6 [5; 10]	7.5 [6; 11]	6 [5; 10]	0.253
Start of prophylaxis, years	3 [1.2; 4.9]	3 [1.8; 5]	3 [1; 4]	0.295
Symptoms of depression or anxiety disorder, n	55 (91.7%)	21 (95.5%)	30 (90.9%)	0.525
Effectiveness of primary antibiotic prophylaxis, n	52 (86.7%)	14 (63.6%)	19 (57.6%)	A and C <0.001*
Refusals of antibiotic prophylaxis, n	33 (55%)	22 (100%)	11 (33.3%)	<0.001*
Continuation of antimicrobial treatment, n	27 (45%)	0	22 (66.7%)	
Use of two or more medications, n	28 (46.7%)	6 (27.3%)	22 (66.7%)	0.004*
Reasons for changing the antibiotic, n				
Adverse effects, allergy	6/28 (21.4%)	2/6 (33.3%)	4/22 (18.2%)	0.423
No effect	22/28 (78.6%)	4/6 (66.7%)	18/22 (81.8%)	
Use of nitrofurans, <i>n</i>	40 (66.7%)	12 (54.5%)	25 (75.8%)	0.1
Duration of antibiotic prophylaxis, months	6 [2; 24]	2 [1; 2]	24 [12; 48]	<0.001*
Adverse effects, n	29 (48.3%)	7 (31.8%)	21 (63.6%)	0.021*
Satisfaction with antibiotic prophylaxis, n	14 (23.3%)	2 (9.1%)	11 (33.3%)	0.038*
Willingness to take long-term antimicrobials, n	3 (5%)	0	3 (9.1%)	0.146

Table 1. Comparative data of patients depending on the duration of antibiotic prophylaxis. *Me* $[Q_1; Q_2]$ Таблица 1. Сравнительные данные пациентов в зависимости от длительности антибиотикопрофилактики. Ме [Q,; Q,]

Note. *Statistically significant changes in parameters (p <0.05).

Примечание. *Изменения показателей статистически значимы (р <0.05).



Importance for the patient

Fig. 3. Perception of postcoital cystitis by patients. Рис. 3. Восприятие проблемы посткоитального цистита пациентами.

to the PC problem independently. Therefore, the time to qualified advice may be delayed.

"Because of the long-term nature of the condition and the fact that it's not a threat to the patient's life, it's not taken seriously." Given that PC does not pose a direct threat to the patient's life, the impact of PC on the patient's quality of life and psychoemotional state is often underestimated. In our study, women emphasized that physicians treat this problem in a trivial way, not giving due importance to their complaints. This phenomenon is evidenced by the survey's findings, wherein patients evaluated their physicians' approach to their concerns on a scale ranging from 1 to 10 (Fig. 3). The median score was 3 points, with an IQR of 3. The minimum (min) score

was recorded as 1, whereas the maximum (max) score was 10. This suggests a low assessment of the disease severity by healthcare providers. Conversely, the data regarding the patients' own perceptions of the significance of the PC problem exhibited notable variations. *Me* was 10, the IQR was 0, and the min and max values were 4 and 10, respectively. The analysis indicates a significant difference in the perception of the problem severity between patients and physicians (p < 0.001).

"It is highly important that information about this issue be disseminated through social networks and other forms of media. Women should learn about this condition before they kill the microflora and develop resistance to antibiotics over years of treatment." Patients emphasize the importance of raising awareness about PC among women. The lack of available information on the prevention and treatment of PC, as well as the failure of physicians to inform women about potential treatment options, negatively affects the psychoemotional state of patients.

DISCUSSION

Recurrent UTIs are a significant problem for many female patients. Clinicians often underestimate the impact of this supposedly trivial condition on patients' physical and mental health [13]. This leads to women trying to seek assistance independently, which often entails conducting their own online research and creating web forums to address their concerns. Unfortunately, these online spaces frequently offer advice that is neither professional nor reliable [11]. The researchers from the United Kingdom analyzed information from a popular web forum for patients with recurrent UTIs. Patients have expressed concern and dissatisfaction with the lack of attention to this problem in the medical community. Therefore, available methods of prophylaxis are limited, and they are often ineffective. The researchers concluded that recurrent UTIs may have a significant impact on women's psychoemotional health.

In this study, women emotionally described the difficulties they faced. They experienced frustration due to frequent PC exacerbations, fear of sexual intercourse, and even suicidal thoughts. In 82.6% of cases, patients reported symptoms of depression or anxiety.

Scott et al. [14] conducted a qualitative analysis where participants were interviewed on a variety of topics related to UTIs [14]. The findings showed that many of the patients are afraid of the negative effects of antibiotics and are frustrated that healthcare providers are not addressing their concerns and optimizing antibiotic use. They believe that physicians need to change treatment strategies to address these concerns and direct more research efforts toward developing non-antibacterial methods to prevent and treat recurrent UTIs. These findings are consistent with the results of our study. Among the 60 patients who started AP, 33 women (55%) refused this strategy for various reasons, including personal beliefs that the use of antibiotics for prophylaxis is unwarranted due to its irrationality, concerns regarding its decreased effectiveness, potential allergic reactions, the needy for frequent use, and adverse effects. Among all patients, the overall satisfaction with prophylaxis was 23.3%, whereas only three patients (5%) expressed a willingness to undergo long-term AP.

Finally, PC significantly affects the psychoemotional state of patients. Women have described this problem as being underestimated by physicians, including the late prescription of prophylactic strategies. The effectiveness of AP decreases over time, and patients are often unwilling to use this method on a long-term basis, requiring alternative approaches, primarily urethral transposition. This surgical procedure has been shown to be highly effective, even in the long term, and to have significant rehabilitative potential in terms of the quality of life for women [10, 15, 16]. Therefore, urethral transposition should be included in the prophylactic armamentarium, and patients should be informed about this procedure.

CONCLUSION

PC has a multifactorial negative impact on women's lives, affecting their physical, psychoemotional, and social well-being, and it may also have a negative effect on their sexual partner. Patients frequently express concerns that this problem is often underestimated by physicians, including the provision of untimely recommendations for disease prevention.

This study indicates the need for the early prevention of PC, with the most effective approach being extravaginal urethral transposition according to our method.

ADDITIONAL INFO

Authors' contribution. B.K. Komyakov, concept and design of the study, editing the text; M.V. Shevnin, concept and design of the study, collecting and processing materials, statistical analysis, writing text; V.A. Tarasov, collecting materials, literature review; E.S. Spilenya, literature review, editing the text; E.B. Komyakova, A.V. Shestykh, collecting materials, literature review. The authors have approved the version for publication and have also agreed to be responsible for all aspects of the work, ensuring that issues relating to the accuracy and integrity of any part of it are properly considered and addressed.

Ethical review. The study was approved by the local ethical committee North-Western State Medical University named after I.I. Mechnikov (protocol No. 8 dated 2020 Nov 11). All study participants voluntarily signed an informed consent form prior to inclusion in the study.

Consent for publication. The authors received written informed voluntary consent of patients for publication of personal data, including its electronic version. The scope of published data is agreed with the patients.

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ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Вклад авторов. Б.К. Комяков — концепция и дизайн исследования, редактирование текста статьи; М.В. Шевнин — концепция и дизайн исследования, сбор и обработка материалов, статистический анализ, написание текста; В.А. Тарасов — сбор материалов, литературный обзор; Е.С. Шпиленя — литературный обзор, редактирование текста; Е.Б. Комякова, А.В. Шестых — сбор материалов, литературный обзор. Авторы одобрили версию для публикации, а также согласились нести

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ответственность за все аспекты работы, гарантируя надлежащее рассмотрение и решение вопросов, связанных с точностью и добросовестностью любой ее части.

Этическая экспертиза. Проведение исследования одобрено локальным этическим комитетом ФГБОУ ВО «Северо-Западный государственный медицинский университет им. И.И. Мечникова» (протокол № 8 от 11.11.2020). Все участники исследования добровольно подписали форму информированного согласия до включения в исследование.

Согласие на публикацию. Авторы получили письменное информированное добровольное согласие пациентов на публикацию персональных данных, включая его электронную версию. Объем публикуемых данных с пациентами согласован.

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Раскрытие интересов. Авторы заявляют об отсутствии отношений, деятельности и интересов за последние три года, связанных с третьими лицами (коммерческими и некоммерческими), интересы которых могут быть затронуты содержанием статьи.

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