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EVALUATION OF THE EFFICACY 5-FLUOROURACIL ON ERECTILE FUNCTION IN PATIENTS UNDER SURGICAL TREATMENT OF BENIGN PROSTATE HYPERPLASIA

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Abstract

Introduction. The prevalence of erectile dysfunction in benign prostatic hyperplasia (BPH) is 5.2-40%. Urethral strictures as a complication of transurethral resection of the prostate is a risk factor for the development of postoperative erectile dysfunction.

The purpose of the study is to evaluate the effectiveness of the prophylactic use of 5-fluorouracil in relation to erectile dysfunction in patients undergoing surgery for BPH.

Materials and methods. The study included 246 patients who underwent surgery, with an average age of 70.0 ± 8.0 years. The main group included 124 patients who, in addition to the standard postoperative treatment in the hospital, received prophylactic intervention after surgery in the form of washing with a solution of 5-fluorouracil using a modified three-way catheter. The control group consisted of 122 combined patients who underwent surgery for BPH and received standard postoperative treatment. To assess erectile dysfunction, the IIEF-5 questionnaire was used 3 and 6 months after surgery. All statistical analysis procedures were performed using the SPSS 20 program. For qualitative data, the significance of differences in groups was determined by calculating the Chi-square (χ^2) test. For quantitative data, the result was expressed as the median and 25-75 percentiles. Calculations of the significance of differences were made using the Mann-Whitney test.

Results. A statistically significant improvement in the erectile function of patients in both the main and control groups was established after surgery for 6 months ($\chi^2 = 115.356$; $p < 0.001$; $\chi^2 = 115.034$; $p < 0.001$, respectively). At the same time, in the main study group, the indicators had statistically significant differences with the control group. A twofold decrease in subjective symptoms of erectile dysfunction was shown in all patients, however, in the main study group, changes in these indicators were statistically significantly more pronounced ($p=0.014$ after 3 months; $p=0.007$ after six months).

Conclusion. The high efficiency of the prophylactic use of 5-fluorouracil by irrigation of the bladder and urethra in relation to the erectile function of patients who underwent surgery for benign prostatic hyperplasia was established.

Key words: benign prostatic hyperplasia, surgery, 5-fluorouracil, erectile function.

Резюме

ОЦЕНКА ЭФФЕКТИВНОСТИ ПРОФИЛАКТИЧЕСКОГО ПРИМЕНЕНИЯ 5-ФТОРУРАЦИЛА ПРИ ЭРЕКТИЛЬНОЙ ДИСФУНКЦИИ У ПАЦИЕНТОВ, ОПЕРИРОВАННЫХ ПО ПОВОДУ ДОБРОКАЧЕСТВЕННОЙ ГИПЕРПЛАЗИИ ПРЕДСТАТЕЛЬНОЙ ЖЕЛЕЗЫ

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Введение. Распространенность эректильной дисфункции при доброкачественной гиперплазии предстательной железы (ДГПЖ) составляет 5,2-40%. Стриктуры уретры как осложнение трансуретральной резекции простаты является фактором риска развития послеоперационных нарушений эректильной функции.

Цель исследования - оценка эффективности профилактического применения 5-фторурацила в отношении эректильной дисфункции у пациентов, перенесших оперативное вмешательство по поводу ДГПЖ.

Материалы и методы. В исследование включены 246 пациентов, перенесших аденомэктомию, в среднем возрасте 70,0±8,0 лет. В основную группу вошли 124 пациента, получившие помимо стандартного послеоперационного лечения в стационаре профилактическое вмешательство после операции в виде промывания раствором 5-фторурацила с применением модифицированного трехходового катетера. Контрольную группу составили 122 совмещенных пациентов, перенесших оперативное вмешательство по поводу ДГПЖ и получивших стандартное послеоперационное лечение. Для оценки нарушений эректильной функции использовали анкету МИЭФ-5 через 3 и 6 месяцев после оперативного вмешательства. Все процедуры статистического анализа выполнялись с помощью программы SPSS 20. Для качественных данных значимость различий в группах была определена с помощью расчета критерия Хи-квадрат (χ^2). Для количественных данных результат был выражен в виде медианы и 25-75 перцентилей. Расчеты значимости различий были произведены с помощью расчета критерия Манна-Уитни.

Результаты. Установлено статистически значимое улучшение эректильной функции пациентов как основной, так и контрольной групп после оперативного вмешательства на протяжении 6 месяцев ($\chi^2 = 115,356$; $p < 0,001$; $\chi^2 = 115,034$; $p < 0,001$ соответственно). При этом в основной группе исследования показатели имели статистически значимые различия с группой контроля. Показано двукратное снижение субъективных симптомов нарушений эректильной функции у всех пациентов, однако в основной группе исследования изменения этих показателей оказались статистически значимо более выраженными ($p=0,014$ через 3 месяца; $p=0,007$ через полгода).

Заключение. Установлена высокая эффективность профилактического применения 5-фторурацила путем орошения мочевого пузыря и уретры в отношении эректильной функции пациентов, перенесших оперативное вмешательство по поводу доброкачественной гиперплазии предстательной железы.

Ключевые слова: доброкачественная гиперплазия предстательной железы, оперативное вмешательство, 5-фторурацил, эректильная функция.

Түйіндеме

5-ФТОРУРАЦИЛДІ ҚУЫҚ АСТЫ БЕЗІНІН ГИПЕРПЛАЗИЯСЫНА БАЙЛАНЫСТА ОПЕРАЦИЯ ЖАСАЛҒАН НАУҚАСТАРДА ЭРЕКТИЛЬДІ ДИСФУНКЦИЯСЫНЫҢ АЛДЫН АЛУ МАҚСАТЫНДА ҚОЛДАНУДЫҢ ТИІМДІЛІГІН БАҒАЛАУ

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Кіріспе. Қуықасты безінің қатерсіз гиперплазиясында (ҚБҚГ) эректильді дисфункцияның таралуы 5,2-40% құрайды. Қуықасты безінің трансуретральды резекциясының асқынуы ретінде уретральды стриктуралар операциядан кейінгі эректильді дисфункция дамуының қауіп факторы болып табылады.

Зерттеудің мақсаты - 5-фторурацилді ҚБҚГ байланыста операция жасалған науқастарда эректильді дисфункциясының алдын алу мақсатында қолданудың тиімділігін бағалау болды.

Материалдар мен тәсілдер. Зерттеуге аденомэктомия жасалған 246 науқас қатысты, олардың орташа жасы 70,0±8,0 жыл. Негізгі топқа стационарда стандартты операциядан кейінгі емнен басқа, модификацияланған үш өзекті катетерді қолдану арқылы 5-фторурацил ерітіндісімен жуу түріндегі операциядан кейін профилактикалық араласу жүргізілген 124 науқас кірді. Бақылау тобына ҚБҚГ байланыста операция жасалған және операциядан кейінгі стандартты ем алған 122 біріктірілген пациенттер кірді. Эректильді дисфункцияны бағалау үшін операциядан кейін 3 және 6 айдан кейін МИЭФ-5 сауалнамасы қолданылды. Барлық статистикалық талдау шаралары SPSS 20 бағдарламасы арқылы орындалды. Сапалық деректер үшін топтардағы айырмашылықтардың маңыздылығы Хи-квадрат (χ^2) тестін есептеу арқылы анықталды. Сандық деректер үшін нәтиже медиана және 25-75 перцентиль

ретінде көрсетілді. Айырмашылықтардың маңыздылығын есептеулер Манн-Уитни тестінің есебін қолдану арқылы жүргізілді.

Нәтижелер. Негізгі және бақылау топтарындағы пациенттердің эректильді функциясының статистикалық маңызды жақсаруы операциядан кейін 6 айдан соң анықталды ($\chi^2 = 115,356$; $p < 0,001$; $\chi^2 = 115,034$; $p < 0,001$ тиісінше). Сонымен қатар, негізгі зерттеу тобында көрсеткіштер бақылау тобымен статистикалық маңызды айырмашылықтарға ие болды. Барлық емделушілерде эректильді дисфункцияның субъективті белгілерінің екі есе төмендеуі байқалды, алайда негізгі зерттеу тобында бұл көрсеткіштердегі өзгерістер статистикалық тұрғыдан айтарлықтай айқын болды (3 айдан кейін $p=0,014$; 6 айдан кейін $p=0,007$).

Қорытынды. Қуықасты безінің қатерсіз гиперплазиясына операция жасалған науқастардың эректильді қызметіне қатысты қуық пен уретраны жуу арқылы 5-фторурацилді профилактикалық қолданудың жоғары тиімділігі анықталды.

Түйінді сөздер: қуық асты безінің қатерсіз гиперплазиясы, хирургия, 5-фторурацил, эректильді функция.

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Introduction

Benign prostatic hyperplasia (BPH) is the most common benign neoplasm in men over 40 years of age; it is diagnosed in approximately 8% of men in their fourth decade, 50% in those in their fifties, and in 90% of men over 80 years of age [12]. Normally, the prostate gland has a weight of 20-30 g. BPH is characterized by a change in the size of the prostate, as well as clinical symptoms from the lower urinary tract in the form of obstruction (feeling of incomplete emptying of the bladder, weak urine stream) or irritation (dysuria, strangury, frequent urination) [4]. BPH may be asymptomatic, respond to lifestyle changes, or require medication or surgery; the severity of symptoms has a direct correlation with age [8]. In addition to age, risk factors for BPH include obesity, type 2 diabetes, high alcohol consumption, and low physical activity [11, 16, 18].

Treatment for BPH includes both a medical approach and surgery. Indications for surgical treatment of BPH are the following: ineffectiveness of drug therapy, refractory urinary retention, recurrent urinary tract infection, persistent hematuria, the presence of bladder stones, and renal failure [10]. The most commonly performed surgical operation is transurethral resection of the prostate (TURP), which is considered the gold standard for the treatment of BPH. As part of the preoperative assessment, patients should be screened for urinary tract infection: if present, it should be treated prior to surgery. Potential complications of TURP include retrograde ejaculation, erectile dysfunction, hematuria, urethral stricture, and urinary tract infection. Approximately 5-10% of the patients who undergo TURP may need a second operation after 10 years [13]. Open adenectomy is usually performed in the case of a large (>100 cm³) hyperplastic prostate [4].

The development of urethral strictures may be the result of excessive traumatization of the mucosa during endoscopy of the bladder and the use of a resectoscope with the development of inflammatory reactions preceding surgical intervention of sclerotic changes in the wall of the urethra and the prostate itself due to the peculiarities of its morphological structure. These features include the presence of sclerotic processes and hyalinization of vessels in the prostate gland; it increases the risk of postoperative bleeding due to loss of elasticity and the ability of the vessel to hold blood clots that form under thermal exposure during surgery. This is also facilitated by the productive inflammation and granulation formations containing a large number of blood vessels, which increase the possibility of bleeding of the prostate bed after surgery [5, 9].

The prevalence of erectile dysfunction in BPH is 5.2-40%. Patients with this disease are 1.33-6.24 times more likely to have erectile dysfunction than those without it. In a study by Mexican scientists (2021), it was shown that in men at an average age of 65 years, erectile dysfunction against the background of BPH is 70.3%, while its severity ranges from mild to moderate [14]. After surgical treatment of BPH, improvement in erectile function has been registered for three months [15]. However, the development of urethral strictures, as one of the most common complications of transurethral resection of the prostate, is a risk factor for the development of postoperative erectile dysfunction [17].

In the world literature, there are a sufficient number of studies evaluating the effectiveness of the treatment of conditions associated with fibroblast proliferation (strictures, stenosis, keloid scars) using both surgical methods and various drugs, among which the most accepted is the

treatment with the use of local administration of corticosteroids (triamcinolone, methylprednisolone). However, in recent years, evidence has accumulated that up to 50% of such clinical situations are characterized by resistance to corticosteroid treatment [6], which necessitates the search for other drugs with antiproliferative activity. One of these drugs, which have recently attracted the attention of many researchers and practitioners, is 5-fluorouracil [1].

5-Fluorouracil is an antitumor analogue of pyrimidine that has an inhibitory effect on fibroblasts. One of the mechanisms of action of 5-fluorouracil may involve inhibition of type I collagen gene expression, which is induced by TGF- β (transforming growth factor beta, a protein representative of cytokines that controls proliferation and cell differentiation). Thus, the inhibition of excess collagen synthesis occurs similarly to the action of corticosteroids [3, 20].

The aim of our study is to evaluate the effectiveness of the prophylactic use of 5-fluorouracil against erectile dysfunction in patients undergoing surgery for BPH.

Materials and methods

This study included 246 male patients living in the East Kazakhstan region who underwent surgery for benign prostatic hyperplasia (BPH) in the urological departments of the Semey Renal Center and the Emergency hospital in 2020- 2022. Of the operated patients, 131 patients underwent transurethral resection of the prostate, 115 underwent open adenectomy.

Table 1 presents the socio-demographic characteristics of individuals who underwent surgical treatment for BPH. Most of the studied patients were in the age range over 60 years (82.1%) and had the status of a pensioner (80.1%); the average age of the study participants was 70.0 ± 8.0 years.

Table 1.

Socio-demographic characteristics of the patients included in the study.

Characteristics	Number	%
Age (years)	40-50	1 0.4%
	51-60	43 17.5%
	61-70	119 48.4%
	71-80	83 33.7%
Body mass index	> 25	77 31.3%
	25-30	120 48.8%
	>30	49 19.9%
Place of residence	City	187 76.0%
	Village	59 24.0%
Social status	worker	24 9.8%
	employee	9 3.7%
	pensioner	197 80.1%
	unemployed	4 1.6%
	disabled	1 0.4%
	others	11 4.5%
The presence of diabetes	Yes	38 15.44%
	No	208 84.56%

About a quarter of patients lived in rural areas and received a referral for surgical treatment from a doctor in district hospitals. Only 18.7% of patients were referred for treatment by outpatient urologists; approximately the same number of patients initially applied to the ambulance service; about a third of them received a referral from a general

practitioner after consulting by urologist. About 20% of patients were overweight or obese. Concomitant type 2 diabetes mellitus was diagnosed in 22 patients (17.7%) of the study group and in 16 patients (13.1%) of the control group.

The main study group included 124 patients who, in addition to the standard postoperative treatment in the hospital, received prophylactic intervention for five to ten days from the first day after surgery in the form of washing with a solution of 5-fluorouracil using a modified three-way catheter. The control group consisted of 122 patients matched by age, social status, place of residence and body mass index (BMI), who also underwent surgery for BPH. In the control group after surgery, standard treatment was carried out, including antibiotic therapy, hemostatic therapy, antispasmodics, analgesics, alpha-blockers, 5-alpha reductase inhibitors. In this group of patients, the bladder was washed with furacilin using a Foley catheter.

The utility model developed by us of a modified three-way Foley catheter (utility model patent No. 32 dated August 9, 2019) is used for bladder drainage followed by urethral lavage in the early and late postoperative period. This model is an improved model of a three-way Foley catheter [7], which has three channels: for the introduction of medicines and medicines, for excretion of urine, and for inflating the balloon. There are three holes at the distal end of the catheter. Two of them serve to remove urine, and the other one is for the administration of drugs.

To assess the severity of erectile dysfunction, we used the IIEF-5 questionnaire (International Index of Erectile Function) [19], which includes questions about how erectile dysfunction affected the patient's sexual life over the past four weeks. The survey was conducted 3 and 6 months after surgery. In addition, a survey of patients was conducted regarding the presence of retrograde ejaculation 3 and 6 months after surgical treatment.

The results of the study were analyzed using descriptive statistics methods. For categorical variables, data are given as absolute and relative numbers. For qualitative data, the significance of differences in groups was determined by calculating the Chi-square (χ^2) test. For quantitative data, given that the distribution was non-normal, the result was expressed as the median and 25-75 percentiles. Calculations of the significance of differences were made using the calculation of the Mann-Whitney test. The critical level of significance of differences in the groups was taken as $p < 0.05$. All statistical analysis procedures were performed using the SPSS 20 program.

Results and discussion

An analysis of the prevalence of erectile dysfunction, according to a survey, made it possible to judge that before surgery, erectile dysfunction occurred in more than a third of patients in both groups and did not have statistically significant differences in the study group and the control one (Table 2). Ten days after the operation, such disorders were found in the vast majority of cases in both groups, which is associated with damage to the nerve fibers of the pelvic plexus during surgery. Subsequently, the prevalence of erectile dysfunction in both groups progressively decreased, but remained higher than before surgery. At the same time, in the group receiving preventive intervention, the prevalence of erectile dysfunction was lower throughout the entire follow-up period ($\chi^2 = 6.07$; $p = 0.014$; $\chi^2 = 7.16$; $p = 0.007$ at 3 and 6 months, respectively).

Table 2.

Comparative characteristics of erection in individuals of the studied groups in dynamics before and after surgery.

Показатель		Studied groups				Statistical test of significance of differences	
		The main group		Control group			
		Number	%	Number	%	χ^2	p-value
Erectile dysfunction before surgery	Yes	43	34.7	52	42.6	1.64	0.201
	No	81	65.3	70	57.4		
Erectile dysfunction 10 days after surgery	Yes	110	88.7	113	92.6	1.11	0.292
	No	14	11.3	9	7.4		
Erectile dysfunction 3 months after surgery	Yes	80	64.5	96	78.7	6.07	0.014
	No	44	35.5	26	21.3		
Erectile dysfunction 6 months after surgery	Yes	48	38.7	68	55.7	7.16	0.007
	No	76	61.3	54	44.3		

To assess the severity of erectile dysfunction, we used the IIEF-5 questionnaire (International Index of Erectile Function) (Table 3). Before surgery, the median of this indicator in both study groups was approximately the same and was at the level of a moderately severe degree of erectile dysfunction ($p = 0.431$). 10 days after surgery, the index in both groups decreased and corresponded to a severe degree of erectile dysfunction; no statistically significant differences were found in the groups either. Statistically significant differences in the level of erectile disorders in the study groups appeared already 3 months after the operation; this trend continued until the end of the postoperative follow-up period. The severity of symptoms in the main study group was less pronounced and corresponded to moderate-mild and mild erectile

dysfunction after 3 and 6 months, respectively. In the control group, this indicator corresponded to a moderate and moderately mild degree of erectile dysfunction ($p < 0.05$; $p < 0.01$, respectively).

Ejaculation disorders in the studied patients of both groups were represented by retrograde ejaculation (a violation of the process of ejaculation, when the release of seminal fluid is carried out in the proximal direction into the bladder). Such impaired ejaculation before surgery could be associated with dysfunction of the bladder neck or with side effects of long-term use of alpha-blockers [2]. After surgery, retrograde ejaculation has been associated with adenectomy leading to the removal of the support for the seminal tubercle, the formation of urethral stricture, or the use of alpha-blockers [2].

Table 3.

Comparative characteristics of the severity of symptoms of erectile dysfunction in the study groups (international index of erectile function).

IIEF-5	Studied groups						Statistical test of significance of differences	
	The main group			The control group				
	Median	25th percentile	75th percentile	Median	25th percentile	75th percentile	U-test	p-value
Before surgery	7.5	6.1	8.9	7.8	6.3	7.9	906.0	0.431
10 days after surgery	6.1	4.8	8.2	6.2	4.9	8.1	987.1	0.356
3 months after surgery	7.9	6.8	9.1	7.3	5.9	8.3	897.0	0.05
6 months after surgery	12.8	8.1	14.9	10.9	7.3	12.5	806.5	0.01
Dynamics within the group	$\chi^2 = 115.356$; $p < 0.001$			$\chi^2 = 115.034$; $p < 0.001$				

Before the operation, there were no statistically significant differences in the study groups for this indicator. Three months after surgery, ejaculation disorders in the vast majority of patients in both study groups without significant differences depending on the preventive intervention. However, after six months of

follow-up, approximately 15% of patients in the main study group noted partial recovery of ejaculation, while in the group that did not receive preventive intervention, the proportion of such patients was significantly lower (about 5%) ($\chi^2 = 7.34$; $p = 0.007$) (Table 4).

Table 4.

Comparative characteristics of ejaculation in individuals of the studied groups in dynamics before and after surgery

Ejaculation disorder		Studied groups				Statistical test of significance of differences	
		The main group		The control group			
		Number	%	Number	%	χ^2	p-value
Before surgery	Yes	44	35.5	54	44.3	1.977	0.160
	No	80	64.5	68	55.7		
3 months after surgery	Yes	115	92.7	116	95.1	0.588	0.443
	No	9	7.3	6	4.9		
3 months after surgery	Yes	96	77.4	110	90.2	7.336	0.007
	No	28	22.6	12	9.8		

Conclusion

The results of our study indicate that before surgery, 34.7% of patients with BPH in the main group and 42.6% of the control group had symptoms of erectile dysfunction. The differences were not statistically significant. According to the assessment of the international index of erectile function, we can judge a statistically significant improvement in the erectile function of patients in both the main and control groups after surgery for 6 months ($\chi^2 = 115.356$; $p < 0.001$; $\chi^2 = 115.034$; $p < 0.001$, respectively). In the main study group, the rates had statistically significant differences with the control group ($p < 0.05$ 3 months; $p < 0.001$ 6 months after surgical treatment). A survey about the presence of symptoms of erectile dysfunction demonstrates an almost two-fold decrease in subjective symptoms of erectile dysfunction both in the main study group and in the control group after surgery. However, in the main study group, changes in these rates were statistically significantly more pronounced ($p = 0.014$ after 3 months; $p = 0.007$ six months after the intervention). There was also a significant decrease in ejaculation disorders in the main group compared to the control group six months after the operation ($p = 0.007$). These data allow us to conclude that the prophylactic use of 5-fluorouracil by irrigation of the bladder and urethra is highly effective in terms of erectile function in patients undergoing surgery for benign prostatic hyperplasia.

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