IMPACT OF CHARLSON COMORBIDITY INDEX ON POSTOPERATIVE COMPLICATIONS IN ELDERLY PATIENTS WITH HIGH-RISK PROSTATE CANCER

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ABSTRACT

Relevance: *The broad experience accumulated to date in performing radical prostatectomy (RPE) in high-risk patients has significantly reduced the frequency of perioperative complications. Studies that evaluate risk factors and scales to estimate the probability of complications for patients over 70 years are important.*

The study aimed to *determine the safety criteria for performing RPE in patients over 70 years of age with high-risk prostate cancer.*

Methods: *A total of 163 patients who underwent open RPE for high-risk prostate cancer from September 2018 and July 2021 were included in the study. The risk of postoperative complications was calculated using the Charlson Comorbidity Index (CCI). Complications of the postoperative period (90 days from the date of surgical intervention) were evaluated according to the Clavien-Dindo classification. The correlation between the indicators of CCI and postoperative complications was performed.*

Results: *All patients were divided into 2 groups by CCI equal to 2.5. The statistical analysis directly correlated this value with Grade I-II complications ($\chi2=13.610$; $p<0.001$). The most significant correlation revealed during the multifactorial logistic regression analysis of preoperative parameters was established between diabetes mellitus and the incidence of postoperative infectious complications (HR – 2.84; 95% CI: 2.59-3.12; $p<0.001$).*

Conclusion: *The expediency of using CCI to identify a group of patients with a high probability of complications was emphasized. Comprehensive assessment of perioperative risk, chronological age as an isolated factor is not a contraindication for surgical treatment of prostate cancer in men over 70 years of age.*

Keywords: *prostate cancer, radical prostatectomy, comorbidity, Charlson Comorbidity Index (CCI), catheter-associated urinary tract infection, perioperative complications, Clavien-Dindo classification.*

Introduction: The broad experience accumulated to date in performing radical prostatectomy (RPE) in high-risk patients has significantly reduced the frequency of perioperative complications, which, along with satisfactory long-term therapy, results in low local progression and the likelihood of metastasis in prostate cancer makes surgery a successful and widely used method of treating this pathology [1].

However, the problem of choosing surgical tactics among elderly patients (over 70 years old), who, according to various sources, account for up to 50% of patients operated on for prostate cancer, remains unresolved. This issue is particularly acute in patients with a high probability of disease progression. On the one hand, increasing the predicted life expectancy in the male population requires a more radical approach from specialists. On the other hand, age, the presence of concomitant diseases, and, accordingly, the risk of perioperative complications may push the surgical intervention into the background.

Several evaluation scales and indices capable of predicting the development of postoperative complications have been developed and are actively used. Despite the lack of consensus on their reliability and effectiveness, the Charlson Comorbidity Index (CCI) today is the most common [2].

The study aimed to determine the safety criteria for performing RPE in patients over 70 years of age with high-risk prostate cancer.

Materials and Methods: A total of 163 patients who underwent open RPE for high-risk prostate cancer between September 2018 and July 2021 were included in the study. Patients with a previous history of prostate surgery or receiving neoadjuvant therapy were excluded from the study. The mean patient age was 66.2±2.1 (54-76) years, and the mean prostate-specific antigen (PSA) level at biopsy was 13.8±4.2 ng/dl (3.6-46.4). All patients underwent radical prostatectomy with extended pelvic lymphadenectomy. Surgical interventions were performed by one surgical team.

All patients were divided into two groups according to age. Group I comprised 91 (55.9%) patients below 70, while Group II included 72 (44.1%) patients over 70 years.

During the preoperative examination, the following concomitant diseases were identified: chronic coronary heart disease in 11 (6.7%) patients, history of previous myocardial infarction in 8 (4.9%) patients, type 2 diabetes mellitus in 22 (13.5%) patients and chronic obstructive pulmonary disease (COPD) in 7 (4.3%) patients. In some cases, a combination of two or more concomitant pathologies was noted in the same patient. Thus, in 5 (3.1%) cases, a history of diabetes mellitus and a previous myocardial infarction were noted. Chronic coronary heart disease as the second concomitant pathology was observed in 11 (6.7%) patients. Patients with concomitant cardiovascular diseases were examined following the recommendations of the European Society of Cardiology and the European Association of Anesthesiologists (ESC/ESA) [3]. One hundred

twenty-one (74.2%) patients did not have any concomitant diseases, of which 75 (82.4%) patients were included in Group I and 46 (63.9%) – in Group II.

The preoperative physical status of all patients was assessed according to the American Society of Anesthesiologists (ASA) classification by a multidisciplinary team. In some cases, the decision on the possibility of surgical intervention was made after the prescribed therapy.

The Charlson Comorbidity Index was developed in 1987 by Charlson and colleagues to classify comorbid conditions that may influence mortality risk [4]. In our study, the high risk of progression and the likelihood of local prevalence of the process of the presence of cancer were taken into account as risk factors.

Complications of the postoperative period (90 days from the date of surgical intervention) were evaluated according to the Clavien-Dindo classification, initiated in 1992 and updated in subsequent years [5]. All complications were evaluated as «minor» (Grade I-II) and «major» (Grade III-IV). Complications associated with Grade V were not included in the study.

The diagnosis and treatment of catheter-associated urinary tract infections (CAUTI) that occurred in several patients were performed following the standards of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) and Central Disease of Control/ National Healthcare Safety Network (CDC/NHSN) [6]. While in the hospital, all patients were prevented from thromboembolic complications according to generally accepted protocols.

In order to carry out statistical processing, all data on patients and postoperative complications that occurred within 90 days after RPE were entered into the database. Statistical analysis of the results was performed using SPSS 18.0 for Windows software block (SPSS Inc, Chicago, IL, US). The correlation between the CCI value and postoperative complications was analyzed with the calculation of the Pearson coefficient χ . Differences with a significance level of 95 were considered statistically significant ($p<0,05$).

Results: The characteristics of patients in the preoperative period are presented in Table 1. The average age of patients in groups I and II was 62.7±0.4 (54-70) and 71.8±0.2 (71-76) years, respectively ($p<0.001$).

Table 1 – Characteristics of patients in the preoperative period by age groups

Parameters	Group I	Group II	P
PSA*, ng/ml	20,9±0,9 (8,74-49,3)	22,4±0,6 (9,67-32,1)	0.178
Prostate volume, ml	56,8±3,9 (20-155)	48,9±3,8 (25-113)	0.159
BMI**, kg/m²	28,2 (25,5-32,7)	26,3 (24,3-35,1)	0.078
ASA*** classification			0.124
ASA I	10,3%	7,1%	
ASA II	73,3%	71,7%	
ASA III	16,4%	21,2%	
CCI****	2,1±0,05 (2-4)	2,5±0,07 (2-4)	0.012
Gleason score (biopsy)			0.010
6	55 (60,4%)	23 (31,9%)	
7	27 (29,7%)	42 (58,3%)	
≥8	9 (9,9%)	7 (9,7%)	
Clinical stage, T			0.142
2a	1 (1,1%)	6 (8,3%)	
2b	14 (15,4%)	12 (16,7%)	
2c	20 (22,0%)	12 (16,7%)	
3a	30 (33,0%)	27 (37,5%)	
3b	26 (28,6%)	(20,8%)	

Notes: *PSA – Prostate specific antigen; **BMI – Body mass index; *** ASA – American Society of Anesthesiologists; **** CCI – Charlson Comorbidity Index

The above data shows no significant differences between the study groups concerning the total PSA index ($p=0.178$). However, a significant difference between the compared groups was revealed in the Gleason score ($p=0.010$). Patients in Group I had a higher BMI compared to Group II. However, this difference had no statistically significant confirmation ($p=0,078$).

The postoperative complications were diagnosed in 56 (34.3%) patients. In 52 (31.9%) cases, complications were classified as Grade III according to the Clavien-Dindo classification, and Grade III-IV complications were noted in 4 (2.4%) patients. In 23 (14.1%) cases, one patient had two or three complications at a time.

The main complication graded as I-II was lymphorrhea, diagnosed in 16 (9.8%) patients. Five patients underwent percutaneous lymphocele drainage, regarded as a Grade III-IV complication.

Other complications associated with Grade I-II were urethrovesical anastomosis leakage, hematuria, pneumonia, and lower extremity deep vein thrombosis. They were diagnosed in 6 (3.7%), 7 (4.3%), 4 (2.5%) and 3 (1.8%) patients respectively. In 15 (9.2%) patients in the postoperative period, the presence of CAUTI was diagnosed.

Acute coronary syndrome developed in 5 (3.1%), gastrointestinal bleeding - in 1 (0.6%) and hemorrhagic stroke – in 2 (1.2%) patients. These patients required continued treatment in the intensive care unit.

The performed correlation analysis between Grade I-II complications and age groups did not demonstrate a significant relationship ($\chi^2=0.472$; $p=0.492$). A similar analysis for Grade III-IV complications also revealed no significant correlation ($\chi2=1,050$; $p=0.306$).

In the next stage, all patients were divided into 2 groups by CCI index equal to 2.5. The statistical analysis di-

rectly correlated this value with Grade I-II complications ($\chi 2 = 13.610$; *p<0.001*).

Similar results were obtained compared to Grade III-IV complications ($\chi 2 = 12.515$; *p<0.001*). Moreover, the most significant correlation revealed during the multifactorial logistic regression analysis of preoperative parameters was established between diabetes mellitus and the incidence of postoperative infectious complications (HR 2.84; 95% CI, 2.59-3.12; *p <0.001*).

Discussion: Demographic changes in populations over 65 years require a review of the decision-making process for the treatment of many diseases, including prostate cancer in elderly patients. Until recently, the age over 70 years was considered a relative limitation for the implementation of RPE due to the generally low life expectancy of patients of this age group and, accordingly, the lack of advantages of such aggressive therapy as well as high rates of complications and mortality, today the issue of treatment of elderly patients with this pathology requires a radical revision.

The introduction into clinical practice of modern diagnosis and preoperative preparation methods At the same time, a high risk of postoperative complications tasks the surgeon to ensure the expediency of surgical intervention and determine the type of surgery considering risk factors such as age, cardiovascular, respiratory, endocrine and other concomitant diseases.

One of the most valuable studies was performed by Begg and colleagues, where the authors analyzed the rates of postoperative and late urinary complications in men undergoing prostatectomy. In the structure of complications of the early postoperative period among elderly patients, cardiac (5.5%), respiratory (11%), vascular (4.7%), surgical (6.6%), and infectious complications (0.8-2%) should be distinguished, as well as an increase in the 30-day mortality rate. The frequency of complications increases in proportion to the age of patients. The incidence of at least one complication among patients subjected to RPE aged 65-69, 70-74, and over 75 years was 28%, 31% and 35%, respectively [7]. The authors emphasized that the rate of complications is significantly reduced if the procedure is performed in a high-volume hospital and by a surgeon who performs a high number of such procedures.

At the same time, the question of the «leading» role in the development of postoperative complications of risk factors such as age or the presence of concomitant diseases is still debatable. A limited number of papers have been published on the study of the role of concomitant diseases in the development of perioperative complications in patients undergoing RPE, and they all differ according to the principle of distribution of patients according to age groups, by the number and types of concomitant pathologies accepted for consideration.

In order to determine the risk factors for the development of postoperative complications in the studied cohort of patients, we conducted a study of 163 patients who underwent RPE in connection with prostate cancer and also performed a correlation analysis of the following factors as age, preoperative morbidity (CCI) and the severity of early postoperative complications (Clavien-Dindo classification). The structure of early postoperative complications is presented as follows:

complications directly associated with surgery, neurological, cardiorespiratory, and infectious complications.

Lymphocele development should be highlighted among postoperative surgical complications. The development of this complication is associated with extended pelvic lymphadenectomy and undoubtedly increases the duration of hospitalization, which, in turn, is an unfavorable risk factor for developing nosocomial infection.

In our study, lymphorrhea was diagnosed in 16 (9.8%) patients. It is noteworthy that prolonged lymphorrhea was diagnosed in 10 patients in Group I and 6 patients in Group II. This complication has been classified as a Grade III complication. Subsequently, 5 (31.3%) patients needed percutaneous drainage of the formed lymphocele. Three of these patients belonged to Group II.

Routine microbiological urine analysis on Day 7 after surgery revealed a positive result in 21 (12.9%) of 163 patients. However, in 9 cases, the uropathogen was detected in a concentration not exceeding 10^5 CFU/ml. This condition meets the criteria of asymptomatic CAUTI and does not require antibacterial therapy. In 12 patients, the diagnosis of symptomatic CAUTI was made along with the clinical condition and the positive urine culture ($\geq 10^5$ CFU/ml). During microbiological examination of urine, the following uropathogens were isolated as a monoculture in 12 patients: *E.coli* (4 cases), *Klebsiella pneumonia* (3 cases), *Pseudomonas aeruginosa* (1 case) and *Staph. epidermidis* (1 case). In other cases, the infection was polymicrobial. All cases of postoperative UTI developed without it in the preoperative period. It should be noted that 7 patients in this group suffered from diabetes mellitus. The leakage of ureterovesical anastomosis was diagnosed in 2 patients; one of them had hematuria, which required irrigation of the bladder and prolongation of bladder catheterization. The remaining patients were bacteriologically negative.

As stated above, the duration of urine catheter use is the main risk factor for developing CAUTI and bacteriuria. In our study, the leakage of urethrovesical anastomosis in the early postoperative period in 11 (6.7%) patients required a prolongation of bladder catheterization. Bacteriuria was diagnosed in 5 (45.5%) of 11 patients. Two of them belonged to Group I of the study.

In the remaining patients, the results of microbiological analyses were negative (no growth was detected), *and Candida albicans with CFU of* less than 1000 were isolated in three cases. This group of patients was not treated.

Nosocomial pneumonia is the second most common hospital infection after urinary tract infections. According to various studies, the risk of developing nosocomial pneumonia ranges from 0.3 to 20% or higher, depending on the department's profile, the epidemiological situation in the medical institution, and patients' clinical and individual characteristics. In intensive care units, nosocomial pneumonia accounts for 27-47% of the total number of infectious complications, and mortality is equal to 30-70%. Risk factors for the occurrence of hospital-acquired pneumonia are pulmonary diseases, including COPD, age (over 60 years), smoking, obesity, the nature and duration of surgery and anesthesia [8].

In our study, the incidence of nosocomial pneumonia was 2.5%. Two of the 4 patients belonged to Group II. COPD was diagnosed in one patient from Group II; the other was diagnosed with diabetes mellitus. In Group I, one

patient had a history of COPD, while the other had no concomitant diseases. Therapy and dynamic control of pneumonia followed the generally accepted clinical recommendations, considering the findings of physical examination, radiology, and laboratory tests [9].

In five patients, the early postoperative period was complicated by the development of acute coronary syndrome; one of the patients was subsequently diagnosed with myocardial infarction. Hemorrhagic stroke was diagnosed in one patient. The patients were transferred to the intensive care unit and discharged from the hospital on Days 13 and 18, respectively.

In order to calculate the probability of postoperative complications, specialists have proposed several tests and scales, but there is no consensus on their prognostic significance. In addition, the role of the age factor is still debatable. Even though age is closely associated with high rates of complications in the early postoperative period, we suggested that age alone is not a contraindication to surgical intervention in patients with high-risk prostate cancer.

In several studies comparing the prognostic role of age and CCI in the development of postoperative complications and an increase in mortality rates, CCI was identified as a more significant predictor of an increase in morbidity and mortality than age [10].

Similar data was obtained in our study. We found no differences in the frequency of complications in the early postoperative period between the two age groups. However, higher CCI was an independent risk factor for complications. This highlights the potential value of CCI in risk stratification for patients undergoing surgery for prostate cancer. At the same time, it should be noted that type 2 diabetes mellitus was established as a main risk factor for infectious complications in the early postoperative period (HR 2.84; 95% CI, 2.59–3.12; $p < 0,001$).

CCI can be used with a greater degree of reliability to calculate the risk of postoperative complications in prostate surgery and accordingly be used as an argument when deciding whether surgery is necessary. Undoubtedly, patients over 70 years of age, having a higher risk of perioperative complications, with a satisfactory physical status and the absence of concomitant diseases, have every chance to undergo surgery well. However, in the presence of at least one of the concomitant diseases listed in CCI, the risk of postoperative complications increases significantly. Persons under 70 years of age who have one or more of the concomitant diseases indicated in the CCI index may also have a high probability of developing complications.

Thus, in the treatment of prostate cancer in patients with a high CCI index, it is mandatory to conduct evaluation tests in the preoperative period, discuss their results, and, accordingly, determine the prognosis of the course of the next postoperative period.

Conclusion: The obtained results did not demonstrate a correlation between age and the development of complications in the 90-day postoperative period. The expediency of using CCI to identify a group of patients with a high probability of complications was emphasized. High rates were independent risk factors for complications, which underlines the potential usefulness of this scale in risk stratification. Thus, subject to a comprehensive assessment of perioperative risk, chronological age as an isolated factor is not a contraindication to radical surgical treatment of prostate cancer in men over 70 years of age.

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АҢДАТПА

ҚУЫҚ АСТЫ БЕЗІНІҢ ҚАТЕРЛІ ІСІГІ БАР ЕГДЕ ЖАСТАҒЫ ЕМДЕЛУШІЛЕРДЕ ОПЕРАЦИЯДАН КЕЙІНГІ АСҚЫНУЛАРҒА ЧАРЛЬСОН ІЛЕСПЕЛІ АУРУЛАР ИНДЕКСІНІҢ ӘСЕРІ

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Өзектілігі: Бүгінгі күні тәуекел дәрежесі жоғары емделушілерде радикалды простатэктомияны (РП) жүргізудің мол тәжірибесі операциядан кейінгі асқынулардың жиілігін айтарлықтай төмендетті. 70 жастан асқан науқастарда асқынулардың ықтималдығын бағалау үшін қауіп факторларын және ұпайларды бағалайтын зерттеулер маңызды.

Зерттеудің мақсаты *қуық асты безінің қатерлі ісігімен ауыратын 70 жастан асқан емделушілерде ЖП жүргізудің қауіпсіздік критерийлерін анықтау болды.*

Әдістері: *Зерттеуге 2018 жылдың қыркүйегінен 2021 жылдың шілдесіне дейін жоғары қауіпті қуық асты безінің қатерлі ісігі бойынша ашық РП өткен 163 пациент қамтылды. Операциядан кейінгі асқынулардың қаупі Чарльсонның қатар жүретін ауру индексі (CCI) көмегімен есептелді. Операциядан кейінгі кезеңдегі асқынулар (операция жасалған күннен бастап 90 күн) Клавиен-Диндо классификациясы бойынша бағаланды. CCI ұпайлары мен операциядан кейінгі асқынулар арасында корреляция анықталды.*

Нәтижелері: *Барлық науқастар СКИ 2,5 коэффициенті бойынша 2 топқа бөлінді. Статистикалық талдау бұл мәнді I-II дәрежелі асқынулармен тікелей байланыстырды (χ2=13,610; p<0,001). Операция алдындағы параметрлердің көп нұсқалы логистикалық регрессиялық талдауы арқылы анықталған ең маңызды корреляция қант диабеті мен операциядан кейінгі инфекциялық асқынулардың жиілігі арасында анықталды (OR – 2,84; 95% CI: 2,59-3,12; p<0,001).*

Қорытынды: *Асқыну ықтималдығы жоғары пациенттер тобын анықтау үшін CCI қолданудың орындылығына баса назар аударылады. Операциядан кейінгі қауіпті кешенді бағалау, оқшауланған фактор ретінде хронологиялық жас 70 жастан асқан ерлерде простата обырын хирургиялық емдеуге қарсы көрсетілім болып табылмайды.*

Түйінді сөздер: *қуық асты безінің қатерлі ісігі, радикалды простатэктомия (РП), ілеспелі ауру, Чарльсон ілеспелі ауру индексі (CCI), катетермен байланысты зәр шығару жолдарының инфекциясы, операциядан кейінгі асқынулар, Клавиен-Диндо классификациясы.*

ВЛИЯНИЕ ИНДЕКСА КОМОРБИДНОСТИ ЧАРЛСОНА НА ПОСЛЕОПЕРАЦИОННЫЕ ОСЛОЖНЕНИЯ У ПОЖИЛЫХ ПАЦИЕНТОВ С РАКОМ ПРЕДСТАТЕЛЬНОЙ ЖЕЛЕЗЫ ВЫСОКОГО РИСКА

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Актуальность: *К настоящему времени накопленный богатый опыт выполнения радикальной простатэктомии (РПЭ) у пациентов высокого риска позволил существенно снизить частоту периоперационных осложнений. Важны исследования, оценивающие факторы риска и шкалы для оценки вероятности осложнений у пациентов старше 70 лет.*

Целью *исследования было определение критериев безопасности выполнения РПЭ у пациентов старше 70 лет с раком предстательной железы высокого риска.*

Методы: *в исследование были включены 163 пациента, перенесших открытую РПЭ по поводу рака предстательной железы высокого риска с сентября 2018 г. по июль 2021 г. Риск послеоперационных осложнений рассчитывали с помощью индекса коморбидности Чарлсона (CCI). Осложнения послеоперационного периода (90 дней от даты оперативного вмешательства) оценивали по классификации Clavien-Dindo. Выявлена корреляция между показателями CCI и послеоперационными осложнениями.*

Результаты: *Все пациенты были разделены на 2 группы по коэффициенту CCI, равному 2,5. Статистический анализ напрямую коррелировал это значение с осложнениями I-II степени (χ2=13,610; p<0,001). Наиболее значимая корреляция, выявленная при многофакторном логистическом регрессионном анализе предоперационных показателей, установлена между сахарным диабетом и частотой послеоперационных инфекционных осложнений (ОР – 2,84; 95% ДИ: 2,59-3,12; p<0,001).*

Заключение: *Подчеркнута целесообразность использования CCI для выявления группы пациентов с высокой вероятностью осложнений. Комплексная оценка периоперационного риска, хронологический возраст как изолированный фактор не является противопоказанием к хирургическому лечению рака предстательной железы у мужчин старше 70 лет.*

Ключевые слова: *рак предстательной железы, радикальная простатэктомия (РПЭ), коморбидность, индекс коморбидности Чарлсона (CCI), катетер-ассоциированная инфекция мочевыводящих путей, периоперационные осложнения, классификация Clavien-Dindo.*

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