



# Analysis of Complications Development Predictors after Radical Prostatectomy

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#### Abstract

**BACKGROUND:** The standard treatment for prostate cancer is radical prostatectomy (RP). This surgical technique results in typical complications such as intraoperative blood loss, urethral strictures (vesicourethral anastomosis), urinary incontinence, erectile dysfunction, lymphocele, and the ureter or rectum injury.

AIM: The study aims to analyze the development of complications after RP.

**MATERIALS AND METHODS:** The article presents a retrospective analysis of clinical cases with an established diagnosis of prostate cancer from 2012 to 2018 in Irkutsk, Russian Federation. During this period, 52 patients met the study criteria. A multivariate analysis established Non-Nerve-sparing retropubic RP (RRP) (odds ratio [OR]–0.9; 95% confidence interval [CI]–1.9; –0.07; p = 0.035) as a significant incontinence predictor after 2 years.

**RESULTS:** Multivariate analysis also established previous transurethral operations as a significant predictor of the vesicourethral anastomosis stricture (OR 6.09; 95% CI 0.71; 11.4; p = 0.026), which indicates a 6 times risk of developing a vesicourethral anastomosis stricture if the patient already had one or more transurethral surgery. Obesity (OR 0.12; 95% CI 0.03; 0.21; p = 0.008), diabetes (OR 2.3; 95% CI 0.45; 4.2; p = 0.015) and coagulopathy (OR 3.1; 95% CI 0.5; 5.7; p = 0.019) became independent predictors of lymphocele development.

Funding: This research did not receive any financial support Competing Interests: The authors have declared that no competing interests exist Open Access: This is an open-access article distributed

Edited by: Ksenija Bogoeva-Kostovska Citation: Vorobev V, Beloborodov V, Luchkevich V, Shmakov D, Baklanova O, Sidorov S, Sharakshinov B.

Analysis of Complications Development Predictors after

CopenAccess Maced JMed Sci. 2021 Nov2; (§): 1575-1579. https://doi.org/10.3889/oamjms.2021.7165 Keywords: Lymphocele; Prostatectomy; Prostate cancer; Urethral stricture; Urinary incontinence

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Jniversity, Irkutsk, Russian Federation. E-mail: vorobevlaaad@rambler.ru Received: 27-Aug-2021 Revised: 16-Sep-2021 Accepted: 12-Nov-2021 Copyright: © 2021 Vladimir Vorobey.

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Radical Prostatectomy

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under the terms of the Creative Commons Attribution-NonCommercial 4.0 International License (CC BY-NC 4.0) **CONCLUSIONS:** The study revealed some new information on the possible predictors of such complications as urinary incontinence in the late period, the lymphocele, and stricture of the vesicourethral anastomosis. Some of the results require further study and confirmation.

# Introduction

Prostate cancer is the second most common malignant men's disease. The incidence varies widely, from 1.5 in Nepal to 115 in Australia (per 100,000 population), with the inverse mortality ratio – from 0.1 in Australia to 0.8 in Nepal (per 100,000 population) [1].

According to GLOBOCAN 2018, there were 1.3 million new cases of prostate cancer worldwide, 449.8 thousand in Europe, 297.2 thousand in Asia, and 234.3 thousand in North America. According to the WHO, in 2018, prostate cancer among men with malignant neoplasms took 2<sup>nd</sup> place (after lung cancer), and its share was 13.5%. The number of patients with prostate cancer in the world who have been registered for 5 years has reached 3.7 million people (96.7/100 thousand population) [2], [3].

Among the male population of the Russian Federation, the incidence of malignant neoplasms in 2018 such as prostate cancer was 14.9% (2009–10.7%),

42,518 of new cases of prostate cancer for the  $1^{st}$  time. The incidence rate of prostate cancer is 62.43/100 thousand population. The increase in incidence from 2009 to 2018 reached 62.53% with an average annual growth rate of 5.92% [4].

Mortality rates are also alarming. In 2018, 13,007 people died from prostate cancer in Russia, which is 30.45% more than in 2009 (9971). Over 10 years (from 2009 to 2018), the increase in the mortality rate was 6.51% [5]. The standard treatment for prostate cancer is radical prostatectomy (RP) [6]. The cancer-specific 10-year survival rate for localized cancers after RP is 99% [7].

This surgical technique leads to typical complications such as intraoperative blood loss, urethral strictures (vesicourethral anastomosis), urinary incontinence, erectile dysfunction, lymphocele, and the ureter or rectum injury [8]. Currently, there are no convincing data on the difference in the complications' development after classical open retropubic RP (RRP) and robotic-assisted

laparoscopic prostatectomy (RALP) RP [9], [10]. RRP has an 80–97% chance of urinary retention maintaining 1 year after surgery, compared with an 89–100% chance after RALP. A prospective multicenter study predicts a risk ratio of urinary incontinence 1 year after treatment at 1.08 (95% confidence interval [CI]: 0.87–1.34), and odds ratio (OR) of 0.81 (95% CI: 0.66–0.98) for erectile dysfunction, regardless of technique (RALP vs. RRP) [11].

The lymphocele development is most likely after an extended lymph node dissection (10.3%) compared to a limited dissection (4.6%) [12], especially after applying an extraperitoneal approach [13]. The study aims to analyze the complications' development after RP.

# **Materials and Methods**

The local ethical committees of (BLINDED) and (BLINDED) approved the clinical trial. The retrospective study took place at the surgical department of the (BLINDED). The clinical part of the study includes an analysis of the surgical treatment results of patients with an established diagnosis of prostate cancer for 2012–2018.

The inclusion criteria for the study were:

- The confirmed diagnosis of prostate cancer
- The patient underwent radical retropubic prostatectomy
- Multi-slice spiral computed tomography (MSCT) or magnetic resonance imaging (MRI) of the small pelvis and prostate biopsy verified the diagnosis before surgery
- The patient is over 18 years old
- Histological type is adenocarcinoma of the prostate.

Non-inclusion criteria:

- Neoadjuvant and adjuvant treatments
- Positive surgical margin
- Patients with distant metastasis of prostate cancer
- Changes in the surgical team.

Due to various reasons, the patient did not fulfill the examination and treatment standard or underwent another operation that did not meet the criteria of the group.

#### Study group characteristics

The study presents a retrospective analysis of clinical cases with an established diagnosis of prostate cancer from 2012 to 2018. During this period, 52 patients met the study criteria.

# Analysis/diagnostic and treatment methods

The obligatory examination included the patients' complaints and anamnesis, an objective examination, clinical blood and urine tests, a biochemical blood test, coagulogram indices, the electrolyte blood composition analysis, X-ray and ultrasound of the abdominal cavity organs and genitourinary system, MSCT or MRI of the genitourinary system, chest, abdominal cavity, and pelvic organs, skeletal bone scintigraphy.

Surgical treatment included radical retropubic prostatectomy with preservation of the neurovascular bundle (unilateral or bilateral preservation) in localized forms; in all cases, there was extended lymph node dissection. A team of two urologists performed surgical operations. The surgical technique is standard; the vesicourethral anastomosis had six separate interrupted sutures with 3-0 monocril.

#### Data analysis

The authors used STATISTICA for Windows 10.0 (Statsoft, Inc, USA), Statistical Package for the Social Sciences Statistics 23.0 (IBM, USA), and Stata 14.2 (StataCorp, USA) to analyze the initial data and surgical treatment results.

#### Preoperative parameters

The average age of the patients was  $64.2 \pm 5.49$  years. The median age of disease detection was one (0.5; 2) month. Tables 1 and 2 present the patients' preoperative parameters.

#### Table 1: Staging of prostate cancer

Disease stage on TNM	n = 52	%
T1N×Mo	8	15.3
T2NxMo	31	59.6
T3aNxMo	4	7.6
T3bNxMo	9	17.3
Total points on the Gleason scale	n = 52	%
6 and less	25	48.0
7	18	34.6
8 and more	9	17.3

#### Postoperative period

After surgical treatment, all patients stayed in the intensive care unit for 12 h. On the 12<sup>th</sup> day after surgery, we removed the urethral catheter. 2 years after surgical treatment, we assessed long-term results.

#### Ethics approval

The research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. The research was approved by the local ethics committees of (BLINDED). Informed consent was signed by participants.

Table 2: Preoperative parameters of patients in comparison groups

Parameter	(n = 52)
Height, cm	172.7 ± 5.8
Weight, kg	80.0 ± 11.9
Smoking, n (%)	3 (5.7)
Myocardial infarction, n (%)	1 (1.9)
Stroke, n (%)	1 (1.9)
Vascular atherosclerosis, n (%)	12 (23)
Heart rhythm disturbances, n (%)	4 (7.6)
Hypertension, n (%)	25 (48)
Diabetes, n (%)	7 (13.4)
Urolithiasis, n (%)	7 (13.4)
Chronic urinary tract infections, n (%)	9 (17.3)
Nephroptosis, n (%)	2 (3.8)
Chronic kidney disease, n (%)	3 (5.7)
Kidney cysts, n (%)	11 (21.1)
Kidney cancer, n (%)	1 (1.9)
Varicose veins of the pelvis, n (%)	1 (1.9)
Pelvic venous congestion, n (%)	3 (5.7)
Erythrocytosis, n (%)	1 (1.9)
Erythropenia, n (%)	2 (3.8)
Anemia, n (%)	16 (30.7)
Leukocytosis, n (%)	5 (9.6)
Coagulopathy, n (%)	3 (5.7)
Proteinuria, n (%)	18 (34.6)
Leukocyturia, n (%)	8 (15.3)
Hematuria, n (%)	17 (32.6)
Hyperglycemia, n (%)	13 (25)
Uremia, n (%)	4 (7.6)
Hyponatremia, n (%)	1 (1.9)
Hypernatremia, n (%)	1 (1.9)

## Results

Complication

More than 1000 ml of blood loss

Multivariate Logit Regression:  $\gamma^2 = 7.25$ ; p < 0.026

#### Treatment results

The median period of postoperative follow-up was 48 (36; 60) years. All 52 (100%) patients recovered. During the observation period, there was no cancerspecific mortality among the patients included in the study. There were also no signs of the disease relapse. The average duration of the surgical operation was 177 ± 40 min, the volume of intraoperative blood loss was 1000 (550; 1600) ml, with a minimum of zero and a maximum of 2000 ml.

Twelve patients had intraoperative periprostatic fibrosis (23%). The intraoperative ureteral injury

Table 3: Predictors of complications after RP

Hyperglycemia	4.3	-1.5(-3.1; 0.8)	0.063
More than 3 h of operation	2.14	0.8(-0.2; 1.9)	0.147
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	Hyperglycemia	4.3	-1.5(-3.1; 0.8)	0.063	-1.5(-3.1; 0.15)	0.076
	More than 3 h of operation	2.14	0.8(-0.2; 1.9)	0.147	-	-
	Periprostatic fibrosis	2.55	1.0(-0.2; 2.3)	0.114	-	-
Urinary incontinence after 24 months Multivariate Logit Regression:	Height over 175 cm	1.18	-0.06(-0.19; 0.05)	0.291	-	-
χ <sup>2</sup> = 14.24; p < 0.006	Obesity	1.88	-0.04(-0.11; 0.02)	0.199	-0.08(-0.18; 0.1)	0.080
	Vascular atherosclerosis	1.38	-1.1 (-3.3; 1.01)	0.296	-	-
	Hypertonic disease	4.16	-1.5(-3.2; 0.08)	0.063	-1.1(-3.0; 0.64)	0.203
	Hyperglycemia	1.73	-1.2(-3.4; 0.89)	0.248	-	-
	Non-Nerve-sparing RRP	5.14	-0.7(-1.4; 0.02)	0.050	-0.9(-1.9; -0.07)	0.035
	More than 3 h of operation	1.35	0.009(-0.006; 0.02)	0.241	-	-
	Blood loss of more than 1000 ml	2.37	1.09(-0.31; 2.5)	0.129	0.001(-0.0002; 0.002)	0.74
Vesicourethral anastomosis strictures	Obesity	1.87	-0.06(-0.16; 0.03)	0.213	-0.05(-0.2; 0.12)	0.534
Multivariate Logit Regression: $\chi^2$ = 19.09; p < 0.0008	Previous transurethral surgery	13.77	4.0 (1.5; 6.5)	0.001	6.09 (0.71; 11.4)	0.026
	Chronic cystitis	2.5	1.7 (-0.2; 3.7)	0.094	-0.01(-4.0; 4.0)	0.995
	Operating blood loss>300 ml	1.98	-0.001(small diap)	0.191	-0.002(-0.006; 0.001)	0.162
Lymphocele	Height over 180 cm	3.99	0.15(-0.007; 0.31)	0.061		
Multivariate Logit Regression: $\chi^2$ = 17.56; p < 0.0006	Obesity	10.21	0.12 (0.03; 0.21)	0.008		
	Diabetes	5.59	2.3 (0.45; 4.2)	0.015		
	Chronic cystitis	1.82	1.4 (-0.5; 3.3)	0.153		
	Coagulopathy	5.67	3.1 (0.5; 5.7)	0.019		
	More than 3 h of operation	4.84	2.1(-0.08; 4.3)	0.059		
	Blood loss of more than 1000 ml	2.21	1.3(-0.4; 3.1)	0.151		

Sian

Over 70 years old

Urolithiasis disease

Initial anemia

Vascular atherosclerosis

RRP: Retropubic radical prostatectomy

Open Access Maced J Med Sci. 2021 Nov 22; 9(B):1575-1579

occurred in one (1.9%) case. Urinary incontinence 24 months after surgery persisted in 10 (19.2%) cases, mild (<one pad/day) for eight (15.3%), moderate (no more than 2 pads/day) for two (3.8%) patients. The dynamics of the continent's recovery after 24 months revealed the absence of the indicator increase.

Five (9.6%) patients had vesicourethral anastomosis strictures. All cases required endoscopic correction (DVIU), in case of recurrence - urethroplastv surgery (n = 2, 3.8%). As a result, all patients are relieved of bladder outlet obstruction. Six (11.5%) patients had postoperative lymphocele and two (3.8%) patients required therapeutic actions (puncture or surgical revision and drainage). A rare complication was Studer ileoconduitis injury in a patient with prostate cancer after the apical resection of the prostate during radical cystectomy.

#### Logistic analysis

Univariate analysis OR (95% CI)

-0.05(-0.1: 0.05)

-1.4(-3.0: 0.2)

0.8 (-0.7; 2.4)

0.6(-0.5; 1.8)

0.96

3.43

1.16

1.28

To determine the predictors of complications. we performed univariate and multivariate logistic regression analysis. Predictor variables came out of the initial parameters (partially displayed in Tables 1 and 2), as well as intraoperative data. Table 3 presents information on predictor factors (univariate and multivariate logistic regression analysis).

The results helped to build a model for predicting the risk of high blood loss (more than 1000 ml). Univariate analysis revealed no reliable (p< 0.05) predictors. A multivariate analysis of predictors with a significance level of p < 0.2 revealed no reliable predisposing variables. Thus, there were no predictors of excessive blood loss.

Univariate analysis of the maintaining incontinence risk 2 years after surgical treatment

p

0.334

0.092

0.285

0.258

Multivariate analysis

p

0.113

OR (95% CI)

-1.3(-3.0; 0.32)

established Non-Nerve-sparing RRP as a significant predictor (p < 0.05) (OR -0.7; 95% CI -1.4; 0.02; p= 0.05), other factors were not significant (p > 0.05). A multivariate analysis (predictors with a p < 0.2 level) also established Non-Nerve-sparing RRP as a significant predictor of maintaining incontinence (OR-0.9; 95% CI-1.9; -0.07; p = 0.035), which indicates a 90% risk of persisting urinary incontinence after Non-Nerve-sparing RRP.

Previous transurethral surgeries (OR 4.0; 95% Cl 1.5; 6.5; p = 0.001) became an independent predictor of the vesicourethral anastomosis stricture (p < 0.05). A multivariate analysis (predictors with a p < 0.2 level) demonstrated a similar pattern (OR 6.09; 95% Cl 0.71; 11.4; p = 0.026), which indicates a 6 times risk of developing such complication if the patient already had one or more transurethral surgery.

Obesity (OR 0.12; 95% CI 0.03; 0.21; p = 0.008), diabetes (OR 2.3; 95% CI 0.45), and coagulopathy (OR 3.1; 95% CI 0.5; 5.7; p = 0.019) were independent predictors of lymphocele (p < 0.05). 4.2; p = 0.015). A multivariate analysis (predictors with p < 0.2, then p < 0.1 and p < 0.05) did not give reliable results.

### Discussion

The obtained results correlate with the data presented earlier in scientific publications. The comparative analysis is difficult due to the small number of works on the predictors of a specific type of complications after RRP. The incidence of identified complications among the cases included in the study is slightly lower than the average data in large meta-analyses [8]. It is necessary to continue the study in larger samples and compare the obtained data with the results of other authors. A significant advantage of this study is an isolated analysis (no relapse, one team of surgeons, no positive surgical margin, no other methods of treatment, and some others), of various factors, influence the likelihood of postoperative complications, one important disadvantage is a small sample size.

The study did not demonstrate the correlation between significant blood loss and any of the factors, or the effect of blood loss on any complications development, which is likely due to the relatively small sample size. Thus, in a large study [14], the Surgical Apgar Score (SAS) demonstrated the connection between intraoperative blood loss and the development of complications. Each 1-point increase in SAS after open RP resulted in a 24% reduction in the chances of any complication (95% CI 0.66–0.88).

Vesicourethral anastomosis strictures occur in 5–8% of cases after RP. Such a complication requires subsequent surgical correction using transurethral

scar resection or perineal reanastomosis [15]. The correction of all cases of post-RP urethral strictures was successful. The obtained data established 6 times risk of strictures development after previous transurethral surgeries are fully consistent with the current concept of the urethral stricture disease problem [16], [17]. Some studies have demonstrated the connection between the risk of developing anastomotic stricture and the time of catheter removal [18]. However, for this study, it is not possible to trace the factor due to the programmed removal of the catheter on the 12<sup>th</sup> day.

In a previously published study of incontinence predictors 24 months after surgery, significant factors were age (OR 1.130; p = 0.030), surgery duration (OR 1.009; p = 0.005), and previous transurethral resection of the prostate (OR 0.218; p = 0.034), which do not correspond to the data obtained by the authors. Surgery duration factor (up to 2.2-3 and more than 3 h), previous transurethral surgery, and age did not show the connection with the risk of maintaining incontinence. The obtained data on an increase in the likelihood of urinary incontinence after Non-Nerve-sparing RRP indirectly indicate a positive role of the neurovascular bundle preservation and less trauma in localized malignant processes. The obtained data correlate with another study indicating the best continental outcomes (OR, 4.77; 95% CI 2.18; 10.44; p = 0.0001) after Nervesparing RRP [19].

Lymphocele is a typical complication with a probability of up to 15–40% in general, and significant lymphocele requiring treatment up to 2.6–5% [20], [21]. According to previously published scientific works [20], there were no predictors of this complication. There was evidence [22] about the role of age and the absence of the obesity factor influence (OR 1.14; p = 0.08). Our results on a 2 times risk of lymphocele in diabetes and a 3 times risk in coagulopathies require further study.

The study revealed some new information on the possible predictors of complications such as urinary incontinence in the late period, the lymphocele, and stricture of the vesicourethral anastomosis. Some of the results require further study and confirmation.

#### Conclusions

Radical prostatectomy results in typical complications such as intraoperative blood loss, urethral strictures (vesicourethral anastomosis), urinary incontinence, erectile dysfunction, lymphocele, and the ureter or rectum injury. The development of complications after radical prostatectomy was analyzed. A multivariate analysis established Non-Nerve-sparing RRP (OR-0.9; 95% CI-1.9; -0.07; p=0.035) as a significant incontinence predictor after 2 years. It was also established previous transurethral operations as a

significant predictor of the vesicourethral anastomosis stricture. Some of the results require further study and confirmation.

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