Current evidence between hospital volume and perioperative outcome: Prospective assessment of robotic radical prostatectomy safety profile in a regional center of medium annual caseload

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Abstract

Introduction: We aimed to present the safety profile of robotic radical prostatectomy (RARP) performed in a single center of medium surgical volume since its introduction and identify predictors of postoperative complications.
Methods: We prospectively collected clinical data from 317 consecutive patients undergoing RARP between August 2011 and November 2019 in a medium-volume center. Surgical procedures were performed by a single experienced surgeon. Complications were collected according to the Martin criteria for reporting and the Clavien-Dindo classification for rating. Preoperative, intraoperative, and postoperative data were analyzed and compared with available literature.
Results: A total of 102 complications were observed in 96 (30.3%) patients and were minor in 84.4% of cases (Clavien grade 1 and 2). Transfusion rate was 1.3%. Complications of grade 4b or 5 did not occur. The most frequent complications were urinary retention (7.3%) and anastomotic leak (5.9%). At multivariate analysis, the nerve-sparing technique was an independent predictor of complications (odds ratio [OR] 0.55; p=0.02).
Conclusions: The study shows that a high safety profile may be achieved in a medium-volume hospital. The nerve-sparing technique was a predictor of complications. Further studies are needed to define the current relationship between surgical volume and perioperative outcome for RARP.

Introduction

Robotic surgery was developed to overcome problems faced during conventional laparoscopic surgeries and represents today the epitome of minimally invasive surgery. Since its introduction in urology, robot-assisted surgery has shown great technical advantages in the execution of radical prostatectomy (RP), becoming today the reference surgical approach for the treatment of localized prostate cancer (PCa). The diffusion of the robot-assisted radical prostatectomy (RARP) technique has grown at the same time, as many studies showing surgical robotic outcomes, comparable to the conventional open surgical results with lower peri-operative complications rates [1,2]. However, in RP series performed with robotic procedure, the association between high-volume surgery and improved surgical outcome has proved to be particularly solid [3,4].

This data can be interpreted by the fact that RARP is a complex technical procedure presenting many potential risks of intra or post-operative complications and requiring for surgeon a long learning curve determining initially lower level outcomes compared to conventional open techniques [5]. In this context, scientific evidences supporting the use of the RARP technique are mainly based on studies from high volume centers; however, due to the geographical diffusion of this technology, many patients are treated in centers of lower volume. The safety and quality level of RARP procedure in smaller hospitals, therefore, represents today a non-negligible theme in the field of public health.

The aim of the present study is to objectively assess using a standardized and validated reporting methodology [6] peri-operative complications of the RARP technique in a European center of medium surgical volume. The secondary end-point is to identify pre- and intra-operative predictors of surgical complications.

Methods

Patient population

The study includes prospective clinical data of 317 consecutive patients undergoing RARP between August 2011, start date of the robotic program at San Giovanni Regional Hospital (Bellinzona, Switzerland) and November 2019.

Data collection was done following the principles outlined in the Declaration of Helsinki and after institutional review board approval.

Before surgery all patients were assessed thorough physical examination, including body mass index (BMI - defined as weight in kilograms by height in square meters) and detailed medical interview, including chronic pharmacological therapy (in particular antiplatelet or anticoagulant drugs) and smoking. Health-significant comorbidities were scored using the American Society Anesthesiologists (ASA) and the Charlson Comorbidity Index (CCI) scores.

Surgical technique

Surgical procedures were performed by a single surgeon (B.M.) trained in robotic surgery with the learning curve exceeded, using da Vinci Si System® (Intuitive Surgical Inc. Sunnyvale, CA - USA), through a transperitoneal access, according to Menon [7] technique.

Thirty minutes before the start of surgical procedure all patients received parenteral administration of antibiotic prophylaxis with a broad spectrum 3rd generation cephalosporin. Post-

operative antibiotic therapy (oral quinolone) was continued until discharge. Bilateral extended pelvic lymphadenectomy was performed according to the preoperative risk assessment [8]. In all patients para-anastomotic drainage was not placed. Anti-thrombotic prophylaxis with low molecular weight heparin was administered until discharge.

In agreement with own clinical practice bladder catheter was removed in the 6th post-operative day; cystographic control was performed in all patients before catheter retrieval. Patients were discharged 24 hours after catheter removal.

Data analysis

Dedicated pathologists have processed and examined the preparations in accordance with the ISUP protocol for RP [9]. Surgical complications were reported satisfying all ten Martin criteria [10] for their description. The Clavien-Dindo system [11] was used to classify the severity of individual complications.

Statistical analysis

Quantitative data were summarized as mean with the corresponding standard deviation (SD) or as median with the corresponding interquartile range (IQR) as appropriate. Qualitative data were presented as absolute numbers with percentages. To analyze the association between surgical time, blood loss and date of surgery, the Pearson correlation coefficient was used. In order to identify potential predictors of postoperative complications we first performed a univariate logistic regression followed by a multivariable logistic regression model. All tests were two-sided and p-value < 0.05 was considered to be statistically significant. All statistical analyses were performed with Stata version 15 (StataCorp LP, College Station, TX, USA)

Results

Table 1 shows pre-operative clinical characteristics of patients. Table 2 show peri-operative surgical data. The duration of surgery has significantly decreased throughout the series (correlation coefficient = - 0.66, coefficient of determination (R^2) = 0.43, p = 0.00) (Figure 1). Intraoperative blood losses remained constant (correlation coefficient = 0.002, R^2 = 0.0001, p = 0.89) (Figure 2)**.** The detailed list of 102 surgical complications is shown in table 3. The data were collected up to three months after the intervention. Overall, complications occurred in 30.3% (96/317) of patients. Analyzed for severity, most complications were minor: 84.4% of complications were grade 1 or 2. No intra-operative surgical or anesthesiologic complications, requiring temporary suspension of procedure, occurred. In five cases (5.2%) the complication occurred 30 days after the procedure. Overall, blood transfusion rate was 1.3%. Bleeding complications occurred in 3.4% (11/317) of patients and account for 10.8% (11/102) of all complications. Active bleeding occurred in 2 (1.6%) patients; one case of hematuria treated with bladder irrigation (not requiring blood transfusion) and one case of pelvic bleeding requiring open surgical revision. Considering the risk of bleeding, it is of interest to report that APT or AOC therapy was overall used in 16.1% (51/317) of patients. However, of patients requiring blood transfusion, nobody took APT or OAC therapy.

Acute urinary retention at the time of bladder catheter removal was successfully treated with the repositioning of bladder catheter for further 7 days, except for one case (requiring 16 days). Anastomotic leak was observed in 19 patients. In two cases, complication occurred in the first postoperative day and was managed with placement of bilateral "mono-J" ureteral stent, removed

after 7 and 14 days (bladder catheter in place for 22 and 35 days) respectively. The other cases consisted in an anastomotic leak at routine cystogram treated conservatively with an indwelling bladder catheter until a negative cystogram was obtained [median (range): 32(11-62) post-operative day].

Four patients with symptomatic lymphocele causing lymphedema of the lower limb were treated with compressive stockings and OAC therapy; one case was associated with a deep vein thrombosis. Three patients with symptomatic infected lymphocele required percutaneous drainage. Concerning visceral complications, two patients who underwent extended adhesiolysis during RARP (one with history of diverticolitis and left hemicolectomy) developed in the first post-operative day peritonitis secondary to perforation of the small intestine. The patients underwent open surgical revision with bowel resection. A third patient developed in the third postoperative day obstructive jaundice on a cholelithiasis basis and was treated with oral antibiotic therapy. The other patients were suffering from prolonged paralytic ileus, all resolved with gastrointestinal prokinetic agents.

The cases of respiratory complications were secondary to lung atelectasis associated to monolateral pleural effusion and treated with oral antibiotic therapy and respiratory physiotherapy. Concluding with other medical complications, neurological damage was reported in five patients with transient monolateral deficiency of obturator nerve, all spontaneously resolving within 60 days.

Classifying complications based on the infectious nature, documented or suspected, these have affected 21(6.6%) patients; they were classified as lower urinary tract infections (n=8), respiratory tract infections (n=2), wound infections (n=2), hyperpyrexia of not known origin (treated with intravenous broad-spectrum antibiotics; n=5), lymphocele infection (n=3) and balanoposthitis (n=1).

The results of the univariate and multivariate logistic regression analysis are reported in table 4.

Discussion

The current expansion of RARP technique, linked to several factors including increased patient demand and market pressure, makes it essential to evaluate the conditions under which procedure is performed.

In surgery, a measure of quality is represented by the rate of perioperative complications. Factor associated with this outcome is hospital volume [12]. The literature addressing RARP technique is heterogeneous and characterized by studies with different statistical methods and cut-offs to define the effective center volumes. The most extensive studies have been conducted on populations of North America.

Using the Nationwide Inpatient Sample (NIS) database, Trinh et al. [13] identified 11,889 patients who underwent RARP between 2008 and 2009 in centers with a median annual hospital volume of 121 (range 66-184) cases, finding a total post-operative complication rate of 8.2% and transfusion rate of 2.0%.

Using the same database, Yu et al. [3] analyzed complications in 2,348 RARP performed in the last quarter of 2008. The authors divided the centers of origin into low (1-15), medium (16-29), high (30-54) and very high (55-166) annual surgical volume, finding a significant difference (p

<0.01) in surgical complications rate (11.2%, 7.6%, 6.7% and 6.9%, respectively). Defining the center of the present study through these categories, it would be of high volume but with a much higher complication rate.

Transfusion rate in low-volume hospitals was 2.4% versus 2.3%, 1.0% and 0.7% of medium, high and very high-volume centers, respectively (p = 0:06). In the present study, the transfusion rate was 1.3%, figures which stand in the range between a center of medium and high volume. Liu et al. [14] analyzed clinical data of 4,036 laparoscopic and robotic prostatectomies performed from 2005 to 2010 and included in the National Surgical Quality Improvement Program Database (NSQIP). The data refer to centers defined at high volume (cut-off not shown). The overall 30-day postoperative complications rate was 5% with mortality of 0.05%. Transfusion rate was 1.3%, comparable to our hospital.

The low complication rate shown in the North American studies described above may be the result of several methodological factors. In fact, using the NIS database registration of postoperative complications is limited to those occurring during hospital stay [3,13]; moreover, short duration of hospital stay may represent an additional factor in reducing documented complications. Second, only complications predictive of mortality such as severe complications or blood transfusions are identified. Lastly, in the case of NSQIP database, the comparison is limited by the fact that the results derive not only from robotic but also laparoscopic procedures.

Considering with the same methodology the complications of grade 3 occurred in the present study (4 or 5 did not occur), these were 4.7%, similar to those of high volume centers described in the North American databases. In this context, series derived from individual centers generally provide more details and use more standardized data collection methods.

In a study conducted according to all ten Martin criteria in a high volume hospital (103 patients / year, University of Padua) Novara et al. [15] reported a total complications rate of 22%, with 3% of grade 3 and 4. These results are similar to those reported in the present study. The most frequent complications described were bleeding (5.3%), lymphorrhea (4.3%), and hematoma (2.4%).

Two other studies performed in high-volume centers, the Florida Hospital Celebration Health [16] and the Vattikuti Urology Institute [17], conducted respecting nine of Martin's criteria, reported much lower rates: an overall complication rate of 5% and 9.8% and a transfusion rate of 0.5% and 2.2% respectively.

Other European studies reported in the literature were conducted according to the Clavien-Dindo classification and Martin criteria; their results were comparable with the results of the present study.

The surgical volume estimated in these studies is heterogeneous and ranges from 21 to 250 patients per year [18-24]. Major complications occurred rarely and generally in the same frequency in all centers (rates from 3 to 7%). Blood transfusion rates ranged from 1 to 5%. Overall complications rates, including also minor events, are highly variable (from 6 to 28%), indicating an heterogeneous method of collection. A clear relationship between volume and surgical outcome did not emerge from these studies.

Two of these studies were conducted respectively in a medium [24] (50 cases per year) and high volume [21] (105 cases per year) center in the same Country of our hospital. Our overall and major complication rates are similar to hospital of greater volume (28% and 3% respectively).

The aforementioned studies investigated the relationship between perioperative complications and hospital volume, however, another factor to consider should be the surgeon's volume.

Hu et al. [25] using the data of Center of Medicare and Medicaid Services, analyzed 608 procedures of laparoscopic and robotic radical prostatectomy in patients over 65 years, performed from 2003 to 2005. The authors reported an overall complication rate higher than those reported in the present study (29% versus 22% and 18% in hospital 1 and 2 respectively) not finding any association between surgeon volume (analyzed as variable continuous) and perioperative complications, length of hospital stay or anastomosis stricture.

Likewise, Budäus et al. [26] using data derived from 2,666 laparoscopic and robotic prostatectomies performed from 2002 to 2008 at the Florida Hospital, investigated the relationship between surgical experience and two end-points: rates of intra-hospital complications and blood transfusion.

The surgeon's volume was divided according to the number of annual procedures performed in low (<16) medium (16-63) and high (> 63). The overall rate of life-threatening complications during hospital stay was 14%, 8% and 6% for low, medium and high-volume surgeons ($p < 0.01$), respectively. Transfusion rates were 3.5%, 1% and 0.5% ($p < 0.01$).

In the present study, being a single surgeon, hospital volume coincides with surgeon volume. Surgeon volume of the present study correspond to medium tertile. According to Budäus study, blood transfusion rate confirms those of a medium volume surgeon. Overall complications rates are much higher probably due to methodological differences: considering grade 3 complications (4 or 5 did not occur) surgeon of our hospital appear to have similar results to the high-volume surgeons reported by Budäus.

Several studies conducted in patients undergoing radical prostatectomy investigated simultaneously hospital or surgeon volume and their results suggest that the importance of one or other factor depends on the end-point of interest [25,27,28]. Surgeon's volume seems to have a significant effect on outcomes directly related to specific surgical maneuvers while hospital volume seems to influence patient peri-operative care.

Positive surgical margin rate is an intra-operative measure of the cancer quality of the procedure and has been shown to be associated with the surgeon's experience. In the present study, this rate is higher than the average rate reported in the literature for pT2 stages (16 and 9%, respectively) but similar for pT3 (40 and 37%, respectively) [29].

In the present study, nerve-sparing procedure was the only significant predictive factor of complications in univariate and multivariable analysis. Other factors related to patient characteristics such as BMI [14], comorbidities [17], prostate volume [15] or cancer characteristics such as PSA [17] have been reported to predict the risk of complications; these have not been confirmed in our series.

In clinical practice it is not possible (and not ethical) to assess the relationship between surgical volume and complications through a prospective randomized study, that is to randomly assign patients between centers at different volumes. Investigations on this topic are consequently of observational nature. Unlike many retrospective studies reported in the literature, the present study is prospective. Complications were collected and described in accordance with the recommended criteria of standardization. Data accuracy makes it possible to use the results obtained

as measures of internal and external quality control and as a realistic tool of counseling for patients candidates to RARP.

This study has several limitations. The analysis is focused on peri-operative data; functional (urinary continence and erectile dysfunction) and long-term oncologic results were not reported. Surgeon volume, shown to be a predictor of short-term peri-operative complications [15,26] cannot be evaluated. Finally, caution must be used comparing the results to other centers of equal volume, because of difference in patient characteristics, experience of surgeons and post-operative protocols used.

Conclusions

The present study shows the peri-operative results of RARP performed in a regional center of medium volume. The complication rate is similar to those reported by other high-volume European centers using the same standardized data collection tools. This data suggests that inverse correlation between hospital volume and peri-operative complications rate may currently be not significant considering centers of high and medium volume. In this series, nerve sparing technique was found predictor of post-operative complications at multivariable analysis. Further studies are needed to confirm these results.

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Figures and Tables

Fig. 1. Operating time in minutes (Y-axis) over the years of study (X-axis), 95% confidence interval (correlation coefficient=- 0.66, R^2=0.43, p=0.00).

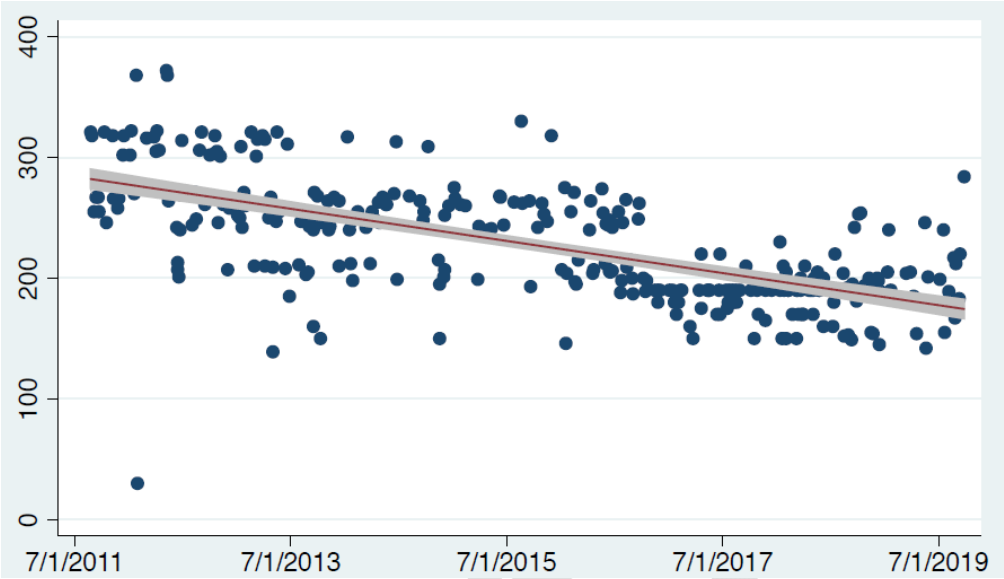

Fig. 2. Intraoperative blood loss in milliliters (Y-axis) over the years of study (X-axis), 95% confidence interval (correlation coefficient=0.002, R^2=0.0001, p=0.89).

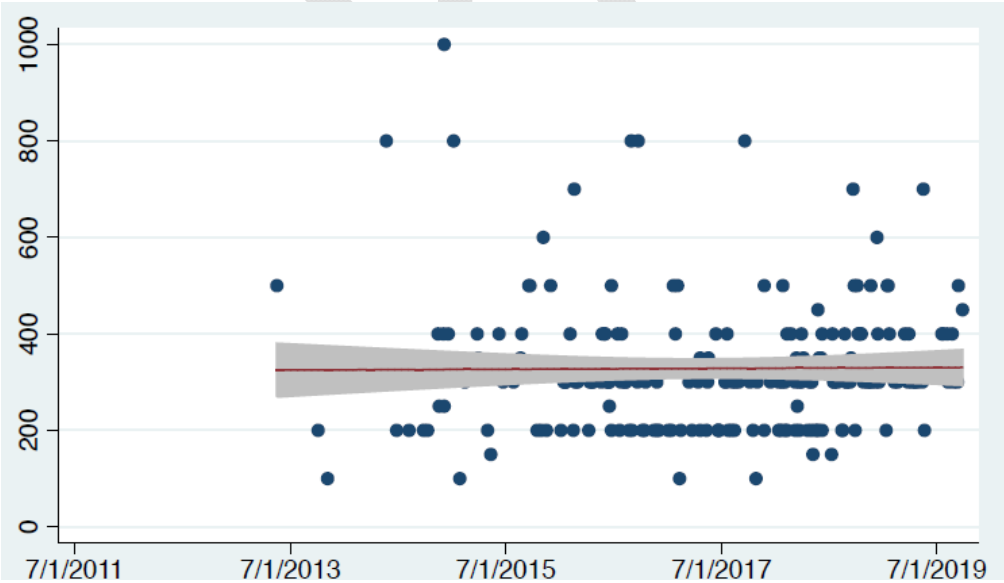

Table 1. Preoperative clinical data of patients undergoing robotic radical prostatectomy (n=317)	
Variable	
Age (yrs), mean±SD	63.3±5.9
BMI (kg/m^2), mean±SD	26.5±3.5
Prostate volume (cm^3), median(IQR)	37 (29–48)
Clinical stage, n (%)	
T1b	0 (0.0)
T1c	87 (28.8)
T2a	114 (37.7)
T2b	37 (12.3)
T2c	38 (12.6)
T3	26 (8.6)
T4	0(0.0)
PSA (ng/ml), median (IQR)	10 (7.0–14.7)
D'Amico risk group, n(%)	
1	34 (11.3)
2	139 (46.3)
3	127 (42.4)
AMI, n (%)	
No	304(95.9)
Yes	13 (4.1)
Smoke, n (%)	
No	250 (78.9)
Yes	67 (21.1)
COPD, n (%)	
No	306 (96.5)
Yes	11(3.5)
Hypertension, n (%)	
No	190 (59.9)
Yes	127 (40.1)
Stroke, n (%)	
No	317 (100.0)
Yes	0 (0.0)
Diabetes, n (%)	
No	282 (89.0)
Yes	35 (11.0)
Immune system disorders, n (%)	
No	304 (95.9)
Yes	13(4.1)
LUTS, n (%)	
No	271 (85.8)
Yes	45 (14.2)
TURP, n (%)	
No	307 (96.8)
Yes	10 (3.2)
Prostatitis, n (%)	
No	285 (89.9)

Yes	32 (10.1)
Bladder surgery, n (%)	
No	315 (99.4)
Yes	2 (0.6)
Abdominal surgery, n (%)	
No	208 (65.6)
Yes	109 (34.4)
APT/AOC, n (%)	
No	266 (83.9)
TAA	46 (14.5)
TAO	4 (1.3)
TAA+TAO	1 (0.3))
ASA, n (%)	
1	81 (25.5)
2	155 (48.9)
3	68 (21.5)
4	13 (4.1)
CCI, n (%)	
0	5 (1.6)
1	51 (16.1)
2	133 (41.9)
3	95 (30.0)
4	26 (8.2)
5	6 (1.9)
7	1 (0.3)

AMI: acute myocardial infarction; ASA: American Society of Anesthesiologists; APT: antiplatelet therapy; BMI: body mass index; CCI: Charlson comorbidity index; COPD: chronic obstructive pulmonary disease; IQR: interquartile range; LUTS: lower urinary tract symptoms; NA: not applicable; OAC: oral anticoagulation therapy; PSA: prostate-specific antigen; SD: standard deviation; TURP: transurethral resection of prostate.

Table 2. Perioperative clinical data of patients undergoing robotic radical prostatectomy (n = 317)	
Variable	
Operation time (min), mean±SD	226.8±49.2
PLND, n (%)	
No	36 (11.4)
Yes	281 (88.6)
Blood loss (ml), mean±SD	328.3±140.6
Hernia repair, n (%)	
No	307 (96.8)
Yes	10 (3.2)
Nerve-sparing, n (%)	
No	89 (37.4)
Monolateral	114 (47.9)
Bilateral	35 (14.7)

Conversion to open surgery, n (%)	
No	317 (100.0)
Yes	0 (0.0)
DaVinci® technical defects, n (%)	
No	317 (100.0)
Yes	0 (0.0)
Pathological stage, n (%)	
pT2a	30 (9.5)
pT2b	3 (0.9)
pT2c	135 (42.6)
pT3a	92 (29.0)
pT3b	57 (18.0)
pT4	0 (0.0)
Gleason sum, n (%)	
3+3	24 (7.6)
3+4	123 (38.8)
4+3	91 (28.7)
4+4	32 (10.1)
3+5	4 (1.2)
4+5	30 (9.5)
5+4	12 (3.8)
5+5	1 (0.3)
Surgical margins, n (%)	
Negative	230 (72.6)
Positive	87 (27.4)
T2/all T2	27/168 (16.1)
T3/all T3	60/149 (40.2)
pN+, n (%)	
No	232 (82.6)
Yes	49 (17.4)
N° of LN removed, mean±SD	14.3±6.8
Hospital stay (day), median (IQR)	8 (8–9)
Bladder catheter removal (day), median (IQR)	6 (6–6)

IQR: interquartile range; PLND: pelvic lymph node dissection; pN+: positive node; SD: standard deviation.

Table 3. Postoperative surgical complications of patients undergoing robotic radical prostatectomy (n=317)	
Variable	
Patients affected by complications, n (%)	
No	221 (69.7)
Yes	96 (30.3)
Complications (day of onset), n (%)	
<30	91 (94.8)
30–90	5 (5.2)
>90	0 (0.0)
Clavien grade, n (%)[*§]	
I	53 (55.2)
II	28 (29.2)
IIIa	7 (7.3)
IIIb	8 (8.3)
IVa	0 (0.0)
IVb	0 (0.0)
Blood transfusion, n (%)	
No	313 (98.7)
Yes	4 (1.3)
Pulmonary complications, n (%)	
No	315 (99.4)
Yes	2 (0.6)
Visceral complications, n (%)	
No	300 (94.6)
Yes	17 (5.4)
Cardiovascular complications, n (%)	
No	316 (99.7)
Yes	1 (0.3)
Neurologic complications, n (%)	
No	312 (98.4)
Yes	5 (1.6)
DVT, n (%)	
No	314(99.1)
Yes	3 (0.9)
Wound infections, n (%)	
No	315 (99.4)
Yes	2 (0.6)
Acute urinary retention, n (%)	
No	294 (92.7)
Yes	23 (7.3)
Anastomotic leak, n (%)	
No	298 (94.1)
Yes	19 (5.9)
Genital/LUT infections, n (%)	
No	309 (97.5)
Yes	8 (2.5)

Pelvic/scrotal/abdominal wall hematoma, n (%)	
No	308 (97.2)
Yes	9 (2.8)
Symptomatic lymphocele, n (%)	
No	310 (97.8)
Yes	7 (2.2)
Active bleeding/hematuria, n (%)	
No	315 (99.4)
Yes	2 (0.6)

*Major per patient complication; §≥1 complication per patient. DVT: deep venous thrombosis; LUT: lower urinary tract.

Table 4. Potential pre- and intraoperative risk factors associated with postoperative complications in univariable and multivariable logistic regression analysis						
Variable	**Univariable logistic regression**			**Multivariable logistic regression**		
	OR	**95% CI**	**p**	**OR**	**95% CI**	**p**
Age (yrs)	1.01	0.96–1.06	0.57	0.96	0.89-1.05	0.43
BMI (kg/m^2)	1.00	0.90–1.11	0.92	–	–	–
Prostate volume (cm^3)	1.00	0.98–1.02	0.70	–	–	–
Clinical stage	0.95	0.72–1.24	0.72	–	–	–
PSA (ng/ml)	1.01	0.98–1.05	0.29	–	–	–
D'Amico risk group	1.25	0.72–2.16	0.41	–	–	–
ASA score	1.27	0.71–2.27	0.41	–	–	–
CCI score	1.32	0.88–1.97	0.16	1.45	0.75–2.80	0.26
APT/AOC	1.58	0.71–3.53	0.25	–	–	–
Diabetes	0.68	0.23–1.97	0.48	–	–	–
COPD	1.27	0.41–3.92	0.67	–	–	–
Smoke	0.84	0.31–2.29	0.74	–	–	–
Operation time	1.00	0.99–1.01	0.53	–	–	–
Blood loss	0.99	0.99–1.00	0.75	–	–	–
PLND	4.31	0.53–34.51	0.17	3.00	0.36–24.72	0.31
Nerve-sparing	0.50	0.31–0.82	0.01	0.55	0.34–0.92	0.02
Associated surgery	1.24	0.47–3.29	0.65	–	–	–

Univariable logistic regression shows bivariate associations without adjustment; multivariable logistic regression results are adjusted for all effects shown. ASA: American Society of Anesthesiologists; APT: antiplatelet therapy; BMI: body mass index; CCI: Charlson comorbidity index; CI: confidence interval; COPD: chronic obstructive pulmonary disease; OAC: oral anticoagulation therapy; OR: odds ratio; PLND: pelvic lymph node dissection.