Clinical factors affecting perioperative outcomes in robot-assisted radical prostatectomy

TOMOHIKO MURAKAMI, SATOSHI OTSUBO, RYO NAMITOME, MASAKI SHIOTA, JUNICHI INOKUCHI, ARIO TAKEUCHI, EIJI KASHIWAGI, KATSUNORI TATSUGAMI and MASATOSHI ETO

Department of Urology, Graduate School of Medical Sciences, Kyushu University, Fukuoka 812-8582, Japan

Abstract. The present study investigated clinical factors affecting perioperative outcomes in robot-assisted radical prostatectomy (RARP). The study included 625 Japanese cases treated with RARP between 2009 and 2017. The association between clinical factors (age, overweight status, prostate volume, clinical T-stage, nerve sparing, lympho-node dissection, and the number of experienced cases) and perioperative outcomes (operation time, estimated blood loss, catheterization duration, and perioperative complication) were analyzed. Results revealed that overweight status, prostate volume, lymph-node dissection, and the number of experienced cases were associated with operation time. For estimated blood loss, the identified risk factors were overweight status, prostate volume, nerve sparing, lymph-node dissection, and the number of experienced cases. Lymph-node dissection and the number of experienced cases were also associated with catheterization duration. Additionally, only lymph-node dissection was associated with increased perioperative complication. Taken together, the present study identified several clinical factors affecting perioperative outcomes in RARP. This information may help surgeons to estimate perioperative outcomes as well as to inform patients.

Introduction

Prostate cancer is the most common cancer in men except cutaneous cancer, and the second-leading cause of cancer-related mortality among men in developed countries (1). Surgical intervention is curative treatment for low- to intermediate-risk localized prostate cancer with established evidence (2,3), and has become applied to high-risk or advanced prostate cancer (3,4). The intervention has even also recently been challenged as a treatment for metastatic prostate cancer in clinical trials (5).

In the past decade, robot-assisted radical prostatectomy (RARP) was rapidly expanding globally due to its minimally invasive, but precise and fine procedures. Now, RARP has become the most common surgical intervention in developed countries. Due to these advantages, RARP is associated with reduced blood loss, reduced transfusion rate and reduced hospital stay as well as favorable perioperative complication rate, compared with open or laparoscopic radical prostatectomy (6-8). However, still, adverse perioperative outcomes have still occurred even in RARP (9).

Perioperative outcomes are critical to both patients and surgeons, where several factors have been identified to affect in RARP. For example, obesity can result in adverse perioperative outcomes based on technical difficulty during procedures (10-12), which is supposed to also affect oncological outcome among men treated with open radical prostatectomy, but not with laparoscopic or robot-assisted radical prostatectomy (13,14). Obesity has been recognized to be more common in Western countries, but relatively rare in Asian countries, suggesting that this difference may affect perioperative outcomes in RARP. In addition, several clinical factors such as prostate volume and number of experienced cases have been reported to affect perioperative outcomes from Western countries (7). However, reports from Asia on perioperative outcomes in RARP are scarce. Therefore, to clarify perioperative outcomes as well as clinical factors affecting perioperative outcomes in RARP among Asian population, we investigated perioperative outcomes among Japanese men in our institution.

Patients and methods

This study enrolled case series who underwent RARP as primary treatment for prostate cancer at Kyushu University Hospital (Fukuoka, Japan) from June 2009 to March 2017. The eligibility criteria included: i) Histopathologically-diagnosed adenocarcinoma of the prostate, and ii) no evidence of metastasis by imaging modality including computed tomography scan and bone scintigraphy. The exclusion criteria included: i) Conversion to distinct procedures such as open radical prostatectomy, and ii) major cardiovascular, liver, or renal

Correspondence to: Dr Masaki Shiota, Department of Urology, Graduate School of Medical Sciences, Kyushu University, 3-1-1 Maidashi, Higashi-ku, Fukuoka 812-8582, Japan
E-mail: shiota@uro.med.kyushu-u.ac.jp

Table I. Univariate and multivariate analyses of clinical factors affecting total operation time.

Variable	Univariate analysis		Multivariate analysis	
	Mean (SEM)	P-value	Least squares mean (SEM)	P-value
Age, years				
<65	245.1 (3.6)		272.6 (3.6)	
≥65	246.6 (3.3)	0.75	268.2 (3.8)	0.20
Overweight				
Absence	240.9 (2.9)		261.2 (3.5)	
Presence	257.0 (4.3)	0.0019[b]	279.6 (3.9)	<0.0001[d]
Prostate volume, ml				
<30	241.2 (3.0)		259.3 (3.1)	
≥30,<50	253.2 (4.4)		269.9 (3.7)	
≥50	256.7 (9.0)	0.037[a]	282.0 (6.5)	0.0002[c]
cT-stage				
cT1	227.2 (4.1)		267.1 (3.8)	
cT2	248.9 (2.9)		270.2 (3.1)	
cT3	307.7 (9.2)	<0.0001[d]	273.9 (7.1)	0.62
Nerve sparing				
None	255.4 (3.0)		269.2 (3.4)	
Ipsilateral	230.2 (5.3)		270.5 (4.7)	
Bilateral	231.5 (5.5)	<0.0001[d]	271.5 (4.8)	0.89
Lympho-node dissection				
No procedure	214.3 (2.2)		225.7 (3.6)	
Underwent procedure	302.4 (2.9)	<0.0001[d]	315.1 (4.0)	<0.0001[d]
Number of experienced cases				
1-200	232.8 (4.2)		267.3 (4.1)	
201-400	261.1 (4.2)		284.3 (4.0)	
401-625	244.0 (4.0)	<0.0001[d]	259.6 (4.0)	<0.0001[d]

[a]P<0.05; [b]P<0.01; [c]P<0.001; [d]P<0.0001. SEM, standard error of mean.

diseases, and/or other severe comorbidities intolerable to operation. This study was performed in accordance with the principles described in the Declaration of Helsinki and the Ethical Guidelines for Epidemiological Research enacted by the Japanese Government, and was approved by the Ethics Committee of Kyushu University (Fukuoka, Japan). The right of opt-out was provided to all patients.

RARP was performed by seven surgeons using the da Vinci Surgical System (S and Si, Intuitive Surgical, Sunnyvale, CA, USA). Basically, the transperitoneal six-port technique was employed in the Trendelenburg position accompanied with the lithotomy position. Nerve sparing was performed by combination of antegrade and retrograde approaches, and athermal technique, based on the risk of extraprostatic extension determined by preoperative cancer risk (15,16), and preoperative patients' potency and preference. Lympho-node dissection for the bilateral regions along the external and internal iliac vessels and within the obturator fossa was performed according to the operation date based on the risk of lympho-node involvement determined by preoperative cancer risk (15,16). Before catheter removal,

cystography was performed to check the urinary leakage based on the surgeons' decision.

All data were collected prospectively, including the following parameters: Age, the presence of overweight defined as a body-mass index ≥25 kg/m^2, estimated prostate volume at diagnosis by trans-rectal ultrasound examination, prostate-specific antigen at diagnosis, clinical and pathological stages, biopsy and pathological Gleason score, resection margin status, and lymph-node involvement, as well as the operation procedures of nerve sparing and lymph-node dissection. Perioperative outcome parameters such as operation time defined as time from skin incision to the end of skin closure, estimated blood loss, catheterization duration defined as time to removal of urethral catheter, and postoperative complication classified using the Dindo modification of the Clavian Grading System (17) during 30 days postoperation were also collected.

All statistical analyses were performed using JMP 13 software (SAS Institute, Inc., Cary, NC, USA). Univariate and multivariate analyses were performed using regression models. All P-values were two-sided and P<0.05 was considered to indicate a statistically significant difference.

Table II. Univariate and multivariate analyses on clinical factors affecting estimated blood loss.

Variable	Univariate analysis		Multivariate analysis	
	Mean (SEM)	P-value	Least squares mean (SEM)	P-value
Age, years				
<65	298.2 (19.1)		363.2 (27.1)	
≥65	259.6 (17.4)	0.14	354.9 (28.3)	0.75
Overweight				
Absence	238.8 (15.3)		304.7 (26.6)	
Presence	361.6 (22.7)	<0.0001[d]	413.4 (29.1)	<0.0001[d]
Prostate volume, ml				
<30	265.0 (16.2)		314.3 (23.4)	
30≤x<50	275.8 (23.4)		326.7 (28.2)	
≥50	388.0 (47.8)	0.052	436.1 (48.7)	0.046[a]
cT-stage				
cT1	305.5 (23.2)		401.8 (28.7)	
cT2	263.4 (16.2)		365.0 (23.2)	
cT3	276.1 (51.5)	0.33	310.3 (53.8)	0.24
Nerve sparing				
None	251.1 (16.3)		307.7 (25.9)	
Ipsilateral	264.9 (28.4)		336.8 (35.2)	
Bilateral	377.3 (29.7)	0.0009[c]	432.7 (36.1)	0.0039[b]
Lympho-node dissection				
No procedure	248.2 (16.0)		286.7 (27.0)	
Underwent procedure	328.9 (21.4)	0.0026[b]	431.4 (30.0)	<0.0001[d]
Number of experienced cases				
1-200	338.7 (22.5)		412.3 (31.2)	
201-400	218.4 (22.5)		300.2 (30.0)	
401-625	274.5 (21.2)	0.0009[c]	364.7 (30.1)	0.0018[b]

[a]P<0.05; [b]P<0.01; [c]P<0.001; [d]P<0.0001. SEM, standard error of mean.

Results

This study enrolled a total of 625 Japanese men who underwent RARP for prostate cancer. As shown in Table S1, the patients' median age was 65 years [interquartile range (IQR), 61-69 years]. Median body-mass index was 23.7 kg/m² (IQR, 22.0-25.6 kg/m²), where overweight was recognized in 195 men (31.2%). Median prostate-specific antigen at diagnosis was 7.1 ng/ml (IQR, 5.3-10.0 ng/ml). In most cases, clinical stage and biopsy Gleason score were T1/2 and ≤7, respectively. Fifty-seven cases (9.1%) were treated with neoadjuvant hormone therapy. Ipsilateral and bilateral nerve sparing were performed in 20.2 and 18.4% of cases, respectively. Lymph-node dissection was performed in 35.8% of cases. Resultant pathological profiles including tumor stage, Gleason score, resection margin status, and lympho-node involvement are listed in Table S1.

Perioperative outcomes are listed in Table S2. The median operation time was 235 min (IQR, 199-289 min), where the median console-operation time was 177 min (IQR, 144-234 min). The median estimated blood loss was 200 ml (IQR, 100-350 ml). The median catheterization duration was 6 days (IQR, 5-7 days). The perioperative comorbidities with any grade and grade ≥3 were documented in 100 patients (16.0%) and 13 men (2.1%), respectively. The perioperative complications with >1% frequency were lymphorrhea or lymphocele (3.0%), wound complications (2.1%), urine leak (1.8%), ileus (1.1%), and postoperative hemorrhage (1.1%).

Accordingly, clinical factors affecting the perioperative outcomes above were analyzed. First, we investigated the association with operation time. As shown in Table I, overweight, prostate volume, lymph-node dissection, and number of experienced cases were identified as factors affecting operation time on multivariate analysis. With regard to estimated blood loss, the associated factors with blood loss on multivariate analysis were identified as overweight, prostate volume, nerve sparing, lymph-node dissection, and number of experienced cases (Table II). Non-performance of lymph-node dissection and number of experienced cases were associated with decreased catheterization duration on multivariate analysis (Table III). Additionally, only performing lymph-node dissection was associated with increased for any

Table III. Univariate and multivariate analyses of clinical factors affecting catheterization duration.

Variable	Univariate analysis		Multivariate analysis	
	Mean (SEM)	P-value	Least squares mean (SEM)	P-value
Age, years				
<65	6.5 (0.15)		6.6 (0.20)	
≥65	6.1 (0.13)	0.046[a]	6.4 (0.21)	0.20
Overweight				
Absence	6.2 (0.12)		6.3 (0.20)	
Presence	6.6 (0.18)	0.078	6.7 (0.22)	0.092
Prostate volume, ml				
<30	6.2 (0.12)		6.2 (0.17)	
30≤x<50	6.5 (0.18)		6.7 (0.21)	
≥50	6.3 (0.37)	0.31	6.6 (0.36)	0.051
cT-stage				
cT1	6.4 (0.18)		6.6 (0.21)	
cT2	6.3 (0.12)		6.6 (0.17)	
cT3	5.7 (0.39)	0.34	6.3 (0.40)	0.63
Nerve sparing				
None	6.1 (0.12)		6.5 (0.19)	
Ipsilateral	6.5 (0.22)		6.4 (0.26)	
Bilateral	6.9 (0.23)	0.0052[b]	6.6 (0.27)	0.74
Lympho-node dissection				
No procedure	6.2 (0.12)		6.2 (0.20)	
Underwent procedure	6.4 (0.16)	0.40	6.8 (0.22)	0.0099[b]
Number of experienced cases				
1-200	7.6 (0.16)		7.8 (0.23)	
201-400	5.9 (0.16)		6.1 (0.22)	
401-625	5.5 (0.15)	<0.0001[c]	5.6 (0.22)	<0.0001[c]

[a]$P<0.05$; [b]$P<0.01$; [c]$P<0.0001$. SEM, standard error of mean.

grade of perioperative complications on multivariate analysis (Table IV).

Discussion

This prospective case series of RARP showed comparable perioperative outcomes to that of previous studies. Median operation time was 235 min while median or mean operative time was 90-291.1 min in previous studies, where lympho-node dissection was time-consuming as indicated Table I (7). Additionally, median estimated blood loss (200 ml) was comparable with that reported in previous studies (69-534 ml) (7). Median catheterization duration (6 days) was also comparable with that for previous studies (5-11.4 days) (7). Furthermore, overall complication rate (16.0%) was similar to that observed in previous studies (3-26%) (7). Similarly, each complication rate in this study such as lymphorrhea or lymphocele (3.0%), wound complications (2.1%), and urine leak (1.8%) were similar to those reported in previous studies (7).

In addition, this study has revealed clinical factors affecting perioperative outcomes in RARP such as operation time, estimated blood, catheterization duration, and perioperative complication, which are critical to both patients and surgeons. In this study, overweight, large prostate volume, and performing lymph-node dissection were risk factors of prolonged operation time. Consistently, both high body-mass index (18-20) and larger prostate volume (21-24) were previously identified as risk factors of longer operation time. Additionally, performing lymph-node dissection is a time-consuming procedure, resulting in longer operation time. Similarly, overweight, large prostate volume, and performing nerve sparing and lymph-node dissection were risk factors for increased estimated blood loss. Consistently, larger prostate volume was reported to be associated with increased blood loss (21-24). However, inconsistently, it was reported that higher body-mass index was not associated with increased blood loss in RARP (18,19). Although this discrepancy may be due to differential prevalence of overweight and obesity between Western and Asian countries, further investigation would be required. Moreover, performing nerve sparing and lymph-node dissection are both procedures that require bleeding, resulting in increased blood loss. Thus, these parameters appeared to

Table IV. Univariate and multivariate analyses on clinical factors affecting any grade perioperative complications.

Variable	Univariate analysis		Multivariate analysis	
	Odd ratio (95% CI)	P-value	Odd ratio (95% CI)	P-value
Age, years				
<65	Ref		Ref	
≥65	0.80 (0.52-1.23)	0.30	0.65 (0.41-1.04)	0.075
Overweight				
Absence	Ref		Ref	
Presence	1.05 (0.65-1.64)	0.85	1.09 (0.67-1.76)	0.74
Prostate volume, ml				
<30	Ref		Ref	
30≤x<50	1.14 (0.71-1.81)		1.15 (0.71-1.88)	
≥50	1.20 (0.53-2.70)	0.82	1.57 (0.67-3.68)	0.56
cT-stage				
cT1	Ref		Ref	
cT2	1.39 (0.85-2.29)		1.08 (0.62-1.87)	
cT3	1.46 (0.58-3.66)	0.39	0.60 (0.22-1.67)	0.42
Nerve sparing				
None	Ref		Ref	
Ipsilateral	0.52 (0.26-0.94)		0.59 (0.29-1.20)	
Bilateral	0.78 (0.43-1.36)	0.087	0.88 (0.44-1.76)	0.32
Lympho-node dissection				
No procedure	Ref		Ref	
Underwent procedure	3.30 (2.13-5.16)	<0.0001[a]	3.70 (2.23-6.14)	<0.0001[a]
Number of experienced cases				
1-200	Ref		Ref	
201-400	1.19 (0.71-2.00)		0.96 (0.54-1.71)	
401-625	0.84 (0.49-1.43)	0.42	0.58 (0.31-1.09)	0.13

[a]P<0.0001. CI, confidence interval.

be robust factors for predicting operation time and blood loss. However, although number of experienced cases was identified a significant factor of operation time and blood loss, consistent tendency was not observed among number of experienced cases.

In addition, performing lymph-node dissection and number of experienced cases were associated with prolonged and reduced catheterization duration in our cohort, respectively. Since we reduced duration of catheterization as we become experienced, the number of experienced cases was obviously associated with reduced catheterization duration. Previously, prostate volume (21,24), but not body-mass index (18) was reported to be associated with longer catheterization duration. However, this study failed to show significant results with prostate volume. Furthermore, performing lymph-node dissection was revealed to critically increase the risk of post-operative complication, which may, at least in part, be due to the complication with lymphorrhea or lymphocele. Therefore, the increased postoperative complication by performing lymph-node dissection may result in prolonged duration of catheterization. Previously, consistently with this study, most

studies failed to demonstrate the association of body-mass index (18) and prostate volume (25) with perioperative complication rate although one report demonstrated the association of prostate volume with perioperative complication (21). Thus, high body-mass index did not appear to be associated with prolonged catheterization duration as well as increased complication rate in RARP. In this study focusing on RARP, overweight was not associated with prolonged catheterization duration and increased perioperative complication. However, perioperative complication was more frequent in obese men when treated with open radical prostatectomy, but not with RARP (26,27). Thus, RARP has been suggested to overcome the challenging situation in obese men by its refined operability with advanced technology, resulting in reduced perioperative complication.

The present study had several limitations. First, operation was performed during relatively long periods of 8 years by seven surgeons with varied experiences using their slightly different procedures, which were not included as parameters. Second, non-severe perioperative complications might be overlooked in some cases. Finally, this study may not include

a possible risk factor influencing perioperative outcomes such as preoperative comorbidities and the presence of median lobe of prostate.

In conclusion, this study identified several risk factors affecting perioperative outcomes in RARP. This information will help surgeons to estimate perioperative outcomes as well as inform to patients. In addition, overweight was associated with longer operation time and increased blood loss, but not with longer catheterization duration and increased complication rate, suggesting RARP may overcome challenging situations in obese men, resulting in reduced perioperative complication.

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