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Original Article

Standardized report for early complications of radical prostatectomy

Wei-Ming Cheng^a, Tzu-Ping Lin^{a,b,*}, Chih-Chieh Lin^{a,b}, Eric Yi-Hsiu Huang^{a,b},
Hsiao-Jen Chung^{a,b}, Junne-Yih Kuo^{a,b}, William J.S. Huang^{a,b}, Yen-Hwa Chang^{a,b},
Alex T.L. Lin^{a,b}, Kuang-Kuo Chen^{a,b}

^a Division of Urology, Department of Surgery, Taipei Veterans General Hospital, Taipei, Taiwan, ROC^b Department of Urology, School of Medicine, and Shu-Tien Urological Research Center, National Yang-Ming University, Taipei, Taiwan, ROC

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Abstract

Background: Radical prostatectomy (RP) is one of the curative treatment options for patients with prostate cancer to achieve long-term survival, but it is accompanied by potential complications. The Martin criteria used as a format for reporting complications has become standard in recent years. However, it has not been applied in RP in Asian countries. In the present study, we investigated the early complications of RP developing within 90 days in our institute according to the Martin criteria.

Methods: Between January 2003 and November 2011, patients with organ-confined adenocarcinoma of the prostate who received RP in our institute were retrospectively reviewed. The operation was done as open RP, or minimally invasive RP, including laparoscopic RP and robot-assisted laparoscopic RP (RaLP). The preoperative, operative, postoperative, and pathological parameters were recorded for analysis. Definitions of complications were adopted from previous reports. Surgical and medical complications developed within 90 days postoperatively were identified respectively; severity of each complication was classified according to Clavien–Dindo classification. Clavien–Dindo classification grade III or higher complications were viewed as major complications.

Results: A total of 359 patients were included; 280 (78%) underwent open RP, 45 (12.5%) received laparoscopic RP, and 34 (9.5%) had RaLP. The overall complication rate was 40.1%, and the major complication rate was 13.1%. There was no surgical mortality. Diarrhea requiring conservative treatment (13.6%), minor urine leakage (9.5%), and gout attack (4.2%) were the leading complications. Minimally invasive RP had higher rates of lymph leakage ($p = 0.015$) and upper-extremity neuropathy ($p = 0.048$). Body mass index $>25 \text{ kg/m}^2$ and use of neoadjuvant hormone therapy were predictors for overall and major complications, whereas diabetes mellitus also predicted the development of major complications. Besides lower case volume and learning curve for RaLP, patients' higher age at surgery and higher risk for disease progression compared to the Western series may be responsible for the higher complication rates.

Conclusion: The early complication rates of RP in our patients were slightly high compared to the Western series. By standardized report, being overweight, diabetes mellitus, and use of neoadjuvant hormone therapy were identified as predictors of early complications in our series.

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Keywords: complications; prostatectomy; prostatic neoplasms

1. Introduction

Prostate cancer is one of the leading malignant neoplasms among male Taiwanese. Treatment should be tailored individually based on the risk of disease progression, life expectancy at diagnosis, and possible complications of each treatment modality, as well as the patient's preference and expected compliance. As the screening test with serum

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* Corresponding author. Dr. Tzu-Ping Lin, Division of Urology, Department of Surgery, Taipei Veterans General Hospital, 201, Section 2, Shih-Pai Road, Taipei 112, Taiwan, ROC.

E-mail address: tplin63@vghtpe.gov.tw (T.-P. Lin).

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Table 1
Definitions of complications of radical prostatectomy.

System	Complications	Severity ^a	Definitions/management
Wound	Prolonged wound pain	I	Intravenous opioid analgesics needed for 7 d or more postoperatively
	Wound dehiscence	IIIa	Wound debridement under local anesthesia in operation room
	Wound infection	I	Wet dressing as wound care
	Abscess formation	IIIa	Proved by sonography and treated with aspiration
	Prolonged lymph secretion	I	Drainage needed for >14 d, without evidence of anastomosis leakage
	Suture of drainage catheter	IIIb	Clinically evident, and explorative laparotomy for removal
Urology	Urinary leakage	I	Proved by cystography, and Foley catheter retention for >14 d
		IIIa	Same as above, and change of Foley catheter with cystoscopy
		IIIb	Same as above, and repair under general anesthesia
	Significant hematuria	I	More severe than usual condition
		II	Resulting in acute urinary retention; Toomey irrigation and blood transfusion needed
	UTI/epididymitis	II	Clinically evident with positive urine culture, treated with intravenous antibiotics
	Acute urinary retention	I	Not due to hematuria; estimated residual urine >150 mL or manual reinsertion of Foley catheter
	Meatal stenosis	IIIa	Treated with urethral sounding under local anesthesia
	Anastomotic stenosis	II	Proved by cystoscopy, and urethral sounding under local anesthesia
		IIIa	Proved by cystoscopy, and transurethral incision under spinal anesthesia/general anesthesia
	Hydronephrosis	IIIa	Proved by sonography, and percutaneous nephrostomy or double-J stenting needed
	Distal ureteral injury	IIIb	Intraoperative repair
	Dislodgment of Foley catheter	IIIa	Cystoscopy for reinsertion
	Spontaneous clip voiding	I	Reported by the patient
Stitches in the urinary bladder	IIIa	Removed by cystoscopy	
Hematology	Postoperative blood transfusion	II	Postoperative hemoglobin <9–10 g/dL, or decreased by >3 g/dL, and blood transfusion was done
	Postoperative bleeding	IIIb	Reoperation because of postoperative bleeding
	DIC	II	Clinically evident and proved by laboratory examinations
Neuromuscular disease	Delirium	II	Clinically evident, treated with haloperidol
	Gout attack	II	Clinically evident, treated with colchicine
	Upper-extremity neuropathy	I	Observation and rehabilitation
	Lower-extremity neuropathy	I	Observation and rehabilitation
	Obturator nerve injury	IIIb	Intraoperative nerve repair
	Rhabdomyolysis	II	Elevation of serum creatinine and myoglobin, treated with hydration and alkalization of urine
	Pressure sore	I	Grade I pressure sore, under observation and changing position
		IIIa	Pressure sores of grade II or more, and dressing needed
Compartment syndrome	IIIb	Emergent fasciotomy needed	
Nephrology	Hyponatremia	I	Treated with electrolytes supplement
	Acute renal insufficiency	I	Postoperative serum creatinine >1.5 mg/dL in patients with preoperative normal serum creatinine level
Gastroenterology	Injury to rectal serosa	I	Intraoperative superficial injury without repair
	Bowel injury	IIIb	Intraoperative bowel injury with repair
	Ileus	II	Prolonged nil by mouth postoperatively and gastrointestinal decompression needed
		II	Clinically suspected, treated with proton pump inhibitor
	Stress ulcer	II	Positive occult blood reaction in stool or gastric juice, treated with proton pump inhibitor
	Gastrointestinal bleeding	IIIa	Upper GI endoscopy needed for hemostasis
		I	Observation without medical treatment
		II	Treated with antidiarrheal medication
	Diarrhea	I	Observation without medical treatment
Elevated liver function tests	I	Observation without medical treatment	
Acute cholecystitis	IIIa	Clinically evident, treated with percutaneous drainage	

(continued on next page)

Table 1 (continued)

System	Complications	Severity ^a	Definitions/management
Cardiology	Tachyarrhythmia	I	Clinically evident, treated with electrolytes supplement
		II	Clinically evident, treated with antiarrhythmics
	Acute coronary syndrome	II	Clinically evident, treated with antiangina agent
	Postoperative hypertension	II	Clinically evident, treated with antihypertensive medication
Dermatology	Intraoperative hypotension	II	Clinically evident, treated with inotropic agents
	Allergic exanthema	II	Clinically evident, treated with topical agent
	Herpes zoster	II	Clinically evident, treated with topical agent

DIC = disseminated intravascular coagulopathy; UTI = urinary tract infection.

^a Severity grade based on Clavien–Dindo classification.

prostate-specific antigen (PSA) and digital rectal examination has become widespread, more patients with prostate cancer could be diagnosed at organ-confined status, making possible more curative treatment, such as radical prostatectomy (RP),¹ can be performed via open, laparoscopic, or robot-assisted laparoscopic methods.² These three approaches have complications in common, and each is also prone to additional specific complications. Development of complications not only results in prolonged hospitalization and excessive costs, but also endangers patients. Thus, studies focused on postoperative complications are crucial. However, different definitions of complications as well as different categorization of severity in different surgical series make comparisons difficult. In 2002, Martin³ proposed the “Martin criteria” to evaluate the quality of operative complication reports, and the criteria have become the standard format in many surgical fields, including urology. To our knowledge, there are no such standardized complication reports concerning RP in Asian people. In the present study, we retrospectively reviewed complications developing within 90 days after RP in our institute and reported them using the Martin criteria.

2. Methods

The preoperative, operative, and postoperative parameters of patients with organ-confined adenocarcinoma of the prostate receiving RP by any of 10 attending urologists in our institute between January 1, 2003 and November 30, 2011 were retrospectively reviewed. The pathological details were also recorded. The low, intermediate, or high risk for disease progression was defined according to the National Comprehensive Cancer Network Guideline in Prostate Cancer Version 3 2010.⁴ The operation could be open RP (ORP) or minimally invasive RP (MIRP), including laparoscopic RP (LRP) and robot-assisted laparoscopic RP (RaLP, which was launched in our institute in December 2009). Standards from the Martin criteria modified by Donat et al⁵ for urological oncologic surgery were used in this study. Surgical and medical complications developing within 90 days postoperatively were included as early complications. They were divided into eight fields: including wound, urology, hematology, neuromuscular disorder, nephrology, gastroenterology, cardiology, and dermatology. Definitions of complications were adapted from other RP complication reports,^{6–9} and graded according to the

Clavien–Dindo classification.¹⁰ The definitions of complications are shown in Table 1. Clavien–Dindo classification grade III or higher was viewed as a major complication. Two-sample *t* test and Fisher exact test were used for continuous variables; Pearson χ^2 test and Mann–Whitney *U* test were used for categorical variables. A *p* value <0.05 was considered significant.

3. Results

During the study period, a total of 363 consecutive patients underwent RP in our institute. Four patients were excluded because of rare histology (3 sarcoma and 1 basal cell carcinoma). Median age at surgery was 67 years; median preoperative PSA was 9.37 ng/mL; 280 patients (78%) received ORP, and 45 patients (12.5%) underwent LRP; RaLP was done in 34 patients (9.5%). Because of similar physiological change during operation and similar stage with regard to the learning curve, we combined LRP and RaLP as MIRP for further analysis. Other demographic data are shown in Table 2.

Patients receiving MIRP were older ($p < 0.001$), and, although operation time was longer in the MIRP group ($p < 0.001$), the amount of intraoperative blood loss ($p < 0.001$) and intraoperative blood transfusion rate ($p < 0.001$) were significantly lower than those in the ORP group. However, more lymph nodes could be obtained during ORP ($p < 0.001$), and there was a lower positive surgical margin rate ($p < 0.001$). Duration for the postoperative urethral catheterization was longer in the ORP group ($p < 0.001$), but duration for the retention of drainage catheter was shorter ($p < 0.009$). Postoperative follow-up was also shorter in the MIRP group ($p < 0.001$). There was no statistical difference between the two groups concerning other patient characteristics.

The detailed complications of RP are listed in Table 3. The overall early complication rate was 40.1%, whereas the major complication rate was 13.1% [including major surgical complications (12%) and major medical complications (1.1%)]. There was no surgical mortality in our series. Diarrhea under conservative treatment was the most common complication (13.6%), followed by minor anastomotic leakage (9.5%) and gout attack (4.2%). Compared to ORP, the MIRP group had higher rates of lymph leakage (6.3%, $p = 0.015$) and upper-extremity neuropathy (2.5%, $p = 0.048$).

Table 2
Demographic data of patients who underwent radical prostatectomy.

		All	ORP	MIRP	<i>p</i>
Patient numbers		359 (100.0)	280 (78.0)	79 (22.0)	
Age, y		66.2 ± 7.7	65.4 ± 7.7	69.1 ± 6.8	<0.001*
BMI, kg/m ²		24.7 ± 2.8	24.6 ± 2.7	25.0 ± 3.2	0.259
Preoperative PSA, ng/dL		14.46 ± 19.44	15.07 ± 20.03	12.17 ± 16.96	0.252
Clinical stage	T1	130 (36.2)	97 (34.6)	33 (41.8)	0.431
	T2	186 (51.8)	146 (52.1)	40 (50.6)	
	T3	41 (11.4)	35 (12.5)	6 (7.6)	
	T4	2 (0.6)	2 (0.7)	0 (0)	
TRUS Gleason score	≤6	198 (55.2)	162 (57.9)	36 (45.6)	0.147
	7	106 (29.5)	75 (26.8)	31 (39.2)	
	≥8	53 (14.8)	41 (14.6)	12 (15.2)	
Neoadjuvant hormone therapy		53 (14.8)	42 (15.0)	11 (13.9)	1
Prior abdominal operation		43 (12.0)	36 (12.9)	7 (8.9)	0.85
Charlson Comorbidity Index score	0	196 (54.6)	159 (56.8)	37 (46.8)	0.291
	1	93 (25.9)	66 (23.6)	27 (34.2)	
	2	44 (12.3)	35 (12.5)	9 (11.4)	
	3	15 (4.2)	10 (3.6)	5 (6.3)	
	4	9 (2.5)	8 (2.9)	1 (1.3)	
	5	2 (0.6)	2 (0.7)	0 (0)	
Operative ASA score	1	20 (6.1)	18 (7.1)	2 (2.7)	0.345
	2	237 (72.3)	184 (72.2)	53 (72.6)	
	3	71 (21.6)	53 (20.8)	18 (24.7)	
Operation time, min		378.8 ± 135.9	337.1 ± 102.7	520.9 ± 130.1	<0.001*
EBL, mL		1495.7 ± 1130.5	1763.9 ± 1075.0	536.5 ± 740.7	<0.001*
Intraoperative BT		243 (68.2)	236 (84.3)	9 (11.4)	<0.001*
Prostate size, g		39.44 ± 22.95	40.27 ± 21.80	36.31 ± 26.99	0.188
LN dissection numbers		7.3 ± 5.2	8.1 ± 5.3	4.6 ± 3.3	<0.001*
Pathological stage	0	2 (0.6)	2 (0.7)	0 (0)	0.899
	1	3 (0.8)	2 (0.7)	1 (1.3)	
	2	181 (50.4)	141 (50.4)	40 (50.6)	
	3	172 (47.9)	134 (47.9)	38 (48.1)	
	4	1 (0.3)	1 (0.4)	0 (0)	
Operative Gleason score	≤6	98 (27.3)	80 (28.6)	18 (22.8)	0.243
	7	215 (59.9)	166 (59.3)	49 (62.0)	
	≥8	46 (12.8)	34 (12.1)	12 (15.2)	
Positive surgical margin		89 (24.8)	58 (20.7)	31 (39.2)	0.001*
SV invasion		50 (13.9)	43 (15.4)	7 (8.9)	0.197
Postoperative					
Hospitalization, d		9.3 ± 4.8	9.3 ± 5.0	9.3 ± 3.8	0.887
Foley catheterization, d		14.7 ± 11.9	16.4 ± 12.7	8.4 ± 4.2	<0.001*
Drain retention, d		6.4 ± 3.7	6.1 ± 3.7	7.2 ± 3.3	0.009*
Adjuvant hormone therapy		112 (31.2)	93 (33.2)	19 (24.1)	0.711
Adjuvant radiotherapy		15 (4.2)	9 (3.2)	6 (7.6)	0.108
Follow-up, mo		38.2 ± 26.0	41.6 ± 26.5	26.2 ± 20.5	<0.001*

Data are presented as *n* (%) or mean ± SD.

**p* < 0.05.

ASA = American Society of Anesthesiology; BMI = body mass index; BT = blood transfusion; EBL = estimated blood loss; LN = lymph nodes; MIRP = minimally invasive radical prostatectomy; ORP = open radical prostatectomy; PSA = prostate specific antigen; SV = seminal vesicle; TRUS = transrectal ultrasound.

On univariate analysis, body mass index (BMI, *p* = 0.002), operation time (*p* = 0.008), estimated blood loss (*p* = 0.023), duration of urethral catheterization (*p* < 0.001) and drainage catheter retention (*p* < 0.001), hospital stay (*p* < 0.001), use of neoadjuvant hormone therapy (*p* = 0.019), and adjuvant hormone therapy (*p* = 0.035) were associated with the development of complications. BMI > 25 kg/m² [odds ratio (OR) 2.03, 95% confidence interval (CI) 1.31–3.15, *p* = 0.002] and neoadjuvant hormone therapy (OR 1.97, 95% CI 1.07–3.62, *p* = 0.029) were significant risk factors for

overall complications on multivariate analysis. As for major complications, BMI (*p* = 0.008), duration of urethral catheterization (*p* < 0.001) and drainage catheter (*p* = 0.007), hospital stay (*p* < 0.001), presence of comorbidities of type 2 diabetes (*p* = 0.037) and severe renal disease (*p* = 0.032), and use of adjuvant hormone therapy (*p* = 0.013) were predictive in univariate analysis, but only BMI > 25 kg/m² (OR 2.48, 95% CI 1.28–4.81, *p* = 0.007) and type 2 diabetes (OR 2.54, 95% CI 1.16–5.55, *p* = 0.019) reached statistical significance in multivariate analysis (Table 4). As for minor

Table 3
Complications of radical prostatectomy within 90 days.

	Severity grade	All (%)	ORP (%)	MIRP (%)	<i>p</i>
All complications		144 (40.1)	110 (39.3)	34 (43.0)	0.624
Major complications	III + IV	47 (13.1)	41 (14.6)	6 (7.6)	0.386
Surgical complications		108 (30.1)	84 (30.0)	24 (30.4)	0.234
Major	III + IV	43 (12.0)	37 (13.2)	6 (7.6)	0.536
Minor	I + II	65 (18.1)	47 (16.8)	18 (22.8)	0.504
Medical complications		55 (15.3)	41 (14.6)	14 (17.7)	0.314
Major	III + IV	4 (1.1)	4 (1.4)	0 (0)	0.580
Minor	I + II	51 (14.2)	37 (13.2)	14 (17.7)	0.069
Wound		31 (8.6)	20 (7.1)	11 (13.9)	0.070
Prolonged wound pain	I	4 (1.1)	3 (1.1)	1 (1.3)	1.000
Wound dehiscence	IIIa	8 (2.2)	8 (2.9)	0 (0)	0.208
Wound infection	I	5 (1.4)	3 (1.1)	2 (2.5)	0.308
Abscess formation	IIIa	4 (1.1)	2 (0.7)	2 (2.5)	0.215
Suture of drainage catheter	IIIb	1 (0.3)	1 (0.4)	0 (0)	1.000
Prolonged lymph secretion	I	8 (2.2)	3 (1.1)	5 (6.3)	0.015*
Urology		76 (21.2)	59 (21.1)	17 (21.5)	0.499
Urinary leakage	I	34 (9.5)	26 (9.3)	8 (10.1)	0.829
IIIa		1 (0.3)	1 (0.4)	0 (0)	1.000
IIIb		1 (0.3)	1 (0.4)	0 (0)	1.000
Significant hematuria	I	6 (1.7)	5 (1.8)	1 (1.3)	1.000
II		7 (1.9)	7 (2.5)	0 (0)	0.355
UTI/epididymitis	II	6 (1.7)	4 (1.4)	2 (2.5)	0.617
Acute urinary retention	I	8 (2.2)	5 (1.8)	3 (3.8)	0.381
Meatal stenosis	IIIa	5 (1.4)	4 (1.4)	1 (1.3)	1.000
Anastomotic stenosis	II	1 (0.3)	1 (0.4)	0 (0)	1.000
IIIa		13 (3.6)	11 (3.9)	2 (2.5)	0.741
Hydronephrosis	IIIa	1 (0.3)	1 (0.4)	0 (0)	1.000
Distal ureteral injury	IIIb	1 (0.3)	1 (0.4)	0 (0)	1.000
Dislodgement of Foley catheter	IIIa	7 (1.9)	7 (2.5)	0 (0)	0.355
Spontaneous clip voiding	I	1 (0.3)	1 (0.4)	0 (0)	1.000
Stitches in urinary bladder	IIIa	1 (0.3)	1 (0.4)	0 (0)	1.000
Hematology		12 (3.3)	12 (4.3)	0 (0)	0.076
Postoperative blood transfusion	II	10 (2.8)	10 (3.6)	0 (0)	0.126
Postoperative bleeding	IIIb	1 (0.3)	1 (0.4)	0 (0)	1.000
DIC	II	1 (0.3)	1 (0.4)	0 (0)	1.000
Neuromuscular disorder		13 (3.6)	8 (2.9)	5 (6.4)	0.104
Delirium	II	1 (0.3)	0 (0)	1 (1.3)	0.220
Gout attack	II	15 (4.2)	13 (4.6)	2 (2.5)	0.537
Upper-extremity neuropathy	I	2 (0.6)	0 (0)	2 (2.5)	0.048*
Lower-extremity neuropathy	I	4 (1.1)	3 (1.1)	1 (1.3)	1.000
Obturator nerve injury	IIIb	1 (0.3)	1 (0.4)	0 (0)	1.000
Rhabdomyolysis	II	1 (0.3)	1 (0.4)	0 (0)	1.000
Pressure sore	I	2 (0.6)	1 (0.4)	1 (1.3)	0.392
IIIa		2 (0.6)	1 (0.4)	1 (1.3)	0.392
Compartment syndrome	IIIb	2 (0.6)	1 (0.4)	1 (1.3)	0.392
Nephrology		5 (1.4)	3 (1.1)	2 (2.5)	0.304
Hyponatremia	I	1 (0.3)	1 (0.4)	0 (0)	1.000
Acute renal insufficiency	I	4 (1.1)	2 (0.7)	2 (2.5)	0.212
Gastroenterology		23 (6.4)	18 (6.4)	5 (6.4)	0.155
Injury to rectal serosa	I	1 (0.3)	1 (0.4)	0 (0)	1.000
Bowel injury	IIIb	2 (0.6)	2 (0.7)	0 (0)	1.000
Ileus	II	11 (3.1)	7 (2.5)	4 (5.1)	0.268
Stress ulcer	II	1 (0.3)	0 (0)	1 (1.3)	0.220
Gastrointestinal bleeding	II	2 (0.6)	1 (0.4)	1 (1.3)	0.392
IIIa		2 (0.6)	2 (0.7)	0 (0)	1.000
Diarrhea	I	38 (10.6)	31 (11.1)	7 (8.9)	0.682

Table 3 (continued)

	Severity grade	All (%)	ORP (%)	MIRP (%)	<i>p</i>
Elevated liver function tests	II	11 (3.1)	9 (3.2)	2 (2.5)	1.000
I		3 (0.8)	3 (1.1)	0 (0)	1.000
Acute cholecystitis	IIIa	2 (0.6)	2 (0.7)	0 (0)	1.000
Cardiology		8 (2.2)	7 (2.5)	1 (1.3)	1.000
Tachyarrhythmia	I	2 (0.6)	2 (0.7)	0 (0)	1.000
II		2 (0.6)	1 (0.4)	1 (1.3)	0.392
Acute coronary syndrome	II	2 (0.6)	2 (0.7)	0 (0)	1.000
Postoperative hypertension	II	1 (0.3)	1 (0.4)	0 (0)	1.000
Intraoperative hypotension	II	1 (0.3)	1 (0.4)	0 (0)	1.000
Dermatology		9 (2.5)	7 (2.5)	2 (2.5)	1.000
Allergic exanthema	II	8 (2.2)	6 (2.1)	2 (2.5)	0.690
Herpes zoster	II	1 (0.3)	1 (0.4)	0 (0)	1.000

**p* < 0.05.

DIC = disseminated intravascular coagulopathy; MIRP = minimally invasive radical prostatectomy; ORP = open radical prostatectomy; UTI = urinary tract infection.

complications, no risk factors could be identified by univariate analysis in the present study.

We compare the complications of ORP and MIRP of our series to those of other Western standardized reports in Table 5^{9,11} and Table 6,^{6,7,9,11–13} respectively. Overall complication rate of ORP (39.3%) was comparable to that in other series, but there was a higher major complication rate in our study (14.6%). By contrast, our MIRP series had higher overall (43%) and major complication rates (7.6%) than did the pure RaLP series, but were comparable to those of pure LRP reports.

4. Discussion

Complications of surgery, which may vary in different countries, are key information for patients in making informed decisions. Well-documented complication reports have been published in Western countries, but a comprehensive report concerning RP is not yet available in Taiwan. Patients with prostate cancer in Taiwan might not be able to undergo RP by their own choice, which may potentially damage the patient–physician relationship. Moreover, communication and comparison among different complication reports could improve the understanding of specific surgeries and hence, prevent the development of complications. However, patient selection, tumor selection, and surgical experience, as well as assessment tools, definitions, and the time at which the evaluation is performed, will influence the presentation of postoperative outcome. The Martin criteria provides a standardized system to ensure consistency and clarity in reporting. A true comparison across different series or surgical approaches may be possible in such situations,³ but it may be expensive and time-consuming to analyze and present the complications fulfilling the Martin criteria. Lack of consensus on complication definitions is also an issue. This

Table 4
Univariate and multivariate analyses of risk factors for all and major complications of radical prostatectomy.

	All complications			Major complications		
	Univariate analysis		Multivariate analysis	Univariate analysis		Multivariate analysis
	No	Yes		<i>p</i>	No	
Age, y	65.9 ± 7.5	66.6 ± 8.0	0.447	66.0 ± 7.7	67.7 ± 7.7	0.161
BMI >25 kg/m ²	78 (37.3)	75 (54.0)	0.003	125 (41.1)	28 (63.6)	0.005
			<i>p</i> = 0.002			<i>p</i> = 0.007
			95% CI 1.305–3.148			95% CI 1.275–4.807
Preoperative PSA, ng/mL	14.3 ± 20.9	14.7 ± 17.1	0.829	14.2 ± 19.9	16.0 ± 15.9	0.555
TRUS Gleason score						
≤6	122 (56.7)	76 (53.5)	0.1	172 (55.3)	26 (56.5)	0.093
7	68 (31.6)	38 (26.8)		97 (31.2)	9 (19.6)	
≥8	25 (11.6)	28 (19.7)		42 (13.5)	11 (23.9)	
cT						
cT1	75 (34.9)	55 (38.2)	0.573	114 (36.5)	16 (34.0)	0.44
cT2	117 (54.4)	69 (47.9)		162 (51.9)	24 (51.1)	
cT3	22 (10.2)	19 (13.2)		35 (11.2)	6 (12.8)	
cT4	1 (0.5)	1 (0.7)		1 (0.3)	1 (2.1)	
Risk groups						
Low	55 (25.6)	43 (29.9)	0.255	87 (27.9)	11 (23.4)	0.802
Intermediate	136 (63.3)	79 (54.9)		185 (59.35)	30 (63.8)	
High	24 (11.2)	22 (15.3)		40 (12.8)	6 (12.8)	
ASA score						
1	14 (7.2)	6 (4.5)	0.37	17 (6.0)	3 (7.0)	0.842
2	135 (69.6)	102 (76.1)		207 (72.6)	30 (69.8)	
3	45 (23.2)	26 (19.4)		61 (21.4)	10 (23.3)	
Charlson Comorbidity Index						
0	117 (54.4)	79 (54.9)	0.823	174 (55.8)	22 (46.8)	0.512
1	54 (25.1)	39 (27.1)		79 (25.3)	14 (29.8)	
2	44 (20.5)	26 (18.1)		59 (18.9)	11 (23.4)	
Myocardial infarction	2 (0.9)	1 (0.7)	1	2 (0.6)	1 (2.1)	0.344
Heart failure	1 (0.5)	2 (1.4)	0.567	3 (1.0)	0 (0)	1
Coronary artery disease	24 (11.2)	17 (11.8)	0.851	35 (11.2)	6 (12.8)	0.756
Cerebrovascular accident	7 (3.3)	5 (3.5)	1	11 (3.5)	1 (2.1)	1
Peripheral arterial occlusion disease	5 (2.3)	2 (1.4)	0.707	5 (1.6)	2 (4.3)	0.23
Chronic obstructive pulmonary disease	6 (2.8)	4 (2.8)	1	8 (2.6)	2 (4.3)	0.626
Gastric ulcer	29 (13.5)	16 (11.1)	0.505	40 (12.8)	5 (10.6)	0.674
Autoimmune disease	5 (2.3)	0 (0)	0.086	5 (1.6)	0 (0)	1
Mild liver disease	13 (6.0)	7 (4.9)	0.631	18 (5.8)	2 (4.3)	1
Type 2 diabetes	26 (12.1)	23 (16)	0.294	38 (12.2)	11 (23.4)	0.037
						<i>p</i> = 0.019
						95% CI 1.162–5.549
Lymphoma	1 (0.5)	1 (0.7)	1	1 (0.3)	1 (2.1)	0.245
Severe renal disease	2 (0.9)	4 (2.8)	0.224	3 (1.0)	3 (6.4)	0.032
						<i>p</i> = 0.085
						95% CI 0.799–33.507
Solid tumor	17 (7.9)	12 (8.3)	0.884	25 (8.0)	4 (8.5)	0.781
Severe liver disease	1 (0.5)	0 (0)	1	1 (0.3)	0 (0)	1
Preoperative antiandrogen usage	24 (11.2)	29 (20.1)	0.023	43 (13.8)	10 (21.3)	0.177
			<i>p</i> = 0.029			
			95% CI 1.073–3.623			
Preoperative TURP	16 (7.4)	12 (8.3)	0.758	25 (8.0)	3 (6.4)	1
Prior other abdominal surgery	29 (13.5)	18 (12.5)	0.786	39 (12.5)	8 (17.0)	0.392
Operation route						
ORP	170 (79.1)	110 (76.4)	0.604	239 (76.6)	41 (87.2)	0.101
MIRP	45 (20.9)	34 (23.6)		73 (23.4)	6 (12.8)	
Lymph node dissection numbers	7.6 ± 2.8	6.9 ± 5.0	0.717	7.4 ± 5.2	7.0 ± 5.2	0.616
Intraoperative blood transfusion	145 (67.4)	100 (69.4)	0.69	212 (67.9)	33 (70.2)	0.765
Pathological stage ≥3	106 (49.3)	67 (46.5)	0.606	152 (48.7)	21 (44.7)	0.606
Pathological nodal status						
N0	209 (97.2)	136 (94.4)	0.149	300 (96.2)	45 (95.7)	0.724
N1	5 (2.3)	8 (5.6)		11 (3.5)	2 (4.3)	
N2	1 (0.5)	0 (0)		1 (0.3)	0 (0)	
Positive surgical margin	52 (24.2)	37 (25.7)	0.746	78 (25.0)	11 (23.4)	0.813
Seminal vesicle invasion	26 (12.1)	24 (16.7)	0.22	42 (13.5)	8 (17.0)	0.511

Data are presented as *n* (%) or mean ± SD.

ASA = American Society of Anesthesiology; BMI = body mass index; CI = confidence interval; MIRP = minimally-invasive radical prostatectomy; ORP = open radical prostatectomy; PSA = prostate specific antigen; TRUS = transrectal ultrasound; TURP = transurethral resection of the prostate.

awaits development by professional societies focused on particular diseases and surgical approaches. As the severity grading system depends on the intervention to manage a complication, clinically significant functional complications may be missed. Moreover, interobserver variability due to the

subjective nature of the grading system may exist.¹⁴ The Martin criteria has become the mainstay in Europe and in the USA, but to our knowledge, the present study is the first standardized report of complications of RP in an Asian country.

Table 5
Comparison of complications of open radical prostatectomy with other published series.

		Rabbani ⁹	Charlsson ¹¹	VGH-TPE
Patient numbers		3458	485	280
Age, y		59.4	63	66
BMI, kg/m ²		27.7		24.5
PSA		5.6	7.4	9.32
Clinical stage	T1	59.5	51.8	34.6
	T2	36.9	37.8	52.1
	T3	3.5	10.4	12.5
TRUS Gleason score	≤6	58.7		57.9
	7	32.6		26.8
	≥8	8.8		14.6
Overall complications		39.6	38.5	39.3
All major complications		16.3	6.8	14.6
Surgical complications		28	36.3	30
Major surgical complications		14.7	5.4	13.2
Medical complications		11.6	2.2	14.6
Major medical complications		1.6	1.4	1.4

Data are presented as %, unless otherwise indicated.

BMI = body mass index; PSA = prostate specific antigen; TRUS = transrectal ultrasound; VGH-TPE = Veterans General Hospital, Taipei.

Both overall and major complication rates of the three surgical treatment approaches in our institute were higher, especially that for MIRP. A smaller case number and learning curve may influence the development of complications.^{15,16} A higher risk for disease progression, presenting as higher serum PSA, higher clinical stage, and higher biopsy Gleason score, as well as older age in our patient group compared to other series, may also help explain the higher complication rates.

Being overweight (BMI > 25 kg/m²), the presence of comorbidity of diabetes mellitus, and use of neoadjuvant hormone therapy were predictors of overall and major complications in our patients. This finding is similar to the findings from the Memorial Sloan Kettering Cancer Center; Rabbani et al⁹ suggested that greater BMI, Charlson

comorbidities score (especially diabetes mellitus), neoadjuvant hormone therapy, ethnicity, larger prostate size, higher biopsy Gleason score, ORP, and greater estimated blood loss, are predictors for the development of complications. Patients with diabetes mellitus are more at risk of poor wound healing, respiratory infection, myocardial infarction, and increased length of hospital stay when undergoing cardiac and noncardiac surgeries.¹⁷ However, in other series, obese patients had prolonged operation time and increased estimated blood loss, especially during the learning curve, but failed to show association with higher complication rates.^{18–21} Similarly, because of increased surgical difficulty, prolonged operation time and increased estimated blood loss were also observed in patients who received neoadjuvant hormone therapy, but there was no significant difference when it came to complication rates.²² The current consensus is that no neoadjuvant hormonal therapy should be given because it has no obvious benefit in disease control whereas it may adversely affect surgical outcome;^{23,24} furthermore, in our experience, it may confer a higher surgical complication rate of RP.

There were several limitations of the present study. First, this was a retrospective analysis, and hence minor complications might not be described as precisely as in prospective studies. Second, the study was based on a single center, which may not be representative of the whole nation's experience. Third, all the surgeries were not done by a single urologist, and differences in surgical skill and experience may also have confounded the analysis of complications.

In conclusion, by standardized report, the early complication rates of RP in our patients were slightly higher compared to Western series. Higher patient age and higher risk for disease progression may be important to this difference. BMI > 25 kg/m², diabetes mellitus, and use of neoadjuvant hormone therapy were predictors of development of early complications in our series.

Table 6
Comparison of complications of minimally invasive radical prostatectomy with other published series.

Author		Rabbani et al ⁹	Hruza et al ⁷	Carlsson et al ¹¹	Novara et al ¹²	Coelho et al ¹³	Agarwal et al ⁶	VGH-TPE
Route		LRP	LRP	RALP	RALP	RALP	RALP	MIRP
Patient numbers		1134	2200	1253	415	2500	3317	79
Age, y		59.7	63.8	62	62.3	61	60	70
BMI, kg/m ²		27.6	26.8		26.6	28	27	25.1
PSA, ng/mL		5.3	7.6	6.3	6.4	4.9	5	9.42
Clinical stage	T1	71.3		61.5			74	41.8
	T2	26.1		34.7			24	50.6
	T3	2.6		3.8			2	8
TRUS Gleason score	≤6	57.3	42.6		74	64	50	45.6
	7	36.9	48.1		17.3	28.5	39.5	39.2
	≥8	5.8	9.3		4.5	7.5	10.1	15.2
Overall complications		57.1	28.5	8.8	21.6	5.6	9.5	43
All major complications		13	6.8	3.5	3.2	1.1	2.5	7.6
Surgical complications		38.5	24.3	8.6		4.1	7.3	30.4
Major surgical complications		10.7	6	3.3		0.6	2.4	7.6
Medical complications		18.6	4.3	0.2		1.5	2.3	17.8
Major medical complications		2.3	0.8	0.2		0.4	0.2	0

Data are presented as %, unless otherwise indicated.

BMI = body mass index; LRP = laparoscopic radical prostatectomy; MIRP = minimally invasive radical prostatectomy; PSA = prostate specific antigen; RaLP = robot-assisted laparoscopic radical prostatectomy; TRUS = transrectal ultrasound; VGH-TPE = Veterans General Hospital, Taipei.

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