Predictors of Urinary Continence Recovery after Modified Radical Prostatectomy for Clinically High-Risk Prostate Cancer

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Purpose: To retrospectively determine predictors of urinary continence (UC) recovery in clinically high-risk prostate cancer (PCa) patients treated with modified radical prostatectomy (RP).

Materials and Methods: A total of 184 patients with clinically high-risk PCa who underwent modified RP in a single Chinese center were retrospectively reviewed. Pelvic floor muscle training with biofeedback was routinely performed after catheter removal. UC was defined as wearing 0 or 1 protective pad daily. Univariate and multivariate Cox regression analyses were performed to determine the predictors of UC recovery.

Results: The median age at surgery was 69.5 years (range 48-82), and the median follow-up duration was 40 months (range 12-111). Only 40 patients (21.7%) received a nerve-sparing procedure. For patients with restored UC, the median time to continence was 1 month (range 1-24). UC recovery at 1 month, 6 months, 12 months and the most recent follow-up was observed in 99 (53.8%), 158 (85.9%), 171 (92.9%) and 174 (94.6%) patients, respectively. Multivariate Cox regression analysis showed that patient age < 70 years (hazard ratio 1.684, $P = .003$) and smaller prostate volume (hazard ratio 0.989, $P = .036$), but not the surgical approach or treatment with a nerve-sparing procedure, independently predicted UC recovery.

Conclusion: Age < 70 years and smaller prostate volume were independent predictors of UC recovery in clinically high-risk PCa patients. The adverse factors of high-risk disease were not significantly associated with UC recovery. These results may help surgeons preoperatively counsel patients regarding expected UC outcomes following RP.

Keywords: prostatectomy; methods; recovery of function; postoperative complications; treatment outcome; urinary incontinence.

INTRODUCTION

Prostate cancer (PCa) is the most commonly diagnosed malignancy and the second leading cause of cancer-related death among men in Western countries.[1] Traditionally, China has been considered as one of the lowest ranking nations with respect to PCa occurrence. However, the incidence of PCa in China has increased dramatically over the past two decades.[2] Because prostate-specific antigen (PSA) screening was not performed routinely, most patients have presented with advanced tumors with nodal involvement and/or metastases.[3] The optimal treatment for patients with clinically high-risk PCa remains under debate. However, surgical treatment has become increasingly popular, and some recent studies demonstrated more favorable oncological and functional results for radical prostatectomy (RP) than for external beam radiotherapy and/or androgen deprivation therapy (ADT) in clinically high-risk PCa patients.[4-6] Although effective cancer control is the most important goal for both patients and surgeons, incontinence following RP exerts the greatest negative effect on patients' quality of life.[7] In the subgroup of clinically high-risk PCa patients, a non-nerve-sparing technique and more aggressive local resection have typically been recommended for obtaining optimal oncological outcomes. Presumably, the recovery of urinary continence (UC) is to some degree affected by wide surgical resection. Both surgeons and patients have been concerned about the poor UC outcomes after RP. This concern regarding incontinence may occasionally affect therapy decision making and prevent the patients with clinically high-risk PCa from receiving curative treatment. Nevertheless, a paucity of studies is available regarding the factors that influence UC recovery after RP in patients with clinically high-risk PCa. In this study, we aimed to investigate the predictive factors of UC recovery following RP among 184 patients with clinically high-risk PCa who received follow-up for a minimum duration of 12 months at a single institution in China.

MATERIALS AND METHODS

Patient Selection

Between December 2004 and December 2012, 756 patients diagnosed with PCa underwent RP at The Third Affiliated Hospital of Sun Yat-sen University. All clinical data, including demographic characteristics, clinicopathological characteristics and follow-up results, were prospectively recorded in a computerized database as approved by our institutional review board. The clinical data were retrospectively reviewed, and we identified 184 patients with clinically high-risk PCa according to the D'Amico risk stratification scheme[8] (clinical stage ≥ T2c or Gleason score ≥ 8 or PSA > 20 ng/mL) for UC recovery evaluation. All patients were continent before surgery. The preoperative data included age at surgery, body mass

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Table 1. The clinicopathological characteristics of 184 patients with clinically high-risk prostate cancer.

Characteristics	Number or Mean	Percentage or Range
No. of patients	184	
Age (years)	69	48-82
BMI (kg/m^2)	23.8	20.4-26.1
Previous TURP	15	8.2
PSA level (ng/mL)	30.5	1.89-104.3
< 10	35	19.0
10-20	52	28.3
> 20	97	52.7
Biopsy Gleason score		
≤ 6	67	36.4
7	46	25.0
≥ 8	71	38.6
Clinical stage		
T1	48	26.1
T2	124	67.4
T3	12	6.5
Prostate volume (mL)	44.0	10.6-120.1
Neoadjuvant ADT	36	19.6
Surgical approach		
LRP	134	72.8
RRP	50	27.2
Surgery duration (min)	205.7	110-440
Hospital stay (days)	18.7	9-39
Estimated blood loss (mL)	238.4	30-3000
Nerve sparing		
No	144	78.3
Unilateral	7	3.8
Bilateral	33	17.9
Pathological Gleason score		
≤ 6	49	26.6
7	57	31
≥ 8	78	42.4
Pathological stage		
T2	113	61.4
T3-4	71	38.6
N1	28	15.2
Anastomotic leakage	44	23.9
Anastomotic stricture	17	9.2
Follow-up duration (months)	43.2	12-111

Abbreviations: BMI, body mass index; PSA, prostate-specific antigen; TURP, transurethral resection of the prostate; ADT, androgen deprivation therapy; RRP, open retropubic radical prostatectomy; LRP, laparoscopic radical prostatectomy.

index (BMI), serum PSA level, history of transurethral resection of the prostate (TURP), clinical stage, biopsy Gleason score, prostate volume and neoadjuvant ADT. The prostate volume was measured via transrectal ultrasonography.[9] All patients preoperatively underwent computed tomography or magnetic resonance imaging and a radionuclide bone scan to exclude distant metastases. The patients were fully informed with regard to the surgical approach (open retropubic vs. laparoscopic) and its possible complications. The choice of therapy was determined via consultation between the surgeons and the patients.

Surgical Technique

The surgery was performed using a transperitoneal approach. All patients underwent extended bilateral pelvic lymph node dissection before RP. Laparoscopic radical prostatectomy (LRP) and open retropubic radical prostatectomy (RRP) were performed on 134 and 50 patients, respectively. The technique of RP with modified prostate apex dissection was applied as previously reported.[10] A nerve-sparing procedure was discreetly performed based on age, clinical stage, the PSA level, sexual function and the patient's request. All operations were performed by a single surgeon (X.G.). Routine cystography was performed at 7-10 days after surgery. The urethral catheter was removed if no anastomotic leakage was detected based on cystography. All of the patients were instructed to carry out daily pelvic floor muscle training (PFMT) after catheter removal. Biofeedback was simultaneously applied to assist the patients with contracting the pelvic floor muscles via electrical stimulation or verbal instruction. All patients received adjuvant ADT for 9 months beginning 3 months after surgery.

Follow-up

Postoperative follow-up was performed quarterly for the first 2 years, semi-annually for the next 3 years, and annually thereafter and consisted of PSA measurement, digital rectal examination and other clinical assessments (e.g., chest X-ray and bone scan) as indicated. Biochemical recurrence was defined as PSA levels greater than 0.2 ng/mL based on two consecutive measurements within 3 months. The UC state and pad use were assessed simultaneously at the follow-up visits or during telephone interviews by a special interviewer. UC was defined as wearing no pad or wearing a protective pad daily. Patients who used two or more pads a day were considered incontinent. Patients who did not achieve UC at 12 months after surgery underwent urodynamic measurements to determine the type of incontinence. The primary outcome measure was predictors of UC recovery after RP for clinically high-risk PCa. The secondary outcome measure was the median time to UC, and the percentage of patients exhibiting UC recovery at different time point.

Statistical Analysis

Kaplan-Meier analysis and the log-rank test were used to compare time to UC and the percentage of continent

Table 2. Cox regression analysis of factors predictive of urinary continenece recovery during follow-up.

Variables	Univariate		Multivariate	
	HR (95% CI)	*P* Value	HR (95% CI)	*P* Value
Age group (< 70 years vs. ≥ 70 years)	1.858 (1.358-2.541)	< .001	1.684 (1.191-2.382)	.003*
BMI (kg/m^2)	1.062 (0.938-1.202)	.344	1.068 (0.934-1.22)	.337
Previous TURP (Yes vs. No)	0.906 (0.524-1.567)	.724	0.751 (0.385-1.461)	.398
PSA (ng/mL)	1.002 (0.996-1.008)	.522	1.003 (0.997-1.009)	.333
Prostate volume (mL)	0.99 (0.981-0.999)	.029	0.989 (0.978-0.999)	.036*
Neoadjuvant ADT (Yes vs. No)	1.006 (0.692-1.464)	.974	1.038 (0.696-1.549)	.853
Surgical approach (RRP vs. LRP)	0.896 (0.642-1.251)	.52	0.851 (0.587-1.232)	.392
Surgery duration (min)	0.998 (0.995-1.001)	.267	1.001 (0.997-1.005)	.602
Nerve sparing		.704		.868
Unilateral vs. No	1.379 (0.644-2.955)		1.242 (0.56-2.757)	
Bilateral vs. No	0.988 (0.665-1.468)		1.023 (0.667-1.569)	
Pathological Gleason score		.986		.915
7 vs. ≤ 6	1.023 (0.689-1.518)		1.092 (0.716-1.664)	
≥ 8 vs. ≤ 6	0.993 (0.687-1.436)		1.039 (0.669-1.612)	
pT stage (pT3-4 vs. pT2)	0.793 (0.582-1.081)	.142	0.771 (0.527-1.128)	.18
Lymph node involvement (positive vs. negative)	0.88 (0.575-1.345)	.554	0.941 (0.577-1.534)	.806
Anastomotic leakage (Yes vs. No)	0.72 (0.505-1.029)	.071	0.742 (0.503-1.095)	.133
Anastomotic stricture (Yes vs. No)	0.911 (0.544-1.524)	.722	0.991 (0.558-1.759)	.974

* Variables displaying a significance difference based on multivariate Cox regression analysis. Significance was defined as $P < .05$.
Abbreviations: BMI, body mass index; PSA, prostate-specific antigen; TURP, transurethral resection of the prostate; ADT, androgen deprivation therapy; RRP, open retropubic radical prostatectomy; LRP, laparoscopic radical prostatectomy; HR, hazard ratio; CI, confidence interval.

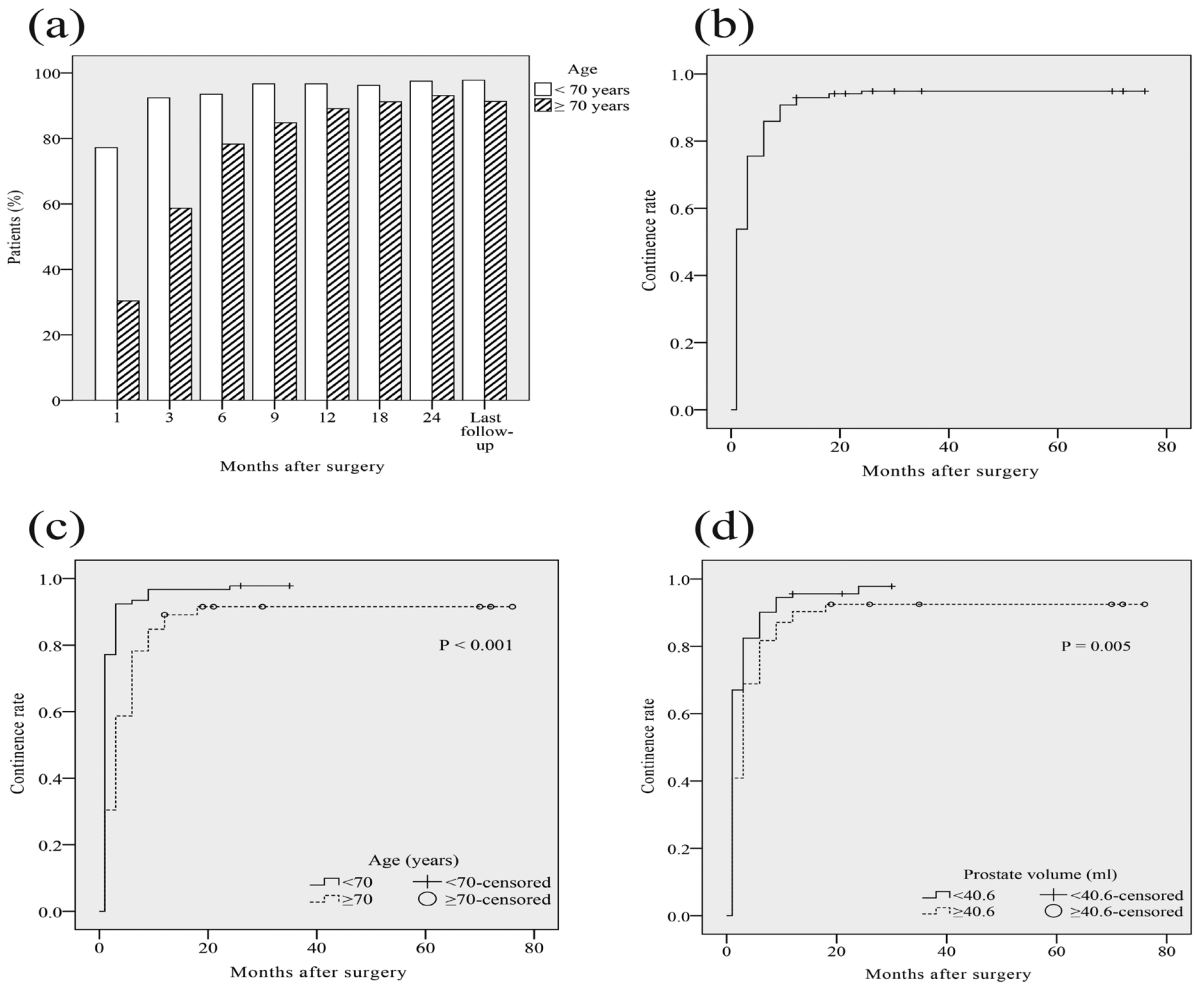

Figure. The continence rate of the two age groups during follow-up; **(a)** Kaplan–Meier estimates of urinary continence recovery in all of the patients after radical prostatectomy **(b)** and in the subgroups stratified according to the median age **(c)** and prostate volume **(d)**. Level of statistical significance was defined as $P < .05$.

patients at follow-up. Univariate and multivariate Cox regression analyses were performed to determine the predictors of UC recovery during the follow-up. All statistical tests were two-sided, and a P value of < .05 was considered statistically significant. The data were analyzed using IBM Statistical Package for the Social Science (SPSS Inc, Chicago, Illinois, USA) version 19.0.

RESULTS

The clinicopathological characteristics of the 184 patients are summarized in **Table 1**. The median age at surgery was 69.5 years (range 48-82), and the median follow-up duration was 40 months (range 12-111). Fifteen patients had a history of TURP. No patient received neoadjuvant chemotherapy. Considering the unfavorable pathological characteristics of clinically high-risk PCa, only 40 (21.7%) patients were cautiously selected to undergo a nerve-sparing procedure (7 for a unilateral nerve-sparing procedure and 33 for a bilateral nerve-sparing procedure). The mean operation time was 203 minutes (range 120-330) and 212 minutes (range 110-440) for LRP group and RRP group, respectively. Forty-four (23.9%) patients exhibited anastomotic leakage and were treated by prolonged urethral catheterization. The catheter was not removed until the cystography showed an intact anastomosis. Seventeen patients (9.2%) developed a symptomatic anastomotic stricture that required endoscopic treatment. For the patients who achieved UC, the median time to continence was 1 month (range 1-24). The median time to continence is 1 month in LRP group and 3 months in RRP group. The number of patients exhibiting UC recovery at 1 month, 6 months, 12 months and at the most recent follow-up was 99 (53.8%), 158 (85.9%), 171 (92.9%) and 174 (94.6%), respectively. For the 13 patients who did not achieve UC at 12 months after surgery, 3 patients need 3 pads per day, 7 patients need 4 pads per day, and 3 patients need 6 pads per day. Only 3 (1.6%) patients with incontinence at 12 months recovered UC by the most recent follow-up, and no patient with incontinence at 24 months regained UC. All 13 patients with incontinence at 12 months were found to exhibit stress urinary incontinence (SUI) based on urodynamic measurements. Among these patients, 3 patients exhibited grade I SUI and 10 patients exhibited grade II SUI according to Burkhard's criteria.[11] No patient exhibited grade III SUI, and no patients underwent male anti-incontinence surgery (e.g., artificial urinary sphincter implantation). **Table 2** shows the factors that were predictive of UC recovery during the follow-up. Multivariate Cox

regression analysis showed that patient age < 70 years (hazard ratio 1.684, 95% confidence interval [CI]: 1.191-2.382, $P = .003$) and smaller prostate volume (hazard ratio 0.989, 95% CI: 0.978-0.999, $P = .036$) were independent predictive factors of UC recovery during follow-up. Patients with larger prostate and older than 70 years exhibited a delayed restoration of UC. No significant association was detected between UC recovery and BMI, the PSA level, previous TURP, neoadjuvant ADT, the pathological Gleason score, the pathological stage, the surgical approach, nerve-sparing procedure, anastomotic leakage and anastomotic stricture. **Figure** shows the UC rate of the two age groups during the follow-up and the Kaplan–Meier estimates of UC recovery.

DISCUSSION

Recent studies have demonstrated that RP produces excellent oncological outcomes for not only localized PCa but also clinically high-risk PCa.[4,5] Accompanied with the surgery, the significant negative impact on quality of life is post-prostatectomy incontinence. It is likely that UC recovery is somewhat affected by wide resection during surgery in clinically high-risk PCa patients. For these patients, determining whether RP results in a satisfactory UC outcome without compromising cancer control and identifying the predictive factors of UC recovery are matters of concern. However, the majority of studies have focused on UC recovery among the entire cohort of PCa patients, and few studies have examined UC recovery in the subgroup of clinically high-risk PCa patients. We retrospectively investigated the UC recovery outcomes of clinically high-risk PCa patients who received modified RP and found that the UC outcomes were comparable to those of localized PCa patients who received RP. In the subgroup of patients with clinically high-risk PCa, the reported rate of incontinence has varied between 5.8% and 22%.[12-14] This wide variation in the reported data has been attributed to the definition of UC, the surgical technique, and the time point and methodology used for assessing UC. We have adopted the most commonly used definition of UC: the use of zero or one protective pad daily.[15] It has been generally accepted that UC improves over time and that most patients achieve UC within 12 months postoperatively.[16,17] In the present study, the UC rate improved from 53.8% at 1 month to 92.9% at 12 months. However, very few incontinent patients at 1 year postoperatively became continent thereafter.[18,19] Our study showed a similar result, in which only 3 patients regained UC after 1 year, and no patients regained UC after 2 years. The proposed risk factors of UC recovery after RP include preoperative factors (e.g., age,[18] the prostate volume[20] and previous TURP[21]), the surgical technique (e.g., a nerve-sparing technique,[11] the experience level of the surgeon,[22] the surgical approach,[16] bladder neck preservation[23] and the performance of apical dissection[24]) and postoperative factors (e.g., the performance of pelvic floor muscle training,[25] the use of biofeedback,[5] anastomotic leakage and anastomotic stricture[15]). Age at surgery has consistently been considered as the most important factor associated with UC recovery after RP.[15,18] In this study, 92 patients (50%) were 70 years of age or older. We found that patient age < 70 years was an independent predictive factor of UC recovery. This finding is in accordance with the results reported by Kundu and colleagues and Kim and colleagues[18,20] The role of the prostate volume in UC recovery after RP remains controversial. Kim and colleagues performed a retrospective analysis of 452 patients with clinically localized PCa who underwent robot-assisted RP to investigate the factors that predicted early recovery of UC.[20] The results of their study demonstrated that factors including younger age (< 70 years) and smaller prostate volume (< 40 mL) independently predicted recovery of UC within 3 months after surgery. However, Pettus and colleagues did not detect a correlation between prostate size and UC at one year following RP.[24] Our results showed that smaller prostate volume is an independent predictor of UC recovery based on multivariate analysis. The patients with a larger prostate experienced a delayed restoration of UC. The reason for this effect may be that a larger prostate complicates the manipulation of the prostate apex and the urethra and the mobilization of the prostate during surgery; moreover, the surgery may even occasionally injure the external urethral sphincter. The nerve-sparing technique was once considered as the most important surgical technique for UC recovery. Burkhard and colleagues evaluated the UC of 536 patients treated with attempted nerve-sparing RP who received follow-up for a minimum duration of 1 year.[11] They found that UC was highly associated with the use of a nerve-sparing technique. However, the predictive value of this factor has been extensively debated, as some studies have presented conflicting findings. Marien and colleagues evaluated UC in 1100 patients who underwent nerve-sparing RP.[26] These patients exhibited similar CU rates at 24 months regardless of whether a bilateral or unilateral nerve-sparing technique was performed. In the present study, UC recovery was not significantly associated with the performance of a nerve-sparing procedure. The results regarding the effect of the nerve-sparing technique on UC recovery were disparate. We propose that the primary reason for this discrepancy is that attempted nerve sparing does not truly indicate that the nerves are adequately preserved. The neurovascular bundles are often unintentionally injured due to periprostatic adhesions or obscured dissection planes. Therefore, the actual status of the so-called “spared nerves” is undetermined. The other surgical technique in this cohort that is related to UC may be the modification of prostate apex dissection. Eastham and colleagues argued that meticulous dissection of the prostate apex resulted in both an improvement in time to continence and the overall rate of UC.[21] The purpose of this modification was to preserve the urethral musculature, the periurethral fascial attachments and the continence-associated nerves during surgery.[10] This technique may also preserve maximal functional urethral length, which might improve early UC.[27] Our preliminary results indicated that this technique improved UC recovery.[10] Regarding other surgical factors, no difference was observed in UC recovery according to the surgical approach or the history of TURP. In addition, the experience level of the surgeon may affect the time to UC following RP.[22] In this cohort, all of the procedures were performed by a single surgeon. With regard to postoperative factors, PFMT and biofeedback are the most commonly used conservative treatments for hastening the restoration of UC. Kampen and colleagues conducted a randomized controlled study to evaluate the effect of PFMT on incontinence after RP in clinically localized PCa patients.[25] Their study showed that the PFMT-treated group exhibited improvements in both the duration and the degree of incontinence compared

to the control group. In the PFMT-treated group, UC was restored in 88% of the patients after 3 months. In our study, PFMT with biofeedback was routinely performed after catheter removal. Most patients exhibited UC within 1 year. However, the UC rate at 3 months (75.5%) was lower than that in Kampen and colleagues There may be two reasons for this difference: (1) the present study included older patients, of which half of the patients were greater than 70 years of age; (2) all of the patients in the present study suffered from clinically high-risk PCa, and these patients more frequently experience urinary incontinence compared to the clinically localized PCa patients who were included in Kampen's study. There are several limitations to the present study. First, this study was a retrospective analysis of a relatively small number of patients with clinically high-risk PCa. Second, this study did not evaluate the UC status based on a validated questionnaire, and the acceptance of a safety pad may represent a confounding factor. Third, because the entire cohort received either RRP or LRP, the findings of the present study may have limited external generalizability to UC recovery after robotic prostatectomy. Finally, the focus of our study was to determine the predictor of UC recovery. Only a small number of patients were performed nerve-sparing procedure and all patients received adjuvant ADT, so we did not assessed sexual function.

CONCLUSION

The present study demonstrated the value of age < 70 years and smaller prostate volume, but not the PSA level, the cancer stage, the Gleason score, previous TURP, the surgical approach or the use of a nerve-sparing technique, for predicting UC recovery after RP in patients with clinically high-risk PCa. The adverse factors of high-risk PCa were not significantly associated with UC recovery. These results may help surgeons preoperatively counsel patients regarding expected UC outcomes following RP.

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CONFLICTS OF INTEREST

None declared.

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