Short-term therapeutic outcomes of robotic-assisted laparoscopic radical prostatectomy for oligometastatic prostate cancer: a propensity score matching study

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Abstract

Background: The role of local treatment in oligometastatic prostate cancer (PCa) is gaining interest with the oligometastases hypothesis proposed and the improvement of various surgical methods and techniques. This study aimed to compare the short-term therapeutic outcomes of robotic-assisted laparoscopic radical prostatectomy (RALP) for oligometastatic prostate cancer (OPC) *vs.* localized PCa using propensity score matching.

Methods: Totally 508 consecutive patients underwent RALP as a first-line treatment. The patients were divided into two groups according to oligometastatic state: the OPC group ($n = 41$) or the localized PCa group ($n = 467$). Oligometastatic disease was defined as the presence of two or fewer suspicious lesions. The association between the oligometastatic state and therapeutic outcomes of RALP was evaluated, including biochemical recurrence (BCR) and overall survival (OS). A Cox proportional hazards model was used to assess the possible risk factors for BCR.

Results: Totally 41 pairs of patients were matched. The median operative time, the median blood loss, the overall positive surgical margin rate, the median post-operative hospital stays, and the post-operative urinary continence recovery rate between the two groups showed no statistical significance. The 4-year BCR survival rates of the OPC group and localized PCa group were 56.7% and 60.8%, respectively, without a significant difference ($P = 0.804$). The 5-year OS rates were 96.3% and 100%, respectively ($P = 0.326$). Additionally, the results of Cox regression showed that oligometastatic state was not an independent risk factor for BCR ($P = 0.682$).

Conclusions: Our findings supported the safety and effectiveness of RALP in OPC. Additionally, oligometastatic state and sites did not have an adverse effect on BCR independently.

Keywords: Oligometastatic; Prostate cancer; Robotics; Propensity score matching

Introduction

Prostate cancer (PCa) is the most generally diagnosed solid malignancy and the second leading cause of cancer-related death in males in the United States. Due to the cost of the prostate-specific antigen (PSA) test and the poverty rate in China, the majority of the patients are diagnosed with metastatic PCa (mPCa) at the time that they first visit a doctor. As a systemic treatment, androgen deprivation therapy (ADT) has been regarded as a milestone for over 50 years to treat patients with mPCa.[1]

Different from the "systematic hypothesis" that local treatment should not affect survival,[2,3] Weichselbaum and Hellman[4] proposed an "oligometastases hypothesis," arguing that cancer comprises many intermediate states when it extends from a disease that remains localized to one that is systemic when being first detectable. The treatment of local or metastatic disease would improve overall survival (OS) and even provide a cure in patients with oligometastases.[4] Current advances in clinical and molecular imaging techniques have permitted the early identification of a significant population of patients with oligometastases and afford opportunities for early intervention.[5,6] Many studies have confirmed this clinical theory, including surgical resection of lung metastases from a variety of primary sites,[7] adrenal metastases from lung cancer,[8] and liver metastases from breast cancer and

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colon cancer,[9-15] resulting in a cure in some patients. In analogy with these malignancies, the eradication of PCa with oligometastases is a promising way to delay disease progression. Nascent evidence from oligometastatic PCa (OPC) indicates that local treatment of the primary tumor prolongs progression-free survival (PFS) and OS.[16-18] Furthermore, local treatment of the metastasis in limited numbers can be beneficial to delay the progression and the initiation of systemic treatments. Thus, there is an increasing interest in the role of local treatment in OPC. However, studies analyzing the use of robotic-assisted laparoscopic radical prostatectomy (RALP) for treating OPC are limited.

Attributable to no consistent definition and standard treatments for OPC and selecting bias by the difference in data, we used propensity score matching to retrospectively compare the peri-operative and oncological outcomes of RALP as a first-line treatment for a selected cohort of OPC patients.

Methods

Ethical approval

All procedures performed in studies involving human participants were in accordance with the *1964 Declaration of Helsinki* and its later amendments. As a retrospective study and data analysis were performed anonymously, this study was exempt from the ethical approval. Written informed consent was obtained from all participants.

Patients

A total of 508 consecutive patients with PCa who underwent RALP by one single surgeon from April 2012 to October 2017 were enrolled in the research. Oligometastatic disease was defined as the presence of two or fewer hot spots by ^{99m}Tc-methylene diphosphonate whole-body bone scan, ^{18}F-fluorodeoxyglucose positron emission tomography/computed tomography (PET-CT) or gadolinium-diethylenetriamine pentaacetic acid whole-body magnetic resonance imaging (MRI), without the presence of visceral metastases. All patients underwent a whole-body bone scan, and 100 of the patients with suspicious metastatic lesions were confirmed by whole-body MRI examination. Seven patients with suspected visceral metastases or multiple lymph node metastases outside the pelvis received PET/CT examination. It turned out that they were non-metastatic. All of the patients received RALP as the first-line treatment method. Subsequent treatment options were determined by the post-operative pathological results, follow-up results, and patient's own decisions. A total of 15 patients received ADT during the follow-up to today in the localized PCa group and 13 patients received ADT in the OPC group due to biochemical recurrence (BCR) or N^+ stage. Patients were categorized into either the OPC group ($n = 41$) or the localized PCa group ($n = 467$) by two authors in consensus who were blinded to peri-operative and oncological outcomes at the time of data collection.

Pre-operative data were collected, including age, body mass index (BMI), PSA, biopsy Gleason Score (GS), and clinical stage. All intra-operative data included operative time, blood loss, and post-operative data including pathologic stage, pathologic GS, post-operative hospital stays, as well as pathologic results, such as surgical margin status. By comparing clinical and pathological characteristics between the two groups, we found that pre-operative PSA, post-operative pathological GS, and pathological staging between the two groups before propensity score matching were statistically significantly different. To reduce selection bias and make the two groups of data have good consistency, we considered age, pre-operative PSA, BMI, pathological GS, and pathological T staging as predictors, setting the matching tolerance as 0.1, performing 1:1 patient matching on the basis of each patient's propensity score, and ultimately yielding 41 pairs. No significant differences were found between the two groups after propensity score matching.

RALP technique and data collection

We performed the RALP as described previously.[19-21] Surgical data were recorded, including operative time, blood loss, and surgery-related complications. Specimens were fixed, coated with Indian ink, and cut into systemic stepwise sections at 5-mm intervals. Post-operative pathologic results included the positive surgical margin (PSM) and GS. PSM was defined as the presence of malignant glandular cells on the inked surface of the specimen. In the OPC group, all patients had pelvic lymph node dissection, among whom seven were found to have positive lymph nodes, with a positive rate of 17.1%. In the localized PCa group, all intermediate or high-risk patients had pelvic lymph node dissection, among whom six were found to have positive lymph nodes, with a positive rate of 16% (6/38).

Patients were followed up for clinical outcomes and PSA level at the first 6 weeks, every month in the first year after RALP, and every 6 months during the next 5 years. Post-operative continence was defined as achieving the use of 0 or one pad for "security" daily, and post-operative continence was evaluated by the 1-year pad-free rate. Post-operative follow-up time was set to the end of the study or death, and the primary endpoint was BCR, defined as two consecutive increased PSA levels of >0.2 ng/mL after RALP. The second endpoint was the occurrence of death, defined as OS.

Statistical analysis

Continuous and normally distributed variables were presented as the mean ± standard deviation; non-normally distributed variables were presented as the median with interquartile range. Comparison of groups in matched data was executed by means of the paired *t* test for continuous variables and the Wilcoxon test for categorical variables. Cumulative incidence rates for BCR-free survival (BRFS) and OS rates were estimated using the Kaplan-Meier method. The Cox proportional hazards model was used to assess the possible risk factors for BCR. The possible risk factors were age, BMI, pre-operative PSA, pathological T stage, post-operative GS, and oligometastatic state. The risk factors included in multivariate analysis were selected for a *P* value less than 0.15 in univariate analysis. SPSS

22.0 for Windows (SPSS, Inc, Chicago, IL, USA) was used for all other statistical calculations and analyses. Statistical significance was considered as a P value less than 0.05.

Results

Patients characteristics

The baseline characteristics of all patients (overall data, $n = 508$) before propensity score matching and the data for the matching patients (matching data, $n = 82$) are all shown in Table 1. Patient characteristics including age and BMI between the two groups showed no statistical significance (all $P > 0.05$). However, pre-operative PSA ($P = 0.006$), post-operative GS ($P = 0.017$), and pathologic T stage ($P = 0.004$) were significantly different between the two groups before propensity score matching. By propensity score matching, the median pre-operative PSA was 19.00 *vs.* 19.57 ng/mL in the OPC group and the localized PCa group. No significant differences were found between the two groups after propensity score matching (all $P > 0.05$).

Peri-operative, pathologic, and survival outcomes after propensity score matching

After propensity score matching, peri-operative, pathologic outcomes, BRFS, and OS were compared between the two groups. The operation parameters and pathological and survival information are shown in Table 2. The overall

Table 1: Characteristics of patients with prostate cancer who underwent robotic-assisted laparoscopic radical prostatectomy before and after propensity score matching.

Characteristics	Before propensity score matching				After propensity score matching			
	OPC ($n = 41$)	Localized PCa ($n = 467$)	Statistics	P	OPC ($n = 41$)	Localized PCa ($n = 41$)	Statistics	P
Age (years), mean ± SD	67.0 ± 6.8	66.7 ± 6.8	0.060*	0.952	67.0 ± 6.8	67.1 ± 7.6	0.010*	0.992
BMI (kg/m^2), mean ± SD	24.6 ± 2.4	24.3 ± 2.9	0.308*	0.757	24.6 ± 2.4	25.5 ± 3.0	–1.773*	0.080
Pre-operative PSA, n (%)			2.760†	0.006			0.846†	0.400
0–3.9 ng/mL	0	10 (2.1)			0	0		
4.0–9.9 ng/mL	8 (19.5)	153 (32.8)			8 (19.5)	14 (34.1)		
10.0–19.9 ng/mL	13 (31.7)	149 (31.9)			13 (31.7)	7 (17.1)		
≥20.0 ng/mL	20 (48.8)	155 (33.2)			20 (48.8)	20 (48.8)		
Pathologic stage, n (%)			–2.897†	0.004			–0.838†	0.402
T2a	2 (4.9)	82 (17.6)			2 (4.9)	3 (7.3)		
T2b	6 (14.6)	39 (8.4)			6 (14.6)	4 (9.7)		
T2c	10 (24.4)	166 (35.5)			10 (24.4)	15 (36.6)		
T3a	11 (26.8)	104 (22.3)			11 (26.8)	9 (22.0)		
T3b	12 (29.3)	76 (16.2)			12 (29.3)	10 (24.4)		
Post-operative GS, n (%)			–2.389†	0.017			–0.149†	0.882
6	2 (4.9)	76 (16.2)			2 (4.9)	1 (2.4)		
7	21 (51.2)	262 (56.1)			21 (51.2)	22 (53.7)		
8	7 (17.1)	56 (12.0)			7 (17.1)	8 (19.5)		
9	9 (21.9)	71 (15.3)			9 (21.9)	10 (24.4)		
10	2 (4.9)	2 (0.4)			2 (4.9)	0		

* t values. † Z values. OPC: Oligometastatic prostate cancer; PCa: Prostate cancer; SD: Standard deviation; BMI: Body mass index; PSA: Prostate-specific antigen; GS: Gleason score.

Table 2: Peri-operative, pathologic, and survival outcomes after propensity score matching.

Parameters	OPC ($n = 41$)	Localized PCa ($n = 41$)	Statistics	P
Operative time (min), median (IQR)	140 (120.0–175.0)	130.0 (105.5–165.0)	–1.110*	0.267
Blood loss (mL), median (IQR)	160 (100–200)	150 (100–200)	–0.479*	0.632
Post-operative hospital stay (day), median (IQR)	6 (5–8)	6 (5–8)	–0.077*	0.939
PSM +, n (%)	15 (36.6)	15 (36.6)	0.000†	1.000
Upper	9 (21.9)	8 (19.5)	0.074†	0.785
Lower	11 (26.8)	13 (31.7)	0.236†	0.627
Post-operative 1 month PSA decline rate (%)	95.4	97.0	0.683†	0.499
4-year BRFS (%)	56.7	60.8	0.011†	0.804
5-year OS (%)	96.3	100	0.963†	0.326
Follow-up (months), median (IQR)	26.4 (16.9–41.0)	18.3 (12.3–36.4)	–0.813*	0.410

* Z values † χ^2 values. OPC: Oligometastatic prostate cancer; PCa: Prostate cancer; IQR: Interquartile range; PSM: Positive surgical margin; PSA: Prostate-specific antigen; BRFS: Biochemical recurrence free survival; OS: Overall survival.

median operative time was 140 *vs.* 130 min, and the median blood loss was 160 *vs.* 150 mL in the OPC group and the localized PCa group, respectively, without significant differences ($P = 0.267$, $P = 0.632$, respectively). The overall PSM rates in the OPC group and the localized PCa group were both 36.6%. The upper and lower PSM rates were 21.9% and 26.8%, respectively, in the OPC group and 19.5% and 31.7%, respectively, in the localized PCa group without significant differences ($P = 0.785$, $P = 0.627$, respectively). The median post-operative hospital stays were 6 days in both groups ($P = 0.939$). Among the 82 patients, there were no severe complications. Only one patient had prolonged pelvic drainage output in the OPC group, and one patient had urinary retention after catheter removal, who was relieved after the oral administration of alpha-blockers in the localized PCa group.

Figure 1 shows the post-operative urinary continence recovery rate generated after propensity score matching. The third, the sixth, and the twelfth month continence recovery rates were 51.2%, 75.6%, and 93.8%, respectively, in the OPC group and 62.6%, 74.7%, and 82.3%, respectively, in the localized PCa group. No significant differences were found between the two groups ($P = 0.915$). However, the 12th month continence recovery rate in the OPC group was much better than that in the localized PCa group, although no significant difference was found.

The median follow-up was 26.4 months in the OPC group and 18.3 months in the localized PCa group. A total of 75 patients who did not receive neoadjuvant ADT before surgery or ADT immediately after surgery were included in this analysis. The post-operative 1 month PSA decline rate was 95.4% in the OPC group and 97.0% in the localized PCa group without a statistically significant difference ($P = 0.499$). The 4-year BRFS rate was 56.7% in the OPC group and 60.8% in the localized PCa group [Figure 2]. Only one patient died of PCa in the OPC group during the follow-up. The 5-year OS rate was 96.3% and 100% in the OPC group and the localized PCa group [Figure 3]. Neither the BRFS rate nor the OS rate were significantly different between the two groups after propensity score matching ($P = 0.804$, $P = 0.326$, respectively).

Comparison of survival analysis of patients with different bone metastasis lesions

To further analyze whether different metastatic lesions affect the occurrence of BCR, 27 patients with a single metastatic lesion without immediate post-operative ADT were divided into four groups based on the site of lesions: single rib metastases group ($n = 8$), single thoracolumbar metastases group ($n = 9$), single pelvic metastases group ($n = 6$), and single other bone metastases group ($n = 4$). There were no significant differences in the basic characteristics among the four groups [Supplementary Table 1, http://links.lww.com/CM9/A153]. The 1-year BRFS rates were 72.9%, 66.7%, 40.0%, and 75.0%, respectively [Supplementary Figure 1, http://links.lww.com/CM9/A152].

Analysis of risk factors for oncological outcomes

After propensity score matching, BRFS rates were found to have no significant difference between the groups. To

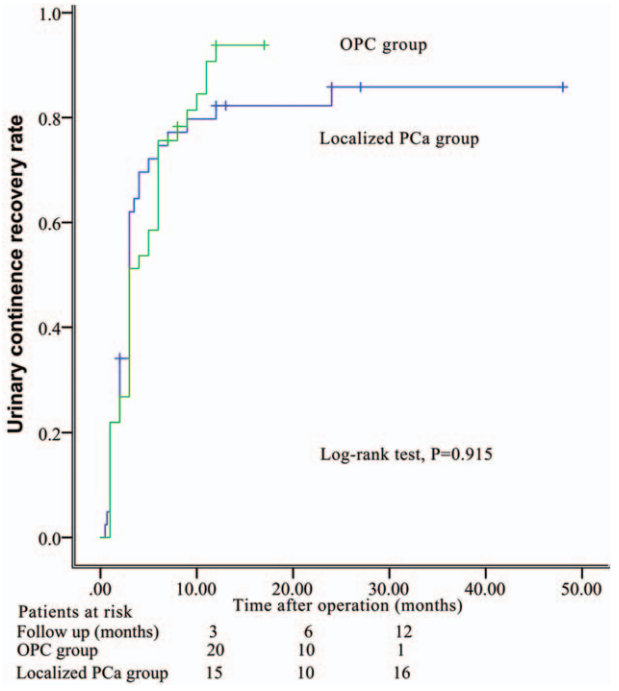

Figure 1: The post-operative urinary continence recovery rate generated after propensity score matching. OPC: Oligometastatic prostate cancer; PCa: Prostate cancer.

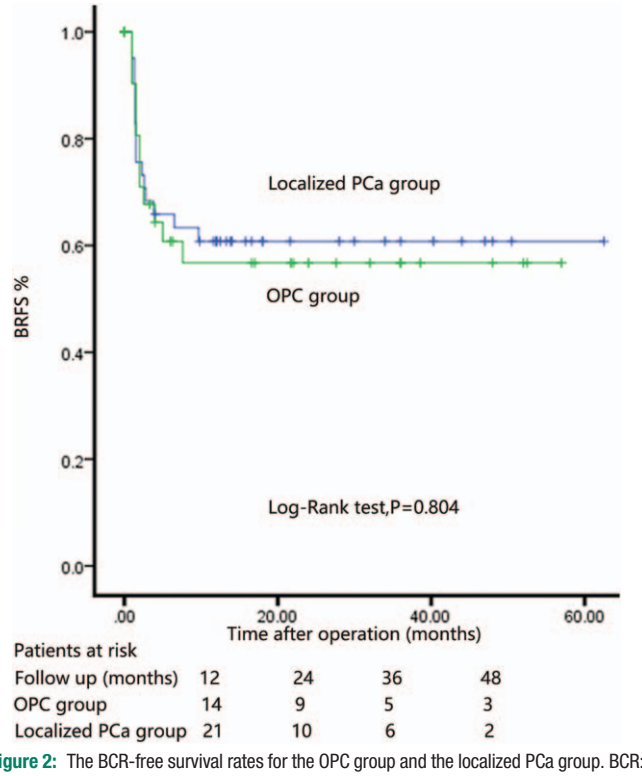

Figure 2: The BCR-free survival rates for the OPC group and the localized PCa group. BCR: Biochemical recurrence; BRFS: Biochemical recurrence free; OPC: Oligometastatic prostate cancer; PCa: Prostate cancer.

further analyze the risk factors of tumor progression, a Cox proportional hazards model was used to assess the association of possible risk factors of BCR in univariate and multivariate analysis. A total of 305 patients were included in the series, excluding those who received peri-operative adjuvant radiotherapy or androgen-deprivation therapy. The possible risk factors were age, BMI, pre-operative PSA, pathological stage, post-operative GS, oligometastatic state. In univariate analysis, pre-operative PSA, pathological stage, oligometastatic state, and post-operative GS were significant risk factors for BCR ($P < 0.05$). In multivariate analysis, pre-operative PSA (hazard ratio [HR] for >20 and <10: 6.606; 95% confidence interval [CI], 2.497–17.468, $P = 0.0001$; HR for 10–20 and <10: 3.651; 95% CI, 1.349–9.882, $P = 0.0108$), post-operative GS (HR for = 7 and ≤6: 1.790; 95% CI, 0.528–46.071, $P = 0.3489$; HR for >7 and ≤6: 7.381; 95% CI, 2.155–25.284, $P = 0.0015$) and pathologic T stage (≥T3a and <T3a: 1.932; 95% CI, 1.118–3.340, $P = 0.0183$) rather than oligometastatic state were independent risk factors of BCR [Table 3].

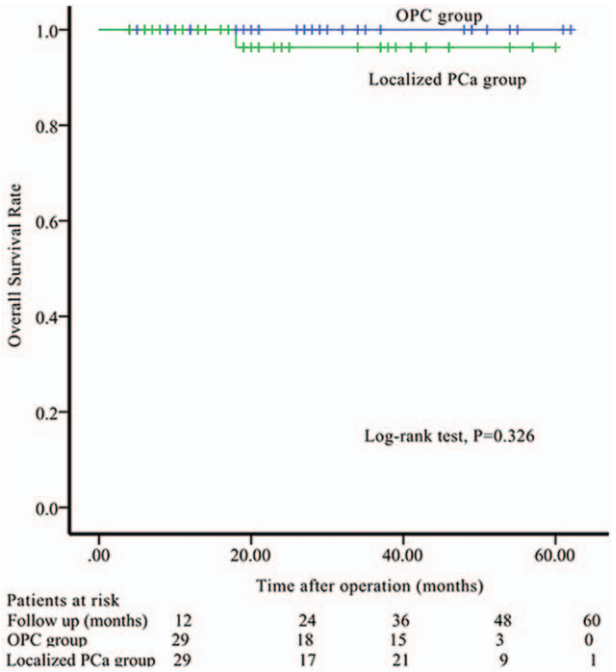

Figure 3: The overall survival rate for the OPC group and the localized PCa group. OPC: Oligometastatic prostate cancer; PCa: Prostate cancer.

Discussion

Local treatment has been shown to be effective and safe by previous studies in late-stage PCa in recent years.[22] As a cytoreductive surgery, radical prostatectomy has also been confirmed to have great efficacy in improving cancer-specific survival and OS in patients with mPCa.[17,23] Although the number of metastases was not investigated and included in the studies mentioned above, the researchers all discussed that it should be regarded as the burden of cancer and needs to be treated as an important factor.

According to Weichselbaum and Hellman,[4] oligometastases are defined as an intermediate state between localized and metastatic disease. The exact definition of oligometastases is controversial and uncertain, while most

Table 3: Cox multivariable analysis showing predictors of biochemical recurrence.

	Univariate analysis		Multivariate analysis	
Covariates	**HR (95% CI)**	***P***	**HR (95% CI)**	***P***
Post-operative GS				
≤6*	1		1	
=7	3.1 (0.929–10.248)	0.0658	1.8 (0.528–6.071)	0.3498
>7	17.2 (5.324–55.509)	<0.0001	7.4 (2.155–25.284)	0.0015
Pre-operative PSA				
<10 ng/mL*	1		1	
10–20 ng/mL	5.7 (2.164–14.899)	0.0004	3.7 (1.349–9.882)	0.0108
>20 ng/mL	12.0 (4.727–30.315)	<0.0001	6.6 (2.497–17.478)	0.0001
Age				
≤59 years*	1			
60–74 years	0.8 (0.427–1.680)	0.6354		
>74 years	1.5 (0.654–3.242)	0.3579		
BMI				
<24 kg/m^2*	1			
≥24 kg/m^2	1.0 (0.655–1.668)	0.8541		
Pathologic T stage				
<T3a*	1			
≥T3a	5.1 (3.136–8.354)	<0.0001	2.0 (1.118–3.340)	0.0183
Oligometastatic state				
Negative*	1			
Positive	2.0 (1.057–3.843)	0.0333	1.1 (0.593–2.224)	0.6816

*Reference group. HR: Hazard ratio; CI: Confidence interval; GS: Gleason score; PSA: Prostate-specific antigen; BMI: Body mass index.

researchers consider that oligometastases and polymetastases are biologically distinctive, based on the findings that several differentially expressed micro-RNAs between the two states can predict different oncological outcomes.[24] Although some original studies define oligometastases as ≤3, ≤4, and ≤5 metastatic lesions, including bone, lymph nodes, or any other organs,[25-27] here, we define it as ≤2 bone metastatic lesions, which is more restricted than previous studies, as we cautiously treated this type of patients because of a lack of experience.

With the maturity and improvement of minimally invasive technology and robotic surgery, the interest and confidence of radical treatment in advanced PCa and even in OPC has grown in recent years. Gandaglia and his colleagues retrospectively reported that RP with a multimodal approach might represent a safe and feasible option in selected patients with mPCa and provide acceptable oncologic outcomes with a minimum of a 5-year follow-up.[18] Further, Jang *et al* reported a retrospective study in patients with OPC treated by RALP, comparing oncological outcomes, and finally found that RALP improved PFS and cancer-specific survival.[28] RALP has also been a conventional surgical procedure in our center and was proven to be safe and feasible.[29] However, these studies were limited by their small scale, unequal baseline characteristics, and inconsistent assessment criteria.

Propensity score matching is a statistical matching technique that attempts to estimate the effect of an exposure factor, a treatment or other intervention by reducing the bias of confounding variables. It can improve the quality of an observational study by simulating a prospective study. Although it can provide a reference for others by using pre-operative data to make propensity score matching, many patients' pathological data, such Gleason score, would have the possibility of upgrading or downgrading. This does not really reflect the patient's disease state. So, we use post-operative pathological data to make propensity score matching. On the result of the study, we will further design clinical trials to confirm the effect of surgical treatment for OPC.

Here, we present a short-term therapeutic outcome study of RALP for OPC after propensity score matching by reducing the impact of interference factors. After the special processing of the data, we found that there were no significant differences in peri-operative parameters, post-operative complications, PSM and urinary continence between the two groups. However, we need to classify that we apply propensity score matching that equalizes patients' baseline characteristics, especially the clinical and pathological stage, indicating that RALP might play a role in highly selected patients with OPC.

When considering post-operative survival outcomes, the results showed that OPC patients had the same post-operative 1-month PSA decline rate, BRFS, and OS with localized PCa patients, although the median follow-up of 26.4 months was relatively short, indicating that the state of oligometastases did not affect the effectiveness of RALP. Further, we analyzed the impact of different metastatic lesions in post-operative survival and found no significant differences. Based on this trend, we found that the patients with single thoracolumbar and single pelvic metastases might progress faster than others. The results confirmed that there were no advantages in patients with localized PCa over those with OPC when receiving RALP as a cytoreductive surgery. Finally, we analyzed the risk factors of oncological outcomes between the two groups and found that the PSA level, GS, and pathologic T stage were prognostic factors in predicting BCR using multivariate analysis. Based on the results of the survival analysis, we believe that the assessment of the status of primary lesion such as PSA, GS, and pathological T stage are more important, verifying the hypotheses that oligometastases are not identical to polymetastases.

There are several limitations in the study. The first is low evidence power in clinical applications because we selected oligometastases as an exposure factor in a retrospective observational study. The second is the lack of a control group of OPC patients who initially receive ADT instead of RALP, which prevented us from comprehensively assessing the oncologic outcomes associated with RP. However, the disease-free survival observed in our study was higher than that observed in men managed with ADT alone. A randomized clinical trial in comparing RALP and ADT alone as a first-line treatment will be helpful in further verification. Another limitation is that the relatively shorter follow-up restricts the observation of the oncological outcomes of RALP, which needs to be further investigated.

In conclusion, we retrospectively analyzed the short-term therapeutic outcomes of RALP for OPC after propensity score matching by reducing the impact of interference factors. Our preliminary results support the safety and effectiveness of RALP in OPC.

Conflicts of interest

None.

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