



Impact of protruded median lobe on perioperative, urinary continence and oncological outcomes of Retzius-sparing robot-assisted radical prostatectomy

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Background: To investigate the effect of protruded median lobe (PML) on the perioperative, oncological, and urinary continence (UC) outcomes among patients underwent Retzius-sparing robot-assisted radical prostatectomy (RS-RARP).

Methods: 231 consecutive patients who had undergone RS-RARP were collected and analyzed. Patients were divided into three groups based on the PML degree: PML<5 mm (n=99); 5≤PML<10 mm (n=91); PML≥10 mm (n=41). The perioperative outcomes, short-term oncological, and UC outcomes were compared among the three groups. Those outcomes were also compared in patients with significant PML (>10 mm) who underwent the traditional or Retzius-sparing RARP.

Results: The median PML was significantly associated age (P<0.001) and prostate volume (P<0.001). Perioperative characteristics including console time, estimated blood loss (EBL), intraoperative transfusion rate, and complications were not statistically different among the three groups (P=0.647, 0.574, 0.231, 0.661, respectively). The rate of positive surgical margin (PSM) were not significantly different in the three groups (P=0.065). No significant difference regarding UC and biochemical recurrence (BCR) at 12-month follow-up was observed in the three groups (P>0.05). Comparison between the two approaches in men with significant PML showed better recovery of UC (HR =1.83, 95% CI: 1.117–3.01, log-rank P=0.002) and similar BCR (log-rank P=0.072) after RS-RARP.

Conclusions: RS-RARP is an oncologically and functionally equivalent approach for patients with PML. Compared with the traditional approach, RS-RARP offers benefits regarding UC for cases with significant PML.

Keywords: Median lobe; urinary continence (UC); Retzius-sparing; perioperative; oncological safety

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Introduction

Radical prostatectomy (RP) has been well-demonstrated to be a definitive strategy for the treatment of localized prostate cancer. Cancer free, urinary continence (UC) and potency have been proposed as the standard to evaluate RP (1). Robot-assisted radical prostatectomy (RARP) is now the most widely adopted approach, offering the benefits of a minimally invasiveness while providing excellent oncological and optimal functional outcomes (2).

The presence of a protruded median lobe (PML) is reported to increase the difficulty of performing RARP (3), because PML may obscure the plane of the posterior vesicoprostatic junction (*Figure 1A,B*). Since Sarle *et al.* described the first case of RARP for a patient with a large median lobe and highlighted the possible difficulties in 2005 (3), several studies have reported that increased operative time, hospital stay (4,5) and blood loss was associated with significant PML (6). In addition, PML is correlated with poor early UC recovery (7) and increased positive surgical margin at base (PSMB) (8). Therefore, patients with a large median lobe as challenging cases are recommended to be performed by experienced surgeons (9). Some maneuvers have been proposed to expedite the RARP in cases with significant PML, including preoperative evaluation of the presence and degree of PML, entering the bladder more cephalad to allow for full visualization of the prostate and identification of the urethral orifices. Recently, the Carter-Thomas device was reported to pull the prostate and median lobe up towards the patient's abdominal wall for cases with significant PML (5). However, all the techniques are accomplished by using the anterior approach which is in an antegrade manner, making the identification of the plane between the posterior bladder neck and the prostate challenging in patients with significant PML.

Retzius-sparing robot assisted radical prostatectomy (RS-RARP), first described by Galfano *et al.* in 2010 (10,11), is demonstrated to result in earlier recovery of UC (12-17). Different from the traditional approach, Retzius-sparing approach of RARP is technically achieved by passing through the posterior plane while the bladder neck is also dissected posteriorly. Therefore, this technique may potentially facilitate RARP in cases with significant PML. However, there has been no literature reporting the safety and efficacy of RS-RARP in patients with PML till now.

This study was therefore designed to retrospectively investigate the impact of PML on RS-RARP. The perioperative outcomes, short-term oncological and UC

outcomes were analyzed. We present the following article in accordance with the STROBE reporting checklist (available at: <http://dx.doi.org/10.21037/tau-20-1229>).

Methods

Patients and study design

Between March 2018 and December 2019, we retrospectively included 338 consecutive patients who underwent Retzius-sparing approach of RARP performed by the same surgeon (Dr. HG, n >100 before the initiation of this study) in our center. Patients without preoperative magnetic resonance imaging (MRI) (n=36) or with neoadjuvant hormone therapy (n=62), transurethral resection of the prostate (TURP, n=7) were excluded. Patients with suspicious pelvic lymph nodes or distant metastasis (n=2) were also excluded. Finally, 231 patients were included in the current study. For each patient, clinical data including age, body mass index (BMI), preoperative total prostate-specific antigen (PSA), prostate volume measured by transrectal ultrasound (TRUS), American Society of Anesthesiologists (ASA) score, biopsy Gleason score, clinical stage, risk stratification, pathological stage, pathological Gleason score, positive surgical margin (PSM) and PSMB, UC (defined as 0 pads/day), and biochemical recurrence (BCR) were collected. Likewise, perioperative variables such as reduction of hemoglobin (Hb), reduction of hematocrit (HCT), operative time, console time, estimated blood loss (EBL), length of stay (LOS), transfusion rate, early postoperative complications were collected and analyzed. Postoperative outcomes in terms of UC and BCR (two consecutive PSA >0.2 ng/mL) were also analyzed. Since more than half of the included patients had moderate-to-severe erectile dysfunction preoperatively, we did not assess the potency outcomes. Included patients were divided into three groups according to the degree of PML determined on preoperative magnetic resonance imaging (MRI): Group 1, PML <5 mm (n=99); Group 2, 5 ≤ PML <10 mm (n=91); Group 3, PML ≥10 mm (n=41) (7). Differences of clinical and pathological features between the three groups were analyzed. All procedures performed in this study were in accordance with the Declaration of Helsinki (revised in 2013) and approved by the Ethics Committee of the Drum Tower Hospital, Medical School of Nanjing University (2017-044-02). Because of the retrospective nature of the research, the requirement for informed consent was waived.

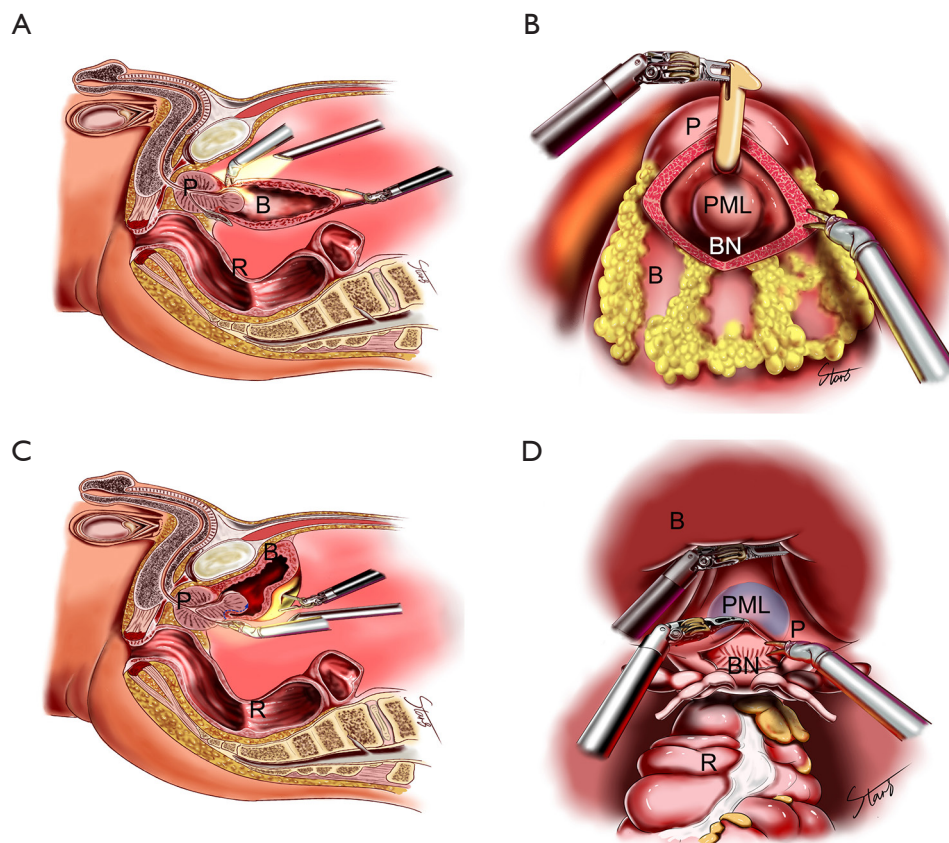


Figure 1 (A,B,C) Sagittal view of the impact of a protruded median lobe on the traditional (A) and Retzius-sparing (C) approach of robot-assisted radical prostatectomy. (B,C,D) Intraoperative view showing the exposure of the bladder neck posteriorly in the traditional (B) and Retzius-sparing (D) approach. B, bladder; P, prostate; R, rectum; BN, bladder neck; PML, protruded median lobe.

MRI examination and measurement of PML

All patients underwent pelvic MRI using a 3.0-T MR scanner (Achieva 3.0 T TX, Philips Medical Systems, Netherlands) by a 16-channel phased array coil as described previously (18). PML was measured from T2-weighted midsagittal images. The longitudinal distance from the bladder neck to the highest portion of the median lobe of the prostate was assessed. The bladder neck was defined as the proximal opening of the prostatic urethra. Significant PML was defined as the longitudinal distance longer than 10 mm (8).

Surgical techniques and pathological evaluation

All surgical procedures were performed by the same surgeon (Dr. H.G.) using the da Vinci SI robot system (Intuitive Surgical, Sunnyvale, CA, USA). The Retzius-sparing

approach of RARP was performed via the transperitoneal approach as described in our previous study (19). For dissection of the bladder neck, the prostatovesical junction was identified after removal of the peri-vesical fat and gentle retraction of the prostate posteriorly. Afterward, the bladder neck was identified and carefully dissected posteriorly, with monopolar cautery. With careful dissection, detrusor muscles located on the base of the median lobe could be preserved (*Figure 1C,D*). In patients with high risk disease, extended lymph node dissection was performed. All patients were managed according to our standard postoperative protocol for RARP. Catheter was removed 7–12 days after RS-RARP with a negative cystography.

After surgery, whole-mount tissue was fixed in 10% formalin, paraffin embedded, microtome cut into 4 mm slices and stained with hematoxylin-eosin after painting with ink according to the Stanford Protocol (20). All

whole mount histology slides were subsequently digitalized by a scanning system (NanoZoomer Digital Pathology, Shizuoka, Japan). All pathologic images were interpreted by a dedicated genitourinary pathologist (over 10 years of experience). PSM was defined as the inked surface showed prostate cancer.

Comparison between traditional and Retzius-sparing approach of RARP

To compare the outcomes between the patients with significant PML (≥ 10 mm) underwent the traditional or Retzius-sparing approach of RARP, Patients with significant PML who underwent traditional approach by the same surgeon (Dr. H.G.) during the period of June 2014 to September 2017 were included from the database in our center. The inclusion and exclusion criteria were set as the same as those for the Retzius-sparing approach. Finally, 43 patients were included for analysis. The clinical and pathological features were compared between the two groups. The perioperative, oncological, and UC outcomes between two approaches were also assessed statistically.

Statistical analysis

Nonparametric continuous variables were presented as median and interquartile range (IQR). The Pearson chi-square test or Fisher exact test was used to compare categorical data, while the Kruskal-Wallis test was used for comparison of nonparametric continuous data for the three groups. Survival curve was applied for the time to recovery of continence and BCR. SPSS 22.0 (SPSS, Chicago, IL, USA) was used for all statistical analysis. A $P < 0.05$ was considered to be significant, and all P values were two-sided.

Results

Baseline information

The preoperative data were shown in *Table 1*. The median (IQR) follow-up was 19 [14–25] months. There is no statistically significant difference between the three groups in terms of preoperative body mass index (BMI), prostate-specific antigen (PSA), ASA, biopsy Gleason score, clinical staging and risk stratification. The median (IQR) PML for each group was 0 mm (0–3.20 mm), 6.67 mm (5.93–8.07 mm), 13.42 mm (11.70–15.66 mm), respectively, and

was significantly associated age ($P < 0.001$) and prostate volume ($P < 0.001$) (*Table 1*).

The impact of PML on perioperative outcomes

As shown in *Table 2*, the reduction of Hb and HCT after surgery was similar in the three groups ($P = 0.847$ and 0.819 , respectively). The total operative time and console time was not significantly associated with PML ($P = 0.648$ and 0.647 , respectively). The EBL, as well as blood transfusion, was not significantly associated with the degree of PML ($P = 0.574$ and 0.231 , respectively). There was no significant difference in the three groups in term of the LOS ($P = 0.242$). The most common postoperative complications were ileus and wound pain, which were not significantly different between the three groups ($P = 0.661$).

The impact of PML on oncological outcomes

The pathological outcomes such as postoperative Gleason score and pathological T stage were similar among the three groups ($P = 0.153$ and 0.095 , respectively). The overall PSM rate in patients with significant PML was lower compared with that of patients in the other two groups, but without significant differences ($P = 0.065$). The PSMB in the three groups did not show significant difference either ($P = 0.133$) (*Table 3*).

BCR rate at 12-month follow-up was shown in *Table 3*. No significant difference was observed between the three groups regarding BCR during the one-year follow-up ($P = 0.213$).

The impact of PML on UC outcomes

UC data at different time points after surgery was shown in *Table 3*. Men in Group 1 (PML < 5 mm) trended to have better UC compared to the other two groups at 1-month follow-up, but without significant difference ($P = 0.05$). Otherwise, no significant differences were observed regarding UC in the three groups at 3-, 6-, and 12-month follow-up ($P = 0.295$, 0.463 , and 0.301 , respectively).

Comparison between posterior and anterior approach for cases with significant PML

Table S1 showed the comparison of clinical and pathological outcomes between patients with significant PML (≥ 10 mm) who underwent the traditional or Retzius-sparing approach

Table 1 Patients' characteristics

Characteristics	PML <5	5 ≤ PML <10	PML ≥10	P value
Number of subjects	99	91	41	
Age (years), (median, IQR)	66.0 (60.0,73.0)	71.0 (67.0,77.0)	70.0 (67.0,73.0)	<0.001 ^a
BMI (kg/m ²), (median, IQR)	24.22 (22.49,26.23)	23.88 (21.72,25.70)	23.72 (21.44,26.65)	0.12 ^a
PSA (ng/dL), (median, IQR)	9.03 (6.22,13.10)	10.52 (6.73,18.92)	9.80 (6.49,14.37)	0.215 ^a
Prostate volume (mL), median (IQR)	27.80 (20.96,35.52)	34.40 (25.27,46.19)	49.42 (33.81,61.14)	<0.001 ^a
ASA, n (%)				0.582 ^b
2	23 (23.2)	23 (25.3)	7 (17.1)	
3	76 (76.8)	68 (74.7)	34 (82.9)	
Biopsy Gleason score, n (%)				0.083 ^b
3+3	27 (27.3)	27 (29.7)	21 (51.2)	
3+4	26 (26.3)	14 (15.4)	8 (19.5)	
4+3	20 (20.2)	25 (27.5)	4 (9.8)	
4+4/5+3/3+5	25 (25.3)	23 (25.3)	6 (14.6)	
4+5/5+4/5+5	1 (1.0)	2 (2.2)	2 (4.9)	
Risk stratification, n (%)				0.086 ^b
Low risk	15 (15.2)	15 (16.5)	13 (31.7)	
Intermediate risk	41 (41.4)	29 (31.9)	10 (24.4)	
High risk	43 (43.4)	47 (51.6)	18 (43.9)	
Clinical stage, n (%)				0.561 ^b
T1c	13 (13.1)	17 (18.7)	6 (14.6)	
T2a-b	59 (59.6)	41 (45.1)	24 (58.5)	
T2c	16 (16.2)	18 (19.8)	7 (17.1)	
T3a-b	11 (11.1)	15 (16.5)	4 (9.8)	

^a, P value calculated using Kruskal-Wallis test; ^b, P value calculated using Pearson chi-square test or Fisher exact test. PML, protruded median lobe; BMI, body mass index; PSA, prostate specific antigen; IQR, interquartile range; ASA, American Society of Anesthesiologists.

of RARP. There was no statistically difference in the patient characteristics between the two groups, including age, BMI, preoperative PSA, prostate volume, ASA, biopsy Gleason score, clinical stage and risk stratification. The console time of the Retzius-sparing approach was significantly lower compared with that of the traditional approach (P=0.044). There was no significant difference regarding EBL, blood transfusion rate between the two groups. The complication rate of the Retzius-sparing approach is slightly lower compared with that of the traditional approach, but without significant difference (18.6% *vs.* 9.8%, OR 0.47, 95% CI: 0.13–1.71, P=0.247). No significant difference in terms of postoperative Gleason score and pathological T

staging between the two groups. The overall PSM (25.6% *vs.* 12.2%, OR 0.40, 95% CI: 0.13–1.29, P=0.118), as well as PSMB (9.3% *vs.* 4.9%, OR 0.50, 95% CI: 0.09–2.89, P=0.431), showed no significant difference in the two groups, though the PSM and PSMB rates in men underwent the traditional approach were slightly higher than those who underwent the Retzius-sparing group. Urinary function data at each time point was shown in [Figure S1](#). The UC outcomes of the Retzius-sparing approach were better than those of the traditional approach (HR =1.834, 95% CI: 1.117–3.01, log-rank P=0.002). At 12-month follow-up, the BCR-free survival was slightly lower in the Retzius-sparing group compared with that in the traditional

Table 2 Perioperative characteristics

Characteristics	PML <5	5≤ PML <10	PML ≥10	P value
Number of subjects	99	91	41	
Reduction of hemoglobin (g/L), median (IQR)	21.5 (15.0,28.0)	20.0 (13.5,28.5)	20.0 (15.0,28.0)	0.847 ^a
Reduction of hematocrit, median (IQR)	6.55 (4.43,8.48)	6.60 (4.20,8.40)	6.80 (4.15,8.60)	0.819 ^a
Operative time (min), median (IQR)	170.0 (145.0,190.0)	165.0 (140.0,190.0)	160.0 (142.5,196.5)	0.648 ^a
Console time (min), median (IQR)	110.0 (85.0,130.0)	105.0 (80.0,130.0)	100.0 (87.5,136.5)	0.647 ^a
EBL (mL), median (IQR)	250 (200,400)	300 (150,400)	250 (200,350.0)	0.574 ^a
LOS (day), median (IQR)	7.0 (4.0,10.0)	6.0 (4.0,9.0)	7.0 (4.50,8.50)	0.242 ^a
Blood transfusion, n (%)	2 (2.0)	6 (6.6)	0 (0)	0.231 ^b
Complications, n (%)	10 (10.1)	6 (6.6)	4 (9.8)	0.661 ^b
I	9	3	2	
II	1	3	2	
Nerve sparing (%)	57 (57.6)	50 (54.9)	24 (58.5)	0.904 ^b

^a, P value calculated using Kruskal-Wallis test; ^b, P value calculated using Pearson chi-square test or Fisher exact test. PML, protruded median lobe; IQR, interquartile range; EBL, estimated blood loss; LOS, length of stay.

Table 3 Postoperative characteristics

Characteristics	PML <5	5≤ PML <10	PML ≥10	P value
Number of subjects	99	91	41	
Postoperative Gleason score, n (%)				0.153 ^b
3+3	13 (13.1)	18 (19.8)	13 (31.7)	
3+4	48 (48.5)	32 (35.2)	21 (51.2)	
4+3	24 (24.2)	28 (30.8)	5 (12.2)	
4+4/5+3/3+5	7 (7.1)	9 (9.9)	1 (2.4)	
4+5/5+4/5+5	7 (7.1)	4 (4.4)	1 (2.4)	
Urinary continence (1 months), n (%)	68 (68.7)	47 (51.6)	23 (56.1)	0.05 ^b
Urinary continence (3 months), n (%)	78 (78.8)	63 (69.2)	29 (70.7)	0.295 ^b
Urinary continence (6 months), n (%)	86 (86.9)	72 (79.1)	34 (82.9)	0.463 ^b
Urinary continence (12 months), n (%)	93 (94.5)	79 (88.3)	36 (89.8)	0.301 ^b
BCR at 12-month follow-up, n (%)	2 (2.0)	2 (2.2)	3 (7.3)	0.213 ^b
Pathological T stage, n (%)				0.095 ^b
pT2	57 (57.6)	45 (49.5)	29 (70.7)	
pT3	42 (42.4)	46 (50.5)	12 (29.3)	
PSM, n (%)	26 (26.3)	31 (34.1)	5 (12.2)	0.065 ^b
PSMB, n (%)	3 (3.0)	9 (9.9)	2 (4.9)	0.133 ^b

^b, P value calculated using Pearson chi-square test or Fisher exact test. PML, protruded median lobe; PSM, positive surgical margin; PSMB, positive surgical margin at base.

group, but without significant difference (log-rank $P=0.072$) (Figure S2).

Discussion

The impact of PML on Retzius-sparing approach of RARP remains unknown. In the present study, we investigated the impact of PML (MRI measured) on the perioperative as well as short-term oncological and UC outcomes in patients underwent Retzius-sparing approach of RARP. We also compared those outcomes in patients with significant PML who underwent the traditional or Retzius-sparing approach. Our results demonstrated that perioperative outcomes, PSM rate, short-term BCR, and UC outcomes were not affected by the degree of PML. Moreover, the comparison between the two approaches indicated that the Retzius-sparing approach facilitated the recovery of UC in men with significant PML. To the best of our knowledge, this is the first study to assess the effect of PML on Retzius-sparing approach of RARP and show the potential advantage of this approach for cases with significant PML.

A significant PML is generally suggested being a surgical difficulty for dissection of the posterior bladder neck and seminal vesicles. In fact, increased the operative time (4,5) and blood loss (6) has been indicated in patients with large median lobe who underwent RARP. The results of the present study showed that the perioperative outcomes, including blood loss, operative time, transfusion rate and complications, were not affected by the degree of PML in patients underwent Retzius-sparing approach. This might be attributed to the better visualization and exposure of the posterior border of the bladder neck during Retzius-sparing approach, which was achieved by passing the posterior plane (Figure 1). Of note, significant PML is always associated with large prostate size which is considered to be a potential difficulty for traditional RARP (6,21,22), and especially Retzius-sparing approach due to limited operating space (23). Santok *et al.* investigated the influence of prostate size on Retzius-sparing approach and found that the blood loss was higher in patients with larger prostate (23). In the present study, prostate size was associated with the degree of PML (Table 1), which is similar to the previously published results (24). However, perioperative outcomes such as blood loss and intraoperative transfusion rate were similar in patients with different degree of PML in the present study. This might be because the prostate size in patients with significant PML (42 mL) in our study is much smaller than that in patients with larger prostate size (70 mL)

in Santok's study. The other explanation might be the learning curve and surgeon's experience. In Santok's study, patients were included regardless learning curve. Actually, the console time decreased with the learning curve extended (23). In contrast, the first 100 cases of RS-RARP were not analyzed to reduce the effect of learning curve.

Controversial results have been reported on the impact of PML on PSM. Some studies indicated that the PSM are similar regardless the presence of PML (4-6,25). Jeong *et al.*, on the contrary, reported that the degree of PML was significantly associated with higher PSMB during traditional RARP when PML was measured using preoperative MRI (8). In the present study, the degree of PML was also evaluated by using preoperative MRI. However, no relation was found between PML and overall PSM rate, as well as PSMB. Though the initial PSA level in Jeong's study was higher than that in our present study, the patients in our study had more advanced pathological features and higher Gleason score. Therefore, our results suggest the oncological safety of Retzius-sparing approach regardless the degree of PML. In fact, no association between BCR and PML was observed during the 12-month median follow-up, further suggesting good oncological control of Retzius-sparing approach for cases with PML.

Significant PML is always associated with more surgical damage of the bladder neck, theoretically leading to poor recovery of UC. Some studies indicated that patients with significant PML required a longer time to achieve UC after RARP (26,27) or laparoscopic radical prostatectomy (7). However, results from some other studies showed similar recovery of UC in patients with and without PML underwent RARP (4,5,25). Our results showed lower continence rates among patients with PML at 1-month follow up, but this was not statistically significant ($P=0.05$) and improved with time. 88.3% and 89.8% patients with moderate and significant PML achieved continence at 12-month follow-up, which was similar to that in patients without PML (94.5%) ($P=0.301$). Moreover, the UC outcomes in patients with PML are better compared with previously reported continence rates in patients who underwent the traditional approach (7,27). This might be due to the preservation of urinary related structures within the Retzius space during the Retzius-sparing approach.

Perioperative outcomes, as well as short-term oncological and UC data were similar in patients with different degree of PML who underwent Retzius-sparing approach of RARP, indirectly suggesting the potential advantage of Retzius-sparing approach for cases with PML. To further confirm

this, we retrospectively compared the outcomes between patients with significant PML (≥ 10 mm) who underwent the traditional or Retzius-sparing approach of RARP. Except the console time, the perioperative outcomes were similar in patients underwent the two approaches, though there is a trend towards less EBL, reduction of hemoglobin, and complication rate in the Retzius-sparing group. Also, the oncological outcomes are comparable between the two approaches though the Retzius-sparing group seems to have lower PSM rate (25.6% vs. 12.2%) but higher BCR rate at 12-month follow-up (0 vs. 7.3%). However, the Retzius-sparing approach shows significant less console time and better UC recovery, providing direct evidence showing the advantages of this approach for cases with significant PML. Therefore, Retzius-sparing approach could be considered to be a good option for cases with significant PML if the surgeons are experienced with this approach. However, the Retzius-sparing approach is technically different from the traditional one besides the dissection of the bladder neck (10). It's difficult to assess whether the benefits of Retzius-sparing approach for cases with PML are fully attributed to the dissection of the posterior bladder neck, since several function-related structures within the Retzius space are preserved during Retzius-sparing approach.

Several limitations of this study deserve to mention. First, this is a single-center, single-surgeon retrospective study with relatively small sample size, especially for men with significant PML (≥ 10 mm). Second, our present study lacks long-term oncological outcome data. Third, the learning curve and surgeon's experience may have the potential effect on the conclusion of this study. Despite these limitations, the present study provides the findings regarding the impact of PML on perioperative, oncological and UC outcomes of Retzius-sparing approach of RARP.

Conclusions

In conclusion, Retzius-sparing approach of RARP confers equivalent perioperative, PSM, short-term oncological and UC outcomes among patients with different degrees of PML. Comparison between the traditional and Retzius-sparing approach for cases with significant PML shows better UC outcomes. Retzius-sparing approach could be considered to be a good option for cases with significant PML.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study were in accordance with the Declaration of Helsinki (revised in 2013) and approved by the Ethics Committee of the Drum Tower Hospital, Medical School of Nanjing University (2017-044-02). Because of the retrospective nature of the research, the requirement for informed consent was waived.

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