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Original Article

Effect of puboprostatic ligament preservation during robotic-assisted laparoscopic radical prostatectomy on early continence: Randomized controlled trial



Wattanachai Ratanapornsompong ^a, Suthep Pacharatakul ^b,
Premsant Sangkum ^a, Chareon Leenanupan ^a,
Wisoot Kongcharoensombat ^{a,*}

^a Division of Urology, Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

^b Division of Urology, Department of Surgery, Police Hospital, Bangkok, Thailand

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KEYWORDS

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Abstract *Objective:* To prove the effectiveness of puboprostatic ligament-preserving robotic-assisted laparoscopic radical (RARP) on enhancing early continence.

Methods: Ninety-two patients with localized adenocarcinoma of the prostate scheduled for RARP from April 2018 to January 2019 were prospectively single-blinded and randomized into two groups, standard RARP (Group A) and puboprostatic ligament-sparing RARP (Group B). The outcomes were continent status at Foley catheter removal and 3 months after surgery using the score from the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF), pad usage, pathological margin status, blood loss, operative time, and complications.

Results: Ninety-six patients were randomized (46 patients in each group), with a mean±SD age of 67.30±6.07 years. There were no differences in baseline characteristics. At 3 months after surgery, ICIQ-UI SF score (mean±SD) in Group A was significantly higher than Group B (8.74±4.28 vs. 6.93±3.96, $p=0.038$) but no difference at Foley catheter removal. Group A also had a significant higher score for interference with daily life (median [interquartile range, IQR]: 4 [1, 5] vs. 2 [0, 4]; $p=0.041$) and higher pad use (median [IQR]: 2 [0, 3] vs. 1 [1, 2]; $p=0.041$) at 3 months. One case in Group A had complete or severe incontinence (>5 pads/day) at 3 months. Groups A and B did not exhibit significant difference in margin status ($p=0.828$). There were no differences in operative time, blood loss, drain output or complications.

* Corresponding author.

E-mail address: wisoot2002@hotmail.com (W. Kongcharoensombat).

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Conclusions: Use of puboprostatic ligament-sparing RARP could be a method to accelerate early continence without affecting the final oncological outcome.

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1. Introduction

Prostate cancer is the eighth most common cancer in Thailand, according to GLOBOCAN 2018 [1]. There were 6467 new cases, and 5-year prevalence was found in 14 330 cases [1]. There are treatment options for localized disease, but robotic-assisted laparoscopic radical prostatectomy (RARP) is the most popular method at our institute. The Pentafecta was proposed by Patel et al. [2] to report outcomes of RARP. Continence is one of the most important factors in improving patient quality of life (QoL). Unfortunately, the incontinence rate after radical prostatectomy (RP) is high, affecting up to 80% [3,4], and early postoperative incontinence may affect up to 96% [5]. Most patients will regain continence in the first year after RARP [6], but enhancing continence recovery is still attractive due to better QoL.

Post-radical prostatectomy incontinence is stress urinary incontinence. The exact anatomical etiology of incontinence after RP is still controversial [7], but preservation of the pelvic structure has been proposed to enhance continence [8].

Multiple procedures, such as bladder neck preservation, neurovascular bundle-sparing surgery, puboprostatic ligament preservation, and maximized urethral length, have been used to enhance continence recovery [8]. Puboprostatic ligament-sparing surgery has been shown to improve early continence after retropubic RP [9] and laparoscopic RP [10].

The puboprostatic ligaments are one of the three components of pelvic fascia. The ligaments attach between the pubis and the prostate at the prostate-urethral junction [11]. The function of these ligaments is still unclear but the literature believes that they support the urethra via suspensory mechanism. There is close relationship between puboprostatic ligaments and detrusor apron and pelvic floor muscle complex that are the part of suspensory complex. The suspensory mechanism enhances the early continence via reducing the urethral mobility and the urethra-vesical junction angle [12]. Also, preserved puboprostatic ligaments could keep longer urethral length and fibrovascular support of urethra [13].

The aim of our study is to prove the effectiveness of puboprostatic ligament-preserving RARP on enhancing early continence compared with the standard technique RARP. Moreover, the margin status is also compared between the two groups.

2. Methods

2.1. Study design, setting and participants

This was a single surgeon, single center, randomized single blinded study carried out at Ramathibodi Hospital. The

study was approved by Ethic Committee of Faculty of Medicine, Ramathibodi Hospital (Protocol ID: 03-61-33) prior to commencing the study participant recruitment.

The patients with localized adenocarcinoma of the prostate scheduled for RARP from April 2018 to April 2019 were invited to participate in study. The patients who previously underwent transurethral procedure (*i.e.* transurethral prostatectomy, urethral dilatation, and history of cystoscopy) and pelvic radiation, had clinical lymph nodes and distant metastasis, having stress urinary incontinence before RARP, or unable to provide written informed consent were excluded.

2.2. Randomization and blinding

Eligible patients were randomized into two groups using allocation ratio of 1:1 and the block of four techniques: Group A included patients for whom a standard RARP was performed, and Group B included patients for whom a puboprostatic ligament-sparing RARP was performed. The patients did not know whether they were receiving standard or puboprostatic ligament-sparing RARPs.

2.3. Intervention

All procedures were performed by Dr. Wisoot Kongcharoensombat (W.K.) and assistant Dr. Premsanti Sangkum (P.S.). W.K. and P.S. have performed over 300 RARP procedures over the last 3 years with over 5 years of experience in the RARP. All patients were advised to perform pelvic floor muscle therapy 1 month before the RARP.

The RARP was performed intraperitoneally using the four-arm da Vinci Si HD robotic system (Intuitive Surgical, Sunnyvale, CA, USA). Port placement for both groups is shown in Fig. 1A. Pneumoperitoneum 15 mmHg was used, and a Retzius space was created. Endopelvic fasciae were excised on the lateral side, and then, the anteromedial was approached with caution to not injure pelvic floor muscle. At this point in standard Group A, the puboprostatic ligament was dissected and excised, and the dorsal vein complex (DVC) was controlled with V-Loc™ No. 0 distal to the prostatic apex. In Group B, the modified puboprostatic ligament-sparing technique was used. The endopelvic fasciae attached to the ligaments were excised just lateral to the ligaments. Puboprostatic ligaments were meticulously dissected and kept intact (Fig. 1B). At this point in standard Group A, puboprostatic ligament was dissected and excised and DVC was controlled with V-Loc™ No. 0 at distal to prostatic apex. Anterior retropubic suspension was created using the same V-Loc™ that controlled DVC with the technique described by Walsh [14] (Fig. 1C). The bladder neck was then identified and dissected by the

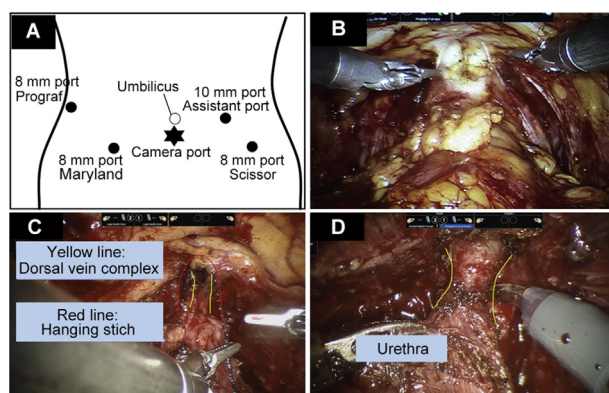


Figure 1 Robotic-assisted laparoscopic radical prostatectomy. (A) Port placement; (B) Puboprosthetic ligaments; (C) Anterior retropubic suspension; (D) Urethra after using collar technique.

technique described by Su et al. [11]. Then, the nerve-sparing technique was performed using at least the extrafascial technique, or the interfascial technique, if feasible. Apical dissection was performed using the collar technique [15] (Fig. 1D). Standard pelvic lymphadenectomy was performed in high clinical risk. Urethrovesical anastomosis was performed with the mucosa-to-mucosa technique using running 3-0 V-Loc™ and stented with a 20 Fr Foley catheter. A Silastic drain 24 Fr was used liberally.

The Silastic drain was retained until the drain output was lower than 50 mL/day or lower than 200 mL/day, with creatinine content measured to prove there was no urine. The patient was discharged after drain removal and had no other complications. The patient retained a Foley catheter until it was electively removed at the outpatient department. Pathologic classification was based on the the American Joint Committee on Cancer staging system for prostate cancer [16].

2.4. Study data collection and outcomes

Pre-operative data, including pre-operative prostate-specific antigen (PSA), highest biopsy grade group, clinical risk, smoking, and underlying factors affecting continence, were prospectively collected. The tumor biopsy grade was divided into five groups, *i.e.* Grade Group I was Gleason score ≤ 6 ; Grade Group II was Gleason score $3+4=7$; Grade Group III was Gleason score $4+3=7$; Grade Group IV was Gleason score $4+4=8$; and Grade Group V was Gleason score 9 and 10 [17]. The clinical risks were categorized as very low, low, favorable intermediate, unfavorable intermediate, high or very high based on National Comprehensive Cancer Network classification [18]. Then, the patients with very low and low risks were combined into low risk group; favorable intermediate and unfavorable intermediate risks into intermediate risk group; and high and very high risk into high risk group.

The primary outcome was urinary continence assessed by using the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF),

for which a higher score means poorer incontinent status [19] at Foley catheter removal day and 3 months after surgery. The continence was also assessed by the pad usage at 3 months after surgery as follows: Continence (a maximum of 1 pad/day), minimal stress incontinence (2–3 pads/day), moderate stress incontinence (4–5 pads/day), and incontinence (more than 5 pads/day) [10]. The responses to ICIQ-UI SF and the pad usage were collected via face-to-face interviews by an independent urological resident at the outpatient department. The secondary outcomes were the pathological margin status (positive surgical margin [PSM]: Yes/no), blood loss, operative time, length of hospital stay and complications. The complications were graded according to Clavien-Dindo classification [20].

2.5. Sample size

The sample size for randomized controlled trials for binary data was calculated using Power and Sample Size Calculations version 3.1.2 (Program developed by Dupont WD and Plummer WD, USA) with the allocation ratio of 1:1. Prior data indicated that the continent rate (maximum 1 pad/day) at 3 months was 48% among patients operated by standard technique and 76% by puboprosthetic ligament sparing technique [10]. If the true continent rate in puboprosthetic ligament sparing technique was 76%, the minimum sample size required was 92 patients (46 in each arm) in order to reject the null hypothesis that the continent rates for both groups are equal with probability (power) 0.08 at alpha 5% significant level (two-side).

2.6. Statistical analysis

Descriptive statistics, *i.e.* number with percentage or mean with its standard deviation (SD) along with 95% confidence intervals (CI) as appropriate, or median with interquartile range (IQR) were used to present the patient characteristics and study outcomes. The continuous variables between Group A and Group B were compared by Student's *t*-test or Mann-Whitney test, as appropriate. Chi-square test or Fisher's exact test were used to test the difference in proportion of categorical variables between the two groups. Uni- and multiple regression analysis were used to explore the correlation between ICIQ-UI score and other variables. Analysis statistics were performed using STATA program version 14 (StataCorp, College Station, TX, USA). A *p*-value of <0.05 was considered indicative of statistically significant differences.

3. Results

3.1. Participant and baseline characteristics

Ninety-two patients were eligible and randomized into two groups A ($n=46$) or B ($n=46$), with a mean age of 67.36 ± 6.07 years and median PSA of 9.77 ng/mL (range: 0.92–64 ng/mL). There were no significant differences in baseline characteristics between groups, including pre-operative PSA, biopsy grade, clinical risk, smoking, and underlying factors affecting continence as shown in Table 1.

Table 1 Baseline characteristics, operative data, clinical and pathological stages and grades.

Data	Total (n=92)	Group A (n=46)	Group B (n=46)	p-Value
Age, mean±SD, year	67.36±6.07	67.15±6.62	67.58±5.52	0.733 ^a
Preoperative PSA, median (range), ng/mL	9.77 (0.925, 64)	11 (0.925, 64)	8.92 (4, 50)	0.281 ^b
Clinical risk, n (%)				
Low	20 (21.74)	10 (21.74)	10 (21.74)	0.486 ^c
Intermediate	43 (46.74)	19 (41.30)	24 (52.17)	
High	29 (31.52)	17 (36.96)	12 (26.09)	
Biopsy grade group, n (%)				
I	30 (32.61)	16 (34.78)	14 (30.43)	0.360 ^c
II	18 (19.57)	8 (17.39)	10 (21.74)	
III	22 (23.91)	8 (17.39)	14 (30.43)	
IV	11 (11.96)	6 (13.04)	5 (10.87)	
V	11 (11.96)	8 (17.39)	3 (6.52)	
DM, n (%)	21 (22.83)	8 (17.39)	13 (28.26)	0.214 ^c
CVA, n (%)	8 (8.70)	6 (13.04)	2 (4.35)	0.267 ^d
OSA, n (%)	2 (2.17)	1 (2.17)	1 (2.17)	1.000 ^d
BMI, mean±SD, kg/m ²	24.70±3.22	24.40±3.39	25.00±3.04	0.367 ^a
Smoking, n (%)	31 (33.70)	13 (28.26)	18 (39.13)	0.270 ^d
Pathological stages and grades				
T stage, n (%)				
T2	50 (54.35)	23 (50.00)	27 (58.70)	0.592 ^c
T3a	22 (23.91)	13 (28.26)	9 (19.57)	
T3b	20 (21.74)	10 (21.74)	10 (21.74)	
Gleason grade group, n (%)				
I	18 (19.57)	10 (21.74)	8 (17.39)	0.978 ^c
II	30 (32.61)	14 (30.43)	16 (34.78)	
III	18 (19.57)	9 (19.57)	9 (19.57)	
IV	7 (7.61)	4 (8.70)	3 (6.52)	
V	19 (20.65)	9 (19.57)	10 (21.74)	
LVI, n (%)	36 (39.13)	18 (39.13)	18 (39.13)	1.000 ^c
PNI, n (%)	68 (73.91)	32 (69.57)	36 (78.26)	0.342 ^c
Positive LN, n (%)	4 (4.35)	3 (6.52)	1 (2.17)	0.617 ^d
Prostate weight, median (IQR), g	42.35 (23.3–108)	41 (23.3–89.6)	44.1 (26.4–108)	0.271 ^b
CV nerve sparing, n (%)				
Non-nerve sparing	6 (6.52)	4 (8.70)	2 (4.35)	0.164 ^c
Unilateral sparing	19 (20.65)	6 (13.04)	13 (28.26)	
Bilateral sparing	67 (72.83)	36 (78.26)	31 (67.39)	

BMI, body mass index; CV, cavernous; CVA, cerebrovascular accident; DM, diabetes mellitus; IQR, interquartile range; LN, lymph node; LVI, lymphovascular invasion; OSA, obstructive sleep apnea; PNI, perineural invasion; PSA, prostate-specific antigen; SD, standard deviation.

^a Student's *t*-test.

^b Wilcoxon rank-sum test.

^c Chi-square test.

^d Fisher's exact test.

There were no differences in the pathological results, *i.e.* T stage, Gleason grade group, lymphovascular invasion (LVI), perineural invasion (PNI), positive lymph node and prostate weight between two groups (Table 1). The majority of patients were bilateral cavernous (CV) nerve sparing (78.26% and 67.39%, in Group A and B respectively). There was no difference in the nerve sparing between groups.

3.2. Primary outcome

At the time of Foley catheter removal, the mean ICIQ-UI SF score was better (lower score) for Group B than Group A but there was no statistically significant difference (mean±SD:

12.41±4.23 vs. 14.11±4.67, *p*=0.071). At 3 months post-operation, ICIQ-UI SF score in Group B was significantly better than Group A (mean±SD: 6.93±3.96 vs. 8.74±4.28, *p*=0.038). Table 2 presents comparison of ICIQ-UI SF scores and pad usage by groups.

In addition, there was no significant difference in the ICIQ-UI SF score for Q4 that asked how much the leaking urine interfere with the everyday life was ranged from 0 (not at all) to 10 (a great deal), higher score indicating greater interfering with the everyday life between groups at Foley catheter removal while Group A had a significant higher score than Group B at 3 months post-operation (median [IQR]: 4 [1,5] vs. 2 [0, 4]; *p*=0.041).

Table 2 ICIQ-UI SF between Group A and Group B at the time of Foley catheter removal and at 3 months.

Data	Total (<i>n</i> = 92)	Cut ligament (<i>n</i> = 46)	Preserve ligament (<i>n</i> = 46)	<i>p</i> -Value
At the time of Foley catheter removal				
Q3: How often do you leak urine? <i>n</i> (%)				
Never	0	0	0	
About once a week or less often	3 (3.26)	3 (6.52)	0	
Two or three times a week	5 (5.43)	1 (2.17)	4 (8.70)	
About once a day	11 (11.96)	3 (2.17)	8 (17.39)	
Several times a day	36 (39.13)	18 (39.13)	18 (39.13)	
All the time	37 (40.22)	21 (45.65)	16 (34.78)	
Score [0–5], mean (SD)	4.07 (1.02)	4.15 (1.09)	4 (0.94)	0.477 ^a
Q4: How much urine do you usually leak? <i>n</i> (%)				
None	0	0	0	
A small amount	36 (39.13)	13 (28.26)	23 (50.00)	
A moderate amount	44 (47.83)	25 (54.35)	19 (41.30)	
A large amount	12 (13.04)	8 (17.39)	4 (8.70)	
Score [0–4], mean (SD)	3.47 (1.35)	3.78 (1.35)	3.17 (1.30)	0.030 ^a
Q5: Overall, how much does leaking urine interfere with the everyday life? mean (SD)				
ICIQ-UI SF score [0–21], median (IQR)	5.70 (2.66)	6.17 (2.77)	5.23 (2.50)	0.092 ^a
	13.26 (4.52)	14.11 (4.67)	12.41 (4.23)	0.071 ^a
At 3 months				
Q3: How often do you leak urine? <i>n</i> (%)				
Never	2 (2.17)	0		
About once a week or less often	19 (20.65)	8 (17.39)	11 (23.91)	
Two or three times a week	19 (20.65)	10 (21.74)	9 (19.57)	
About once a day	25 (27.17)	10 (21.74)	15 (32.61)	
Several times a day	24 (26.09)	16 (34.78)	8 (17.39)	
All the time	3 (3.26)	2 (4.35)	1 (2.17)	
Score [0–5], mean (SD)	2.64 (1.22)	2.87 (1.20)	2.41 (1.22)	0.074 ^b
Q4: How much urine do you usually leak? <i>n</i> (%)				
None	2 (2.17)	0	2 (4.35)	
A small amount	75 (81.52)	37 (80.43)	38 (82.61)	
A moderate amount	14 (15.22)	8 (17.39)	6 (13.04)	
A large amount	1 (1.09)	1 (2.17)	0 (0.00)	
Score [0–4], median (SD)	2.30 (0.89)	2.43 (0.93)	2.17 (0.82)	0.159 ^a
Q5: Overall, how much does leaking urine interfere with the everyday life (0–10)?				
mean (SD)	2.90 (2.59)	3.46 (2.68)	2.34 (2.39)	
median (IQR)	3 (0,5)	4 (1,5)	2 (0, 4)	0.041 ^c
ICIQ-UI SF score [0–21], median (IQR)	7.84 (4.20)	8.74 (4.28)	6.93 (3.96)	0.038 ^a
Pad usage (piece), <i>n</i> (%)				
0–1 (continence)	54 (58.70)	21 (45.65)	33 (71.74)	0.036 ^b
2–3 (minimal stress incontinence)	34 (36.96)	21 (45.65)	13 (28.26)	
4–5 (moderate stress incontinence)	3 (3.26)	3 (6.52)	0	
>5 (incontinence)	1 (1.09)	1 (2.17)	0	
Pad usage, median (IQR)	1 (0.5–2)	2 (0–3)	1 (1–2)	0.041 ^c
Pad usage				
Not used	23 (25.00)	12 (26.09)	11 (23.91)	0.810
At least once	69 (75.00)	34 (73.91)	35 (76.09)	

ICIQ-UI SF, incontinence questionnaire-urinary incontinence short form; IQR, interquartile range; SD, standard deviation.

^a Student's *t*-test.^b Wilcoxon rank-sum test.^c Chi-square test or Fisher's exact test.

The number of continent patients (maximum 1 pad/day) was significantly higher in Group B than in Group A (n [%]: 33 [71.74] vs. 21 [45.65], $p=0.036$). The median number of pad usage in Group A was also significantly higher than Group B (median [IQR]: 2 [0, 3] vs. 1 [1,2] pads; $p=0.041$). Fig. 2 presents the number of pad usage in each group.

After adjusting with the following covariates (*i.e.* clinical risk, biopsy grade group, CV nerve sparing [non-nerve-sparing vs. nerve sparing], prostate weight, and body mass index [BMI]) using multiple linear regression, there was no significant difference in ICIQ-UI SF score at the time of Foley catheter removal. However, at 3 months post operation, ICIQ-UI SF score in Group A was still significantly higher than that in Group B by 2.03 (95% CI: 0.25–3.81, $p=0.026$) while there were no significant differences in the score ICIQ both at foley catheter removal and at 3 months post-operation among clinical risk groups, biopsy grade groups, CV nerve sparing, prostate weight, and BMI.

There was one case in Group A of complete or severe incontinence (more than 5 pads/day) at 3 months after surgery. The nerve sparing could not be done for four cases in Group A and two cases in Group B due to severe adhesion on the posterolateral side of the prostate gland. However, after excluding non-nerve-sparing cases, the ICIQ-UI SF score was still better for Group B (7.02 ± 4.01) than Group A (8.92 ± 4.33) ($p=0.037$).

Pearson’s correlation coefficient (r) for the correlation between ICIQ-UI SF score at 3 months post operation and number of pad use was 0.778 ($p < 0.001$). This indicates the strong relation between the score at 3 months and number of pad use. Univariate regression analysis showed that the ICIQ-UI SF scores increased with increasing numbers of pad usage (Coefficient [Coef.] [95% CI]: 0.23 [0.19, 0.27], $p < 0.001$).

3.3. Secondary outcomes

Hospital stay was not statistically different between Groups A and B, with a median stay of 6 days for both groups ($p=0.268$). The median operative time was comparable in the two groups (Group A: 135 min [range: 90–212 min] and Group B: 120 min [range: 60–300 min]; $p=0.132$). The median drain output was higher in group B (237 mL; range: 0–2030 mL) compared with group A (170 mL; range: 0–3310 mL), but the difference was not significant

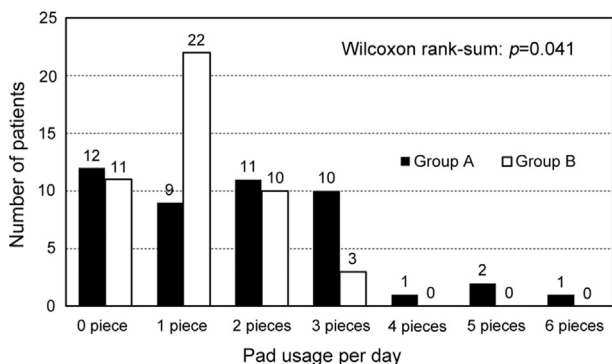


Figure 2 The number of pad use in each group.

($p=0.474$). The mean catheterized time was comparable, with 15.19 ± 4.61 days for Group A and 13.84 ± 4.00 days for Group B ($p=0.138$).

There was no difference in complication rate based on Clavien-Dindo classification [20] ($p=0.834$). The most common complication was postoperative low-grade fever. There were no cases of anastomosis leakage and urosepsis in either group. The blood transfusion rate was comparable (6.25% in both groups; $p=1.000$). There was a higher rate of lymphatic leakage, defined by drain output >200 mL/day on post-operative Day 4 and proven to contain no urine, in Group B (nine cases; 19.57%) than in Group A (four cases; 8.7%), but the difference was not statistically significant ($p=0.135$). In Group A, there was one case of intraperitoneal collection requiring percutaneous drainage and one case of scrotal hematoma resolved with conservative management. In Group B, there was one case of postoperative ischemic stroke that resulted in right hemiparesis. There was urinary retention after Foley catheter removal for one case in Group B, which was treated conservatively, and the patient could void spontaneously after catheter removal in the next 2 weeks.

Positive margins were detected in 34.78% of patients in Group A and in 36.96% of patients in Group B ($p=0.828$). The positive urethral margin was comparable in both groups, with 26.09% of Group A and 19.57% of Group B ($p=0.456$). Postoperative PSA at 3 months was not statistically different, with a median PSA in Group A of 0.003 ng/mL (range: 0.003–1.28 ng/mL) and 0.003 ng/mL in Group B (range: 0.003–1.55 ng/mL) ($p=0.341$). Groups A and B did not exhibit significant differences regarding their margin status ($p=0.828$). Tables 3 and 4 present the peri-operative, post-operative and pathological outcomes between groups.

4. Discussion

The post-prostatectomy incontinence rate in the literature was up to 80% [3,4]. The etiology of post prostatectomy has not been completely understood. Several factors, such as patient’s age, continent status before surgery, surgeon factor, operative technique, and postoperative factors, have been found to influence incontinence [21].

Most patients will regain continence in the first year after RARP [6]. Many factors can contribute to early return of continence, but the factor that can be modified is the surgical technique. In our study, all patients were informed to perform pre-operative pelvic floor muscle training. There were data that this patient information regarding potential urinary incontinence has a positive impact on post-operative patient-reported outcome measures (PROMs) [22].

In our study, we did not include magnetic resonance imaging (MRI) information, however, randomize control study design would make the distributions of confounding factors (both known and unknown) equal in both groups. A lot of studies supported that multiparametric MRI has had the real impact on prostate cancer treatment option and also has improved surgical technique. A study by Song et al. [23] showed that pre- and postoperative membranous urethra length measured from MRI had impact on postoperative incontinence. In addition, multiple

Table 3 Perioperative and post-operative outcomes.

Data	Total (n=92)	Group A (n=46)	Group B (n=46)	p-Value
Operative time, median (IQR), min	130 (60–300)	135 (90–212)	120 (60–300)	0.132 ^a
Blood loss, median (range), mL	300 (50, 1600)	300 (100, 1000)	300 (50, 1600)	0.780 ^a
Admit, median (range), day	6 (4, 101)	6 (4, 12)	6 (4, 101)	0.224 ^a
Drain output, median (range), mL	182 (0, 3310)	170 (0, 3310)	237 (0, 2030)	0.474 ^a
Complication, n (%)	41 (44.57)	20 (43.48)	21 (45.65)	0.834 ^b
Blood transfusion, n (%)	6 (6.52)	3 (6.52)	3 (6.52)	1.000 ^b
Lymph leak, n (%)	13 (14.13)	4 (8.70)	9 (19.57)	0.135 ^b
Fever, n (%)	21 (22.83)	12 (26.09)	9 (19.57)	0.456 ^b
UTI, n (%)	2 (2.17)	1 (2.17)	1 (2.17)	1.000 ^b
Ileus, n (%)	3 (3.26)	0	3 (6.52)	0.242 ^b
Hematuria, n (%)	2 (2.17)	2 (2.17)	2 (2.17)	1.000 ^b
Intraabdominal collection, n (%)	1 (1.09)	1 (2.17)	0	0.999 ^b
AUR, n (%)	1 (1.09)	0	1 (2.17)	0.999 ^b
Scrotal hematoma, n (%)	1 (1.09)	1 (2.17)	0	0.999 ^b
Stroke, n (%)	1 (1.09)	0	1 (2.17)	0.999 ^b
Catheterized time, mean±SD, day	14.52±4.34	15.19±4.61	13.84±4.00	0.138 ^a
PSA 3 month, median (range), ng/mL	0.003 (0.003–1.55)	0.003 (0.003–1.28)	0.003 (0.003–1.55)	0.341 ^a

AUR, acute urinary retention; UTI, urinary tract infection; PSA, prostate-specific antigen.

^a Student's *t*-test or Wilcoxon rank-sum test.

^b Chi-square test or Fisher's exact test.

parameters from MRI were able to predict postoperative incontinence including displacement of the vesico-urethral junction (VUJ), proximal membranous urethra (PMU) and anorectal junction (ARJ) from the study of Ha et al. [24]. In a study by Nakane et al. [25], post-operative membranous urethral length and bladder neck width were associated with early improvement in continent status. Therefore, the pre-operative multiparametric MRI might predict that patient will improve early continence from membranous urethral length and urethro-vesical junction angle.

In our study, there was multiple limitations. Many patients were diagnosed from PSA testing and systematic random TRUS biopsy and proceeded to operation without taking multiparametric MRI. Another reason that most of the patients in our setting were not performed

multiparametric MRI before surgery because the waiting time for MRI was about 6 months. The clinical localized patient would proceed to operation without MRI due to shorter operative queue.

Poore et al. [9] showed that puboprostatic ligament sparing in open radical retropubic prostatectomy achieved early continence at 6.5 weeks compared with the standard technique at 12 weeks. However, the continence rate at 1 year was similar in both groups. In that study, continence was defined as the patient remaining dry without the use of pads or wearing a maximum of 1 pad/day and with a pad that was completely dry at least 5 days/week.

A study by Stolzenburg et al. [10] that used the laparoscopic technique found a significant decrease in the period for early continence in the group of patients with puboprostatic ligament-sparing nerve-sparing endoscopic extraperitoneal RP (nsEERP) when compared to standard nsEERP [10]. Early return to continence at 3 months after the procedure was confirmed in 24 (48%) patients in the standard group and 38 (76%) patients in the intervention group. No difference was found between the groups after 3 months. Continence in that trial was defined as maximum pad usage of 1 pad per day.

In the present study, puboprostatic ligament-sparing RARP was compared with the standard technique. Continence was defined as 1 pad per day or no pad. The continence rate was higher in the intervention group at 3 months (71.74%) compared with the standard group (45.65%). The ICIQ-UI SF module has been fully validated and is currently being used internationally in both clinical outcomes and research. We used the ICIQ-UI SF score to compare between the two group, and the results showed better scores in the intervention group. The score includes symptom and quality-of-life questions that more clearly clarify the continent status

Table 4 Pathological outcomes.

Data	Total (n=92)	Cut ligament (n=46)	Preserve ligament (n=46)	p-Value*
Margin, n (%)				
Negative	59 (64.13)	30 (65.22)	29 (63.04)	0.828
Positive	33 (35.87)	16 (34.78)	17 (36.96)	
Margin urethra, n (%)				
Negative	71 (77.17)	34 (73.91)	37 (80.43)	0.456
Positive	21 (22.83)	12 (26.09)	9 (19.57)	

*p-Value from Chi-square test.

than only considering pad usage. However, a strong (Spearman) positive correlation between the ICIQ-SF score and the number of pads used was also observed ($R^2=0.7823$, $p<0.001$) in our study.

The ICIQ-SF mean scores after 3 months seem relatively high for both groups. However, when we explore the question 5 of ICIQ-SF score that asked about how much does leaking urine interfere with the everyday life, the QoL score was significantly better in the intervention group (median [IQR]: 4 [1,5] vs. 2 [0, 4], $p=0.041$) while neither score of how often nor how much urine leak was difference (Table 3). This implied that the intervention group had strong improvement in QoL although there was still some leakage. If we evaluate the amount of urine leakage with the finer scale such as 24 h pad weight, we might be able to demonstrate more significantly difference in the amount of urine leakage between groups.

According to the results, the puboprostatic ligament-sparing technique enhanced early return of continence. The puboprostatic ligaments are paired fibrous streaks that extend from the endopelvic fascia to the inferior aspect of the pubis bones. It could be assumed that the urethral suspensory mechanism might help continence. Furthermore, the ligament-sparing technique provided maximal urethral length [21]. These factors lead to an earlier return of continence.

The study by Asimakopoulos et al. [26] stated that the puboprostatic ligament had continuity with the bladder, and Myers [27] proposed the term "pubovesical ligament". Asimakopoulos et al. [26] aimed to preserve the complete periprostatic anatomy by developing a plane between the detrusor apron and the prostate. At catheter removal, 24 of 30 patients (80%) did not use pads. This explained that more normal periprostatic anatomy preservation might lead to earlier return of continence.

In general, the patients who face the incontinence will have conservative treatment including pelvic floor muscle training and anticholinergic medicine. Many patients improve the continence after prescribing anticholinergic medicine due to decrease in bladder compliance and overactive bladder. The most of patient will eventually improve in symptom but some patient still have troublesome incontinence. In our institute, the subsequent management is performing cystoscopy to identify the urethral stricture and bladder neck contracture. If there is no anatomical problem, the patient will be offered sling procedure or artificial urinary sphincter according to severity and indication. For the low to moderate incontinence, we perform the male urethral sling that shows the effective improvement in continence [28]. In the severe incontinence, we prefer to perform the artificial urinary sphincter.

This study had some limitations, including short-term follow-up. We followed up the patients for 3 months after RARP. At Month 3, one third of the patients still had required pad usage. Longer follow-up in the future study to explore the duration of continence and pad use is suggested. In addition, this study did not include the impact on sexual function. This study used ICIQ-UI SF to evaluate subjective incontinence symptoms and impact on QoL (QoL) of urinary incontinence. The general HRQoL questionnaires such as SF36 and EQ-5D may be included in the future studies in order to explore overall QoL of the patients. In this study, we

calculated the sample size based on the continence rate instead of ICIQ-UI SF score. Although a small sample size could reduce the statistical power to detect a difference between intervention and control groups, in our study the significant difference between ICIQ-UI SF score at 3 months was found while there was no difference detected at the time of foley catheter removal due to small sample size, which leads to a lack of statistical power.

5. Conclusion

In conclusion, we propose the use of puboprostatic ligament-sparing RARP as a method to accelerate early continence without affecting the final oncological outcome.

Authors contribution

Study design: Wisoot Kongcharoensombat, Wattanachai Ratanapornsompong.

Carried out the study and data collection: Wattanachai Ratanapornsompong, Suthep Pacharatakul, Prem Sant Sangkum, Chareon Leenanupan, Wisoot Kongcharoensombat.

Data analysis: Wattanachai Ratanapornsompong.

Interpretation of the results: Wattanachai Ratanapornsompong, Wisoot Kongcharoensombat.

Drafting of manuscript: Wattanachai Ratanapornsompong, Wisoot Kongcharoensombat.

Critical revision of the manuscript: Wattanachai Ratanapornsompong, Wisoot Kongcharoensombat.

Conflicts of interest

The authors declare no conflict of interest.

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