Original Article

Ten-Year Oncologic Outcomes of Prostate Cancer after Robotic-Assisted Laparoscopic Radical Prostatectomy: Single Center Experience

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Objective: To evaluate oncologic outcomes after robotic-assisted laparoscopic radical prostatectomy (RALRP) compared with and without neurovascular bundle (NVB) sparing, and to study associating factors that affect biochemical recurrence (BCR) and survival outcome.

Materials and Methods: All charts of prostate cancer patients who underwent RALRP during 2007 and 2017 were reviewed. Collected data included demographic information, initial prostate-specific antigen (PSA), operative technique, pathology report, perioperative data, complications, BCR rate, time to recurrence, and overall survival rate. All variables were compared among the non-NVB sparing, unilateral NVB sparing, and bilateral NVB sparing groups.

Results: A total of 1,048 patients were included in this study. Pathological staging was pT1 in 2.3%, pT2 in 57.1%, and pT3 in 40.6% of patients. The median follow-up time was 5 years. The BCR rates were 17.3%, 20.0%, and 21.4% in the non-NVB sparing, unilateral NVB sparing, and bilateral NVB sparing groups, respectively (p = 0.339). Unilateral or bilateral NVB sparing had no effect on mean time to BCR (8.83 vs. 8.89 years; p = 0.544). There was no significant difference in 10-year overall survival among the non-sparing, unilateral sparing, and bilateral sparing groups (98.6%, 98.7%, and 99.4%, respectively; p = 0.562). Multivariate analysis confirmed that NVB sparing did not affect the BCR rate (hazard ratio: 1.108, 95% confidence interval: 0.827 to 1.942; p = 0.549).

Conclusion: The results of the present study revealed that NVB sparing in RALRP had no significant impact on BCR rate or survival outcome compared to the non-NVB sparing group.

Keywords: Prostate cancer, Robotic-assisted laparoscopic radical prostatectomy, Oncologic outcomes, Biochemical recurrence, Neurovascular bundle sparing

Prostate cancer is the most common urological cancer, and it is the sixth most common cancer in Thailand[1]. Robotic-assisted laparoscopic radical prostatectomy (RALRP) has become a standard treatment for prostate cancer. This surgical technique is more specifically defined as neurovascular bundle (NVB) sparing or non-NVB sparing RALRP. Almost all of the studies reported about short term oncologic outcomes of NVB sparing in open radical prostatectomy, laparoscopic radical prostatectomy and the functional outcomes after NVB sparing. Our review of the literature revealed no comparative study of the effect of NVB sparing on oncologic outcomes after RALRP in Thailand.

Accordingly, the purpose of the present study was to investigate oncologic outcomes after RALRP compared with and without NVB sparing, and to study associating factors that affect biochemical recurrence (BCR) and survival outcome.

Materials and Methods

Medical charts of all prostate cancer patients who underwent RALRP during 2007 and 2017 at Siriraj Hospital (Bangkok, Thailand) were retrospectively reviewed. All operations were performed by experienced, board-certified urologists. Collected demographic and anthropometric information consisted of age, American Society of Anesthesiologists (ASA) classification, and body mass index (BMI). Initial prostate-specific antigen (PSA) was classified as <10, 10 to 20, or >20 ng/ml. The operative techniques were categorized into the 3 following groups: non-NVB sparing, unilateral NVB sparing, and bilateral NVB sparing. All of specimens were pathologically graded using TNM staging system (8th edition, 2017) and Gleason grading system. Perioperative data consisted of operative time and estimated

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blood loss (EBL). Clavien-Dindo classification was used to determine postoperative complications. Detectable PSA was defined as a failure of PSA to fall into undetectable levels[2]. BCR was defined as an increase in serum PSA >0.2 ng/ml with a subsequent confirmatory value[3]. Follow-up time, time to BCR, and survival data were also collected. Patients who had second primary malignancy were excluded. This study was approved by the Siriraj Institutional Review Board (SIRB) of the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand (COA No. 668/2561(EC1)).

Statistical analysis

Demographic and clinical characteristics were summarized using descriptive statistics. Categorical data are shown as number and percentage, and continuous data are given as either mean ± standard deviation for normally distributed data or as median and range for non-normally distributed data. Rates and ratio were analyzed with Chi-square test. Estimated blood loss and operative time were compared among groups using Pearson's correlation coefficient. Kaplan-Meier analyses were used to determine BCR-free survival and overall survival, and the results were compared using log-rank tests. Multivariate Cox proportional hazard models were used to determine the predictive factors for BCR. All analyses were performed with SPSS Statistics version 23 and a p-value <0.05 indicated statistical significance.

Results

A total of 1,048 patients were included in this study. Pathological staging was pT1 in 2.3%, pT2 in 57.1%, and pT3 in 40.6% of patients. The median follow-up time was 5 years. There were 636 patients (60.7%) who underwent non-NVB sparing, 75 patients (7.2%) who underwent unilateral NVB sparing, and 337 patients (32.2%) who underwent bilateral NVB sparing.

Demographic and clinical data are shown in Table 1. The mean age of patients in the non-NVB sparing group (68.53 years) was significantly higher than the mean age of patients in the unilateral NVB sparing (64.84 years) and bilateral NVB sparing (63.64 years) groups (p<0.001). There were no significant differences among groups for ASA classification or BMI. The non-NVB sparing cohort had a significantly higher initial PSA (iPSA) greater than 20 ng/ml than the other two groups (28.8% of non-NVB sparing, 5.9% of unilateral NVB sparing, and 6.2% of bilateral NVB sparing;

Table 1. Demographic and clinical data

Characteristics	Non-NVB sparing (n = 636)	Unilateral NVB sparing (n = 75)	Bilateral NVB sparing (n = 337)	p-value
Age (years)				<0.001
Mean (SD)	68.53 (7.33)	64.84 (7.25)	63.64 (6.91)	
95% CI	67.95 to 69.1	63.17 to 66.5	62.90 to 64.38	
ASA, n (%)				0.164
1	68 (10.7)	13 (17.3)	49 (14.5)	
2	471 (74.1)	55 (73.3)	245 (72.7)	
3	97 (15.3)	7 (9.3)	43 (12.8)	
BMI				0.553
Mean	24.52	24.31	24.70	
SD	3.23	2.98	3.04	
95% CI	24.27 to 24.78	23.62 to 25.00	24.37 to 24.76	
iPSA, n (%)				<0.001
<10	256 (41.9)	35 (51.5)	214 (66.5)	
10 to 20	179 (29.3)	29 (42.6)	88 (27.3)	
>20	176 (28.8)	4 (5.9)	20 (6.2)	
Gleason grade group, n (%)				0.001
1	94 (16.0)	9 (13.2)	78 (24.6)	
2	232 (39.5)	35 (51.5)	143 (45.1)	
3	104 (17.7)	8 (11.8)	44 (13.9)	
4	74 (12.6)	9 (13.2)	27 (8.5)	
5	84 (14.3)	7 (10.3)	25 (7.9)	
Pathologic stage, n (%)				<0.001
pT1	13 (2.1)	1 (1.3)	10 (3.0)	
pT2	318 (50.2)	44 (58.7)	235 (69.7)	
pT3	302 (47.7)	30 (40.0)	92 (27.3)	
Adjuvant RT or ADT (%)	273 (51.8)	22 (41.5)	97 (37.9)	0.001

A p-value <0.05 indicates statistical significance
NVB = neurovascular bundle; SD = standard deviation; CI = confidence interval; ASA = American Society of Anesthesiologists; BMI = body mass index; iPSA = initial prostate-specific antigen; RT = radiation therapy; ADT = androgen deprivation therapy

Table 2. Oncologic outcomes

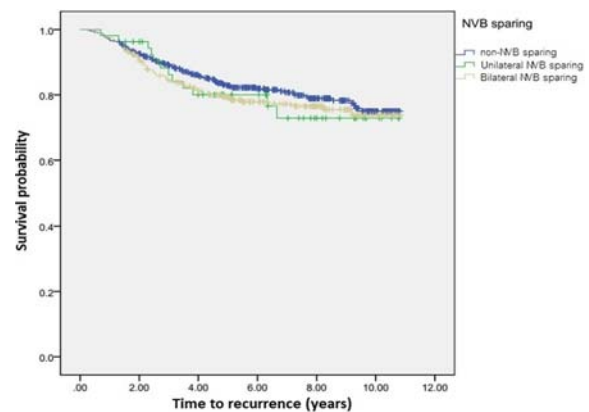| Outcome	Non-NVB sparing (n = 561)	Unilateral NVB sparing (n = 60)	Bilateral NVB sparing (n = 280)	*p*-value
BCR rate, n (%)				
Overall	97 (17.3%)	12 (20.0%)	60 (21.4%)	0.339
pT2	40 (14.5%)	8 (22.2%)	43 (22.9%)	0.061
pT3	55 (20.2%)	3 (13.0%)	17 (20.2%)	0.704
Detectable PSA, n (%)	61 (10.9%)	6 (9.8%)	16 (5.7%)	0.064
PSM rate, n (%)	294 (45.8%)	28 (37.3%)	149 (44.2%)	0.264
Mean time to BCR (years)	9.16	8.83	8.89	
SD	0.15	0.49	0.22	0.544
95% CI	8.86- to 9.46	7.87	8.45 to 9.34	
Mean survival time (years)	9.75	9.8	9.81	0.562
SD	0.03	0.07	0.03	
95% CI	9.68 to 9.82	9.66 to 9.93	9.73 to 9.83	
10-year survival rate (%)	98.6%	98.7%	99.4%	0.522

A *p*-value <0.05 indicates statistical significance
NVB = neurovascular bundle; BCR = biochemical recurrence; PSA = prostate specific antigen; PSM = positive surgical margin; SD = standard deviation; CI = confidence interval
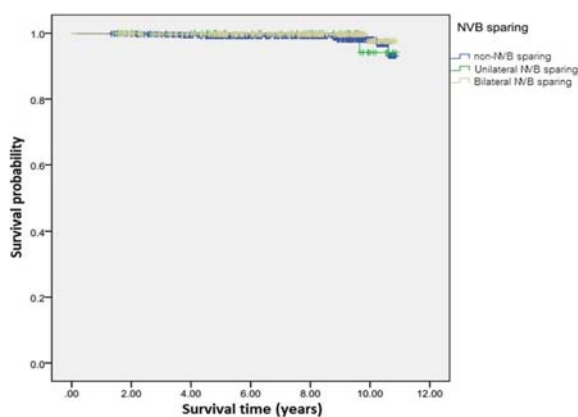
Figure 1. 10-year overall survival.

Figure 2. Biochemical recurrence (BCR)-free survival.

p<0.001). The percentage of Gleason grade group 4 or 5 was lowest in the bilateral NVB sparing cohort (Gleason grade group 4: 12.6% of non-NVB sparing, 13.2% of unilateral NVB sparing, and 8.5% of bilateral NVB sparing; and, Gleason grade group 5: 14.3% of non-NVB sparing, 10.3% of unilateral NVB sparing, and 7.9% of bilateral NVB sparing; *p* = 0.001). The percentage of pT3 was lowest in the bilateral NVB sparing cohort (47.7% of non-NVB sparing, 40% of unilateral NVB sparing, and 27.3% of bilateral NVB sparing; *p*<0.001). The percentage of adjuvant therapy (androgen deprivation therapy [ADT] or radiation therapy [RT]) after surgery was 51.8%, 41.5%, and 37.9% in the non-NVB sparing, unilateral NVB sparing, and bilateral NVB sparing groups, respectively (*p* = 0.001).

     The oncological outcomes are presented in Table 2. There was no significant difference in BCR rates, detectable PSA rates, mean time to BCR, mean survival time, 10-year overall survival rate, and positive margin rates among groups.

The BCR rates were 17.3%, 20.0%, and 21.4% in the non-NVB sparing, unilateral NVB sparing, and bilateral NVB sparing groups, respectively (p = 0.339). The positive margin rates were 45.8% in the non-NVB sparing group, 37.3% in the unilateral NVB sparing group, and 44.2% in the bilateral NVB sparing group (*p* = 0.264). Neither unilateral nor bilateral NVB sparing had significant effect on mean time to BCR (8.83 vs. 8.89 years; *p* = 0.544) or mean survival time (9.8 vs. 9.81 years; *p* = 0.562). There was no significant difference in 10-year overall survival among the three groups (98.6%, 98.7%, and 99.4%, respectively; *p* = 0.562), as shown in Figures 1 and 2.

     Multivariate analysis (Table 3) showed NVB sparing not to be a significant factor for BCR (hazard ratio [HR]: 1.108, 95% confidence interval [CI]: 0.827 to 1.942; *p* = 0.549). Significant predictive factors were Gleason grade group 5 (HR: 6.158, 95% CI: 3.302 to 11.485; *p*<0.001) and pT3 stage (HR: 3.647, 95% CI: 2.668 to 4.984; *p*<0.001).

The perioperative outcomes are summarized in Table 4. There was no significant difference in operative times (199.72, 196.23, 185.26 minutes, respectively; $p = 0.064$), estimated blood loss (median 300 ml in all cohorts; $p = 0.635$), perioperative complication with Clavien-Dindo score ≥ 3 (2.2%, 1.8%, 1.2%; $p = 0.601$), or delayed complication, including inguinal hernia and urinary incontinence (17.2%, 20.7%, 13.3%; $p = 0.243$). Conversion to open surgery occurred in only 5 of all included cases.

Discussion

The results of many studies showed that open radical prostatectomy (ORP), laparoscopic radical prostatectomy (LRP), and RALRP all had similar oncologic outcomes, and that RALRP tended to have benefits that included less complications, higher continence, and higher

Table 3. Predictive factors for BCR by multivariate analysis

Factors	Hazard ratio (95% CI)	p-value
Age	1.018 (0.997 to 1.039)	0.087
PSA		
<10	Reference	
10 to 20	1.175 (0.792 to 1.552)	0.438
>20	1.267 (0.827 to 1.942)	0.277
Gleason grade group		
1	Reference	
2	2.623 (1.691 to 4.068)	<0.001
3	2.18 (1.292 to 3.681)	0.004
4	2.29 (1.283 to 4.088)	0.005
5	6.158 (3.302 to 11.485)	<0.001
Stage		
pT2	Reference	
pT3	3.647 (2.668 to 4.984)	<0.001
NVB sparing		
None	Reference	
Unilateral	0.828 (0.451 to 1.521)	0.543
Bilateral	1.108 (0.781 to 1.769)	0.549

A *p*-value <0.05 indicates statistical significance
BCR = biochemical recurrence; CI = confidence interval; PSA = prostate specific antigen; NVB = neurovascular bundle

potency[4-8]. Similarly, studies in NVB sparing surgery reported that NVB sparing showed comparable oncologic outcomes with better functional outcomes[9-15]. The present study was designed to focus on the impact of NVB sparing in RALRP on oncologic outcomes.

Laura N. Nguyen, et al conducted a systematic review and meta-analysis of the risks and benefits of NVB sparing[12]. Eleven of those studies focused on BCR, and only 1 study focused on RALRP. None of those studies found an increased risk of BCR with any type of nerve sparing after adjusting for prognostic factors (stage, grade, and pre-operative PSA).

The positive margin (PSM) rates, detectable PSA rates, and BCR rates in the present study showed no significant difference among our 3 study groups. Giovanni Cochetti, et al reported PERUSIA (posterior, extraperitoneal, robotic, under santorini, intrafascial, anterograde) radical prostatectomy) that showed overall PSM rate was 20% (17.4% in pT2 and 53.3% in pT3)[14]. In the present study, the PSM rate in bilateral NVB sparing was higher (44.2%), because RALRP was the new operation for our center in 2007 and the surgeon may have less experience. The 10-year overall survival rate, mean time to BCR, and mean survival time also showed no marked difference among groups. Despite the fact that the non-NVB sparing cohort had the highest mean age and the worst tumor characteristics (iPSA, Gleason grade group, pathological T staging), all oncologic outcomes showed no significant difference among groups. The fact that no difference among groups was observed may be due to the significantly higher percentage of adjuvant therapy after surgery that was given to patients in the non-NVB sparing group (non-sparing: 51.8%, unilateral sparing: 41.5%, and bilateral sparing: 37.9%; $p = 0.001$). These adjuvant treatments may have positively influenced oncologic outcomes, especially among patients with pT3 staging.

Subgroup analysis comparing pT2 and pT3 showed that despite the higher pT stage in the non-NVB sparing group, there was no significant difference between groups for BCR-free survival (Figure 3 and Figure 4).

Multivariate analysis for factors significantly associated with BCR confirmed that neither non-NVB sparing nor NVB sparing significantly influenced BCR rate. In contrast, both Gleason grade group and pathological T staging

Table 4. Perioperative and postoperative outcomes

Outcome	Non-NVB sparing	Unilateral NVB sparing	Bilateral NVB sparing	p-value
Operative time (min)				
Mean	199.72	196.23	185.26	
SD	71.71	50.05	49.42	0.064
Estimated blood loss (ml), median (min, max)	300 (20, 2,810)	300 (30, 2,500)	300 (50, 2,000)	0.635
Perioperative complication Clavien-Dindo score ≥3, n (%)	12 (2.2%)	1 (1.8%)	3 (1.2%)	0.601
Delayed complication, n (%)	92 (17.2%)	12 (20.7%)	34 (13.3%)	0.243

A *p*-value <0.05 indicates statistical significance
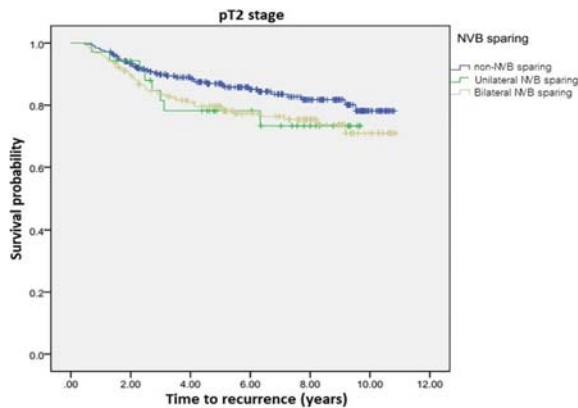NVB = neurovascular bundle; SD = standard deviation

Figure 3. Biochemical recurrence (BCR)-free survival of pT2 stage patients.
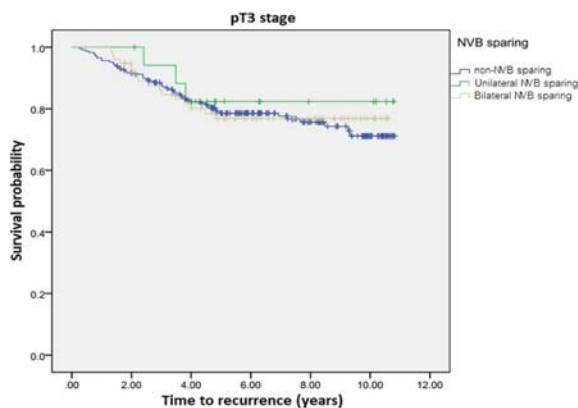

Figure 4. Biochemical recurrence (BCR)-free survival of pT3 stage patients.

were found to statistically significantly affect BCR. Gleason grade group 2 that was significantly worse hazard ratio than Gleason grade group 3 and 4 (2.63 vs. 2.18 vs. 2.29), may because of the highest population in this group.

The limitations of the present study include its retrospective design, the lack of a matched control group, and the fact that our data was derived from a single center. A prospective controlled study is needed to further elucidate the relationship between NVB sparing in RALRP and oncologic outcomes in prostate cancer patients.

Conclusion

The results of the present study revealed that NVB sparing in RALRP had no significant impact on BCR rate or survival outcome compared to the non-NVB sparing group.

What is already known on this topic?

The authors already known that NVB sparing in RALRP improved erection and continence function, but we had to concern about the cancer control.

What this study adds?

The present study can conclude that NVB sparing in RALRP had no significant impact on oncological outcomes.

Potential conflicts of interest

The authors declare no conflicts of interest.

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ผลการรักษาระยะยาว ของการผ่าตัดมะเร็งต่อมลูกหมากโดยใช้หุ่นยนต์ช่วยผ่าตัด ภายในโรงพยาบาลศิริราช ระยะเวลา 10 ปี

นุพัชร ยอดคุณธรรม, ธวัชชัย ทวีมั่นคงทรัพย์, ภควัฒน์ ระมาตร์, ศิรส จิตประไพ, ฐิติภัท หาญสมวงศ์, สุนัย ลีวันแสงทอง, สิทธิพร ศรีนวลนัด, ไชยยงค์ นวลยง, วรัชญ์ วรนิสรากุล

วัตถุประสงค์: เพื่อศึกษาประเมินผลการรักษาในด้านมะเร็งวิทยาของการผ่าตัดมะเร็งต่อมลูกหมากด้วยหุ่นยนต์ช่วยผ่าตัดโดยเก็บรักษาเส้นประสาทและหลอดเลือดรอบต่อมลูกหมาก เทียบกับ ไม่เก็บรักษาเส้นประสาทและหลอดเลือดรอบต่อมลูกหมากผ่าตัด และศึกษาปัจจัยที่มีผลต่อการสูงขึ้นใหม่ของค่าจำเพาะต่อมลูกหมากหลังรับการผ่าตัด

วัสดุและวิธีการ: สืบค้นเวชระเบียนของผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็นมะเร็งต่อมลูกหมากและได้รับการผ่าตัดด้วยหุ่นยนต์ผ่าตัดช่วงปี พ.ศ. 2550 ถึง พ.ศ. 2560 โดยรวบรวมข้อมูลพื้นฐานทั่วไป ค่าจำเพาะต่อมลูกหมากก่อนผ่าตัด วิธีการผ่าตัด ผลชิ้นเนื้อหลังผ่าตัด ข้อมูลระหว่างการผ่าตัดและช่วงพักรักษาตัวในโรงพยาบาล อัตราการสูงขึ้นใหม่ของค่าจำเพาะต่อมลูกหมาก และอัตราการอยู่รอดโดยรวม

ผลการศึกษา: การศึกษานี้รวบรวมผู้ป่วยจำนวน 1,048 ราย แบ่งตามระยะของโรคเป็น pT1 2.3%, pT2 57.1%, pT3 40.6% โดยค่ามัธยฐานของการตรวจติดตามตลอดการศึกษาเท่ากับ 5 ปี อัตราการสูงขึ้นใหม่ของค่าต่อมลูกหมากในกลุ่มไม่เก็บรักษาเส้นประสาท เก็บรักษาเส้นประสาทข้างเดียว และเก็บเส้นประสาททั้งสองข้าง เท่ากับ 17.3%, 20.0% และ 21.4% ตามลำดับ ($p = 0.339$) ระยะเวลาเฉลี่ยของการสูงขึ้นใหม่ของค่าต่อมลูกหมากระหว่างกลุ่ม เก็บรักษาเส้นประสาทข้างเดียว และเก็บเส้นประสาททั้งสองข้าง ไม่แตกต่างกัน (8.83 และ 8.89 ปี ตามลำดับ $p = 0.544$) อัตราการอยู่รอดรวมในระยะเวลา 10 ปี เท่ากับ 98.6%, 98.7%, 99.4% ตามลำดับ $p = 0.562$ นอกจากนั้น จากการวิเคราะห์ปัจจัยต่างๆ ร่วมกัน ยืนยันว่าการผ่าตัดโดยเก็บรักษาเส้นประสาทไม่มีผลกับอัตราการสูงขึ้นใหม่ของค่าจำเพาะลูกหมาก (Hazard ratio 1.108, 95% CI 0.827 ถึง 1.942; $p = 0.549$)

สรุป: การศึกษานี้แสดงให้เห็นว่าการผ่าตัดมะเร็งต่อมลูกหมากด้วยหุ่นยนต์ช่วยผ่าตัดโดยเก็บรักษาเส้นประสาทและหลอดเลือดรอบต่อมลูกหมาก ให้ผลการรักษาในด้านการสูงขึ้นใหม่ของค่าจำเพาะต่อมลูกหมาก และการอยู่รอดของผู้ป่วยไม่แตกต่างกับการผ่าตัดแบบไม่เก็บรักษาเส้นประสาทและหลอดเลือดรอบต่อมลูกหมาก