Oncological Outcomes of Radiotherapy after Radical Prostatectomy in Thai Patients with Prostate Cancer

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Objective: *To determine oncological outcomes between adjuvant and salvage radiotherapy after radical prostatectomy for prostate cancer in Siriraj Hospital.*
Material and Method: *All record forms of patients with prostate cancer who underwent radiotherapy after radical prostatectomy in Siriraj Hospital between 2006 and 2014 were reviewed. Data of demographic information, perioperative findings, pathological reports, biochemical recurrence and metastasis-free survival were evaluated.*
Results: *All of 151 patients with adverse pathological features, there were extra-capsular extension 76%, seminal vesicles invasions 36% and positive margins 75%. Patients with localized, locally advanced disease, and lymph nodes involvement were 16.5%, 76.2% and 7.3% respectively. Sixty-one patients had Gleason score 8 to 10. Sixty percent had concomitant androgen deprivation therapy. Mean duration from surgery to radiotherapy was 11 months with mean cumulative radiation dose was 66 Gy. Median follow-up time was 53 months (range 8 to 117 months). Overall 5-year biochemical recurrence-free survival was 53.1% and 5-year metastasis-free survival was 90.8%. Patients with early adjuvant radiotherapy after surgery within five months showed better biochemical recurrence-free survival compare to surgery alone (70.9% vs. 18.4%; p<0.001) with adjusted hazard ratio = 4.78 (95% CI, 2.80 to 8.09) but no statistical significance when compared to patients with salvage radiotherapy (78.7% vs. 69.1%; p = 0.114). Metastasis-free survival showed no difference between two settings (100% vs. 90.6%; p = 0.05). The incidence of late gastrointestinal and genitourinary toxicities grade 3 to 4 were 5.8% and 10.8%, respectively.*
Conclusion: *Radiotherapy after radical prostatectomy is effective treatment for patients with adverse pathological features. Our study demonstrated that adjuvant radiotherapy can improve biochemical recurrence-free survival and metastasis-free survival.*

Keywords: *Prostate cancer, Adjuvant radiotherapy after prostatectomy, Biochemical recurrence-free survival and metastasis-free survival*

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At present, radical prostatectomy is standard treatment for prostate cancer in terms of oncological and functional outcomes in Asian patients[1]. In localized and locally advanced diseases, adverse pathological features including extra-prostatic extension, positive surgical margin or seminal vesicle invasion are independent predictors for biochemical recurrence[2,3]. Radiation therapy (RT) plays the major role for adjuvant or salvage treatment after surgery. Previous studies from Europe and United states showed benefit from postoperative radiotherapy for better local control and biochemical recurrence-free survival[4-6]. To study the results between adjuvant and salvage radiotherapy after radical prostatectomy in Thai patients with prostate cancer, this study was conducted retrospectively.

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Material and Method

Patients

Between 2006 and 2014, 151 patients

underwent external beam radiotherapy (EBRT) after radical prostatectomy at Siriraj Hospital, Bangkok. Eligible patients after prostatectomy must have had at least one of the following criteria which were extra-prostatic extension, seminal vesicle invasion or positive margin. All records were reviewed after approval of our institutional review board.

Surgery

All operations were performed in Siriraj Hospital including all techniques of open surgery, laparoscopic and robotic assisted approaches.

Pathological reports

Surgical specimens were examined and reported according to 2002 TNM classification. Gleason score, prostate weight, and margin status were routinely determined. Positive surgical margin was defined by pathologist as extension of malignant cells at the inked boarder.

Radiation

All patients underwent EBRT at Radiation Oncology Division, Department of Radiology, Faculty of Medicine Siriraj Hospital. Most of them were given three-dimensional conformal radiotherapy (3D-CRT) or intensity modulated radiotherapy (IMRT) to surgical bed. Treatment was scheduled depending on the radiation oncologists committee. In the present study, "Adjuvant radiation" was defined for early radiotherapy after recovery from surgery, whereas "Salvage radiation" defined as the radiotherapy after PSA recurrence (without evidence of distant metastasis). Adverse effects were recorded according to the Radiation Therapy Oncology Group (RTOG) grading scale. Late radiation toxicities and morbidity were evaluated.

Oncological outcome

Follow-up program including physical examinations and serum PSA were performed every 3 months. Biochemical recurrence (BCR) was defined by two consecutive rising of PSA level >0.2 ng/ml[6] or clinical progression. All BCR cases were evaluated with complete exams to detect local recurrence or distant metastasis. Time from date of surgery to radiotherapy, events or last follow-up were recorded. Time from surgery to first BCR was recorded and analyzed to compare between adjuvant radiation and observation. Time from surgery to second BCR was analyzed to compare between adjuvant and salvage radiation.

Statistical analysis

Data were analyzed with SPSS version 18. Demographic data were presented with mean and ranges. Categorical data were evaluated with Contingency Chi-square. Numerical data were calculated with Mann Whitney U test and independent t-tests. Survival outcome were analyzed with Kaplan Meier analysis.

Results

Among 151 patients with adverse pathological features, 90 patients (59.6%), 52 patients (34.4%) and 9 patients (6%) underwent robotic assisted laparoscopic radical prostatectomy (RALP), laparoscopic radical prostatectomy (LRP) and open approach, respectively. Adjuvant and salvage radiation was scheduled for 103 and 46 patients, respectively. Two patients had palliative radiation stop bleeding. Table 1 shows the patient characteristics. The mean age was 65 years (range 45 to 79 years). Mean preoperative PSA level was 24.6 ng/ml [range 1 to 138 ng/dl]. Pathological results shows that localized diseases, locally advanced diseases, and lymph nodes involvement were 16.5%, 76.2% and 7.3%, respectively. Of 151 patients, 61 (41%) had Gleason score 8 to 10. Adverse pathological features of extra-capsular extension, positive margins, and seminal vesicles invasions were 76%, 75% and 36%, respectively.

Oncological outcome

Median follow-up time was 53 months (range 8 to 117 months). Fig. 1 shows survival analysis in 5-year biochemical recurrence-free survival (BRFS) was 53.1% and 5-year metastasis-free survival (MFS) was 90.8%.

In subgroup analysis, adjuvant radiation (ART) after surgery showed better 5-year BRFS than surgery alone (70.9% vs. 18.4%; $p<0.001$) with adjusted hazard ratio = 4.78 (95% CI, 2.80 to 8.09) as shown in Fig. 2A. But no statistical difference was shown when comparing adjuvant radiation to salvage radiation (SRT) in Fig. 2B (ART vs. SRT = 78.7% vs. 69.1%; $p = 0.114$). There were also no statistical significance when compared between RT alone and combined RT+ADT in both adjuvant and salvage settings (ART alone = 61.2% vs. ART+ADT = 77.1%; $p = 0.119$ and SRT alone = 14.9% vs. SRT+ADT = 37.5%; $p = 0.734$).

Metastasis free survival seems to be improved with adjuvant radiation when compared to salvage radiation (5-year MFS = 100% vs 90.6%; $p = 0.05$,

Table 1. Characteristics of 151 patients by method of radiotherapy

Patient characteristics	Adjuvant radiation (n = 103)	Salvage radiation (n = 46)	*p*-value
Mean age (years)	65.5±7.4	64.3±7.5	0.370
Mean body mass index (kg/m^2)	24.4±3.4	24.9±3.3	0.445
Median preoperative PSA (ng/dl)	16.4 (2 to 138)	15.0 (1 to 108)	0.473
Median time from surgery to RT (months)	5 (1 to 27)	17 (3 to 87)	<0.001
Median time from surgery to 1st BCR (months)	20 (3 to 81)	18 (2 to 75)	0.758
Median time from surgery to 2nd BCR (months)	43 (23 to 79)	54 (20 to 94)	0.724
Radiotherapy technique (n, %)			
IMRT	103 (100)	44 (95.7)	0.103
3D CRT	0 (0)	4 (4.3)	
Median radiation dose (Gy)	66 (60 to 72)	70 (64 to 78)	0.001
Neoadjuvant ADT (n, %)	21 (20.4)	7 (15.2)	0.440
Adjuvant ADT (n, %)	74 (71.8)	16 (34.8)	<0.001
Pathological results (n, %)			
Gleason score			
6	6 (5.8)	4 (8.7)	
7 (3+4)	25 (24.3)	16 (34.8)	0.339
7 (4+3)	23 (22.3)	11 (23.9)	
8 to 10	49 (47.6)	15 (32.6)	
Staging			
T2	10 (9.7)	14 (30.4)	
T3	75 (72.8)	27 (58.7)	
T4	17 (16.5)	5 (10.9)	0.015
N1	8 (7.8)	3 (6.5)	
Adverse pathological features			
Extracapsular extension	84 (81.6)	29 (63.0)	0.015
Seminal vesicle invasion	45 (43.7)	9 (19.6)	0.005
Positive surgical margin	80 (77.7)	32 (69.6)	0.405

Fig. 2C).

Androgen deprivation therapy (ADT)

In the present study, timing and duration of ADT were decided by individual clinical judgment. Pre-operative neoadjuvant ADT was given to 28 patients (18.5%) which mostly had initial PSA > 20 ng/ml. While concomitant adjuvant ADT was used in 90 cases (59.6%) including GnRH agonist (45.7%), Antiandrogen (23.3%), and bilateral orchiectomy (7.9%). Most of the adjuvant GnRH agonist were given in adjuvant radiation more than salvage group (61 vs 8 cases). Mean duration of ADT in adjuvant and salvage groups were 30 and 39 months, respectively.

Radiation

Median duration from surgery to radiotherapy was five months for adjuvant radiation and 17 months in salvage radiation. Mean cumulative radiation dose was 66 Gy (range 60-78 Gy, divided in 30-39 fractions). The toxicities from adjuvant and salvage radiations showed no statistical difference between the two settings. Late RTOG gastrointestinal (GI) toxicities grade 3-4 (mainly rectal bleeding) were 5.8% and 6.5% in adjuvant and salvage radiation respectively. Late genitourinary (GU) toxicities grade 3-4 (mainly hemorrhagic cystitis) were 10.8 % and 6.5% in adjuvant and salvage radiation, respectively, as shown in Table 2.

Discussion

Western studies demonstrated that adjuvant radiation had a beneficial effect on biochemical recurrence, local recurrence and clinical progression than surgery alone[4-6]. Our study demonstrated cumulative 5-year-BRFS at 53.1% and subgroup analysis presented that the result of adjuvant radiation setting was comparable with previous RCT studies[4-6]

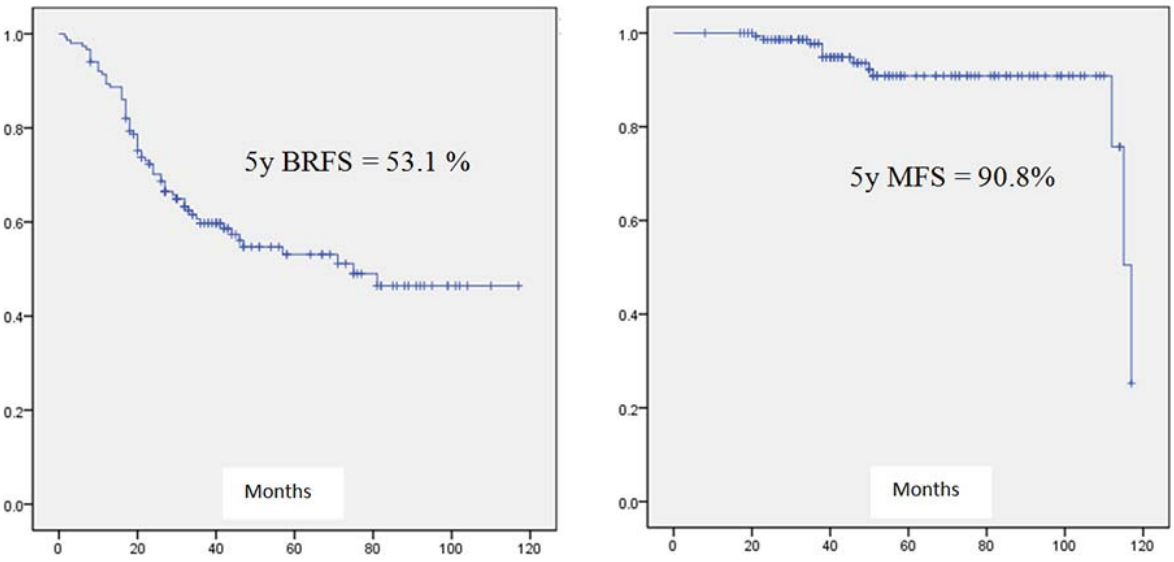
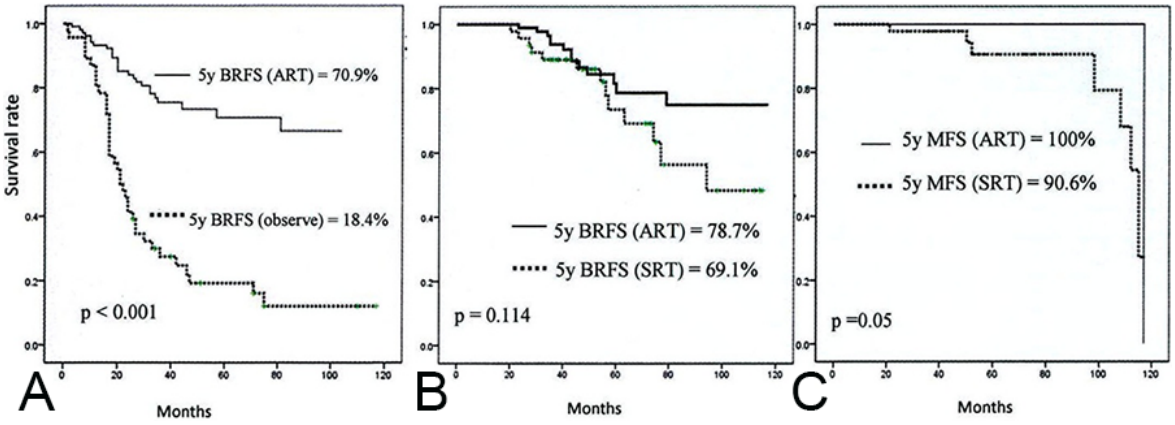


Fig. 1 Biochemical Recurrence-Free Survival (BRFS), and Metastasis-Free Survival (MFS).



Fi g. 2 A) Biochemical Recurrence-Free Survival (BRFS) between adjuvant radiation (line), and surgery alone (dotted). B) Biochemical Recurrence-Free Survival (BRFS) between adjuvant (line), and salvage radiation (dotted). C) Metastasis Free Survival (MFS) between adjuvant (line) and salvage radiation (dotted).

as shown in Table 3. These results confirmed the findings from Ja Yoon Ku et al[7] which had benefit from adjuvant radiation over surgery alone with adjusted hazard ratio = 4.78 (95% CI, 2.80 to 8.09). Five year-MFS was found comparable at 90.8% with 88% from Thompson et al[4]. Survival analysis showed no statistical difference between adjuvant and salvage radiation in terms of 5-year-BRFS and 5-year-MFS (5y-BRFS = 78.7% vs. 69.1%; $p = 0.114$ and 5y-MFS = 100% vs. 90.6%; $p = 0.05$). However, our study failed to show the overall survival because of the low mortality rate. Duration from surgery to radiotherapy in this study provide longer period in adjuvant settings at five months compared to early trends about 3 months from Chen et al[8] and Sowerby et al[9]. Various durations were found in the salvage settings range 11 to 30 months[9,10].

Our results show the survival benefits of early adjuvant radiotherapy after radical prostatectomy for Thai patients with low morbidity. This study reported the incidence of late gastrointestinal (GI) toxicities grade 3 to 4 at 5.8% and genitourinary (GU) toxicities grade 3 to 4 at 10.8% in adjuvant settings compare to slightly lower incidence from Ost et al[11]. While salvage groups developed both GI and GU toxicities only grade 3 at 6.5%. Similar results from Cremers et al[12] showed late GI and GU toxicities grade 3 to 4 at 0.6% and 6% respectively. The late GI toxicity showed to be a little bit higher than other studies due to the radiation technique in early period of IMRT in our hospital; the quality of images in guided radiotherapy (Megavoltage-

Table 2. RTOG toxicities, n (%)

	Adjuvant radiation	Salvage radiation	*p*-value
GI toxicities			
Grade 0: Normal	77 (74.8%)	38 (82.6%)	
Grade 1: Mild diarrhea	18 (17.5%)	5 (10.9%)	
Grade 2: Moderate diarrhea	2 (1.9%)	0 (0%)	0.492
Grade 3: Hematochezia	4 (3.9%)	3 (6.5%)	
Grade 4: Bowel obstruction, perforation	2 (1.9%)	0 (0%)	
GU toxicities			
Grade 0: Normal	54 (52.4%)	20 (43.5%)	
Grade 1: Microhematuria	23 (22.3%)	17 (37.0%)	
Grade 2: Macroscopic hematuria	14 (13.7%)	6 (13.0%)	0.608
Grade 3: Severe hemorrhagic cystitis	7 (6.9%)	3 (6.5%)	
Grade 4: Bladder capacity <100 ml, perforation	4 (3.9%)	0 (0%)	

Table 3. Oncological outcomes and toxicities of comparison studies

Study	Interval (month)	Mean radiation dose	5y BRFS	5y MFS	RTOG toxicity	
					GI gr 3 to 4	GU gr 3 to 4
Our study						
ART	5	66 Gy	78.7%	100%	5.8%	10.8%
SRT	17	68 Gy	69.1%	90.6%	6.5%	6.5%
Thompson et al[5]						
ART	4	60 to 64 Gy	71%	88%	-	-
Bolla et al[6]						
ART	4	60 Gy	74%	-	0%	6%
Wiegel et al[4]						
ART	3	60 Gy	72%	-	0%	3%
Ost et al[10]						
ART	3	74 Gy	85%	-	0%	4%
SRT	15	76 Gy	65%		3%	3%
Cremer et al[11]						
SRT	26	60 to 66 Gy	59%	-	0.6%	6%

Electronic Portal Image Device) was not excellent. The bowel preparation in daily treatment was not good either and actually radiated rectal volume by possibly receiving more doses than planned for. However, this study showed that our radiation complications are acceptable and compatible with other studies as shown in Table 3.

Concurrent ADT can improve BRFS and MFS and are no statistical significant in either adjuvant and salvage settings. As compared to suggestions from Jackson et al[13] and Horwitz et al[14], a longer duration of ADT of more than 12 to 24 months significantly improved BRFS and MFS in high risk patients.

Major limitations in this present study are the retrospective design that can lead to selection bias. Our inclusion criteria did not recruit the patients with adverse pathological features which did not undergo radiotherapy. Therefore the intention-to-treat analysis is neglected. Comparative results between adjuvant and salvage group must be carefully considered. Prospective study with matched control design should be conducted to demonstrate furthermore information.

Conclusion

Radiotherapy after radical prostatectomy is effective treatment for patients with adverse

pathological features with low morbidity. The present study demonstrated that early adjuvant radiotherapy could improve biochemical recurrence-free survival and metastasis-free survival compared to surgery alone.

What is already known on this topic?

Postoperative radiotherapy in patients with locally advanced disease or unfavorable pathological results, significantly improved local control and biochemical recurrence-free survival, compared with surgery alone. But there is no consensus in terms of metastatic rates and overall survival.

What this study adds?

Early postoperative adjuvant radiotherapy within five months could improve biochemical recurrence-free survival with or without androgen deprivation therapy.

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Potential conflicts of interest

None.

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ผลการรักษาด้วยวิธีฉายรังสีตามหลังการผ่าตัดมะเร็งต่อมลูกหมากในโรงพยาบาลศิริราช

วรัชญ์ วรนิสรากุล, สุนัย ลีวันแสงทอง, พิทยา ด่านกุลชัย, นันทกานต์ อภิวโรดม, สิทธิพร ศรีนวลนัด, ธวัชชัย ทวีมั่นคงทรัพย์, บรรณสิทธิ์ ไชยประสิทธิ์, ธีระพล อมรเวชสุกิจ, เอกรินทร์ โชติกวาณิชย์, กิตติพงษ์ พินธุโสภณ, ศิรส จิตประไพ, ภควัฒน์ ระมาตร์, ชลัยรัชฎ์ สุขอวยชัย, ไชยยงค์ นวลยง

วัตถุประสงค์: เพื่อศึกษาการดำเนินโรคของผู้ป่วยที่รักษาด้วยการฉายรังสีหลังการผ่าตัดมะเร็งต่อมลูกหมากในโรงพยาบาลศิริราช และเปรียบเทียบผลการรักษาระหว่างกลุ่มที่ฉายรังสีทันทีและกลุ่มที่รอฉายรังสีหลังมะเร็งกลับเป็นซ้ำ

วัสดุและวิธีการ: ทบทวนเวชระเบียนของผู้ป่วยมะเร็งต่อมลูกหมากทุกรายที่เข้ารับการรับการฉายรังสีหลังผ่าตัดมะเร็งต่อมลูกหมากในช่วงปี พ.ศ. 2548 ถึง 2557 บันทึกข้อมูลต่างๆ ประกอบด้วย รายละเอียดผู้ป่วย, ผลการรักษาช่วงเข้ารับการผ่าตัด, ผลชิ้นเนื้อทางพยาธิวิทยาและภาวะแทรกซ้อน จากนั้นวิเคราะห์ข้อมูล เรื่องการกลับเป็นซ้ำของโรค, การกระจายของมะเร็งและอัตราการรอดชีวิตด้วยวิธีทางสถิติ

ผลการศึกษา: จากการรวบรวมข้อมูลพบผู้ป่วยชายทั้งหมด 151 ราย อายุเฉลี่ยประมาณ 65 ปี ที่มีผลชิ้นเนื้อทางพยาธิวิทยาไม่น่าพึงพอใจ (ได้แก่ ตรวจพบมะเร็งที่ขอบชิ้นเนื้อ, มะเร็งกระจายออกนอกต่อมลูกหมาก และมีการลุกลามไปที่ถุงน้ำเชื้อ) แบ่งการกระจายของโรคได้เป็นระยะเริ่มต้น 16.5% ระยะลุกลาม 83.4% และระยะแพร่กระจายที่ต่อมน้ำเหลือง 7.3% โดยมี 60% ของผู้ป่วยทั้งหมดได้รับการรักษาทางฮอร์โมนร่วมด้วย, ระยะเวลาในการรอฉายรังสีหลังผ่าตัดเฉลี่ยประมาณ 11 เดือน ขนาดรังสีที่ได้รับเฉลี่ย 66 เกรย์ ตรวจพบภาวะแทรกซ้อนระยะยาวจากรังสีในผู้ป่วยจำนวน 24 ราย (ความรุนแรงระดับ 3 ถึง 4, ในระบบทางเดินอาหาร 5.8% และระบบทางเดินปัสสาวะ 10.8%) ระยะเวลาติดตามผลการศึกษารักษาเฉลี่ยประมาณ 53 เดือน (8 ถึง 117 เดือน) อัตราการรอดชีวิตจากการกลับเป็นซ้ำของโรคในระยะเวลา 5 ปี โดยรวมเท่ากับ 53.1% และอัตราการรอดชีวิตจากการแพร่กระจายของโรฃในระยะเวลา 5 ปี เท่ากับ 90.8% ผู้ป่วยกลุ่มที่ได้รับการฉายรังสีทันทีหลังผ่าตัดภายใน 6 เดือน มีอัตราการรอดชีวิตจากการกลับเป็นซ้ำของโรคที่ดีกว่ากลุ่มที่ไม่ได้รับการฉายรังสี (70.9% เทียบกับ 18.4%) แต่ไม่แตกต่างอย่างมีนัยสำคัญทางสถิติ เมื่อเทียบกับกลุ่มที่ฉายรังสีหลังจากตรวจพบโรคกลับเป็นซ้ำแล้ว (78.7% เทียบกับ 69.1%)

สรุป: การฉายรังสีหลังการผ่าตัดมะเร็งต่อมลูกหมากเป็นการรักษาที่มีประสิทธิภาพในผู้ป่วยที่มีผลชิ้นเนื้อทางพยาธิวิทยาไม่น่าพึงพอใจ งานวิจัยชิ้นนี้แสดงให้เห็นถึงผลที่ดีของการรักษาในแง่เพิ่มอัตราการรอดชีวิตจากการกลับเป็นซ้ำของโรคและการแพร่กระจายของโรค