Comparison of the oncological and functional outcomes of brachytherapy and radical prostatectomy for localized prostate cancer

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Abstract

Objective:To compare the oncological and functional outcomes of brachytherapy(BT) and radical prostatectomy(RP) in patients with localized prostate cancer(PCa).Methods:We retrospectively analyzed data from 415 patients with localized PCa who were treated with RP (n= 280) or BT (n=135) at Northern Jiangsu People's Hospital between November 2012 and April 2019. Biochemical relapse-free survival(bRFS) and cancer-specific survival (CSS) were compared. Multivariate Cox regression analysis was used to evaluate bRFS. Health-related quality of life(HRQoL) was measured using the Expanded Prostate Cancer Index Composite(EPIC) questionnaire.Results:The BT group was older, had a higher initial PSA, and had a higher proportion of high-risk patients. The median follow-up time was 38.6 months. The 3-year bRFS was 77.3% in the RP group versus 84.0% in the BT group(P=0.246). For the RP group, the 3-year bRFS for patients presenting with low-, intermediate-, and high-risk disease was 90.3%, 79.6% and 71.3%, respectively, compared with 90.9%, 93.8% and 80.7% in the BT group(P=0.948,0.213,0.263, respectively). The 3-year CSS was 96.1% in the RP group versus 94.5% in the BT group(P=0.948). For the RP group, the 3-year CSS for patients presenting with low-, intermediate-, and high-risk disease was 100%, 100% and 92.8%, respectively, compared with 100%, 100% and 92.4%, for the BT group(P=0.620). Based on multivariate Cox regression analysis, clinical T stage ≥ T2b was the main independent prognostic factor for bRFS. Regarding the quality of life, compared with the baseline, both treatments produced a significant decrease in different aspects of HRQoL at 3, 6 and 12 months after treatment. Patients in the BT group had lower HRQoL with regard to urinary irritation/obstruction and bowel function or bother, while patients in the RP group had lower HRQoL concerning urinary incontinence and sexual function or bother. There was no significant difference in HRQOL aspects between the two groups after follow-up for 2 years compared with the baseline.Conclusion:BT provides equivalent oncological control outcomes for patients with localized PCa compared with RP. Clinical T stage ≥ T2b was the independent prognostic factor for bRFS. BT had better HRQoL compared with RP, except for urinary irritation/obstruction and bowel function or bother, but returned to baseline after 2 years.

Background

Prostate cancer (PCa) is the preponderant malignancy in men. In recent years, as the population ages, the Westernized lifestyle is increasingly adopted, and prostate specific antigen (PSA) screening and improved biopsy techniques are implemented, the incidence of PCa has been increasing every year in China[1]. Many treatment options can be used for localized PCa, including active surveillance (AS), external beam radiotherapy (EBRT), radical prostatectomy (RP), and brachytherapy (BT). The optimal treatment for localized PCa is still the subject of controversy.

RP is considered a standard treatment method for localized PCa[2]. However, poor erectile function outcomes and elevated incontinence rates represent major disadvantages[3]. Furthermore, aged patients and those with underlying diseases may have difficulty tolerating radical surgery.

The American Brachytherapy Society consensus guidelines suggest that BT is a safe and effective treatment for patients with localized PCa[4]. Data indicate that BT is the best choice for patients over 75 years of age[5,6].

Moreover, patients tend to place equal emphasis on the expected oncological and functional outcomes associated with each treatment modality. However, few comparative studies have examined the oncological and functional outcomes of BT and RP for localized PCa. Therefore, we conducted a single institutional, retrospective and comparative study evaluating oncological and functional outcomes of BT and RP for localized PCa during the same time period.

Methods

Patient selection

We evaluated 415 patients with localized PCa (T1c-T3aN0M0) who underwent RP (n=280) or BT (n=135) at Northern Jiangsu People's Hospital between November 2012 and April 2019. Patients were divided into low-, intermediate- and high-risk according to the National Comprehensive Cancer Network (NCCN) guidelines[7]: PSA ≤ 10 ng/mL, Gleason score ≤ 6 and stage ≤ T2a for low-risk, PSA 10-20 ng/ml, Gleason score 7 and stage T2b for intermediate-risk, and PSA >20 ng/ml, Gleason score ≥ 8 or stage ≥ T2c for high-risk patients.

Patient evaluation included medical history, physical examination, initial PSA (iPSA) and transrectal ultrasound-guided biopsy. Clinical staging was based on Gleason score, digital rectal examination(DRE), iPSA, and imaging studies (bone scan, pelvic computed tomography or magnetic resonance imaging). The therapeutic decisions were made by the surgeon according to the patient’s discussion and preference.

Treatment

Radical prostatectomy. After infraumbilical incision and access to the extraperitoneal space, dissection of the pelvic lymph nodes was carried out. Following prostate exposure, the endopelvic fascia was opened, with ligation and sectioning of the penis dorsal venous complex. The next step involved dissection and section of the urethra. The prostate was then dissected retrogradely, preserving the neurovascular bundle or not according to the clinical and surgical staging. Finally, Denonvillier fascia separation was performed with prostate removal and hemostasis. Vesicourethral anastomosis was performed employing a urethral catheter, which remained for 10 to 12 days.

Brachytherapy. Preplanning for BT was performed using the prostate volume obtained by transrectal ultrasound (Flex focus 1202; BK, Naerum, Denmark) to determine the overall activity of the radioisotope. Patients underwent epidural anesthesia in the bladder lithotomy position with an indwelling catheter before BT. The radioisotope used in all patients was iodine-125. Iodine-125 seeds were accurately introduced in preplanned positions using a brachytherapy stepping unit (Mick Radio-Nuclear Instruments,

Mount Vernon, NY, USA) with a standard 0.5 cm brachytherapy template implanted via a transperineal approach. The prescribed dose was 145 Gy. Iodine-125 seeds were placed through the needles with a Mick applicator under real-time transrectal ultrasonography guidance. A plain film of the kidney-ureter-bladder was scheduled to confirm the distribution of the implanted seeds after the procedure. The urinary catheter was withdrawn 2 to 5 days after BT. Dosimetric analysis was evaluated by computed tomography (CT) for 4 weeks after implantation. A monotherapy approach with BT was used for low-risk patients; androgen deprivation therapy (ADT) was administered for intermediate-risk (4-6 months) and high-risk patients (2-3 years).

Follow-up

We analyzed the follow-up data obtained by telephone follow-up survey and periodic outpatient reexamination. Follow-up visits consisting of serum PSA and DRE were scheduled every 3 months for the first year, every 6 months in the second year and then annually thereafter. The primary endpoints to determine the oncological outcomes were biochemical relapse-free survival (bRFS) and cancer-specific survival (CSS). Biochemical recurrence for patients undergoing BT was defined as a nadir PSA + 2 ng/mL or more using the Phoenix definition (nadir + 2 ng/mL)[8] and for those undergoing RP as two consecutive PSA ≥ 0.2 ng/mL[9]. bRFS was defined as the time from the treatment to PSA recurrence or death from any cause. CSS was defined as death due to PCa or the presence of uncontrolled metastatic disease at the time of death.

Functional outcomes refer to health-related quality of life (HRQoL). HRQoL was measured in patients treated for localized PCa with RP and BT using the Expanded Prostate Cancer Index Composite (EPIC)[10] questionnaire at baseline and 3, 6, 12, and 24 months after the treatment.

Statistical analysis

Data were expressed as percentage or mean scores ± standard deviation. Differences between categorical variables were compared using the Chi-squared test, and differences between continuous variables were compared using t-test. The Mann-Whitney U test was used to compare medians. We used the Kaplan-Meier method and the log-rank test to estimate bRFS and CSS. A Cox regression model was used for multivariate analysis of bRFS. $P<0.05$ was considered to be statistically significant. All statistical analyses were performed using SPSS Statistics version 23.0 (IBM Corporation, Armonk, NY, USA).

Results

We initially identified 420 patients who met the inclusion criteria for the study, and 5 of these were subsequently excluded due to lack of follow-up.

The clinical characteristics of the study population are shown in Table 1. The BT group was older (77.06 vs. 69.57 years, respectively), had higher initial PSA (iPSA) (42.04 vs. 21.60 ng/mL), and a higher proportion of high-risk patients (74.1% vs. 54.6%) compared to the RP group. There was

no statistical difference between the two groups regarding biopsy Gleason score and clinical T stage. The median follow-up time was 38.6 months (range 5-78 months).

Biochemical recurrence would have occurred in 42 and 16 patients in the RP and BT groups at the time of the last follow-up visit, respectively. Ten patients in the RP group died, 8 due to PCa and the others due to cerebrovascular disease. In the BT group, 14 patients died; 4 due to PCa, 3 due to digestive tract cancer, 2 due to cerebrovascular disease and the others due to unknown causes.

With regard to the oncological outcomes, the 3-year bRFS was 77.3% in the RP group versus 84.0% in the BT group (P = 0.246; Figure 1a). When stratified according to risk, for the RP group, the 3-year bRFS for patients presenting with low-, intermediate-, and high-risk disease was 90.3%, 79.6% and 71.3%, respectively, compared with 90.9%, 93.8% and 80.7% in the BT group (P = 0.948、0.213、 0.263, respectively; Figure 1bcd). Therefore, there was similar biochemical control in the RP and BT groups at 3 years.

The 3-year CSS was 96.1% in the RP group versus 94.5% in the BT group (P = 0.948; Figure 2a). When stratified according to risk, for the RP group, the 3-year CSS for patients presenting with low-, intermediate-, and high-risk disease was 100%, 100% and 92.8%, respectively, compared with 100%, 100% and 92.4%, for the BT group (P = 0.620; Figure 2b).

Based on multivariate Cox regression analysis, clinical T stage ≥ T2b (HR 2.785, 95%CI 1.452-5.343; P = 0.002) was the main independent prognostic factor for bRFS (Table 2). Treatment modality (RP vs BT), age (<75 vs ≥75), PSA (<20 vs ≥20) and Gleason score (≤6 vs 7, ≥8) were not prognostic factors of bRFS.

The HRQoL of the two groups of patients was affected to varying degrees after treatment (Table 3). Compared with the baseline, both treatments produced a significant decrease in different aspects of HRQoL at 3, 6 and 12 months after treatment: patients in the BT group had lower HRQoL with regard to urinary irritation/obstruction and bowel function or bother, while patients in the RP group had lower HRQoL concerning urinary incontinence and sexual function or bother. There was no statistically significant difference in HRQOL aspects between the two groups after 2 years of follow-up compared with the baseline.

Discussion

The treatments of localized PCa include AS, EBRT, RP and BT. RP is considered a standard treatment for early stage PCa[2]. Because of the complete resection of the tumor and detailed pathological analysis, the surgery is selected more commonly by patients. Major advantages of RP include precise assessment of the extent of the disease at a low morbidity cost, high level of confidence in the long-term eradication, ease of detection of recurrence with a tumor marker, and availability for treatment of the long-term complications (i.e. urinary incontinence and erectile dysfunction) that affect the quality of life.

Unfortunately, poor erectile function outcomes and elevated incontinence rates represent major disadvantages[3].

With the development and application of a computerized treatment planning system and new radionuclide, BT for PCa has developed rapidly. BT is a technology by which a radioactive isotope is placed inside or around the tumor. The tumor receives a high dose of radiation without elevating the dose to surrounding normal tissues. Some advantages of BT include being minimally invasive and having a definite effect and fewer complications, which may contribute to its popularity in Western countries[11]. The American Brachytherapy Society consensus guidelines suggest that BT is a safe and effective treatment for patients with localized PCa[4]. Furthermore, BT is considered a great therapeutic option for aged patients and those with complicated medical diseases who may have difficulty tolerating radical surgery[6,5].

In the present study, we analyzed 415 patients with localized PCa who underwent RP (n=280) or BT (n=135). The BT group was older, had higher iPSA, and a higher proportion of high-risk patients. The results indicated that the 3-year bRFS rate was 77.3% (low risk: 90.3%, intermediate risk: 79.6%, and high risk: 71.3%) in the RP group versus 84.0% (low risk: 90.9%, intermediate risk: 93.8%, and high risk: 80.7%) in the BT group. Although the 3-year bRFS for RP was lower compared with BT, there was no statistically significant difference between the two groups (all $P > 0.05$). In addition, there was no significant difference between RP and BT with regard to bRFS by multivariate analysis. The 3-year CSS was 100% for the two groups with low- and intermediate-risk disease. For high-risk disease, the 3-year CSS was 92.8% in the RP group versus 92.4% in the BT group, a non-statistically significant difference ($P > 0.05$).

In a recent study, Giberti C et al.[12] reported similar 5-year biochemical disease-free survival rates for RP (91.0%) or BT (91.7%) in patients with low-risk PCa. Fisher CM et al.[13] reported a comparative study of men with low- to intermediate-risk PCa treated with BT and RP. After RP, the 5-year bRFS were 96.1% and 90.6% for low- and intermediate-risk patients, respectively. After BT, the 5-year bRFS were 92.5% and 95.8% for low- and intermediate-risk disease, respectively. The 5-year CSS for patients was 100% for both RP and BT. This finding argued that excellent disease control outcomes can be achieved after RP and BT for men with early stage localized PCa. Similarly, Colberg et al.[14] reported that BT provided equivalent 5-year bRFS compared with RP in patients with early PCa.

These results were similar with our study. The 3-year bRFS (93.8%) in the BT group was higher than that (79.6%) in the RP group for intermediate risk patients, but the difference between the two groups did not reach statistical significance ($P=0.213$). We considered that this result may be related to lower number of intermediate-risk patients in BT group.

There are a large number of prognostic factors of PCa, such as age, initial PSA, Gleason score, and T stage[15]. Ciezki et al.[16] reported that clinical stage T3, biopsy Gleason score 8-10, higher pretreatment PSA, shorter ADT duration and more frequent PSA testing following therapy were associated with significantly worse bRFS. Zhou et al.[17] reported that clinical stage ≥ T2b, was associated with significantly worse bRFS. Similarly, in the multivariate analysis of the present study, we also considered

clinical stage ≥ T2b as the main independent prognostic factor for bRFS. The treatment modality, age, iPSA and Gleason score exerted no influence on bRFS.

It is necessary to consider not only cancer control but also HRQoL for patients facing the decision of which treatment to choose for localized PCa. HRQoL was measured in patients treated for localized PCa with RP and BT using the EPIC questionnaire at baseline and 3, 6, 12, and 24 months after the treatment. The EPIC is a 50-item questionnaire with eight domains, including urinary function, urinary irritation/obstruction, urinary incontinence, urinary bother, bowel function, bowel bother, sexual function and sexual bother[10]. Each domain is scored from 0 to 100, with higher scores indicating better HRQoL. For HRQoL in this study, compared with baseline, both treatments produced a significant decrease in HRQoL in different aspects at 3, 6 months and 1 year after treatment. Patients in the BT group had lower HRQoL with regard to urinary irritation/obstruction and bowel function or bother, while patients in the RP group had lower HRQoL regarding urinary incontinence and sexual function or bother. The scores reached a nadir 3 months after treatment and then recovered. There was no significant difference in HRQOL aspects between the two groups after 2 years of follow-up.

Chen RC et al.[18] reported a comparative study about the quality of life after RP, EBRT, and BT vs AS. Compared with AS, sexual dysfunction worsened by 3 months in patients who underwent RP, EBRT, and BT. Compared with AS at 3 months, worsened urinary incontinence was associated with RP, acute worsening of urinary obstruction and irritation with EBRT and BT, and worsened bowel symptoms with EBRT. By 24 months, the mean scores between the treatment groups vs AS were not significantly different in most domains. Giberti C et al.[12] reported the functional outcomes after radical retropubic prostatectomy (RRP) versus BT for the treatment of low-risk PCa during a 5-year assessment. At 6 months and 1 year, both treatments produced a significant decrease in aspects of the quality of life, while in BT patients, a significantly higher and longer lasting rate of urinary irritation disorders but better erectile function than in the RRP group. No differences in the functional outcomes were encountered after 5 years in either group.

The incidence of urinary irritation or obstruction was higher after BT, which is related to the dose and distribution of radioactive seeds[19]. Urethral irradiation dose should be reduced as much as possible in order to reduce postoperative urinary irritation or obstruction. Furthermore, Elshaikh et al.[20] found that prophylactic tamsulosin before BT significantly improved lower urinary tract symptoms. Transurethral resection of the prostate (TURP) may be considered for recurrent urinary retention due to bladder outlet obstruction. In this study, three patients eventually required TURP because of prolonged urinary retention. The urinary incontinence and sexual function in the BT group was better than that in the RP group. This is because BT preserves the prostate's anatomical structure and does not directly damage the neurovascular bundle. Therefore, BT is a potential alternative therapeutic modality to RP for patients (especially for aged patients or those with complicated medical diseases) seeking a potentially curative treatment.

Conclusions

BT provides equivalent oncological control outcomes in terms of bRFS and CSS for patients with localized PCa compared with RP. Clinical T stage ≥ T2b was the main independent prognostic factor for bRFS. The BT group had better HRQoL compared with the RP group, except for urinary irritation/obstruction and bowel function or bother, with a return to baseline after 2 years. BT is a potential alternative approach to RP for patients (especially for aged patients or those with complicated medical diseases) seeking attempted potentially curative treatment. These results could provide important information for clinical decision making for patients with PCa.

This study has some limitations. This study is a single institutional, retrospective study. The small number of patients evaluated and the short follow-up period may have influenced the oncological results and posttreatment HRQoL. Prospective, randomized studies with a larger number of patients and a longer follow-up period are required to confirm these encouraging results.

Abbreviations

RP: radical prostatectomy; BT: brachytherapy; iPSA: initial PSA; PCa: prostate cancer; CSS: cancer-specific survival; HRQoL: health-related quality of life; EPIC: Expanded Prostate Cancer Index Composite; bRFS: biochemical relapse-free survival; NCCN: National Comprehensive Cancer Network; ADT: androgen deprivation therapy; DRE: digital rectal examination; CT: computed tomography; EBRT: external beam radiotherapy; TURP: transurethral resection of the prostate.

Declarations

Ethics approval and consent to participate

This study has been approved by the Institutional Ethical Committee of Clinical Medical College of the Yangzhou University. All patients gave written informed consent before participation.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

FW: Study design, data collection and management, statistical data analysis, manuscript writing; YL: Project development; statistical data analysis, manuscript writing, editing and revisions; XFD: Project development, study design, data management, manuscript writing, editing and revisions; YZX, CHG and LYZ: data collection; statistical data analysis. All authors read and approved the final manuscript.

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Tables

Table 1 Clinical characteristics of patients undergoing RP and BT

Characteristic	RP（n=280）	BT（n=135）	Total（n=415）	*P* value
Age (years)				<0.01*
Mean(SD)	69.57(6.46)	77.06(5.67)	72.01(7.13)	
Range	49-88	59-91	49-91	
initial PSA（ng/ml）				<0.01*
≤20	187(66.8%)	52(38.5%)	239(57.6%)	
>20	93(33.2%)	83(61.5%)	176(42.4%)	
Mean(SD)	21.60(21.45)	42.04(36.86)	28.25(28.29)	
Biopsy Gleason score				0.433
≤6	55(19.6%)	30(22.2%)	85(20.5%)	
7	103(36.8%)	41(30.3%)	144(34.7%)	
≥8	122(43.6%)	64(47.4%)	186(44.8%)	
Clinical T stage				0.514
T1c	39(13.9%)	22(16.3%)	61(14.7%)	
T2a	58(20.7%)	36(26.7%)	94(22.7%)	
T2b	70(25.0%)	29(21.5%)	99(23.9%)	
T2c	105(37.5%)	43(31.9%)	142(35.7%)	
T3a	8(2.9%)	5(3.7%)	13(3.1%)	
NCCN risk category				0.001*
low	41(14.6%)	14(10.4%)	55(13.3%)	
intermediate	86(30.7%)	21(15.6%)	107(25.8%)	
high	153(54.6%)	100(74.1%)	253(61%)	

RP:radical prostatectomy, BT: brachytherapy, PSA: prostate-specific antigen, NCCN:National Comprehensive Cancer Network, SD: standard deviation；*P<0.05

Table 2 Multivariable analyses for biochemical relapse-free survival

Factor	Multivariate		
	HR	95%CI	*P* value
Treatment modality			
RP vs BT	0.829	0.410-1.677	0.602
Age (years)			
<75 vs ≥75	0.691	0.366-1.307	0.256
iPSA（ng/ml）			
<20 vs ≥20	1.418	0.792-2.537	0.240
Gleason score			
≤6	1	Ref.	-
7	0.780	0.372-1.633	0.509
≥8	0.284	0.284-0.122	0.478
Clinical T Stage			
≤T2a vs ≥T2b	2.785	1.452-5.343	0.002*

Ref.: reference, RP: radical prostatectomy, BT: brachytherapy, iPSA:initial prostate-specific antigen, CI: confdence interval, HR: hazard ratio, NCCN: National Comprehensive Cancer Network, *P＜0.05

Table 3 The EPIC scores of patients undergoing RP and BT

	RP n=280（ ±SD）	BT n=280（ ±SD）	*P* value （RP vs. BT）
Urinary function			
Baseline	94.5±10.4	96.4±11.2	0.098
3-month	81.7±17.6*	87.5±14.3*	0.001
6-month	86.3±14.2*	92.6±8.9*	0.001
12-month	89.1±13.4*	93.9±12.2*	0.001
24-month	93.8±11.3	95.3±10.7	0.190
Urinary irritative/obstructive			
Baseline	93.3±11.3	95.1±10.7	0.120
3-month	85.4±13.6*	81.3±16.2*	0.011
6-month	94.5±5.9	85.7±12.5*	0.001
12-month	95.6±4.5	88.3±10.2*	0.001
24-month	97.1±5.3	94.4±8.7	0.001
Urinary incontinence			
Baseline	96.3±7.6	98.2±6.3	0.007
3-month	68.5±23.5*	94.3±7.5*	0.001
6-month	76.9±19.3*	96.5±9.7	0.001
12-month	84.2±16.4*	97.5±8.6	0.001
24-month	94.7±12.9	96.7±8.9	0.066
Urinary bother			
Baseline	92.4±12.1	94.8±8.8	0.022
3-month	87.6±15.4*	85.3±16.1*	0.167
6-month	90.4±10.2*	87.7±11.4*	0.019
12-month	92.9±9.1	92.6±10.1	0.770
24-month	93.4±8.7	93.9±9.2	0.598
Bowel function			
Baseline	96.1±7.3	97.5±5.2	0.025
3-month	95.2±8.8	95.1±8.5*	0.912

6-month	94.9±7.5	95.9±8.7	0.224
12-month	95.3±6.7	96.3±6.1	0.130
24-month	95.9±5.4	97.3±5.7	0.001
Bowel bother			
Baseline	97.7±4.3	98.1±3.6	0.320
3-month	96.7±7.4	95.8±7.2*	0.237
6-month	96.9±6.8	97.1±6.8	0.779
12-month	97.2±6.2	97.3±4.8	0.857
24-month	97.5±5.8	97.9±4.1	0.419
Sexual function			
Baseline	54.1±24.7	47.8±25.5	0.016
3-month	22.1±22.5*	44.5±18.8	0.001
6-month	28.9±20.6*	45.8±20.1	0.001
12-month	38.8±22.9*	46.7±23.4	0.001
24-month	50.6±22.3	47.5±22.7	0.190
Sexual bother			
Baseline	80.6±22.8	82.1±20.4	0.115
3-month	62.4±25.7*	78.7±22.6	0.001
6-month	66.3±26.1*	80.9±21.1	0.001
12-month	69.1±23.3*	81.9±19.5	0.001
24-month	77.4±24.8	81.3±19.9	0.086

EPIC Expanded Prostate Cancer Index Composite; RP: radical prostatectomy, BT: brachytherapy ; *P 0.05 (baseline vs. 3-, 6-, 12- and 24-month).

Figures

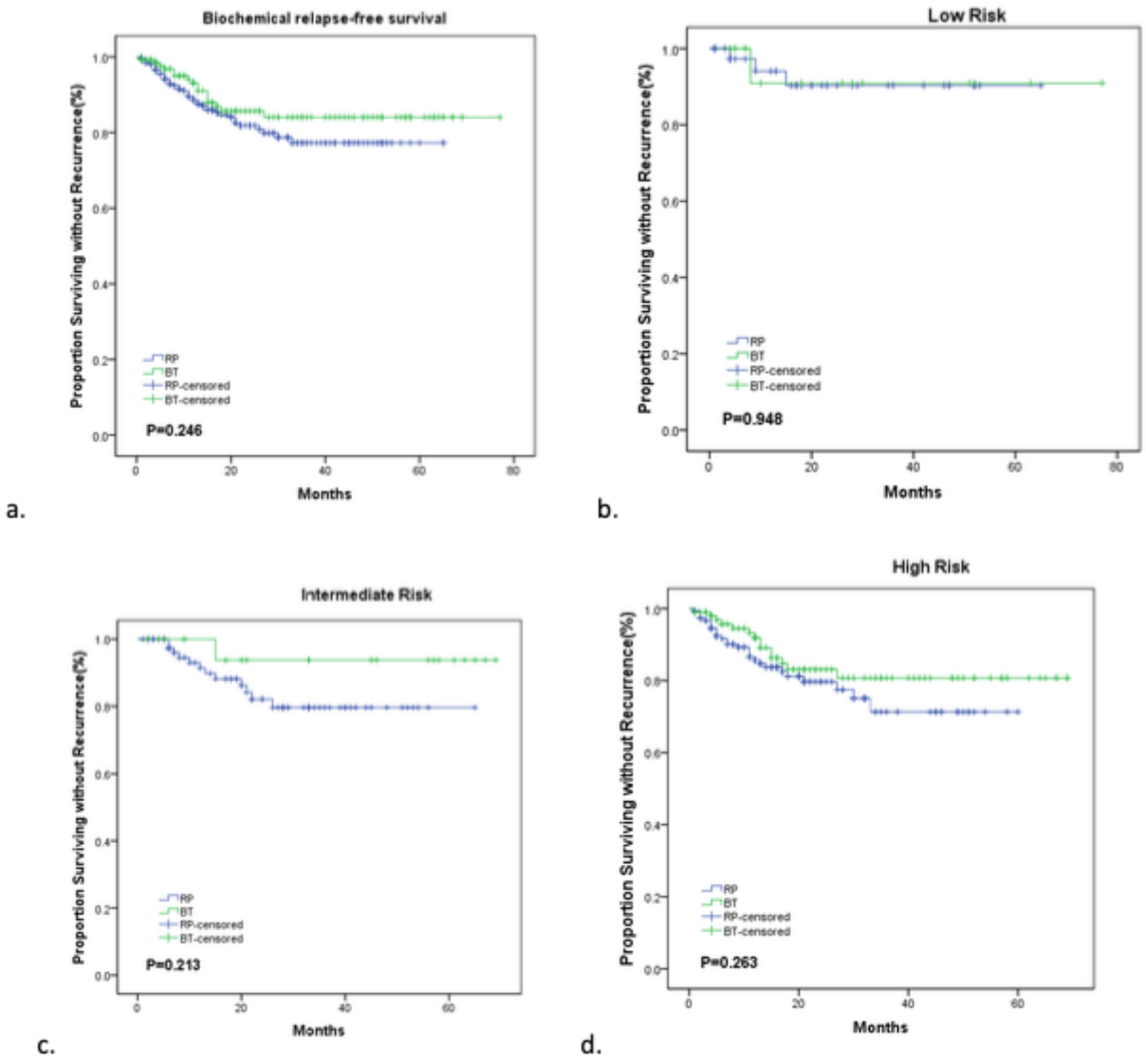

Figure 1

Kaplan-Meier curve for bRFS between RP and BT. a. overall, b. low risk, c. intermediate risk, d. high risk. RP:radical prostatectomy, BT: brachytherapy, bRFS: Biochemical relapse-free survival

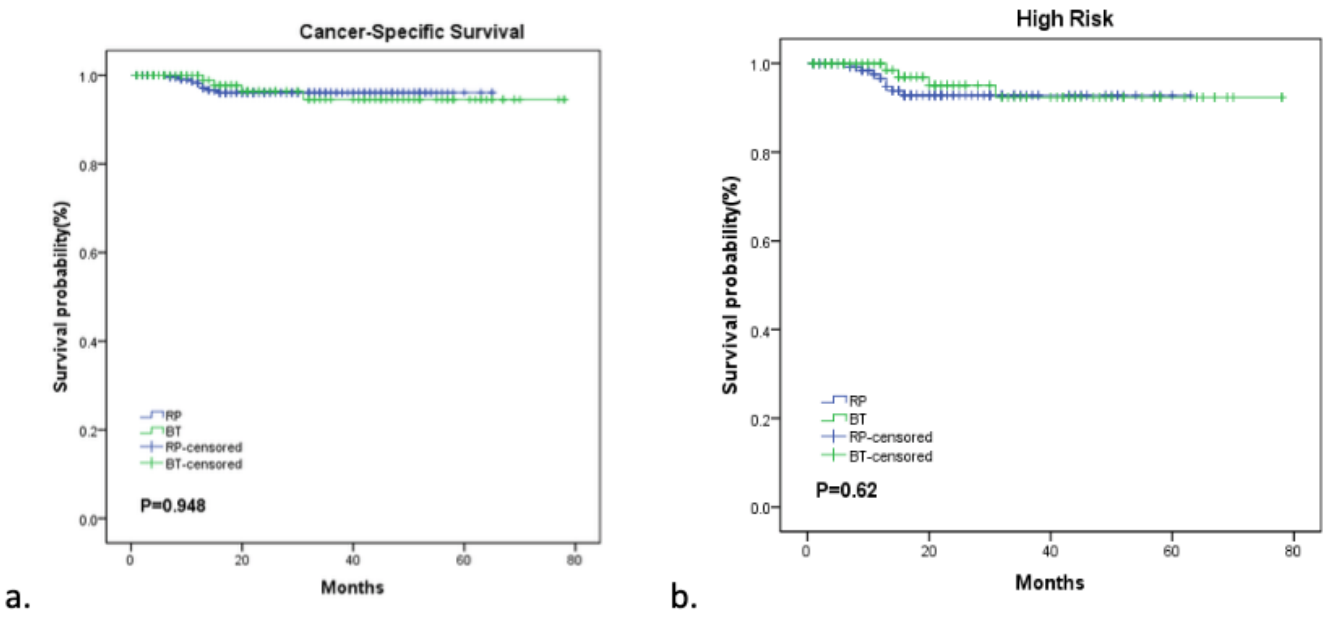

Figure 2

Kaplan-Meier curve for CSS between RP and BT. a. overall, b. high risk. RP: radical prostatectomy, BT: brachytherapy, CSS: Cancer Specific Survival