# Quality of Life After Open or Robotic Prostatectomy, Cryoablation or Brachytherapy for Localized Prostate Cancer

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# Abbreviations and Acronyms

BT = brachytherapy

EBRT = external beam radiation therapy

HRQOL = health related quality of life

ORP = open radical prostatectomy

PBS = percent of baseline score

QOL = quality of life

RAP = robotic assisted laparoscopic radical prostatectomy

RP = radical prostatectomy

Submitted for publication May 6, 2009. Study received institutional review board approval.

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**Purpose**: Health related quality of life concerns factor prominently in prostate cancer management. We describe health related quality of life impact and recovery profiles of 4 commonly used operative treatments for localized prostate cancer.

Materials and Methods: Beginning in February 2000 all patients treated with open radical prostatectomy, robot assisted laparoscopic prostatectomy, brachytherapy or cryotherapy were asked to complete the UCLA-PCI questionnaire before treatment, and at 3, 6, 12, 18, 24, 30 and 36 months after treatment. Outcomes were compared across treatment types with statistical analysis using univariate and multivariate models.

**Results:** A total of 785 patients treated between February 2000 and December 2008 were included in the analysis with a mean followup of 24 months. All health related quality of life domains were adversely affected by all treatments and recovery profiles varied significantly by treatment type. Overall urinary function and bother outcomes scored significantly higher after brachytherapy and cryotherapy compared to open radical prostatectomy and robotic assisted laparoscopic radical prostatectomy. Brachytherapy and cryotherapy had a 3-fold higher rate of return to baseline urinary function compared to open radical prostatectomy and robotic assisted laparoscopic radical prostatectomy. Sexual function and bother scores were highest after brachytherapy, with a 5-fold higher rate of return to baseline function compared to cryotherapy, open radical prostatectomy and robotic assisted laparoscopic radical prostatectomy. All 4 treatments were associated with relatively transient and less pronounced impact on bowel function and bother. **Conclusions:** In a study of sequential health related quality of life assessments brachytherapy and cryotherapy were associated with higher urinary function and bother scores compared to open radical prostatectomy and da Vinci® prostatectomy. Brachytherapy was associated with higher sexual function and bother scores compared to open radical prostatectomy, robotic assisted laparoscopic radical prostatectomy and cryotherapy.

**Key Words**: prostatic neoplasms, quality of life, brachytherapy, cryosurgery, prostatectomy

Oncological outcomes are generally comparable across the available treatment modalities for localized prostate cancer. <sup>1–3</sup> However, HRQOL outcomes

differ. 4-6 As such, HRQOL outcomes have become an important measure for evaluating prostate cancer treatments.

Physicians and patients have been shown to define and report HRQOL outcomes differently but patient reported observations are more salient. 6-8 The UCLA-PCI was developed to query patients on prostate cancer related QOL outcomes. It has proven to be a robust tool with broad usefulness. 10-13 The current study uses the UCLA-PCI to describe HRQOL impact and recovery profiles for open radical prostatectomy, robotic assisted radical prostatectomy, brachytherapy and cryotherapy.

# MATERIALS AND METHODS

# **Patients and Study Design**

From February 2000 to December 2008 all patients undergoing operative treatment of localized prostate cancer at our institution were asked to participate in an institutional review board approved, prospective, longitudinal cohort study of HRQOL outcomes. Operative treatments included ORP, RAP, BT and cryotherapy. Consenting patients were mailed a self-administered UCLA-PCI questionnaire before treatment, and at 3, 6, 12, 18, 24, 30 and 36 months following treatment. HRQOL function and bother scores were determined on a 100-point scale, where lower scores indicate poorer function or more bother.9 Demographic and treatment variables were recorded. Patients were included in the analysis if a baseline and at least 1 followup questionnaire were completed. Patients were excluded from the analysis if multimodal treatment was administered.

#### **Treatment Techniques**

ORP was performed by 1 of 4 fellowship trained urological oncologists (RG, DL, JD, RL) via the retropubic (132) or perineal (3) route. RAP was performed by 1 of 3 fellowship trained (endourology or oncology) surgeons (MF, RG, RL). For ORP and RAP nerve sparing techniques were used where clinically appropriate as determined by the surgeon. BT was performed by a single radiation oncologist (MS) in conjunction with 1 of 3 urologists (DL, RG, PS). A modified peripheral loading low dose rate technique was used with permanent palladium seeds delivering an average dose of 125 Gy. All cryotherapy was performed by a fellowship trained urologist (RG) using a third generation cryotherapy delivery system (Endocare, Inc, Irvine, California).

# Statistical Analysis

Baseline and longitudinal data were compared across treatment types. Continuous data were checked for normality and compared using 1-way ANOVA or the Kruskal-Wallis rank test. Categorical data were compared using the chi-square test. Longitudinal HRQOL outcomes were compared with Kruskal-Wallis rank test using PBS (calculated by dividing followup function or bother score by baseline function or bother score) achieved at each point after treatment. Patients with a function or bother score of less than 30 at baseline were excluded from analyses in that particular domain because they could have a high PBS with a low absolute score. The numbers of participants excluded from domain specific analysis due to low

baseline scores were urinary function 19 (2%), urinary bother 66 (8%), bowel function 6 (1%), bowel bother 31 (4%), sexual function 192 (24%) and sexual bother 208 (27%).

A survival analysis was conducted for each domain, wherein an event was defined as achieving 90% of baseline score. Kaplan-Meier survival curves were compared across treatments using the log rank test for up to 36 months of followup. Finally Cox proportional hazards models were used to characterize the rate of return to 90% baseline according to treatment type. Hazard ratios for return to baseline were calculated for each treatment and treatments that had similar rates of return to baseline were combined. Next we adjusted for baseline score, age, race and Gleason score, and determined adjusted hazard ratios. The effect of nerve sparing surgery was considered for sexual domains. The proportional hazards assumption was checked for all covariates. All statistical analyses were performed using Stata® 10.

# **RESULTS**

During the study period of February 2000 to December 2008 a total of 1,129 patients consented to participate. After exclusions for insufficient followup (149) or multimodality treatment (68 androgen deprivation therapy, 90 adjuvant or salvage EBRT, 37 salvage cryotherapy), 785 patients were included in the analysis. Demographic and clinical characteristics are shown in table 1. Mean followup (defined by the date of last questionnaire received) for the entire cohort was 23.8 months (median 30, range 3 to 36). Mean followup for each treatment type was 31.5 months for ORP, 20.0 for RAP, 30.0 for BT and 23.8 for cryotherapy. Of the total study population 80% returned a followup questionnaire at least 12 months after treatment, 60% after at least 24 months and 40% after 36 months.

HRQOL domains were adversely affected by all treatment modalities. Average PBS for each domain is shown in table 2, with longitudinal trends reflected in the Kaplan-Meier survival curves for return to greater than 90% baseline function and bother (see figure). Cox proportional hazards ratios are shown in table 3.

# **Urinary Function and Bother**

As a cohort men treated with BT or cryotherapy achieved higher HRQOL scores compared to ORP and RAP in the urinary function and bother domains. PBS over time was generally higher for BT and cryotherapy compared to ORP and RAP (table 2). Urinary function mean PBS for BT and cryotherapy tended to plateau by 6 months, while scores for ORP and RAP showed progression during the first 24 months and beyond. Urinary bother scores showed similar trends.

Kaplan-Meier curves for return to baseline urinary function indicate that BT and cryotherapy had higher overall rates of return than ORP and RAP

Table 1. Patient demographic and clinical characteristics

	0	RP	R	AP	Е	BT	Cryot	therapy	p Value
No. pts	135		447		122		81		
Mean pt age (SD)	59	(7)	59	(6)	66	(7)	71	(7)	< 0.001
No. race (%):									
White	102	(76)	341	(76)	89	(73)	60	(74)	0.053
Black	32	(24)	78	(17)	29	(24)	19	(23)	
Other	1	(1)	28	(6)	4	(3)	2	(2)	
No. clinical stage (%):									
T1c or less	112	(83)	340	(76)	98	(80)	57	(70)	0.005
T2a	17	(13)	68	(15)	16	(13)	10	(12)	
T2b+	6	(4)	32	(7)	3	(2)	13	(16)	
Unknown	0		7	(2)	5	(4)	1	(1)	
No. Gleason score (%):									
6 or Less	93	(69)	269	(60)	88	(72)	40	(50)	0.018
7	34	(25)	154	(34)	28	(23)	34	(41)	
8+	8	(6)	24	(5)	6	(5)	7	(9)	
Median ng/ml pretreatment prostate specific antigen (IQR)	5.7 (	4.7, 7.3)	5.2 (	3.9, 6.8)	6.0 (	4.5, 8.2)	6.2 (	5.0, 8.6)	< 0.001
No. nerve sparing status (%):									
Spared	95	(70)	366	(82)	Not applicable		Not ap	Not applicable	
Not spared	40	(30)	81	(18)		•		•	

(see figure). Cox proportional hazards showed that BT and cryotherapy were associated with a 3-fold higher rate of return to baseline urinary function compared to ORP and RAP (table 3). Urinary bother analysis showed similar trends (adjusted HR 1.48 comparing BT and cryotherapy vs ORP and RAP).

#### **Sexual Function and Bother**

Men treated with BT had higher sexual HRQOL scores compared to those treated with the other 3 modalities. All treatments had a more adverse impact on sexual function and bother than on urinary and bowel domains. In the sexual function domain PBS was highest after BT. Sexual function scores for ORP and RAP were significantly lower than for BT but with a trend toward gradual improvement over the first 24 months and beyond (table 2). There was a minimal difference in sexual function scores between the ORP and RAP cohorts during 36 months of followup. Sexual function after cryotherapy was poor with limited improvement over time. Sexual bother HRQOL outcomes were less disparate among groups but favored BT (tables 2 and 3, and figure).

Kaplan-Meier curves showed that overall rates of return to baseline sexual function were low (less than 25%) except in men undergoing BT (approximately 60%, see figure). Adjusted Cox proportional hazards showed that BT had a more than 5-fold higher rate of return to baseline sexual function compared to the other treatments (table 3). Sexual bother disparities were less pronounced, with a 2-fold greater return to baseline comparing BT and cryotherapy to ORP and RAP. Nerve sparing ORP and RAP were analyzed separately, but these re-

sults were not different than the overall results presented in the figure and in table 3.

# **Bowel Function and Bother**

For all treatments there was less negative impact on bowel function and bother. PBS was at or near 100% across followup for all treatments (table 2). Kaplan-Meier curves and Cox proportional hazards models showed a slight disadvantage in bowel function for BT and a slight advantage in bowel bother for RAP.

#### DISCUSSION

The principal finding of our study was that urinary and sexual HRQOL outcomes differed significantly by treatment type during 3 years of followup. Specifically men treated with BT and cryotherapy reported higher urinary HRQOL scores compared to those treated with ORP and RAP, and men treated with BT reported higher sexual HRQOL scores compared to other treatments.

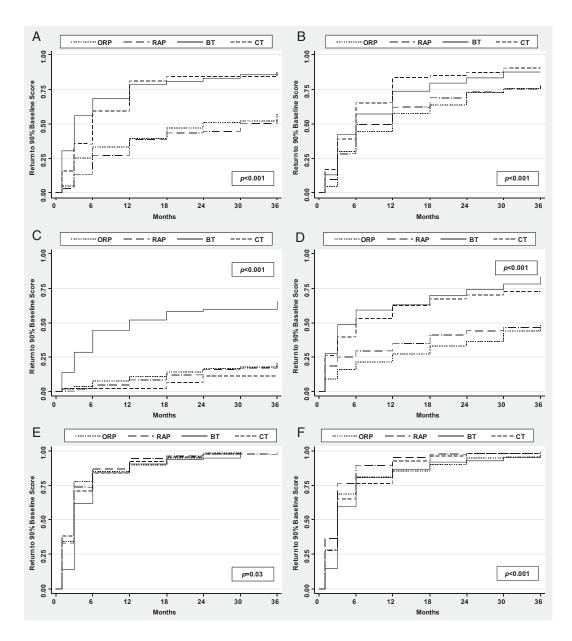
A number of studies have used pretreatment and posttreatment self-assessment surveys to track HRQOL changes following RP, EBRT and brachytherapy, which have historically been the predominant treatments for localized prostate cancer. However, cryosurgery has been increasingly used in recent years. In Furthermore, RP is now commonly performed robotically with some authors suggesting QOL advantages for robotic prostatectomy. Most longitudinal HRQOL studies have not stratified the RP cohort into open and robotic subsets. To our knowledge the current study is the largest prospective, single center study evaluating HRQOL profiles for ORP, RAP, BT and cryotherapy.

Table 2. Average percent baseline scores for HRQOL domains

	Mean Baseline Score (SD)	3 Mos PBS	6 Mos PBS	12 Mos PBS	18 Mos PBS	24 Mos PBS	30 Mos PBS	36 Mos PBS
Urinary function:								
ORP	89 (18)	73	80	79	82	84	82	83
RAP	92 (13)	71	69	74	74	76	75	78
BT	90 (16)	78	92	94	90	90	90	88
Cryotherapy	93 (19)	85	99	106	105	102	109	113
p Value	0.04	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Urinary bother:								
ORP	92 (15)	68	77	84	85	87	88	88
RAP	93 (14)	65	77	81	81	83	85	86
BT	89 (17)	73	83	88	87	94	91	90
Cryotherapy	87 (19)	73	89	97	98	98	97	103
p Value	0.01	0.13	0.11	0.01	0.04	0.05	0.47	0.11
Sexual function:								
ORP	74 (18)	24	37	43	48	46	50	48
RAP	73 (17)	28	33	40	42	45	41	46
BT	64 (19)	66	77	71	68	74	67	73
Cryotherapy	60 (19)	23	32	30	34	36	26	27
p Value	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Sexual bother:								
ORP	86 (20)	27	28	40	46	52	54	58
RAP	84 (20)	41	42	47	51	48	52	45
BT	80 (21)	69	70	63	67	78	67	85
Cryotherapy	80 (21)	55	60	59	58	61	57	50
p Value	0.12	< 0.001	< 0.001	0.01	0.01	< 0.001	0.23	< 0.001
Bowel function:								
ORP	87 (14)	98	102	102	103	104	102	101
RAP	88 (14)	101	102	103	103	101	102	102
BT	84 (16)	96	101	103	106	110	109	107
Cryotherapy	83 (15)	106	99	110	108	108	112	108
p Value	0.02	0.02	0.86	0.13	0.77	0.20	0.27	0.52
Bowel bother:								
ORP	92 (15)	93	102	99	100	102	96	99
RAP	94 (13)	98	100	100	100	97	99	94
BT	88 (18)	90	98	99	96	101	100	99
Cryotherapy	87 (17)	104	102	106	105	107	103	92
p Value	< 0.001	0.003	0.38	0.30	0.27	0.22	0.41	0.56

In the sexual function and bother domains higher QOL scores were reported in men treated with BT compared to those treated with ORP, RAP and cryotherapy. The advantage of BT compared to RP in the sexual function domain has been noted in other longitudinal patient reported HRQOL studies, 4,10,14,15 but some notable studies have offered conflicting evidence. 22 We noted that analysis of sexual function outcomes did not differ significantly when nerve sparing status was considered. This finding is also not unique to our study. With baseline data and longitudinal followup of 417 men treated with EBRT, BT and RP, Talcott et al noted little apparent benefit in nerve sparing techniques to offset the relative disadvantage of RP in the sexual function domain.4 Our study is unique among similar HRQOL studies in the inclusion of a cryotherapy cohort. Sexual function was poorest after cryotherapy. Some investigators have reported substantial potency rates following cryotherapy with penile rehabilitation.<sup>23</sup> We did not uniformly use penile rehabilitation for patients after cryotherapy because we offer cryotherapy to patients with poor baseline sexual function or those for whom sexual function is not a significant concern. Of patients treated with cryotherapy 54% (44) had a baseline sexual function score of less than 30.

With regard to urinary function and bother, HRQOL impact and recovery profiles were generally more favorable for BT and cryotherapy compared to ORP and RAP. We noted that the highest urinary function and bother scores were reported in men treated with cryotherapy. Using contemporary cryosurgical systems, damage to the rhabdosphincter can be avoided in most cases. This has resulted in low rates of urinary incontinence, which is reflected in the high urinary function scores. Posttreatment urinary bother scores exceeded 100% of baseline scores in the cryosurgery cohort. We speculate that the tissue cryodestruction leads to a reduction in outlet obstruction with subsequent improvement in obstructive and irritative symptoms. However, we recognize that



Kaplan-Meier analysis of return to 90% baseline HRQOL score over time, with p values comparing return to baseline curves from log rank test. *A*, urinary function. *B*, urinary bother. *C*, sexual function. *D*, sexual bother. *E*, bowel function. *F*, bowel bother.

while the UCLA-PCI urinary function domain generally serves as a measure of continence, the bother domain is not as reliable a measure of irritative or obstructive symptoms as other available metrics (ie American Urological Association Symptom Score).

The impact on bowel function and bother appeared to be minimal for all treatments. In comparable HRQOL studies the surgical treatment of prostate cancer has been associated with minimal impact on bowel domains while EBRT and BT have been associated with relatively worse bowel function and bother. <sup>4,10</sup> Bowel function was statistically worse in the BT cohort compared to the other treatment cohorts in our study. However,

absolute scores in the bowel function and bother domains were uniformly high for BT, cryotherapy, ORP and RAP. This finding appears to be at odds with previous studies demonstrating more prominent adverse QOL outcomes following BT. The variance of our findings may be due in part to different questionnaires being used (UCLA-PCI vs Expanded Prostate Cancer Index Composite questionnaire), differences in describing data (PBS vs mean score) or the impact of a single center vs multicenter study design. Furthermore, patients treated with BT plus androgen deprivation therapy or EBRT were excluded from analysis in our study, as were those with baseline scores less than 30.

Table 3. Cox proportional hazards models for return to 90% baseline HRQOL score

Treatments*	Univariate Hazard Ratio (95% CI)	Adjusted Hazard Ratio (95% CI)†
Urinary function:		
ORP + RAP	1.0	1.0
Cryotherapy + BT	2.78 (2.28-3.41)	2.98 (2.33-3.82)
Urinary bother:		
ORP + RAP	1.0	1.0
Cryotherapy + BT	1.42 (1.17-1.73)	1.48 (1.17-1.88)
Sexual function:		
ORP, RAP + cryotherapy	1.0	1.0
BT	5.62 (3.87-8.17)	5.71 (3.71-8.77)
Sexual bother:		
ORP + RAP	1.0	1.0
BT + cryotherapy	2.16 (1.69-2.77)	1.99 (1.49-2.67)
Bowel function:		
BT	1.0	1.0
ORP, RAP + cryotherapy Bowel bother:	1.25 (1.02–1.54)	1.24 (0.99–1.55)
ORP, BT + cryotherapy	1.0	1.0
RAP	1.31 (1.13–1.53)	1.28 (1.08–1.51)

<sup>\*</sup> Treatments with similar hazard ratios were grouped together.

In our experience there were no pronounced advantages to RAP vs ORP from the standpoint of HRQOL outcomes. Furthermore, our overall prostatectomy urinary and sexual outcomes appear to be at odds with many prominent reports in the literature. There are several high volume centers in the country where practitioners limit themselves to the performance of 1 procedure, radical prostatectomy. While performing high volumes of the procedure, they are responsible for a relative minority of the procedures performed nationwide. It is from these centers that outcome measures have been prominently reported, most often not using validated questionnaires but patient reported ratings or institution specific questionnaire evaluation. At times the reporting is from a segment rather than from the entire study population. Our study reports outcomes from fellowship trained urologists whose practice covers the entire spectrum of urological oncology and whose experience with the treatment of prostate cancer is substantial but not exclusive. The outcomes, by validated questionnaire, and prospective and longitudinal followup, may prove useful or generalizable to urologists with this type of practice. Our HRQOL outcomes serve as a reminder that popular enthusiasm for robotic prostatectomy merits temperance, and we are careful not to overstate advantages that our data do not support.

The current study has several limitations. The study was designed to evaluate HRQOL outcomes without regard for oncological outcomes but in clinical practice HRQOL outcomes must be considered

in the context of oncological impact. In addition, we were unable to fully account for the impact of comorbid conditions on HRQOL outcomes. Demographic variables recorded were limited to patient age and race, whereas hypertension, diabetes, obesity, hyperlipidemia and smoking history were not specifically considered. However, the impact of such factors should be reflected in baseline QOL scores that we used to calibrate outcomes evaluations by the PBS methodology. Another limitation is that followup was not uniform. Not all patients completed all surveys at all points despite concerted efforts to optimize followup. It is not clear to what degree this may have biased our results and this uncertainty should inform the interpretation of our data. Patients were also not randomized to treatment type, allowing for unmeasured factors to bias HRQOL outcomes. As such, definitive comparative statements about the 4 treatments analyzed are subject to interpretation. Finally overall patient satisfaction was not measured and cannot be correlated with the measured HRQOL outcomes. 14 Nevertheless, differences in HRQOL profiles, particularly the superior sexual outcomes for BT and urinary outcomes for BT and cryotherapy, were sufficiently substantial that we believe them to be predominantly treatment related and not artifacts of study design or execution.

The current study is bolstered by several strengths. The large study population was treated at a single, high volume institution and the local community catchment area allowed for followup at our center. HRQOL outcomes were self-reported using mailed questionnaires, adding validity to sometimes sensitive HRQOL measures. We achieved good patient compliance with followup and survey completion. Followup was prolonged and allowed for a sequential analysis of treatment impact and recovery profiles across 4 commonly used operative prostate cancer treatments.

#### CONCLUSIONS

In a prospective, longitudinal study of HRQOL outcomes using validated self-reported questionnaires we measured the impact and recovery profiles of 4 operative prostate cancer treatments administered at our institution during an 8-year period in 785 patients. Based on these profiles BT and cryotherapy were associated with higher QOL scores with respect to urinary function and bother compared to ORP and RAP. BT was associated with higher scores with respect to sexual function and bother. RAP did not demonstrate significant advantages compared to ORP in any of the HRQOL domains.

<sup>†</sup> Adjusted for age, race, Gleason score and baseline score.

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#### **EDITORIAL COMMENTS**

The authors present a comparative analysis of longitudinal prostate cancer HRQOL outcomes for patients treated at a single institution with a variety of therapeutic modalities. Using the UCLA-PCI the authors report higher urinary function and bother scores with BT and cryotherapy compared to ORP and RAP, and higher sexual function and bother scores with BT than with ORP, RAP or cryotherapy. The subject matter is timely and important, and the use of patient reported outcomes to compare results is to be commended. Nevertheless, the nonrandomized nature of the study design, whereby significant differences in

baseline function and bother scores existed among patients undergoing different treatments, as well as the absence of an EBRT cohort and of data regarding patient satisfaction with treatment, argue for the continued prospective evaluation of HRQOL outcomes after prostate cancer treatment. Such studies are critical for appropriately interpreting our results and counseling our patients accordingly.

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The authors performed a long-term longitudinal prospective study on QOL in patients undergoing treatments for prostate cancer. The article has some recognized limitations including the fact that oncological outcomes were not included, patients who received multimodal therapies were excluded from study and data on EBRT were absent. On the other hand, it is

hard to argue that urologists and patients need more prospective data to provide realistic expectations in regard to long-term morbidity related to treatment. The authors reported significantly lower potency rates despite nerve sparing prostatectomy. Are we to think that most urologists perform as well as experts report or is this a more realistic view that patients should consider? Urology as a field has suffered from the absence of prospective randomized trials in prostate cancer that compare the main treatments with oncological and QOL outcomes. A patient who is diagnosed with clinically localized prostate cancer still faces a difficult task of comparing competing technologies on multiple levels (oncological outcomes, continence, potency). Furthermore, new technologies are not required to provide strong evidence of superiority or equivalence before adoption. If the standard for

evaluating all treatments of prostate cancer were raised then patients and physicians would be able to use more objective criteria in determining the optimal treatment. It is possible that a new emphasis on cost-effectiveness and comparative analyses at a national level will force the issue.

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Given that prostate cancer is one of the most common solid tumors, it is important to focus on the cancer, and how its various treatments affect the quantity and quality of life. Furthermore, since patients with localized prostate cancer now routinely live more than 10 to 15 years after diagnosis, it is critical that we obtain a better understanding of all the facts that could influence the short-term and long-term functional states and HRQOL in patients with prostate cancer. This study evaluates HRQOL for ORP, RAP, cryotherapy and BT for 3 years using the UCLA-PCI questionnaire. While the study has limitations in the lack of randomization, EBRT data and several outcome measures such as comorbidities, marital status, education or income level, the ability to compare with baseline status helps minimize this bias.

These authors reported that BT and cryotherapy had a 3-fold higher rate of return to baseline

urinary function compared to ORP and RAP. However, as they described the UCLA-PCI urinary function domain generally serves as a measure of continence, and the bother domain is not as reliable a measure of irritative or obstructive symptoms as other available metrics (eg American Urological Association Symptom Score, reference 10 in article). Subjects who underwent BT reported higher sexual HRQOL than other treatment groups. These results may guide decision making for treatment selection and the clinical management of HRQOL impairments after treatment for localized prostate cancer.

#### Shunichi Namiki

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