

Prospective longitudinal comparative study of health-related quality of life and treatment satisfaction in patients treated with hormone therapy, radical retropubic prostatectomy, and high or low dose rate brachytherapy for prostate cancer

Sotaro Miwa, Atsushi Mizokami, Hiroyuki Konaka, Satoru Ueno, Yasuhide Kitagawa, Eitetsu Koh, Mikio Namiki

Department of Integrative Cancer Therapy and Urology, Kanazawa University Graduate School of Medical Science, Kanazawa, Japan

Purpose: To evaluate the effects of four different prostate cancer treatments on quality of life (QoL) and patient satisfaction.

Methods: Ninety-six prostate cancer patients were treated with hormone therapy, radical retropubic prostatectomy, high dose rate brachytherapy, or low dose rate brachytherapy. We assessed general, cancer-specific, and prostate disease-specific QoL. More than one year since commencement of treatment, the patients were asked the following questions: 1) How do you feel about your treatment? 2) Would you undergo the same treatment again?

Results: The comparison of baseline and 12-month results showed that general and cancer-specific QoL had changed little in all groups. At baseline, the general and cancer-specific QoL tended to be lower in the hormone therapy patients. In the radical the retropubic prostatectomy patients, all scores on the Medical Outcomes Study 36-Item Short Form were worse than the baseline scores at three months. Scores for the International Index of Erectile Function-5 had also worsened, with no recovery. In the low-dose rate brachytherapy patients, the prostate disease-specific QoL at baseline tended to improve. However, the satisfaction levels for each treatment were reasonably good, and most patients would choose the same treatment again.

Conclusions: The results of each of the four treatments differed in assessments of QoL. In the radical retropubic prostatectomy patients, the decrease in the International Index of Erectile Function-5 scores was especially remarkable and did not show recovery. In contrast, both brachy therapy groups had attained superior sexual function. However, regardless of the quality of life evaluations, most patients surveyed were satisfied with their treatments and would choose the same treatment again.

Keywords: Prostate neoplasms, Quality of life, Treatment satisfaction, Prospective longitudinal comparative study

INTRODUCTION

Many treatment options are available for prostate cancer (PCa). In cases where the PCa is localized, especially in the low risk group, the treatment outcomes of radical retropubic prostatec-

tomy (RRP) and some types of brachytherapy (BT) are excellent regarding long-term survival is concerned [1]. Moreover, data in our previous study indicated that hormone therapy (HT) is useful for long-term survival in cases where low T stage, low grade Gleason score (GS), and low prostate-specific anti-

Corresponding author: Sotaro Miwa

Department of Integrative Cancer Therapy and Urology, Kanazawa University Graduate School of Medical Sciences, 920-8640 13-1 Takaramachi, Kanazawa, Ishikawa, Japan

E-mail: sotaro@oregano.ocn.ne.jp, Tel: +81-76-265-2393, Fax: +81-76-222-6726

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gen (PSA) are present [2].

Health-related quality of life (HRQoL) has become a very important factor in patients' decisions about treatment options. However, it is still hard to factor HRQoL in decisions about treatment because there is still relatively little information available comparing HRQoL factors in various PCa treatment options. On the other hand, for both patients and doctors, patient satisfaction with treatment also seems to be an important factor in evaluating the best possible treatment option.

This study was performed to identify and compare variations in HRQoL developing over a timeline extending from baseline to one year after treatment. The satisfaction of the surveyed patients at more than one year following the commencement of treatment was evaluated. To our knowledge, this is the first report comparing the effects of four different PCa treatments during the same period at one institution.

MATERIALS AND METHODS

Between January 2006 and June 2008, 96 men diagnosed with PCa were treated with HT, RRP, and high dose rate BT (HDR-BT) with or without extra beam radiation therapy (EBRT) or low dose rate BT (LDR-BT). The patients were followed up for various periods ranging from 12 to 54 months. The patients did not have any other severe diseases that may have affected HRQoL, and biochemical or clinical disease progression was not observed during this study period.

The indication for RRP, HDR-BT with or without EBRT and LDR-BT was limited to clinically localized PCa. In addition, we classified the localized PCa patients into three risk group, based on clinical T classification, GS and PSA, according to the D'Amico risk grouping (high-risk was defined as $>cT2b$, primary GS ≥ 8 , or PSA >20 ; low-risk was defined as $<T2a$, primary GS ≤ 6 , or PSA ≤ 10 ; intermediate-risk was defined as other than high-risk or low-risk) [3].

In the first phase of this study design, patients who received neo-adjuvant HT for more than four months or for whom adjuvant or salvage HT was started within one year after treatment were excluded from this study because of the significant influence of how the HT therapy would obscure the subject patients' evaluations of their primary therapies. Two low-risk patients who selected active surveillance were also excluded from this study because of the very small population that they represented.

HT was performed in metastatic PCa patients who were asymptomatic for metastatic PCa and in patients over 75 years with clinically localized PCa.

RRP was performed in cases of localized PCa in low- or intermediate-risk patients. All except one patient (76 years) were less than 75 years. The nerve-sparing (NS) technique was performed if the patients wanted to preserve sexual function. The indications for NS depended on preoperative factors, such as primary GS and the number of positive biopsy cores and intraoperative factors.

HDR-BT with EBRT (40–46 Gy) was recommended and performed in high-risk and intermediate-risk patients. HDR-BT monotherapy was recommended and performed in the low-risk group and in part of the intermediate-risk group. Age was not taken into consideration if performance status was good. Neo-adjuvant HT was performed in some patients who were anxious about the progression of the disease while awaiting treatment. HDR-BT using ^{192}Ir in 2 doses of 9.5 Gy each within 24 hours for a total of 19 Gy or 3 doses of 6.0 Gy each within 24 hours, a total of 18 Gy. HDR-BT was performed by inserting 10 to 12 applicator needles into the prostate using the transperineal approach. The application needles remained inserted during the 24-hour irradiation period.

LDR-BT was recommended and performed in low- and intermediate-risk patients. Age was not taken into consideration if the performance status was good. Patients treated with LDR-BT received about 140 to 160 Gy to the prostate with a ^{125}I seed using a modified peripheral loading technique via the transrectal ultrasound-guided transperineal approach. We performed LDR-BT by the preplanning method.

We measured general HRQoL using the Medical Outcomes Study 36-Item Short Form (SF-36) [4] and cancer-specific HRQoL using the functional assessment of cancer therapy-general (FACT-G) [5]. PCa-specific HRQoL was measured using the FACT-prostate (FACT-P) [6], International Prostate Symptom Score (IPSS) [7], and International Index of Erectile Function-5 (IIEF-5) [8].

SF-36 contains 36 items covering eight domains of HRQoL as follows: physical functioning (PF), role limitations because of physical health problems (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role limitations caused by emotional problems (RE), and mental health (MH). A score ranging from 0 (worst) to 100 (best) was calculated for each domain.

All patients were informed of their cancer diagnosis before being given the HRQoL questionnaires. Questionnaires were administered at four points in time: the baseline survey was before treatment; and follow-up surveys were performed 3, 6, and 12 months after treatment. In this study, we used the self-reported questionnaire method and asked patients to fill it out in the hospital.

After more than one year had elapsed since the commencement of treatment, the patients were sent two questions by mail with regard to treatment satisfaction. One question was "How do you feel about your treatment?" The responses included delighted, pleased, mostly satisfied, mixed, unhappy, and other. The second question was "Would you undergo the same treatment again if you had the chance?" They were given the response options of definitely yes, probably yes, probably not, or definitely not. These questions were based on a previous report by Hoffman et al. [9]. Inappropriate answers (multiple answers or blank answers) were excluded from the evaluation. All data are shown as the mean (standard deviation) or median (range). Patients' background data and HRQoL scores were tested by one-way analysis of variance in the four groups. In two groups, age was analyzed by the Scheffe test, and other

data items were analyzed by the Dunn test. Significance was defined as $P < 0.05$.

RESULTS

The surveys were performed in 19, 31, 25, and 21 cases of HT, RRP, and HDR-BT with or without EBRT, and LDR-BT, respectively. The backgrounds of each group are shown in Table 1. Age was significantly higher in HT than in the other groups ($P < 0.01$). In the clinical stage, the T category showed significant differences between HT and RRP and between HT and LDR-BT (HT vs. RRP, HT vs. LDR-BT, $P < 0.001$). When we categorized the data according to GS into three groupings, < 6 , 7 , and > 8 , significant differences were recognized between HT and RRP, between HT and HDR-BT, and between

Table 1. Patient characteristics

Characteristic	HT (n=19)	RRP (n=31)	HDR-BT (n=25)	LDR-BT (n=21)	P-value
Age (yr)					
Mean \pm SD	74.9 \pm 7.1	66.7 \pm 5.0	67.0 \pm 5.0	66.4 \pm 7.0	$< 0.01^a$
Median (range)	75 (58–86)	66 (58–76)	66 (58–77)	66 (50–79)	$< 0.01^a$
T category					$< 0.001^b$
T1c	6	21	13	16	
T2a	1	8	7	5	
T2b	1	0	4	0	
T3a	0	1	2	0	
T3b	0	1	0	0	
T4	1	0	0	0	
Tx N $>$ 0 or M $>$ 0	10	0	0	0	
Metastases lesions (n)	Bone (4), LN (3), bone & LN (3)				
Gleason score					$< 0.001^c$
≤ 6	3	16	17	14	
7	11	15	7	7	
≥ 8	5	0	1	0	
Initial PSA (ng/mL)					$< 0.001^c$
Mean \pm SD	208.2 \pm 305.7	6.8 \pm 5.1	8.0 \pm 3.2	6.1 \pm 2.1	
Median (range)	122.9 (4.1–1018.4)	5.5 (2.2–29.8)	7.2 (4.1–13.2)	5.5 (2.1–10.4)	
≤ 10	7	16	17	14	
$> 10, \leq 20$	2	15	7	7	
> 20	10	0	1	0	
D'Amico risk classification					NS ^d
Low	3	16	9	12	
Intermediate	5	15	10	9	
High	11	0	6	0	
Neoadjuvant hormone therapy (0–3 mo)		13	16	3	
Nerve-sparing (bilateral)		2			
Nerve-sparing (unilateral)		5			
Nerve-sparing (unknown)		7			
ERBT			17		

HT, hormone therapy; RRP, radical retropubic prostatectomy; HDR-BT, high dose rate brachytherapy; LDR-BT, low dose rate brachytherapy; LN, lymph node; PSA, prostate-specific antigen; SD, standard deviation; NS, not significant; ERBT, extra beam radiotherapy.

^aScheffe test; HT vs. RRP, HT vs. HDR-BT, HT vs. LDR-BT. ^bDunn test; HT vs. RRP, HT vs. LDR-BT. ^cDunn test; HT vs. RRP, HT vs. HDR-BT, HT vs. LDR-BT. ^dDunn test.

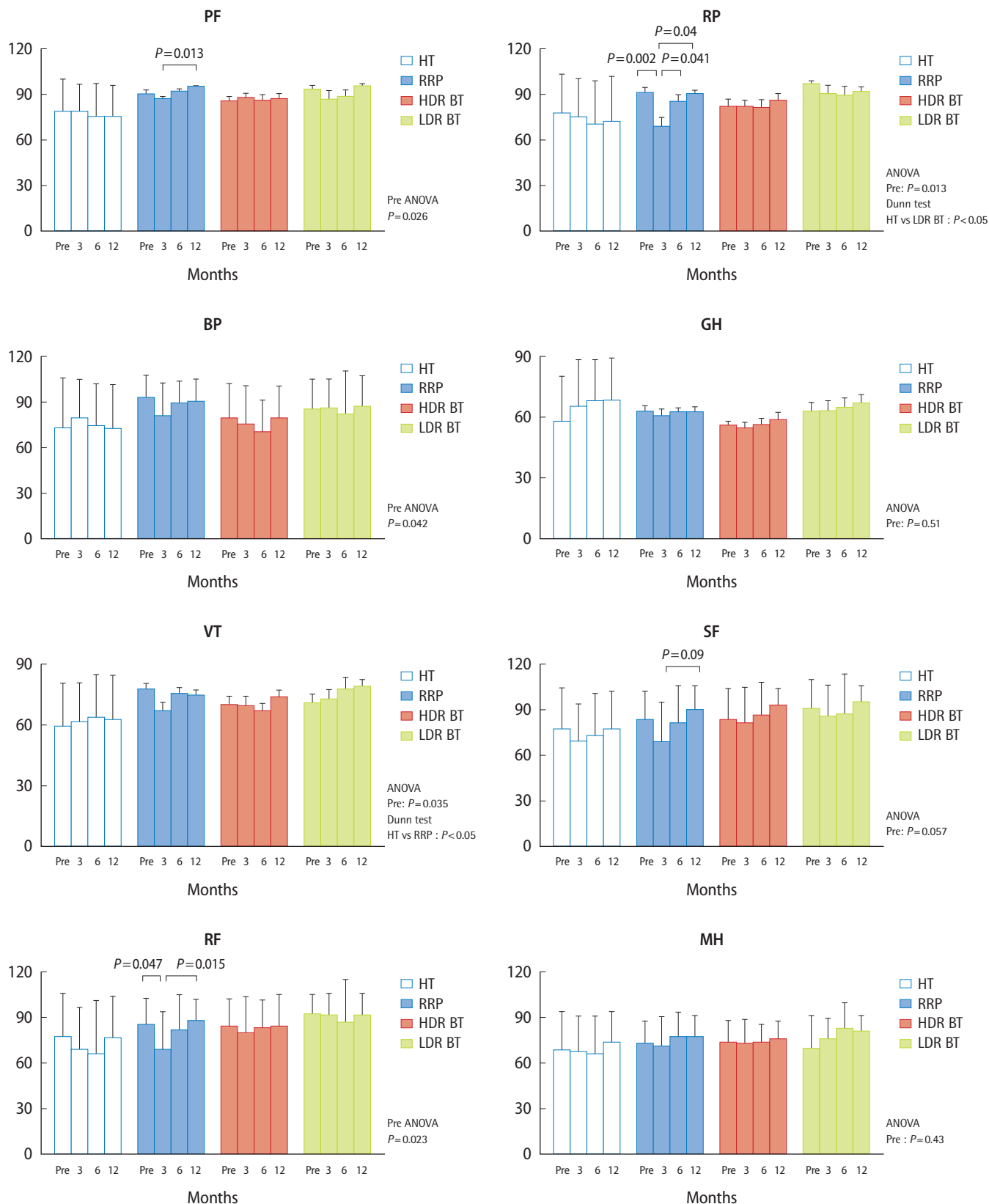


Fig. 1. Effects of four treatments on each domain score of SF-36 in patients with prostate cancer. PF, physical functioning; RP, role limitations because of physical health problems; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role limitations because of emotional problems; MH, mental health; HT, hormone therapy; RRP, radical retropubic prostatectomy; HDR-BT, high dose rate brachytherapy; LDR-BT, low dose rate brachytherapy; ANOVA, analysis of variance.

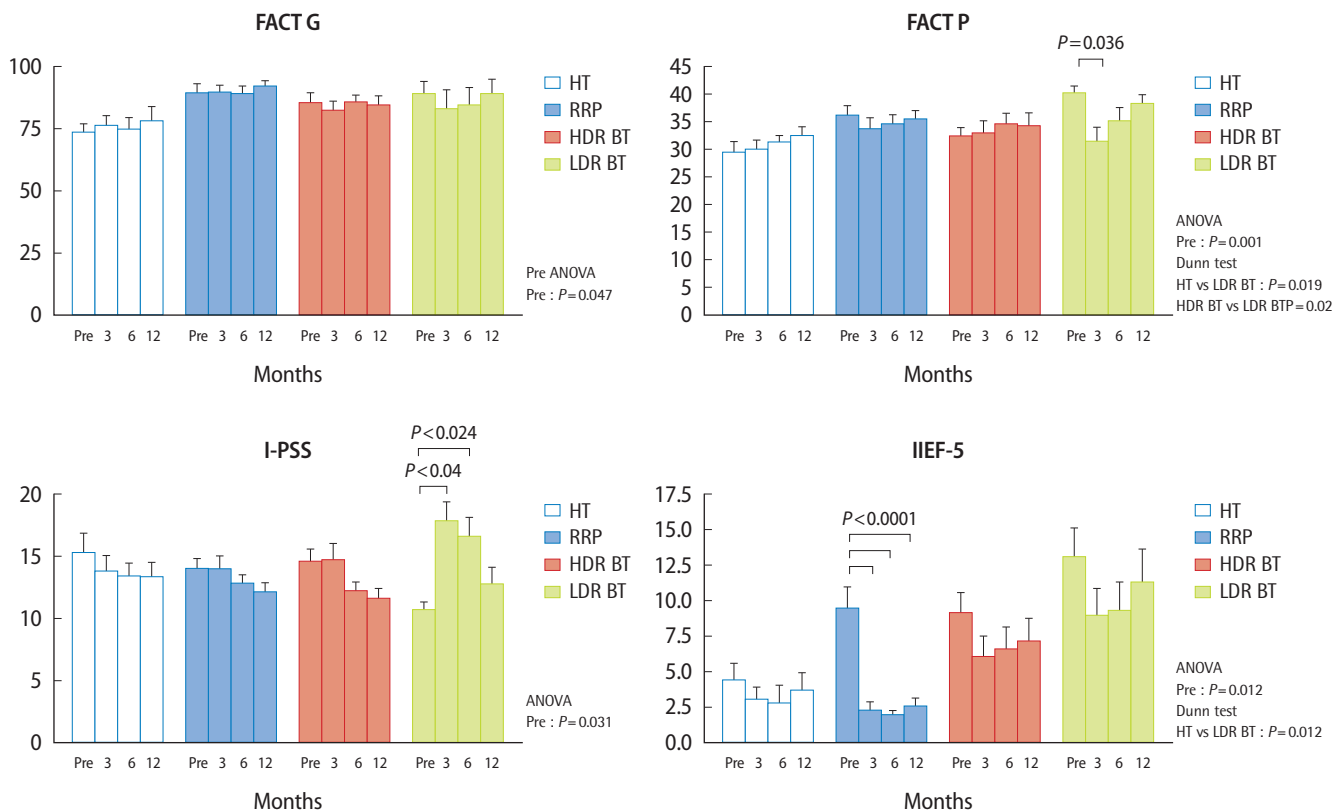


Fig. 2. Effects of the four treatments on scores of functional assessment of cancer therapy-general (FACT-G), FACT-prostate (FACT-P), International Prostate Symptom Score (IPSS), and International Index of Erectile Function-5 (IIEF-5) in patients with prostate cancer. HT, hormone therapy; RRP, radical retropubic prostatectomy; HDR-BT, high dose rate brachytherapy; LDR-BT, low dose rate brachytherapy; ANOVA, analysis of variance.

HT and LDR-BT (HT vs. RRP, HT vs. HDR-BT, HT vs. LDR-BT, $P < 0.001$). The PSA scores for the HT cases were significantly higher than those for the other groups ($P < 0.01$). D'Amico Risk Classification showed that the HDR-BT group included six high-risk patients. The HT group contained one high-risk patient, but there were no significant differences among the four groups.

Figs. 1 and 2 show the data of SF-36, FACT-G, FACT-P, IPSS, and IIEF-5. General and cancer-specific HRQoL measured by SF-36 and FACT-G showed little change when the baseline and the 12-month results in each group were compared. In the HT group, SF-36 and FACT-G tended to show lower scores than in the other treatment groups before treatment, particularly RP and VT (RP, HT vs. LDR-BT, $P < 0.05$; VT, HT vs. RRP, $P < 0.05$). In the RRP group, all SF-36 QoL scores at three months were worse than the baseline scores were. However, these scores showed recovery in the responses to the questionnaire at 12 months. In particular, PF, RP, SF, and RE showed significant improvement between 3 months and 12 months. In the RRP group, the IIEF-5 scores were worse at six months, and recovery was not indicated in responses

Table 2. Patient satisfaction

How do you feel about your treatment

	HT	RRP	HDR-BT	LDR-BT
Delighted	1	6	3	5
Pleased	10	12	8	12
Mostly satisfied	0	1	7	2
Mixed	3	6	4	1
Unhappy	0	0	0	0
Another	0	1	0	0
Satisfaction/total, n (%)	11/14 (79)	19/26 (73)	18/22 (82)	19/20 (95)

HT, hormone therapy; RRP, radical retropubic prostatectomy; HDR-BT, high dose rate brachytherapy; LDR-BT, low dose rate brachytherapy. Dunn test: not significant.

Would you take the same treatment again if you had the chance?

	HT	RRP	HDR-BT	LDR-BT
Definitely yes	2	3	3	5
Probably yes	8	15	11	9
Not	3	4	7	4
Yes/total, n (%)	10/13 (77)	18/22 (82)	14/21 (67)	14/18 (78)

HT, hormone therapy; RRP, radical retropubic prostatectomy; HDR-BT, high dose rate brachytherapy; LDR-BT, low dose rate brachytherapy. Dunn test: not significant.

to the questionnaire at 12 months (pre vs. 3 months, pre vs. 6 months, pre vs. 12 months, $P < 0.0001$). In the HDR-BT group and LDR-BT group, IIEF-5 scores did not show a significant decrease. In the LDR-BT group, the disease-specific HRQoL, FACT-P, IPSS, and IIEF-5 scores were better than the baseline scores in the other groups were (FACT-P, LDR-BT vs. HT, $P = 0.019$; LDR-BT vs. HDR-BT, $P = 0.02$; IIEF-5, LDR-BT vs. HT, $P = 0.012$).

Satisfaction with treatment selection was good in most cases (Table 2). The RRP group showed lower satisfaction (73%) than the other groups did, but this was not significant. The HDR-BT group gave a lower score (66%) than the other groups did (Table 2), in response to the question, "Would you undergo the same treatment again if you had the chance?" However, this difference was not significant.

DISCUSSION

Standard treatment for localized PCa traditionally involves radical prostatectomy and EBRT. However, HDR-BT with ^{192}Ir and LDR-BT using ^{103}Pd or ^{125}I have recently been adopted around the world as minimally invasive treatment methods [1]. Moreover, HT promotes long-term survival in cases of low T stage, low grade GS, low PSA, and in patients showing good response to treatment [2].

As excellent treatment outcomes have become more and more common regardless of the method of treatment chosen, subjective evaluation by patients, such as the HRQoL and patient satisfaction after treatment, have become as important as objective indices, such as overall survival or disease-free survival.

In our institution, the selection of PCa treatments is determined by discussion between the patient and doctor. However, HRQoL and patients' satisfaction after treatment had not been evaluated clearly. Our institution has four primary treatments for PCa: HT, RRP, and two types of BT (HDR-BT and LDR-BT). Although several reports have compared the QoL of two or three different PCa treatments [10-12], to our knowledge, this is the first report comparing the effects of four different treatments on HRQoL and satisfaction in PCa patients in the same period at one institution.

The findings of our study are summarized as follows. Comparison of the baseline scores and 12-month results showed little change in general and cancer-specific HRQoL in all groups. The results specific to each group showed that in the HT groups, general, cancer-specific, and PCa-specific HRQoL scores did not change remarkably during the observation period. Because this was not a randomized study, and the

patients in the HT group were significantly older than those in the other groups were, the original IIEF-5 scores were low in higher ages, and the influence of HT on sexual function remained unchanged.

The RRP group showed significant differences in the SF-36 domains of PE, RP, SF, and RE between 3 and 12 months postoperatively. This group indicated a greater sense of intrusiveness by the treatment than other treatment groups did. IIEF-5 was significantly decreased compared with the other groups, and did not show improvement within 12 months. In this study, definite NS operation was performed on only seven patients (Table 1). However, definite differences were observed between the NS group and the non-NS group (data not shown). Several responses to the questionnaire said that sexual dysfunction was noted as a postoperative adverse event [13,14]. The NS group reported that it took more than two years for the recovery of sexual function [15,16]. Therefore, it is difficult to improve sexual function within less than one year postoperatively, even in patients treated by the NS technique. In our study population, the RRP group did not show an increase in IPSS. Although some patients might have suffered from degradation of urinary function, this fact may not have been reflected by the IPSS score, because the questions were designed specifically to evaluate symptoms of benign prostatic hyperplasia. This is because the IPSS does not specify stress incontinence [7,11].

In both BT groups, the SF-36 data showed no significant differences between baseline and 12 months. Thus, both kinds of BT treatments seemed less intrusive than RRP did. On the other hand, the findings showed that patients with good sexual and urinary function tended to choose LDR-BT. Furthermore, the LDR-BT group showed significant IPSS degradation within three months. However, the values improved to baseline levels within 12 months. Both kinds of BT are considered minimally invasive treatments in comparison with RRP and EBRT [3,17-19]. Hall et al. [20] reported that for 40% of patients, a favorable side-effect profile was the main motivation in selecting BT. Both kinds of BT appeared to have clear advantages over RRP in terms of urinary and sexual function. However, transient irritative and obstructive symptoms were reported [17,21,22]. Desai examined urination condition after LDR-BT based on IPSS score, and reported that IPSS score was poorest one month after treatment and improved gradually thereafter [23]. Our study showed similar results [3,23]. In the present study, patients with good voiding conditions tended to select the LDR-BT treatment and appeared to experience transient bladder irritability and obstruction after treatment.

In this study, we evaluated patient satisfaction more than one year after treatment following QoL evaluations for each treatment. The RRP group showed a low level of satisfaction with the treatment results (73%). Our data were similar to those of Hoffman et al. [9], who reported that patients treated with radical prostatectomy had lower satisfaction scores than those treated with HT and radiation therapy. However, our data showed no significant differences from other treatment groups, and almost all had good satisfaction scores. We believe that complete cure-related satisfaction exceeded QoL-related dissatisfaction. Interestingly, although not significant, the HDR-BT group's response to the question, "Would you undergo the same treatment again if you had the chance?" ranked the lowest in the evaluation. This may be because of the requirement for the patients to rest for 24 hours with needles penetrating the perineal region, combined with postoperative temporary dysuria, which resulted in more discomfort in the perioperative period than the other treatment groups experienced [3]. No previous studies comparing perioperative satisfaction with BT and RRP. Therefore, our findings are significant.

We emphasize the following points regarding the design of our study. First, this was not a randomized study, but a prospective longitudinal comparative study in the same period at one institution. Second, the results were obtained using a self-reported questionnaire. There was likely to be less bias in these results. As Namiki and Arai [17] suggested, a patient's self-reported symptoms are likely to differ from those recorded by his doctor, so it is better whenever possible to have patients fill out self-reported questionnaires. Third, in this study, we evaluated not only HRQoL scores but also patient satisfaction with treatment. More than 70% of patients were satisfied with the treatments they received.

On the other hand, our study had several limitations. First, at 96 patients, the sample was small. The significance of this number is questionable in the comparisons of each sub-group. Nevertheless, we believe that this data illuminated the tendency for each group's QoL and patient satisfaction. Second, because this was a prospective study and not a random study, the average ages in the HT and PSA groups were higher than in the other groups, and the HT group included patients with metastasis. Therefore, it is difficult to compare the HT group and the other groups. However, in this study in the HT group, general conditions were good and exhibited no severe complications. Hence, we believe that our findings could be useful in comparing HT group patients without metastasis and other groups in the future. Third, when evaluating patient satisfaction, blank answers or multiple answers were excluded from

the data collection. Because this study used a self-reported questionnaire, there may have been some bias, so improvement of the data collection method is necessary. Employing a research coordinator to get accurate data seems best [13]. Fourth, in this QoL investigation there were no definite questions regarding stress incontinence for RRP, gross hematuria, melena and diarrhea for BT, or for climacteric symptoms, such as hot flashes and gynecomastia for HT. Therefore, it was impossible to evaluate QoL accurately for all four treatments [13]. Although there were 50 questions in the questionnaire, future evaluations using the expanded PCa index composite (EPIC), which was developed from the University of California, Los Angeles Prostate Cancer Index, would render more significant results because the EPIC includes questions about voiding irritability, incontinence, rectum irritability, and complications in endocrine treatment [15].

This study examined HRQoL and patient satisfaction with four different treatments for PCa. Each treatment had characteristic findings, but the decrease of IIEF-5 in the RRP group was especially remarkable. The HDR- and LDR-BT groups were superior with regard to sexual function.

However, interestingly, the responses showed that most patients who had received a particular treatment were satisfied with their treatment and that they would choose the same treatment again, even if another treatment were more highly recommended. Most patients should be able to select a particular treatment based on their feelings, view of life, and background. Therefore, it is just as important—perhaps even more important—for doctors to know how to monitor and diminish potential adverse events in whatever treatment the patient chooses as it is to determine which treatment method is the best from the physician's point of view.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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