

## Health Related Quality of Life in Japanese Patients with Localized Prostate Cancer: Comparative Retrospective Study of Robot-Assisted Laparoscopic Radical Prostatectomy Versus Radiation Therapy

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### ABSTRACT

**Background** Radical prostatectomy and radiotherapy are standard treatments for localized prostate cancer. When making decisions about treatment, it is important to not only consider medical information such as the patient's age, performance status, and complications, but also the impact on quality of life (QOL) after treatment. Our purpose was to compare health related quality of life (HRQOL) after robot-assisted laparoscopic radical prostatectomy (RARP) versus radiation therapy in Japanese patients with localized prostate cancer retrospectively.

**Methods** Patients with localized prostate cancer receiving RARP or radiotherapy at Tottori University Hospital between October 2010 and December 2014 were enrolled in a retrospective observational study with follow-up for 24 months to December 2016. The Medical Outcome Study 8-Item Short-Form Health Survey was performed before treatment and 1, 3, 6, 12, and 24 months post-treatment.

**Results** Complete responses to the questionnaire were obtained from 154/227 patients receiving RARP, 41/67 patients receiving intensity-modulated radiation therapy, 35/82 patients receiving low dose rate brachytherapy, and 18/28 patients given low dose rate brachytherapy plus external beam radiation therapy. The median physical component summary score of the Medical Outcome Study 8-Item Short-Form Health Survey was significantly lower at 1 month after prostatectomy than radiotherapy, but was similar for both treatments at 3 months, and was significantly higher at 6, 12 and 24 months after prostatectomy. The median mental component summary score was also significantly lower in the prostatectomy group at 1 month, but not from 3 months onwards.

**Conclusion** Our study suggested that HRQOL was inferior at 1 month after RARP, however, recovered at 3 months after RARP and was better than after radiotherapy at 6, 12, and 24 months.

**Key words** health related quality of life; Medical Outcome Study 8-Item Short Form Health Survey; prostate cancer; prostatectomy; radiation therapy

Radical prostatectomy and radiotherapy are standard treatments for localized prostate cancer. When making decisions about treatment, it is important to not only consider medical information such as the patient's age, performance status, and complications, but also the impact on quality of life (QOL) after treatment. It has been reported that patient's satisfaction after robot-assisted laparoscopic radical prostatectomy (RARP) is associated with a high degree to a preoperative education.<sup>1</sup> It is desirable for the patient, family members and health-care professionals to engage in adequate consultation before a decision is made, but choosing among different treatment modalities is complicated.

In Japan, RARP was approved for national health insurance coverage in 2012, after which it rapidly became popular,<sup>2</sup> and has been established as a new standard therapy for localized prostate cancer. Regarding differences of therapeutic outcomes between RARP, laparoscopic radical prostatectomy (LRP), and retropubic radical prostatectomy (RRP), the Japanese clinical

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Abbreviations: BCR, biological recurrence; EBRT, external beam radiation therapy; HRQOL, health related quality of life; IMRT, intensity-modulated radiation therapy; LDR, low dose rate brachytherapy; LRP, laparoscopic radical prostatectomy; MCS, mental component summary; NCCN, National Comprehensive Cancer Network; PCS, physical component summary; PSA, prostate-specific antigen; QOL, quality of life; RARP, robot-assisted laparoscopic radical prostatectomy; RPR, radical perineal prostatectomy; RRP, retropubic radical prostatectomy; RP, role physical; SF-8, Medical Outcome Study 8-Item Short Form Health Survey; SF-36, Medical Outcome Study 36-Item Short Form Health Survey

practice guideline indicates that RARP and LRP have the same oncological effect as RRP, while being less invasive, causing less blood loss, and achieving more rapid postoperative improvement of QOL (e.g., restoration of urinary continence and sexual function).<sup>3</sup>

Previous studies have shown that health related quality of life (HRQOL) declines temporarily after laparoscopic or radical prostatectomy, but recovers within 1 year,<sup>4</sup> and that postoperative QOL does not differ between RARP and open radical prostatectomy.<sup>5</sup> In Japanese patients, HRQOL may not show marked deterioration following RARP,<sup>6</sup> and systematic reviews have found significantly better recovery of urinary continence<sup>7</sup> and erectile function<sup>8</sup> after RARP compared with both RRP and LRP.

Radiotherapy has adverse effects on the bladder, urethra, and rectum in the radiation field.<sup>9</sup> Acute adverse events include urinary tract symptoms and defecation problems, while late events include urethral and rectal bleeding, ulceration, pain, urethral stenosis, and erectile dysfunction. Dysuria is the most common chronic toxicity of low dose rate brachytherapy (LDR),<sup>10, 11</sup> while rectal bleeding is most frequently used as a functional endpoint in patients receiving external beam radiation therapy (EBRT).<sup>12</sup> The risk of secondary cancer also cannot be ignored.<sup>13</sup> Some studies have already compared radical prostatectomy with radiotherapy, but there have been few comparisons of RARP with radiotherapy and most of the previous studies were not done in Japan. Thus, many points are unclear regarding the long-term HRQOL of Japanese patients after RARP.

Accordingly, we performed a comparative retrospective study of HRQOL after RARP versus radiotherapy in Japanese patients with localized prostate cancer.

## SUBJECTS AND METHODS

### Patients

This retrospective observational study enrolled patients with a diagnosis of localized prostate cancer who received RARP or radiotherapy at Tottori University Hospital between October 2010 and December 2014 with follow-up for 24 months to the end of December 2016. The number of patients receiving RARP, intensity-modulated radiation therapy (IMRT), LDR, and LDR combined with EBRT (LDR+EBRT) was 227, 67, 82, and 28, respectively.

### Data collection

HRQOL was investigated before treatment and 1, 3, 6, 12, and 24 months after treatment using the Japanese version of the SF-8 Health Survey (SF-8),<sup>14</sup> which is a

simplified version of the 36-Item Short-Form Health Survey (SF-36).<sup>15</sup> The Japanese versions of both questionnaires have previously been validated. SF-8 comprehensively measures health concepts in eight domains. The eight subscales are weighted to generate two summary scores, the physical component summary (PCS) and mental component summary (MCS). The cut-off value of the SF-8 is set at 50, with higher scores indicating better QOL. We obtained a license to use the SF-8 from iHope International (Kyoto, Japan).

### Statistical analysis

Internal consistency of the SF-8 was assessed by calculating Cronbach's  $\alpha$  coefficient. When performing statistical analysis, the Shapiro-Wilk test was initially carried out to assess the normality of data. Descriptive statistics were calculated for demographic characteristics. For comparison of characteristics between the patients receiving RARP or radiotherapy, age and prostate-specific antigen (PSA) were compared by the Kruskal-Wallis test, while the clinical stage, Gleason score, and nerve-sparing surgery were compared by Cramér's coefficient of association. We explored the relationship between pretreatment pathological stage as the independent variable and the treatment modality as the dependent variable by using multiple logistic regression analysis (partial method) in order to check the degree of influence of HRQOL. The median and interquartile range were calculated for HRQOL scores, and differences of the HRQOL score between RARP and radiotherapy patients at each time point were tested by using the general linear model (repeated measures) followed by Scheffe's multiple comparison test. Spearman's rank correlation analysis was used to investigate correlations between SF-8 scores and the age or pretreatment PSA. A P value < 0.05 (two-sided) was considered significant. IBM SPSS Statistics for Windows (Version 25) was used for all analyses.

### Informed consent

Informed consent was obtained from all individual participants included in the study. Candidate participants were given a detailed explanation about the purpose and methods of the study, the expected benefits of participation, a guarantee of anonymity, and the voluntary nature of participation. Written informed content was obtained from all participants before enrollment and anonymity of personal information was protected by de-identification.

**Table 1. Characteristics of the patients**

Variable	RARP <i>n</i> = 154	IMRT <i>n</i> = 41	LDR <i>n</i> = 35	LDR+EBRT <i>n</i> = 18
Pretreatment age (years)				
Mean ± SD	65.0 ± 6.4	71.6 ± 5.5**	68.2 ± 7.8	70.1 ± 6.7*
Range	48–76	60–80	44–81	57–80
Pretreatment PSA (mg/dL)				
Mean ± SD	9.7 ± 6.6	27.1 ± 28.2**	7.5 ± 2.7	24.7 ± 20.9**
Range	1.2–39.2	4.1–122.5	4.4–14.0	4.7–86.9
Clinical stage, <i>n</i> (%)				
T1c	32 (20.8)	1 (2.4)	8 (22.9)	2 (11.1)
T2a	72 (46.8)	10 (24.4)	22 (62.9)	6 (33.3)
T2b	6 (3.9)	5 (12.2)	0	4 (22.2)
T2c	31 (20.1)	0	5 (14.3)	2 (11.1)
T3a	12 (7.8)	18 (43.9)	0	4 (22.2)
T3b	1 (0.6)	7 (17.1)	0	0
Gleason score, <i>n</i> (%)				
≤ 6	33 (21.4)	2 (4.9)	14 (40.0)	0
7	68 (44.2)	6 (14.6)	20 (57.1)	5 (27.8)
≥ 8	53 (34.4)	33 (80.5)	1 (2.9)	13 (72.2)
NCCN clinical risk, <i>n</i> (%)				
Low	18 (11.7)	1 (2.4)	7 (20.1)	0
Intermediate	74 (48.1)	12 (29.3)	28 (80.3)	3 (16.7)
High	62 (40.3)	28 (68.3)	0	15 (83.3)

Kruskal-Wallis test with Bonferroni's correction: \*\*  $P < 0.01$ , \*  $P < 0.05$  (two-sided)

Significant differences between the RARP group and other groups were assessed by the Kruskal-Wallis test for age and prostate-specific antigen, or by Cramér's coefficient of association for clinical stage and Gleason score.

EBRT, external beam radiation therapy; IMRT, intensity-modulated radiation therapy; LDR, low dose rate brachytherapy; NCCN, National Comprehensive Cancer Network; PSA, prostate-specific antigen; RARP, robot-assisted laparoscopic radical prostatectomy; SD, standard deviation.

## Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Tottori University Faculty of Medicine Ethics Committee (approval no. 18A069) and with the 1964 Helsinki declaration and its later amendments (as revised in Brazil 2013).

## RESULTS

### Patient characteristics

The percentage of patients providing complete responses to the questionnaires was 67.8% (154/227) in the RARP group, while it was 61.2% (41/67) for patients receiving IMRT, 42.7% (35/82) for those treated by LDR, and 64.3% (18/28) for those treated with LDR+EBRT. The clinical characteristics of the study population are outlined in Table 1. In patients receiving RARP, IMRT,

LDR, or LDR+EBRT, the mean age before treatment was 65.0, 71.6, 68.2, and 70.1 years, respectively. The mean pretreatment PSA level was 9.7, 27.1, 7.5, and 24.7 mg/dL, respectively, and PSA was significantly lower in the RARP group than in patients receiving IMRT or LDR+EBRT. When Cramér's *V* was calculated for the relation between clinical stage or the Gleason score and each treatment group, it was 0.37 for the clinical stage and 0.35 for the Gleason score, showing a weak relation with the disease stage.

As shown in Table 2, there was no correlation between pretreatment age or PSA and the mean SF-8 score. Regarding National Comprehensive Cancer Network (NCCN) clinical risk, the risk classification ratios varied among the four groups. However, NCCN clinical risk had no strong influence on the treatment modalities (odds ratio: 0.61).

**Table 2. Correlations between age or preoperative PSA and the baseline SF-8 scores**

N=248	PF	RP	BP	GH	VT	SF	RE	MH	PCS	MCS
Age	-0.068	-0.045	0.029	0.049	0.023	0.039	0.010	0.046	-0.047	0.078
Pretreatment PSA	0.056	0.095	0.006	-0.004	0.018	0.033	0.137	0.087	0.021	0.104

Spearman's rank correlation coefficients are shown.

BP, bodily pain; GH, general health perception; MCS, mental component summary; MH, mental health; PCS, Physical component summary; PF, physical functioning, RE, role emotional; RP, role physical; SF, social functioning, VT vitality.

### HRQOL as determined by the SF-8

When internal consistency of the SF-8 was assessed for all subscales, Cronbach's alpha was 0.9. Figure 1 shows changes of the SF-8 scores (mean and standard deviation) for each treatment group during the follow-up period, including the scores for each domain and the summary scores (PCS and MCS). The mean values for 240 Japanese men aged 60–69 years (national standard value determined in 2007) are also displayed for comparison. Pretreatment scores showed no significant differences between the groups, except the scores for role physical (RP) and PCS. The results obtained during the follow-up period are described below, presented as the median value (interquartile range).

#### Physical functioning

The score for this domain was significantly lower in the RARP group than the LDR group at 1 month after treatment [41.5 (16.7–53.5) vs. 53.5 (27.6–53.5),  $P < 0.05$ ]. There were no significant differences among the groups at 3 months after treatment. At 6, 12, and 24 months, the score was significantly higher in the RARP group than the IMRT group [53.5 (27.6–53.5) vs. 47.8 (27.6–53.5), 53.5 (41.5–53.5) vs. 47.8 (27.6–53.5), and 53.5 (27.6–53.5) vs. 47.8 (27.6–53.5), respectively, all  $P < 0.05$ ]. Also, the score was significantly higher in the RARP group than the LDR+EBRT group at 12 and 24 months after treatment [53.5 (41.5–53.5) vs. 44.6 (27.6–53.5) and 53.5 (27.6–53.5) vs. 44.6 (16.7–53.5), respectively, both  $P < 0.01$ ].

#### Role physical

Before treatment, the score for this domain was significantly higher in the RARP group than the IMRT group [54.1 (21.8–54.1) vs. 47.4 (27.9–54.1),  $P < 0.05$ ]. Conversely, it was significantly lower in the RARP group than in the IMRT and LDR groups at 1 month after treatment [40.7 (21.8–54.1) vs. 47.4 (27.9–54.1) and 40.7 (21.8–54.1) vs. 47.4 (21.8–54.1), respectively, both  $P < 0.05$ ]. There were no significant differences among the groups at 3 and 6 months. However, the RARP group had a significantly higher score than the IMRT group at

12 months [54.1 (27.9–54.1) vs. 47.4 (27.9–54.1),  $P < 0.01$ ] and a significantly higher score than the LDR+EBRT group at 24 months [54.1 (27.9–54.1) vs. 44.0 (27.9–54.1),  $P < 0.05$ ].

#### Bodily pain

The RARP group had a significantly lower score than the IMRT group at 1 month after treatment [52.5 (21.7–60.4) vs. 52.5 (31.6–60.4),  $P < 0.05$ ], but there were no between-group differences at 3 and 6 months after treatment. The RARP group showed a significantly higher score than the IMRT group at 12 months [60.4 (38.2–60.4) vs. 52.5 (31.6–60.4),  $P < 0.05$ ], while there were no significant between-group differences at 24 months.

#### General health perception

There were no significant differences of the scores among the groups at 1, 3 and 6 months after treatment. The RARP group had a significantly higher score than the LDR+EBRT group at 12 months [50.3 (40.4–63.4) vs. 50.3 (34.4–58.5),  $P < 0.05$ ], while there were no significant between-group differences at 24 months.

#### Vitality

There were no significant differences among the groups at 1 and 3 months after treatment. The RARP group had a significantly higher score than the IMRT group at 6 months [53.7 (38.5–60.0) vs. 53.7 (28.7–60.0),  $P < 0.05$ ], but there were no significant between-group differences at the other times.

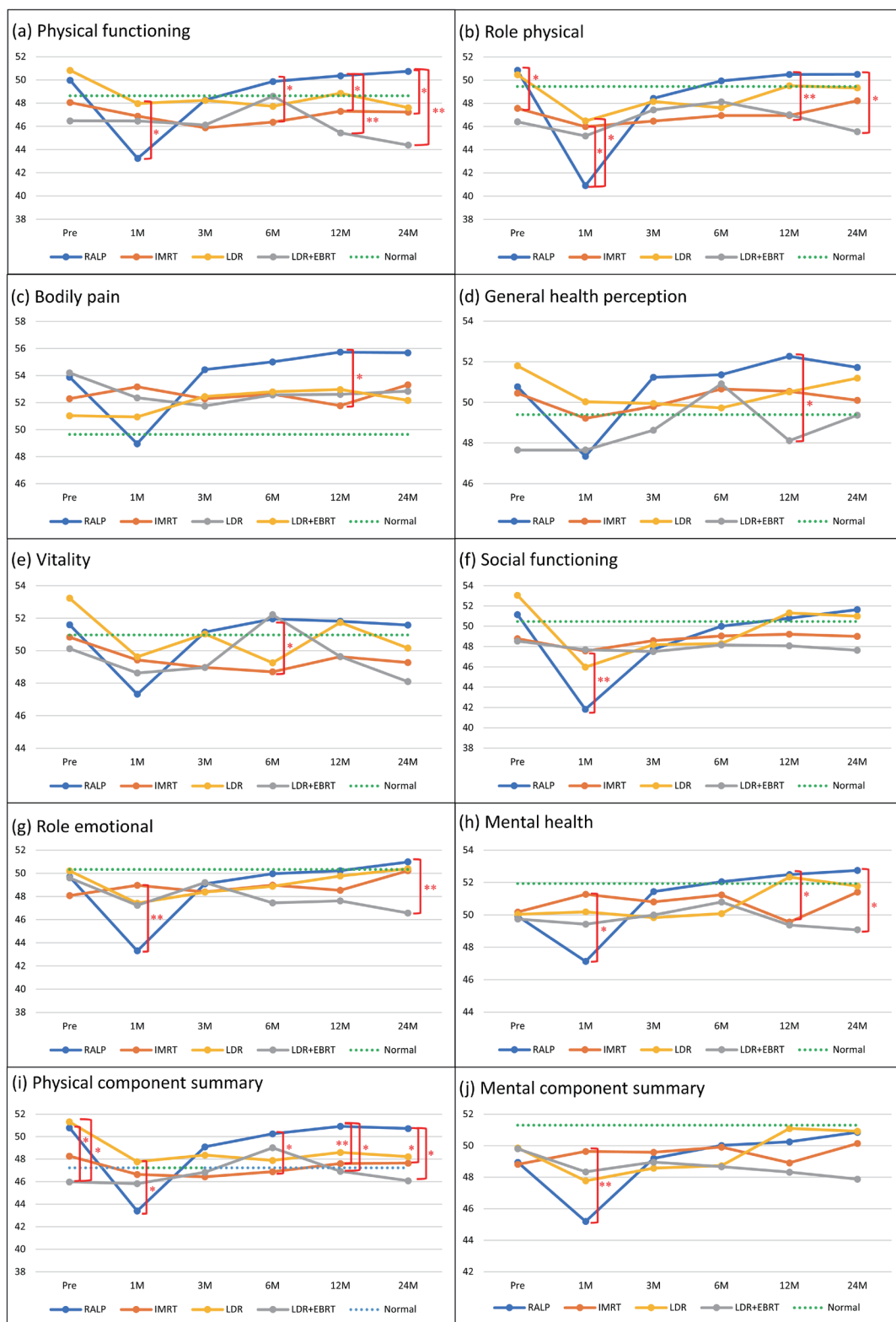
#### Social functioning

The RARP group had a significantly lower score than the IMRT group at 1 month after treatment [37.7 (26.0–55.1) vs. 55.1 (29.2–55.1),  $P < 0.01$ ], but there were no significant between-group differences at the other times.

#### Role emotional

The RARP group had a significantly lower score than the IMRT group at 1 month after treatment [45.1

Post-treatment QOL of prostate cancer patients



**Fig. 1.** Mean SF-8 scores in each group. Error bars represent the standard deviation. RALP group: blue line; IMRT group: orange line; LDR group: yellow line; LDR+EBRT group: gray line; dashed green: national standard value. Although box-and-whisker plots are most frequently used for such data, a line graph has been employed here to facilitate comparison of multiple changes over time. Significant differences determined using the general linear model with Scheffe's test: \* $P < 0.05$ , \*\* $P < 0.01$  (two-sided). 1M, 1 month after treatment; 3M, 3 months after treatment; 6M, 6 months after treatment; 12M, 12 months after treatment; 24M, 24 months after treatment; Normal, national standard value; Pre, pretreatment.

(20.0–54.2) vs. 48.0 (31.4–54.2),  $P < 0.01$ ], but there were no significant differences among the groups at 3, 6, and 12 months. While the RARP group showed a significantly higher score than the LDR+EBRT group at 24 months [54.2 (31.4–54.2) vs. 48.0 (31.4–54.2),  $P < 0.01$ ].

### Mental health

The score was significantly lower in the RARP group than the IMRT group at 1 month after treatment [50.7 (27.6–56.9) vs. 50.7 (36.3–56.9),  $P < 0.05$ ], but there were no significant differences among the groups at 3 and 6 months. The RARP group had a significantly higher score than the IMRT group at 12 months [50.7 (27.6–56.9) vs. 50.7 (36.3–56.9),  $P < 0.05$ ] and a significantly higher score than the LDR+EBRT group at 24 months [56.9 (36.3–56.9) vs. 47.8 (36.3–56.9),  $P < 0.05$ ].

### Physical component summary

The pretreatment PCS score was significantly lower in the LDR+EBRT group than the RARP and LDR groups [47.6 (34.3–55.8) vs. 52.4 (21.6–63.7) and 47.6 (34.3–55.8) vs. 52.6 (39.6–58.2), respectively, both  $P < 0.05$ ], while the score was significantly lower in the RARP group than the LDR group at 1 month after treatment [43.4 (19.7–58.5) vs. 50.0 (25.7–56.7),  $P < 0.05$ ]. There were no significant differences among the groups at 3 months. Scores were significantly higher in the RARP group than in the IMRT group at 6, 12, and 24 months [52.1 (23.6–57.8) vs. 48.1 (25.4–56.6),  $P < 0.05$ ; 52.1 (37.1–59.1) vs. 48.5 (25.4–58.9),  $P < 0.01$ ; and 52.7 (28.4–58.5) vs. 47.9 (30.5–56.3),  $P < 0.05$ , respectively), as well as in the LDR+EBRT group at 12 and 24 months [52.1 (37.1–59.1) vs. 47.7 (34.0–56.6) and 52.7 (28.4–58.5) vs. 45.3 (28.3–56.6), respectively, both  $P < 0.05$ ].

### Mental component summary

While the RARP group had a significantly lower MCS score than the IMRT group at 1 month after treatment [46.5 (26.3–58.5) vs. 52.5 (29.7–57.2),  $P < 0.01$ ], there were no significant differences among the groups at other times.

## DISCUSSION

This retrospective study identified differences of HRQOL between patients receiving RARP and radiotherapy who were followed for 24 months. The HRQOL was inferior at 1 month after RARP, and recovered at 3 months after RARP and was better than after radiotherapy at 6, 12, and 24 months. Treatment for prostate cancer is selected from among various options, such as surgery and radiotherapy, with QOL being an important

consideration.<sup>16, 17</sup> Several previous cross-sectional studies of HRQOL in prostate cancer patients have found no differences of HRQOL among treatment modalities,<sup>18–20</sup> but other studies have shown that QOL differs between radical prostatectomy (excluding RARP) and radiotherapy.<sup>21–23</sup> Since no baseline data were provided in these reports, it is unclear whether the differences of HRQOL were actually related to treatment. In contrast, we obtained pretreatment data and we could properly assess the impact of treatment on HRQOL.

At 1 month after RARP, physical health was worse than at 1 month after radiotherapy, suggesting the influence of surgical invasion, such as pain or post-prostatectomy urinary incontinence,<sup>2</sup> on HRQOL, but the physical health of both groups was similar at 3 months. By 6 months, HRQOL was better with RARP than radiotherapy, similar to the results of a previous study comparing HRQOL at 6 months between RRP and radiotherapy.<sup>24</sup> At 12 months, physical health was worse in the LDR+EBRT group than the RARP group, and it tended to be below the national standard from 3 months onward in patients receiving radiotherapy, suggesting the influence of late adverse events.

At 1 month after RARP, mental health was also worse than at 1 month after radiotherapy, indicating that the postoperative state influenced HRQOL. No other between-group differences were detected, but scores for each group tended to be lower than the national standard.

The median life expectancy of prostate cancer patients undergoing radical prostatectomy was reported to be 13.8 years,<sup>25</sup> so it is important to maintain long-term QOL. Previous studies have found no significant difference of HRQOL at two years after surgery or external beam radiation.<sup>26, 27</sup> A Japanese study showed that HRQOL was better after external radiotherapy than RRP,<sup>28</sup> with higher scores for several SF-8 domains in patients receiving radiotherapy.<sup>23</sup> However, the surgical patients did not undergo RARP and various radiotherapy modalities were included. Investigation of postoperative incontinence after RARP, RPR, RRP, and LRP has shown a superior recovery rate with RARP.<sup>2, 29</sup> Taken together with the present results, we stress that HRQOL recovered at 3 months after RARP and was better than after radiotherapy at 6 months. The prevalence of urinary incontinence is influenced by surgical technique.<sup>7</sup> RARP potentially reduces the risk of urinary incontinence, because significantly better recovery of continence after RARP has been reported.<sup>7</sup> It has already been reported that in terms of urinary incontinence, HRQOL remains worse at 24 months after RARP compared to other methods of prostate

cancer treatment<sup>30</sup>: Our results contrast with this, and the difference in results may be because Chien et al.'s study included patients who did not complete or had incomplete surveys. In our study, the radiation group included many high-risk patients, and none dropped out. However, it is difficult to simply compare the outcomes because the populations are different. To our knowledge, the present study was the first comparative retrospective study of post-treatment SF-8 scores among RARP, IMRT, LDR, and LDR EBRT without dropout cases. These findings could assist healthcare professionals to give patients information about the influence of treatment on HRQOL.

Regarding the clinical characteristics of the study population, the IMRT and LDR+EBRT groups were older than the RARP group, while mean pretreatment PSA was lower in the RARP group than the IMRT group and higher in the RARP group than the LDR+EBRT group. Although such differences could potentially influence HRQOL, there were no differences of pretreatment SF-8 scores, except for role physical and PCS. Also, age and PSA showed no relation with the SF-8 scores. Accordingly, we did not investigate the influence of age, PSA, clinical stage, and Gleason score at diagnosis on HRQOL, however no consensus has been reached.

This study had several limitations. First, the influence of neoadjuvant or adjuvant therapy on HRQOL was not considered.

Second, the LDR+EBRT group included many high-risk patients, and we cannot deny that this may have affected the quality of life after treatment in this group. Although there was no difference in the baseline of HRQOL score between groups, it was difficult to determine the influence of some bias where the RARP group had a better HRQOL score after treatment than the radiotherapy group.

In addition, in our study, the survival rate of prostate cancer patients was 100% during the observation period, but regarding to the biological recurrence (BCR) was not evaluated. The BCR after radical treatment for prostate cancer is a major challenge for medical professionals. Also, disease-targeted QOL should be evaluated as well as HRQOL. Further studies are needed to support our findings, and required to examine the various effectiveness of these treatments with a greater number of patients and a longer follow-up period.

Despite such limitations, HRQOL after RARP was superior half a year up to 2 years compared with radiotherapy. It is possible that these results could help to select treatment for prostate cancer and provide information to support decision-making by patients

and healthcare professionals. However, case risk bias and BCR should always be kept in mind, and this issue requires a separate study. From the perspective of pursuing further investigation, we have been continuing to accumulate cases and long-term follow-up data and plan to give a detailed report separately.

In conclusion, we demonstrated that the HRQOL after RARP was inferior at 1 month compared with radiotherapy, however, the HRQOL subsequently improved, and was better than in radiotherapy patients' 6, 12, and 24 months. These findings could help to select treatment for localized prostate cancer and provide information to support decision-making by patients and healthcare professionals.

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