# Do Patients With Localized Prostate Cancer Treatment Really Want More Aggressive Treatment?

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#### ABSTRAC1

# Purpose

Examine whether patients with prostate cancer choose the more aggressive of two radiotherapeutic options, whether this choice is reasoned, and what the determinants of the choice are.

#### **Patients and Methods**

One hundred fifty patients with primary prostate cancer ( $T_{1-3}N_0M_0$ ) were informed by means of a decision aid of two treatment options: radiotherapy with 70 Gy versus 74 Gy. The latter treatment is associated with more cure and more toxicity. The patients were asked whether they wanted to choose, and if so which treatment they preferred. They also assigned importance weights to the probability of various outcomes, such as survival, cure and adverse effects. Patients who wanted to choose their own treatment (n = 119) are described here.

#### Results

The majority of these patients (75%) chose the lower radiation dose. Their choice was highly consistent ( $P \le .001$ ), with the importance weights assigned to the probability of survival, cure (odds ratio [OR] = 6.7 and 6.9) and late GI and genitourinary adverse effects (OR = 0.1 and 0.2). The lower dose was chosen more often by the older patients, low-risk patients, patients without hormone treatment, and patients with a low anxiety or depression score.

#### Conclusion

Most patients with localized prostate cancer prefer the lower radiation dose. Our findings indicate that many patients attach more weight to specific quality-of-life aspects (eg, Gl toxicity) than to improving survival. Treatment preferences of patients with localized prostate cancer can and should be involved in radiotherapy decision making.

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Several studies have reported that many patients prefer an aggressive treatment, even for little gain in cure. For example, many cancer patients would accept chemotherapy for 1% gain in cure<sup>1,2</sup> or even for no gain at all.3 For radiotherapy, it was reported that some patients would accept postoperative radiotherapy for no gain as well.<sup>4</sup> An exception is a study reporting a willingness to exchange survival for quality of sexual life.5 The aforementioned studies referred to hypothetical decisions. Patients may react differently when they choose their actual treatment. Indeed, a study on breast cancer patients reported a preference for a less aggressive treatment. In that study, however, there was no survival gain attached to the more aggressive option. It remains to be studied, therefore, what patients prefer when a survival gain is presented in an actual choice.

INTRODUCTION

In the aforementioned studies, active treatment was often compared with decline of treatment. Patients may think that any treatment is better than "doing nothing." Treatment as such provides patients with a sense of control.<sup>7,8</sup> In general, active treatment is also promoted by family and physicians. In the present study, in contrast, patients were involved in the choice between two active radiotherapeutic treatments of different dose. The use of a higher radiotherapeutic dose leads to more cure, but also to more adverse effects. 10 Because both options differ only in the chance of cure and adverse effects, and are identical on many other counts, this design provides a better case to study the patients' trade-off between cure and morbidity. In addition, our study concerns an actual choice instead of a hypothetical exercise.

Our research questions were (1) whether patients with localized prostate cancer choose treatment with the higher (74 Gy) or the lower (70 Gy)

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radiation dose, (2) whether their choice is reasoned in that it is consistent with the importance weights they give to the probability of various possible treatment outcomes, and (3) whether we can identify determinants of the treatment preferences.

#### **PATIENTS AND METHODS**

#### **Patients**

Between June 2003 and February 2005, patients with a primary localized prostate carcinoma ( $T_{1-3}$   $N_0M_0$ ), to be treated with three-dimensional conformal radiotherapy (3D-CRT), were included in this study. Exclusion criteria were mental disorders and insufficient knowledge of the Dutch language. Patients were enrolled at two locations; the Radboud University Nijmegen and the Arnhems Radiotherapeutic Institute (both in the Netherlands). The study was approved by the research ethics committees of both hospitals.

#### Procedure

At the first visit to the radiotherapeutic center, the radiation oncologist told the patients that the radiation treatment would be spread out over "a period of over 7 weeks" without mentioning the term "standard treatment" or the exact number of radiation sessions. He informed eligible patients that this study focused on "how to involve the opinion of patients in the treatment." The researcher subsequently explained the patients that the study focused on their opinions and preferences. Patients who agreed to participate were sent a consent form and a baseline questionnaire. At the second visit to the clinic, they were interviewed and received information about two treatment options by means of a decision aid (described in the next section). Then, the patients were asked whether they wanted to choose one of the two treatment options. Finally, each patient was given a brief evaluation questionnaire to be filled out at home.

#### Interview and Decision Aid

In a semistructured interview, the trade-off was mentioned between the risks and benefits of a higher or lower radiation dose. Patients received outcome and risk information on the treatments. The two treatments were explicitly presented as two equivalent treatment options and not as standard treatment versus alternative treatment. One option uses an effective radiation dose of 70 Gy, 11 and the other a dose of 74 Gy. The technique applied is 3D-CRT with three to four beams. Data on the expected outcomes of both treatments were derived from an extensive literature study. 10 Differences in life expectancy were calculated with the population-based yearly survival corrected for the 5-year survival probabilities. 12 Outcome information on 5-year overall survival, difference in life expectancy, 5-year disease-free survival (bNED), erectile dysfunction and severe late GI and genitourinary (GU) adverse effects were discussed. Severe adverse effects were defined as grade 2 or more on the European Organisation for Research and Treatment of Cancer-Radiation Therapy Oncology Group (EORTC-RTOG) definition, <sup>13</sup> and presented as adverse effects that have an impact on daily activities and may require medical intervention. The probability that these outcomes occurred (risk information) was presented by means of numbers and pie charts. Figure A1 shows an example of the decision aid applicable to the largest patient group (ie, ages 57.5 to 72.5 years). The information was also given to the patients, in writing, to take home (Appendix, online only).

Adverse effects were presented identically to all patients, but the effect on life expectancy was tailored to individual patient characteristics in terms of prognostic risk and age category (Table 1). Four separate information groups were distinguished. The first group consisted of low-risk patients, characterized by a prostate-specific antigen (PSA) value less than 10 ng/mL, a Gleason score less than 7, and a tumor status of T1 or T2. The remaining patients were divided into age categories of younger than 57.5 years, 57.5 to 72.5 years, and older than 72.5 years.

At the end of the interview, the patient was asked whether he wanted to choose one of the two treatment options, and if so, which treatment he preferred. After 2 days, the patient's decision was confirmed by telephone. The treatment choice of the patient (ie, 70 or 74 Gy) was carried out.

**Table 1.** Information Groups of Patients and the Associated Losses in Life Expectancy (years) As Compared With Men Without Prostate Cancer

		Treatment A	Treatment B	
Age (years)			(74 Gy)	
All ages	Yes	0	0	
> 72.5	No	1	0	
57.5-72.5	No	2	1	
< 57.5	No	4	2	
	All ages > 72.5 57.5-72.5	All ages Yes > 72.5 No 57.5-72.5 No	All ages Yes 0 > 72.5 No 1 57.5-72.5 No 2	

To ensure that the patients' choices were not determined by biased information, two checks were performed. First, 20 interviews were recorded on audio tape, with permission of the patients. A sample of these tapes was judged by two physicians. They considered the information to be a fair and unbiased representation of the treatments. Secondly, when asked in the evaluation questionnaire, 96% of the patients indicated that both options were presented in an unbiased way.<sup>14</sup>

#### Baseline Measures

To find determinants of the treatment choice, data on variables that may affect this choice were collected. All data were collected at baseline (ie, before the option to choose was introduced) except for the evaluation questions. Patients were asked to judge their own knowledge on prostate cancer and radiotherapy on a 10-point scale (from "very poor" to "excellent"). We measured the level of numeracy (ie, the ability to handle basic probability concepts)<sup>15</sup> by three questions on the calculation of probability. Patients were asked to rate their preference for information on a 10-point scale.<sup>16</sup>

Self-report data were collected on demographic variables (age, marital status, having [grand]children, education and religion). Medical characteristics (T status, pretreatment PSA value, Gleason score and hormone treatment) were extracted from the medical records.

The general participation preference at baseline was measured with two questions about who decides on the choice of treatment. <sup>17</sup> Data were obtained on anxiety and depression by means of the Hospital Anxiety and Depression Scale (HADS). Patients were also asked to rate their general health in the previous week on a 10-point scale. Hopelessness, avoidance, and fighting spirit were assessed with the Mental Adjustment to Cancer scale. <sup>18</sup> Patients rated their cancer worries in three questions. <sup>19,20</sup> Prostate-specific quality of life was assessed by means of the EORTC QLQ-PR25 quality of life prostate cancer module<sup>21</sup> with questions on urinary, bowel, and sexual functioning. Data on the personality traits autonomy and conscientiousness were obtained using a personality assessment instrument. <sup>22,23</sup>

#### Importance Weight

In the evaluation questionnaire, patients were asked about the importance of various outcomes (eg, "Regarding your trade-off between the lower and the higher dose, how important was the probability of bowel problems?"). Patients rated the importance on a five-point scale (1 = not important to 5 = very important). Similar questions covered the probability of bladder and sexual morbidity, the absence/recurrence of the tumor, the possibility of a longer/shorter life, and of the number of radiation sessions required.

### Analyses

Patients choosing the low-dose were compared with those choosing the high-dose. In case of missing data, scale values were calculated only if at least half of the items were filled out, by imputing the mean of the remaining items. For continuous variables, a t test was performed, and for categoric variables the  $\chi^2$  test was used. Continuous data were also analyzed using the  $\chi^2$  test, after subdivision into two categories by use of the median split and presented with P value and odds ratio (OR). Only those variables that differed between patients groups at a level of P < .15 are presented herein. These variables were entered simultaneously in a logistic regression model.

#### **RESULTS**

#### **Participants**

During the inclusion period, a total of 200 patients met the inclusion criteria and were asked to participate in the study. One hundred fifty of them (75%) gave informed consent and were included in the study. Of these 150 patients, 119 decided to choose their own treatment, <sup>14</sup> and their choice is described in this study. Patient characteristics are listed in Table 2.

# **Preferred Treatment**

Of the 119 patients who made a choice, 75% (n = 89) chose the lower radiation dose. Patients found specific quality-of-life aspects more important than the likelihood of survival (Table 3). Post hoc tests showed that patients attached significantly more weight to the probability of GI toxicity than to the probability of a shorter/longer life (P < .001).

Table 4 shows that patients who assigned high importance (ie, above median importance) to the probability of tumor recurrence and survival were more likely to choose the higher dose (as indicated by an OR > 1), whereas patients who assigned high importance to the probability of GI and GU problems were less likely to choose the higher dose (OR < 1). All associations were strongly significant (P < .001), except for the number of radiation sessions (P = .026) and the chance of sexual problems (not significant).

Many patient characteristics failed to show a significant association with the preferred treatment in bivariate analyses (ie, numeracy, information preference, demographic variables [except for age], Gleason score, health, mental adjustment to cancer, worries, baseline quality-of-life, and personality traits). In Table 5, only those patient characteristics that are associated with the choice for the high

**Table 2.** Patient Characteristics of Choosers (n = 119) Characteristic Measure Demographic items Age, years Mean 70 Range 51-84 College education or more 39% Medical variables Tumor stage 16% T1 T2 35% Т3 49% PSA Mean 25 ng/mL 34 ng/mL SD < 10 ng/mL 39% Gleason score Mean 6.5 Range 3-10 < 7 54% Low risk status (ie,  $T_{1-2}$  and PSA < 10 and 20% Gleason < 7Adjuvant hormonal treatment 74% Treatment location 51% Regional Hospital Arnhem University Clinic Nijmegen Abbreviations: PSA, prostate-specific antigen; SD, standard deviation.

Table 3. Importance Weights Given to Possible Treatment Outcomes

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Outcome Measure	Mean	SD		
Probability of shorter or longer life	3.5	1.3		
Probability of tumor recurrence	3.9	1.2		
Probability of severe GI problems	4.1	1.1		
Probability of severe GU problems	3.8	1.1		
Probability of sexual problems	2.8	1.6		
No. of radiation sessions	3.4	1.4		

NOTE. Response scale: 1 = not important to 5 = very important. Abbreviation: GU, genitourinary.

dose with a P < .15 in bivariate analyses are listed. The information group was strongly associated with treatment choice. In the group that had nothing to gain from a high dose in terms of life expectancy (ie, low-risk patients), all patients chose the low dose. Across the four information groups, the higher the expected gain, the lower the proportion of patients who chose the low dose. Concordantly, older patients (70 years or older) were more likely to choose the lower radiation dose, as were patients with a better prognosis, in terms of T1-2 or low-risk status, and patients without hormone treatment. Patients with a clinically high score on anxiety or depression, however, were more likely to choose the high dose. In multiple logistic regression analysis, the only variable that remained statistically significant was information group (P = .006).

## **DISCUSSION**

This study focused on the choice between a higher and a lower radiation dose for localized prostate cancer. Most of the patients in this study (75%) preferred the treatment with the lower radiation dose. Their choices were highly consistent with the importance weights they gave to the probability of the different treatment outcomes.

The fact that many patients preferred the lower dose may be due, in part, to the fact that patients were offered a choice between active treatments and that they were informed by means of a decision aid. A decision aid can lead to a shift towards more quality-of-life-oriented treatment choices. 6,24,27 In most previous studies, however, survival arguments appeared to outweigh quality-of-life aspects in the patients' treatment choice, 1,4,25,26 sometimes even in the absence of a survival gain.<sup>3,4</sup> To date, quality of life appeared to determine the choice of the majority of patients mainly when the choice was either hypothetical,<sup>5</sup> or realistic but without survival gain.<sup>6</sup> As such, it is a new finding that the majority of the patients in our study made a quality-of-life-based choice when presented with a survival gain in an actual treatment decision. Whether the preference for the lower dose may be related to sex, type of disease, or culture remains unanswered. The preference may be related to the fact that our patients, on average, were older and were faced with a less life-threatening disease than most cancer patients previously studied. Excluding the low-risk and oldest patients (groups 1 and 2) from the analysis resulted in less preference for the lower dose (61% instead of 75%).

Our data show not only that many patients indicate a preference for the lower dose, but also that the patients' choices are reasoned in that they are consistent with both their individual clinical

Table 4. Relation Between Choosing the Higher Dose Level and the Importance Weight Given to the Probability of Different Treatment Outcomes Low Dose High Dose Р No % Nο % Odds Ratio Probability of outcome 14.5 < .001 6.7 Survival 36 60 24 40 High weight 50 91 5 9 Low weight 10.8 .001 6.9 Tumor recurrence 48 65 26 35 High weight Low weight 38 93 3 7 25.1 < .001 0.1 Severe GI problems High weight 76 86 12 14 Low weight 11 17 61 14.0 0.2 Severe GU problems < .001 66 86 11 14 High weight Low weight 21 54 18 46 Sexual problems 0.8 0.3 .567 High weight 66 76 21 24 19 70 8 30 Low weight 5.0 .026 0.4 No. of radiation treatments 55 83 17 High weight 11 Low weight 32 65 17 35 Abbreviation: GU, genitourinary.

characteristics and the importance weights they gave to possible outcomes. Consistency with the clinical characteristics was found in that older patients and patients with better prognosis were more likely to choose the lower dose. Such patients have less to gain from the higher dose. Previous reports have also linked treatment preference to age<sup>27-29</sup> and a (perceived) better prognosis.<sup>27,30</sup> The patients without hormone treatment were also more likely to choose the lower dose, probably related to their better prognosis in terms of a low T status (P < .001). Consistency with the importance weights for outcomes was also found. A high weight assigned to cure (in terms of the probability of tumor control and survival) was associated with a preference for the higher dose, whereas a high weight assigned to the risk of severe morbidity (GI and GU) was associated with a preference for the lower dose. This suggests that the patients' treatment decisions reflect reasoned choices. The fact that the importance weight for sexual problems was not related to the choice may be partly due to preexisting or hormone-induced impotence.

Some methodologic comments can be made. The number of patients involved in this study, although considerable, is still relatively low considering the number of determinants tested. Statistical analyses would have benefited from larger groups. Nevertheless, we were able to identify significant determinants of choice. Another consideration is that the standard effective dose used before the start of the study was 70 Gy. Although this information was not shared with the patients, and the treatment options were not specified in Gy, we cannot rule out a possible effect on patients' preferences. Yet another consideration is whether our findings can be generalized to all patients with primary localized prostate cancer. Out of 200 eligible patients, 150 (75%) gave informed consent. The patients who refused to give informed consent did not differ in age and medical characteristics from the participants.<sup>14</sup> Still, we cannot rule out the possibility that they might have made a different treatment choice. Of the 150 patients who participated, 119 patients decided to choose their treatment, and their choice is described in this study. The remaining 31 patients decided to leave the choice to their physician.  $^{14}$  These 31 patients were also asked to indicate whether they would have preferred the low or the high dose. Most were undecided (n = 21), but the remainder (n = 10) preferred the low dose over the high dose, supporting the conclusion that many of the prostate cancer patients prefer the lower radiation dose. No statistical differences in demographic or medical characteristics were found between the 31 nonchoosers and the 119 choosers.

An objection to the study design may be that not all patients received the same risk information. For example, older patients were presented with a smaller difference in life expectancy than younger patients. Thus, the effect of patient characteristics on treatment choice was confounded by differences in risk information. At the same time, it is the strength of this study that the information was individualized, in that it was tailored to specific patient groups. This way, each patient was offered information that most closely matched his personal prognosis, enabling a personalized trade-off. Another objection could be that patients chose the lower dose because the gain presented for the more aggressive option was small. However, a gain of 6% in 5-year survival is comparable to many other oncologic choices. Furthermore, it is unlikely that the preference for the lower dose in our study is caused by a biased presentation of both treatment options, since both physicians and patients considered the information to be unbiased.

As for the presented dose levels of 70 and 74 Gy, in recent years the routine dose for prostate cancer tends to rise to levels of 78 Gy (or even higher with intensity-modulated radiation therapy and smaller treatment margins). At the start of this study, however, such levels were not common in Europe. We decided to offer patients a choice between 70 and 74 Gy, because it was the explicit intent of this study to explore patient preferences between generally accepted treatments instead of between routine and experimental treatments. Moreover, the radiation dose of 70 to 74 Gy is still common practice in many hospitals for the treatment of prostate cancer.

This study showed that, in the specific group of patients with primary localized prostate cancer, many patients preferred the

Characteristic	Low Dose		High Dose				
	No.	%	No.	%	$\chi^2$	Р	Odds Ratio
Information							
Information group					24.9	< .001	NC
Low risk (all ages)	24	100	0	0			
> 72.5 years	28	85	5	15			
57.5-72.5 years	38	65	20	35			
< 57.5 years	0	0	4	100			
Patient's judgement of own knowledge					3.0	.085	2.0
Low (< 6)	29	66	15	34			
High (≥ 6)	57	80	14	20			
Demographics							
Age, years					11.7	.001	0.2
< 70	27	59	19	41			
≥ 70	63	86	10	14			
Medical parameters							
Tumor stage					11.3	.001	4.7
T1 or T2	54	88	7	12			
T3	36	62	22	38			
PSA (pretreatment)					2.3	.131	2.0
< 10 ng/mL	39	83	8	17			
≥ 10 ng/mL	51	70	21	30			
Low risk	0.	, 0		00	9.7	.002	NC
Yes	24	100	0	0	0.,	.002	
No	66	69	29	31			
Hormone treatment	00	00	20	01	5.3	.021	4.1
No	29	91	3	9	0.0	.02.	
Yes	61	70	26	30			
Psychological	01	70	20	30			
Participation preference					3.5	.062	0.4
Low	35	67	17	33	0.0	.002	0.+
High	55	82	12	18			
Anxiety score	55	02	12	10	8.1	.004	4.3
< 8	81	81	19	19	0.1	.004	4.5
< 0 ≥ 8	9	50	9	50			
≥ o  Depression score	Э	50	Э	50	5.1	.024	3.8
< 8	84	79	22	21	5.1	.024	5.0
< 8 ≥ 8	6	79 50	6	50			

NOTE. Only associations with a P < .15 in bivariate analyses are listed. In multiple logistic regression analysis, information group was the only variable that remained statistically significant (P = .006).

Abbreviations: NC, not calculated (due to empty cells); PSA, prostate-specific antigen.

lower radiation dose (ie, the less aggressive treatment). Patients differed in their preferences, but their choices were consistent with their medical status and the importance weights assigned to the probability of different treatment outcomes. Irrationality and incapability to choose are therefore discredited as arguments to deny patients involvement in treatment selection. This study suggests that patients with localized prostate cancer attach more weight to specific aspects of the quality of life (ie, GI toxicity) than to

the probability of survival. The increased risk of morbidity was deemed too high a price for the increased probability of tumor control. It is therefore expected that the new trend of high-dose intensity-modulated radiation therapy will be valued by patients only when the higher tumor control is accompanied by a low complication rate. Treatment preferences of patients with localized prostate cancer can and should be involved in radiotherapy decision making.

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# Appendix

The Appendix is included in the full-text version of this article, available online at www.jco.org. It is not included in the PDF version (via Adobe® Reader®).

### Authors' Disclosures of Potential Conflicts of Interest

The authors indicated no potential conflicts of interest.

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