



Quality of life

Quality of life among prostate cancer patients: A prospective longitudinal population-based study



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ABSTRACT

Purpose: To investigate the course of quality of life (QoL) among prostate cancer patients treated with external beam radiotherapy and to compare the results with QoL of a normal age-matched reference population.

Patients and methods: The study population was composed of 227 prostate cancer patients, treated with radiotherapy. The EORTC QLQ-C30 was used to assess QoL before radiotherapy and six months, one year, two years and three years after completion of radiotherapy. Mixed model analyses were used to investigate longitudinal changes in QoL. QoL of prostate cancer patients was compared to that of a normative cohort using a multivariate analysis of covariance.

Results: A significant decline in QoL was observed after radiotherapy ($p < 0.001$). The addition of hormonal therapy to radiotherapy was associated with a lower level of role functioning. Patients with coronary heart disease and/or chronic obstructive pulmonary disease or asthma had a significantly worse course in QoL. Although statistically significant, all differences were classified as small or trivial.

Conclusion: Prostate cancer patients experience a small worsening of QoL as compared with baseline and as compared with a normal reference population. As co-morbidity modulates patients' post-treatment QoL, a proper assessment of co-morbidity should be included in future longitudinal analyses on QoL.

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Quality of life (QoL) among prostate cancer patients is an important outcome measure of therapy, providing relevant information on how patients experience their functioning in daily life after treatment. Although high survival rates after curative radiotherapy have been reported [1], side effects like fecal or urinary incontinence may occur as a result of prostate radiotherapy. As a substantial proportion of prostate cancer patients report these side effects during follow-up [1–4], QoL may be transiently or permanently reduced.

QoL after therapy may not only be affected by the development of side effects, but also by baseline measures of QoL, e.g., due to the presence of co-morbidity. A previous study showed that as much as 53% of the population aged 55 years and older had at least one mild or severe chronic condition [5]. The question arises as to whether co-morbidity plays an important role in the changes of QoL after treatment among prostate cancer patients. Although QoL has been measured widely among prostate cancer patients [6–8], baseline measures of QoL and the effect of co-morbidity have not been consistently taken into account.

Interpretation of the results of QoL studies is challenging and could be facilitated by comparing the results with QoL measured in the general population in order to determine the additional functional impairment and symptom burden associated with prostate cancer and its treatment [9]. Normative data not only enables comparing QoL scores of prostate cancer patients against those obtained in the normative population, but also offers the opportunity to analyze the impact of covariates such as age and co-morbidity [10].

Therefore, the objective of the current study was twofold. The primary objective was to investigate to what extent QoL changes after completion of curative radiotherapy among prostate cancer patients, with special attention to the influence of baseline QoL and co-morbidity. The second objective was to investigate to what extent QoL of prostate cancer patients differs from that of a normal reference population.

Patients and methods

Study design, patient and normative cohort selection, treatment

The study population of this prospective cohort study was composed of 227 patients with localized or locally advanced prostate cancer. All patients were treated at the University Medical Center

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Groningen and were originally included in two multicenter prospective randomized studies. Ninety-nine patients were included in the European Organization for Research and Treatment of Cancer (EORTC) 22961 trial and 128 patients in the EORTC 22991 trial. The EORTC 22961 trial started in 1997 and was designed to evaluate the influence of adjuvant hormonal treatment with an LHRH (luteinizing-hormone-releasing hormone) analog in patients with locally advanced prostate cancer treated with 3D-CRT. The EORTC 22961 protocol included patients with non-metastatic T1c-T2bN1-2/pN1-2 (after pelvic lymphadenectomy) or T2c-T4N0-2 (UICC 1992 TNM classification) histologically confirmed adenocarcinoma of the prostate. Patients in the long arm (three years) received combined androgen blockade for a period of three years, while patients in the short arm received combined androgen blockade for a period of only six months [11].

In the EORTC 22991 trial, radiotherapy alone, either 3D-CRT or IMRT, was compared with the same radiotherapy combined with adjuvant hormonal therapy in localized T1b-c, T2a, N0, M0 prostatic carcinoma. Patients in the adjuvant hormonal arm started hormonal treatment one week before radiotherapy with anti-androgens each day for a period of one month and additionally two injections of LHRH during the next six months [12]. For the purpose of the current analysis, only patients biochemically failure free at the time of QoL assessments were eligible.

All patients were treated with external beam radiotherapy. A planning CT of all patients was obtained in treatment position (supine). The clinical target volume (CTV) was defined as the prostate and the seminal vesicles. Radiotherapy was delivered with linear accelerators using photons with either 3-dimensional conformal radiotherapy (3D-CRT) or intensity modulated radiotherapy (IMRT). Patients were treated 5 times a week to a total dose of 70 Gy (3D-CRT) or 78 Gy (IMRT).

The patient cohort was compared to a normative cohort of male individuals from the PROFILES study [9]. QoL normative data were obtained from the Health and Health Complaints project from CentERdata. The CentERpanel cohort represents the Dutch-speaking population in the Netherlands, including those without Internet access. From this panel a normative cohort of 519 men was selected, resulting in an age matched comparison between the patient cohort and the normative cohort.

Quality of life assessment

QoL was measured by means of the EORTC Quality of life Questionnaire C30 (EORTC QLQ-C30) [13] prior to the start of radiotherapy and subsequently at 6, 12, 24 and 36 months after completion of radiotherapy. The current analysis covered five QoL scales that were considered to be most likely affected by therapy and/or comorbidity, including global quality of life, physical functioning, social functioning, emotional functioning and role functioning. In addition, six symptom scales were analyzed, including fatigue, pain, dyspnea, insomnia, constipation and diarrhoea. QoL-scores were linearly converted to a scale ranging from 0 to 100, according to EORTC guidelines. For the functional and global health status/quality of life scales, higher scores represent better levels of functioning. For the symptom scales, higher scores represent a greater degree of symptoms.

Statistics

Changes in QoL before and after treatment were estimated by means of a mixed model analysis. The first advantage of a mixed model analysis over a standard analysis of variances (ANOVA) is that it takes into account variability between patients' (baseline) scores. Secondly, a mixed model ANOVA can deal better with missing values than the standard ANOVA model. Using a standard

ANOVA model, one or more missing observations in one patient result in a complete loss of all data of that particular patient, while using the mixed model approach only the missing observations are lost. Other factors included in the model were adjuvant hormonal therapy, radiotherapy technique and co-morbidity. To investigate the clinical relevance of the longitudinal differences, the effect sizes were categorized as proposed in a meta-analysis by Cocks [14] into trivial, small, medium and large differences per scale.

To investigate the differences between prostate cancer patients 3 years after treatment and the normative cohort a multivariate analysis of covariance (MANCOVA) was used. Unbalanced distribution of patient characteristics (Table 1) was accounted for by means of the addition of covariates into the model. To investigate the clinical relevance of the differences with the normative comparison, the effect sizes were categorized as proposed by Cocks [15]: trivial, small, medium or large difference per scale. A *p*-value of 0.05 was considered to be statistically significant.

Results

Sample description and compliance

At baseline, 200 out of the 227 patients completed the QoL questionnaire. The compliance rate six months after treatment was 95% (210 out of 221 patients alive), 96% after one year (208 out of 216 patients alive), 95% after two years (202 out of 213 patients alive) and 88% three years after radiotherapy (184 out of 209 patients alive). The majority of patients was treated with adjuvant hormonal therapy and 3D-CRT. The median age was 70 years (range 53–85).

Baseline patient characteristics and normative cohort characteristics are listed in Table 1. The prevalence of co-morbidities did not differ significantly between the patients and the normative cohort, except for hypertension. Although the patient and normative cohort had the same age range, the average age of the prostate cancer

Table 1
Patients and normative cohort characteristics.

	Patients (%) N = 227		Norm (%) N = 519	
Heart disease	49	(22)	97	(19)
COPD and asthma	24	(11)	46	(9)
Hypertension	62	(27)	176	(34)*
Stroke	5	(2)	4	(1)
Diabetes	21	(9)	47	(9)
Peptic ulcer	4	(2)	8	(2)
Kidney disease	4	(2)	9	(2)
Liver disease	0	(0)	2	(0.4)
Thyroid disease	3	(1)	6	(1)
Age ≤ 70	134	(59)	360	(73)*
<i>Tumor classification</i>				
T1	85	(37)		
T2	68	(30)		
T3	74	(33)		
<i>PSA</i>				
<10	50	(22)		
10–20	97	(43)		
20–40	60	(26)		
>40	20	(9)		
<i>Adjuvant treatment</i>				
Radiotherapy only	71	(31)		
Radiotherapy and hormonal therapy	156	(69)		
<i>Radiotherapy modality</i>				
IMRT	70	(31)		
3D-CRT	157	(69)		

* Statistically significant at 0.05 using Fisher exact test.

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