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Original Paper

Baseline Quality of Life of Patients with Advanced Prostate Cancer

D. Curran,[1] S. Fossa,[2] N. Aaronson,[3] G. Kiebert,[1] E. Keuppens[4] and R. Hall[5]
on behalf of the European Organization for Research and Treatment of Cancer (EORTC), Genito-Urinary Tract Cancer Cooperative Group (GUT-CCG)

[1]Quality of Life Unit, EORTC Data Center, Avenue E. Mounier, 83, Bte 11, 1200 Brussels, Belgium; [2]The Norwegian Radium Hospital, Oslo, Norway; [3]The Netherlands Cancer Institute, Amsterdam, The Netherlands; [4]Akademisch Ziekenhuis VUB, B-1090 Brussels, Belgium; and [5]Freeman Hospital, Newcastle-Upon-Tyne NE7 7DN, U.K.

Quality of life (QoL) is now commonly studied in prostate cancer. However, little is known about the appropriateness of the various QoL instruments in this group of patients. The purpose of this work was to study the baseline QoL assessment of patients with prostate cancer who were randomised into three EORTC phase III studies. The three trials included locoregional prostate cancer patients, poor prognosis metastatic patients and hormone resistance patients, respectively. In the three trials, patients were asked to complete a questionnaire assessing their physical and psychosocial functioning and their symptom levels. These questionnaires included questions from the EORTC QLQ-C30 (version 1): the physical functioning, role functioning, global health/QoL scales and a single pain item. The psychometric properties of the scales were assessed and an analysis was performed to investigate if differences existed in the scale scores between the three groups of patients. 638 baseline questionnaires were available for patients entered into the three trials. The Gutman coefficients of reproducibility and scalability were 0.94 and 0.71, respectively, for the physical functioning scale and 0.97 and 0.90, respectively, for the role functioning scale. The Cronbach's alpha reliability coefficients were 0.68, 0.48 and 0.90 for the physical functioning, role functioning and global health/QoL scales, respectively. The four scales were able to distinguish clearly between the patient populations under study. The physical functioning, role functioning, global health/QoL scales and the single pain item scale from the EORTC QLQ-C30 (version 1) are valid measures when used in the setting of prostate cancer. © **1997 Elsevier Science Ltd.**

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INTRODUCTION

PROSTATE CANCER is the second most common site of cancer affecting males in Western Europe and has recently been reported to be the most common cancer among American men [1, 2]. The mortality rate due to prostate cancer has increased in most countries [1, 3]. Although the reason for the increase in incidence is unclear, factors such as improvement in screening techniques, greater incidence of the disease with advancing age and the increasing distribution of elderly men in Western cultures [4], as well as the changes in social habits and in racial populations may play a role [1].

The principle treatment of advanced prostate cancer is androgen deprivation. However, it is still unclear whether the therapy should be started at the time of diagnosis, even in asymptomatic patients, or whether therapy can be delayed without compromising survival. The most widely used androgen suppression techniques include orchiectomy, therapy with oestrogens, progestogens, different types of anti-androgen,

Correspondence to D. Curran.
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inhibitors of steroid biosynthesis, LH–RH (luteinising hormone–releasing hormone) analogues and various combinations of these alternatives [1]. Each of these therapeutic modalities cause different side-effects and may have different effects on an individual's functioning, both physical and psychosocial. As a result, it is very important that, in addition to efforts aimed at prolonging survival and palliating symptoms, the effect of the different treatment options on the quality of life (QoL) of these patients should also be considered.

A frequently voiced argument from clinicians against QoL assessment is the belief that physicians who treat cancer patients for many years can accurately rate the patient's general condition by scoring the performance status and can assess reasonably well the patient's pain levels. However, in recent years these beliefs have been questioned by several authors [5, 6]. It has also been shown that QoL at baseline may be of use as a prognostic factor for clinical outcomes, including survival [7–9], response to treatment and nausea and vomiting [8–10]. In future prostate cancer trials, it may be useful to include baseline QoL assessments to investigate further its predictive value for the various endpoints under study. In an editorial comment, Weeks recommended that QoL assessments at baseline also be included in all phase III trials to examine whether randomisation succeeded in distributing patient characteristics equally among treatment arms [5].

In 1986, the European Organization for Research and Treatment of Cancer (EORTC) initiated a research programme to develop an integrated, modular approach for evaluating the QoL of patients participating in international clinical trials. This research resulted in the development of a core questionnaire which is referred to as the EORTC QLQ-C30 [11]. The QLQ-C30 incorporates nine multi-item scales: five functional scales (physical, role, cognitive, emotional and social); three symptom scales (fatigue, pain and nausea/vomiting); and a global health and QoL scale. Six single-item scales are also included (dyspnoea, insomnia, appetite loss, constipation, diarrhoea and financial difficulties). The QLQ-C30 has been found to meet the requisite standards of validity (measuring what it is intended to measure), reliability (measuring with sufficient precision) and responsiveness (ability to detect changes) [11–14]. The questionnaire was initially tested in a population of lung cancer patients [11], and subsequently in a population of breast and ovarian cancer patients [12], in head and neck cancer patients [13], and in cancer patients (lung, prostate, breast, myeloma, gastrointestinal and rectal) treated with palliative radiotherapy [14].

The current work was performed to investigate further the characteristics of the EORTC QLQ-C30 domains in three different populations of prostate cancer patients. In particular, we investigated the ability of the questionnaire to distinguish between patient populations with distinctly different development states of the malignancy in question (so-called "Known groups" validity) [15]. A second objective of this study was to compare the physicians' rating of the patients' performance status and pain with the patients' self-assessment of physical functioning and pain.

PATIENTS AND METHODS

Patients with prostate cancer who were randomised into three phase III clinical trials performed by the EORTC Genito-Urinary Tract Cancer Cooperative Group (GUT-CCG) and who completed a baseline (pre-treatment) QoL questionnaire were included in the current analysis. The first trial (EORTC trial 30891) was designed to compare early versus delayed orchidectomy, or early versus delayed treatment with a depot LH-RH analogue (buserelin), respectively, in patients with asymptomatic prostate cancer (T_{0-4} N_{0-2} M_0). The objective of the second trial (EORTC trial 30893) was to compare orchidectomy alone with orchidectomy plus mitomycin C in patients with poor prognosis metastatic prostate cancer. The third trial (EORTC trial 30903) was designed to compare flutamide versus prednisone in hormone-resistant, painful progressive metastatic prostate cancer patients. Henceforth, we will refer to each trial using the terms locoregional prostate cancer trial (30891), poor prognosis metastatic trial (30893) and hormone resistant trial (30903), respectively. The locoregional prostate cancer trial and the hormone resistant trial are still open to patient entry.

The main patient inclusion criteria by trial are presented in Table 1. The common patient inclusion criteria were: histologically or cytologically proven carcinoma of the prostate and patient's informed consent. In the locoregional prostate cancer trial, patients presenting with pain at the time of randomisation were excluded. In the poor prognosis metastatic trial, pain caused by the prostate or its metastases was required. However, in the absence of pain, at least two of the following three characteristics were required: WHO performance status 1 or 2; alkaline phosphatase > upper normal value; or T4 category. In the hormone-resistant trial, only patients with painful progressive metastatic disease with or without complete pain relief when taking analgesics or patients with painful progressive metastatic disease without analgesics were eligible.

As these were large-scale international clinical trials, the investigators believed it was necessary to keep the QoL components of the trials as simple as possible, and thus a choice had to be made as to which QoL issues were to be investigated. Thus, during the development stage of the QLQ-C30 the EORTC GUT-CCG selected generic scales from the QLQ-C30 supplemented by disease and treatment-specific items to be included in their assessment of QoL. As the three patient populations differed with respect to development states of malignancy, different QoL questionnaires were used in the three trials. However, in the three trials it was felt that the physical functioning scale, role functioning scale and the global health/QoL scale from the QLQ-C30 should be included. As pain is also an important component of QoL, particularly in prostate cancer, a single pain item from the QLQ-C30 was also included. Thus, in total, 10 items from the QLQ-C30 (version 1.0) were included in all three trials, i.e. five physical functioning items, two role functioning items, two global health/QoL items and a pain item (see Appendix 1).

Gutman scaling analysis was performed to test the psychometric properties of the two hierarchical scales, i.e. the physical and role functioning scales [16]. The coefficient of reproducibility was used to measure the extent to which a

Table 1. Main eligibility criteria

Characteristics	30891	30893	30903
Previous hormonal therapy	No	No	Yes
M Stage	M0	M1	M1
WHO performance status	0–1	0–2	0–3
Previous radical prostactectomy	No	No/Yes	No/Yes

Table 2. Patient characteristics at baseline by trial

	30891 n=431 n(%)	30893 n=109 n(%)	30903 n=95 n(%)
Age, years			
Median (range)	73 (52–80)	67 (41–80)	70 (55–86)
WHO performance status			
0	294 (68)	15 (14)	13 (13)
1	137 (32)	79 (72)	64 (65)
2	0 (0)	15 (14)	16 (16)
3	0 (0)	0 (0)	5 (5)
Pain caused by the primary tumour or its metastases			
No	428 (99)	10 (9)	1 (1)
Yes	0 (0)	99 (91)	94 (96)
Unknown	3 (1)	0 (0)	3 (3)

respondent's scale score was a predictor of one's response pattern. The coefficient of scalability was used to assess if the scale was unidimensional and cumulative. A general guideline for the interpretation of these measures is that a coefficient of reproducibility higher than 0.9 and a coefficient of scalability greater than 0.6 is considered indicative of a valid unidimensional scale [16].

The reliability (i.e. internal consistency) of the multi-item scales was assessed using Cronbach's alpha coefficient [17]. As recommended by Nunnally, a minimal standard of reliability (Cronbach's alpha coefficient) of 0.70 was sought [18]. To evaluate the validity of the questionnaire scales: (1) Spearman correlation coefficients among the various scales were calculated; and (2) the Kruskal–Wallis non-parametric statistical test was used to assess whether the questionnaire scales could detect significant differences between the three trial populations in self-assessed QoL at baseline [19]. No adjustment for multiple comparisons was performed. Scale scores were calculated by averaging items within scales and transforming average scores linearly to a 0–100 scale, with higher scores representing a higher level of functioning or a higher level of symptoms. In the presence of missing items within a scale, the scale score for that respondent was considered as missing [20].

Physicians completed a case report from prior to the start of treatment. This form included the physician's evaluation of the patient's performance status (WHO criteria) and pain. The patient's self-assessment of physical functioning and pain was compared with the physician's rating of the patient's performance status and pain, respectively. Cohen's Kappa

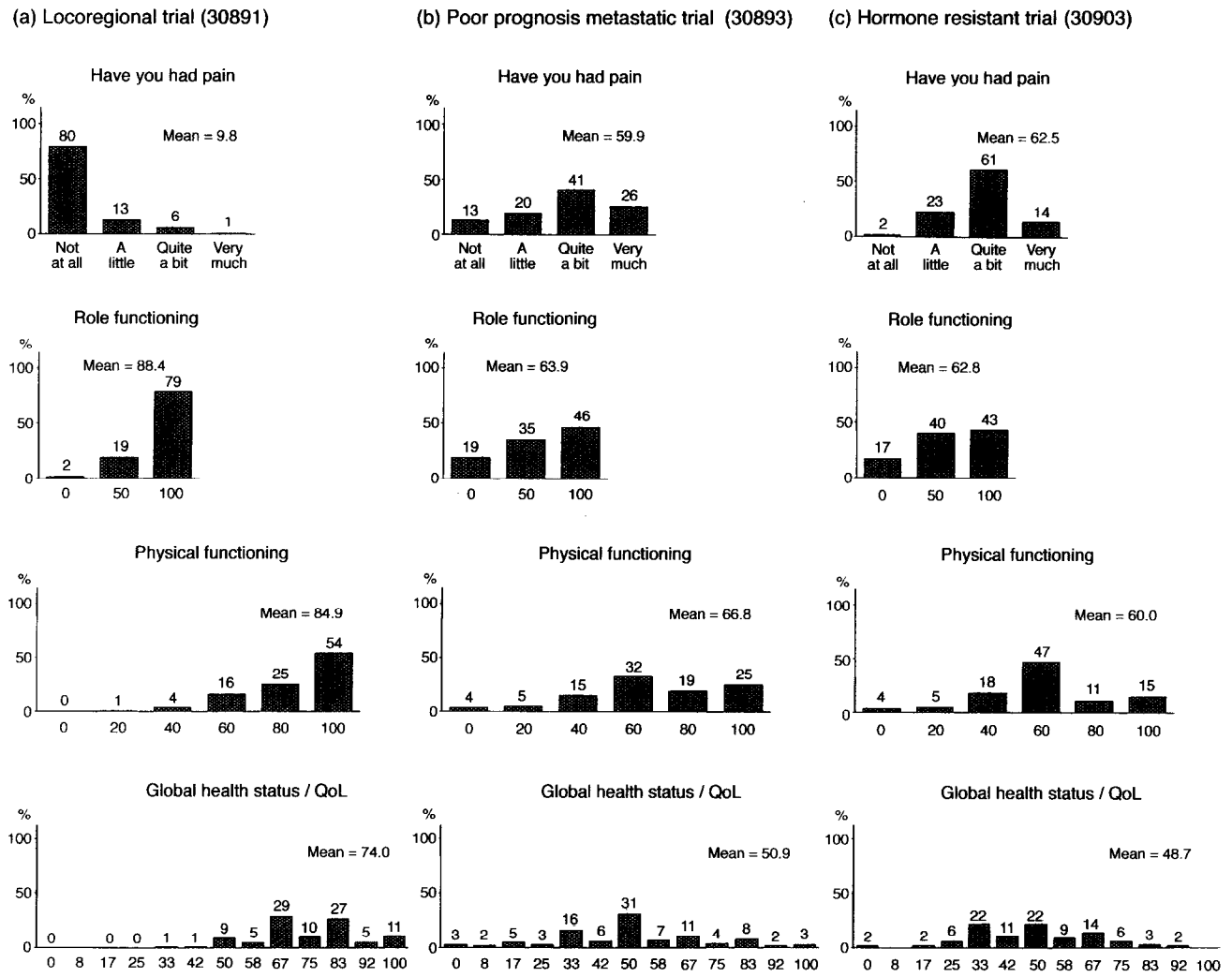

Figure 1. Quality of life scores by trial.

Table 3. Patients' self-assessed pain scores versus doctors'; rating by trial

	Doctors assessment					
	30891		30893		30903	
Patients	No pain *n*(%)	Pain *n*(%)	No pain *n*(%)	Pain *n*(%)	No pain *n*(%)	Pain *n*(%)
Have you had pain?						
During the last week						
Not at all	338 (80)		6 (60)	8 (8)	0 (0)	2 (2)
A little	51 (12)		3 (30)	19 (19)	0 (0)	22 (24)
Quite a bit	26 (6)		0 (0)	45 (45)	1 (1)	55 (59)
Very much	5 (1)		1 (10)	27 (27)	0 (0)	14 (15)

statistic and Cohen's weighted Kappa statistic were used to assess the level of agreement between the physicians' and patients' ratings of pain and physical status, respectively [21]. Cohen's Kappa statistic is determined entirely by the diagonal elements, whereas Cohen's weighted Kappa statistic assigns a weight to the disagreement between the observers.

Software for the Management and Analysis of Randomized Trials (SMART) was used for data management, and StatXact 3 [21] and SAS® was used for the data analysis [22].

RESULTS

431 patients (71%) completed a baseline QoL questionnaire in the trial consisting of locoregional prostate cancer patients, 109 (58%) in the trial of poor prognosis prostatic cancer patients and 98 (77%) in the hormone-resistant metastatic prostate cancer trial. Thus, the analysis was based on a total of 638 patients from 14 countries (The Netherlands, Belgium, France, Switzerland, Spain, United Kingdom, Italy, Portugal, Austria, Czech Republic, Norway, Slovakia, Turkey and Russia). The patient characteristics of these three patient groups are presented in Table 2. Other patient characteristics, determined by the eligibility criteria, are presented in Table 1.

Comparing the characteristics of patients for whom a baseline QoL assessment was available with those for whom no baseline QoL assessment was available, no statistically significant differences were observed with respect to age, performance status or pain score. However, institutional compliance ranged from 0 to 100%. The low compliance rate in the trial of poor prognosis prostatic cancer patients is partially explained by the fact that 40 (21%) patients received orchidectomy first and were then randomised to mitomycin C versus no additional treatment. Thus, the first QoL questionnaire for these patients was filled in after orchidectomy and therefore was not acceptable as a baseline questionnaire.

Missing values

Overall rates of non-response to individual items was less than 2%. For the physical functioning items, non-response rates varied between 0.8 and 1.3%. Non-response rates were 1.3% and 1.7% for the two role functioning items, respectively, 1.1% for the pain item and 2.5% and 2.7% for the two overall health/QoL items, respectively.

Reliability and validity

For the physical functioning scale and Gutman coefficients of reproducibility and scalability were 0.94 and 0.71, respectively, and 0.97 and 0.90 for the role functioning scale, respectively. The Cronbach's alpha reliability coefficients were 0.68, 0.48 and 0.90 for the physical functioning, role functioning and global health/QoL scales, respectively. All inter-scale correlations were statistically significant, indicating that although scales were assessing distinct components of QoL, they were not independent.

Known group comparisons

Figure 1 presents the distribution of QoL scores by scale and trial. In all of the tests comparing QoL scale scores between the three trials the differences in QoL were highly statistically significant ($P \leq 0.001$), with the largest differences being observed between the patients in the locoregional prostate cancer trial versus those in the poor prognosis metastatic disease trial and the hormone-resistant trial.

Pain assessments

Pain scores provided by both the attending physicians and the patients were presented in Table 3. Although Cohen's Kappa statistic of 0.671 was very significant indicating a high level of concordance, in many cases patients' pain scores appeared to be underrated by the physicians. 87 (20%) of the patients for whom the physician documented no pain reported having pain. However, 5% of patients for whom the physician rated the patient as having pain caused by the primary tumour or its metastases responded 'not at all' to the question of pain.

Physical assessment

Physical functioning scores by performance status and trial are presented in Table 4. Although some of the patients whom the physicians included in WHO performance status categories 0 and 1 scored 80 or less and 40 or less, respectively, on the self-assessment scale, in the majority of cases there appeared to be relatively good agreement (Cohen's weighted Kappa statistic = 0.443, $P<0.0001$). For most of the patients who scored very low in physical functioning, but for whom the physician documented performance status 0 or 1, we observed that the physician also documented that the patients had heart or respiratory problems and 1 patient had pain in his joints.

Table 4. Physical functioning scores by WHO performance status and trial

	Physical functioning score		
	0–40	60–80	100
WHO performance status			
WHO 0 ($n = 316$)	13 (4)	106 (34)	197 (62)
WHO 1 ($n = 268$)	40 (15)	161 (60)	67 (25)
WHO 2 or 3 ($n = 36$)	21 (58)	12 (33)	3 (8)

DISCUSSION

This study was performed to generate further evidence regarding the psychometric properties of several of the EORTC QLQ-C30 scales in a group of 638 prostate cancer patients. When used in a culturally diverse sample of prostate cancer patients, the questionnaire exhibited satisfactory scaling properties and validity, low levels of missing data, and an ability to detect baseline differences between subgroups of patients known to differ in clinical status.

Both the physical and role functioning scales were designed as hierarchial Gutman scales, i.e. the questions are ordered by increasing degree of difficulty (see Appendix 1). For both of these scales the hypothesised scale structure was: if a patient responds 'no' to a question in the scale all subsequent responses to questions in that scale should be 'no' (i.e., if a patient scores 'no' for question 2, then that patient should also score 'no' for questions, 3, 4 and 5). However, if a patient responds 'yes' to a given item, the logical response to the next question is not restricted (i.e., a patient who has trouble taking a long walk may or may not have trouble taking a short walk). In previous publications, Cronbach's alpha coefficient has been used to describe the reliability of both of these scales [11–14]. In the paper by Aaronson and associates, Cronbach's alpha coefficients were similar to those found in the current analysis [11]. However, one may question the appropriateness of using the Cronbach's alpha coefficient to test the reliability of these scales for two reasons: (1) the items are restricted to only two response categories; and (2) this method does not take into account the ordering of items. When Gutman scaling analysis was used to investigate the properties of the role functioning and physical functioning scales, both were found to be valid, unidimensional scales.

A more recent, revised version of the EORTC QLQ-C30 has employed a new role functioning scale which encompasses a broader range of activities and allows for a wider range of responses. This alternative role functioning scale yields a substantially higher reliability coefficient than that of the original scale [23], and consequently it is now incorporated in the current version of EORTC QLQ-C30 (version 2.0) [24].

An important property of a QoL questionnaire intended for use in clinical trials is that it be able to detect differences in patients' health states. Given the eligibility criteria of the three trials and the patient characteristics of the patients included in these trials, one would expect that the patients in the locoregional trial would have less pain, be in better physical condition and report a better role functioning and overall QoL than the patients in the poor prognosis prostatic cancer trial. Similarly, one would expect the same trend with respect to the poor prognosis prostatic cancer trial versus the hormone-resistant metastatic prostate cancer trial. As graphically presented in Figure 1, the comparisons of QoL domains between the three trials, which included patients who were known to differ in clinical status, yielded consistent results, i.e. statistically significant differences in functional and symptom levels, in the expected direction, were observed for all of the domains under study. These scales have also been reported to be responsive to changes over time in other cancer populations [11, 12].

In a review of the role of health care providers and significant others in evaluating the quality of life of patients with chronic disease, it was found that health care providers tend to underrate the pain intensity of their patients [25]. In our study we found that, in most cases, the physicians recognised when their patients were in pain, but in a significant minority of cases, physicians' underrated their patients' pain experience. This could partly be explained by the questions and the response categories which were available for both the patients and doctors. For example, the physicians answered the question 'Has the patient pain caused by the prostate cancer or its metastases?', whereas the patient was responding to the question 'During the last week have you had pain?' Thus, it is difficult to define what is perfect agreement between the various sources. In general, pain is difficult to quantify because of its subjectivity and because of the effects of analgesics. Recently, an EORTC Study Group on pain and symptom control has been formed in order to develop and coordinate standard methods of assessing pain and symptoms.

In this study, we did not have the opportunity to investigate the additional domains of the EORTC QLQ-C30 (e.g. other symptoms, emotional and social functioning) as these were not included in all of the three studies. However, the psychometric testing of these additional domains are also necessary to ensure that they are valid and reliable in these groups of patients. There are currently a large number of phase III trials in prostate cancer within the EORTC and in other settings, which employ the QLQ-C30 to assess the patients' health-related QoL. As these studies mature, we will be in a better position to evaluate the efficiency of the instrument in the research setting for which it was originally designed.

It may also be important that, in the design stage of future trials, the participants involved in protocol development have an idea of the distribution of QoL scores at baseline and the possible magnitude of changes over time. As we become more familiar with, and as more reference data become available for the QLQ-C30, we will be in a better position to provide input in the generation of specific research hypotheses and in calculating sample size requirements for the quality of life component of prostate cancer clinical trials.

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APPENDIX 1

Quality of Life items	No	Yes
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2
2. Do you have any trouble taking a long walk?	1	2
3. Do you have any trouble taking a short walk outside of the house?	1	2
4. Do you have to stay in a bed or a chair for most of the day?	1	2
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2
6. Are you limited in any way in doing either your work or doing household jobs?	1	2
7. Are you completely unable to work at a job or to do household jobs?	1	2

During the past week:

	Not at All	A little	Quite a Bit	Very Much
9. Have you had pain?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall *physical condition* during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

Note: number as in the EORTC QLQ-C30 (version 1.0).