

# The relationship of quality of life and distress in prostate cancer patients compared to the general population

## Der Zusammenhang von Lebensqualität und psychischer Belastung bei Prostatakrebspatienten im Vergleich zur Allgemeinbevölkerung

### Abstract

**Background:** The aim of this study is two-fold. The first part compares quality of life (QoL) data of prostate cancer patients with those of a representative and age-specific sample of the general population and analyzes the influence of cancer related as well as socio-demographic parameters on QoL. Secondly, differences in QoL depending on the experienced psychological distress will be shown both in prostate cancer patients and in the general population.

**Material and Methods:** A sample of 265 prostate cancer patients completed both the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and the Hospital Anxiety and Depression Scale (HADS) during their stay in the hospital. A total HADS cut off score of 15 was used to indicate psychological distress and significant emotional concerns in patients and men of the general population. The results of the patients were compared with those of the general population (N=444).

**Results:** Prostate cancer patients reported significantly worse levels of social and emotional functioning as well as more symptoms like insomnia, constipation and diarrhea compared to the general population. Patients and men of the general population with a total HADS score  $\geq 15$  reported lower QoL in all sub-scales except for diarrhea in comparison to people without distress.

**Discussion:** Psychological distress is accompanied by lower QoL and therefore should be taken into consideration when QoL is assessed. Furthermore, clinicians should be trained by professionals to detect distress in their patients and to pay more attention to their emotional concerns, which are strongly associated with the patients' well-being and QoL during their stay in hospital.

**Keywords:** cancer, oncology, prostate, general population, quality of life, distress

### Zusammenfassung

**Zielstellung:** Die vorliegende Studie verfolgt zwei Ziele. Zum einen werden Prostatakarzinompatienten und eine bevölkerungsrepräsentative altersspezifische Vergleichsstichprobe hinsichtlich ihrer Lebensqualität verglichen und der Einfluss von krankheitsspezifischen und soziodemographischen Variablen untersucht. Zum anderen werden Unterschiede in der Lebensqualität in Abhängigkeit von der erfahrenen psychischen Belastung sowohl bei Prostatakrebspatienten als auch in der Allgemeinbevölkerung dargestellt.

**Methodik:** Insgesamt beantworteten 265 Prostatakarzinompatienten beide Fragebögen während ihres stationären Krankenhausaufenthaltes; den European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) und die Hospital Anxiety and Depression Scale (HADS). Ein HADS-Summenwert von  $\geq 15$  Punkten wurde als Indiz einer vorliegenden psychischen Belastung in beiden

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Stichproben herangezogen. Die Ergebnisse der Patienten wurden mit denen der Allgemeinbevölkerung (N=444) verglichen.

**Ergebnisse:** Prostatakrebspatienten berichteten im Vergleich zur Allgemeinbevölkerung ein signifikant schlechteres soziales und emotionales Funktionsniveau sowie vermehrt Symptome von Schlafstörungen, Verstopfung und Durchfall. Sowohl Patienten als auch die männliche Allgemeinbevölkerung mit einem HADS-Summenwert  $\geq 15$  berichteten in allen Skalen (mit Ausnahme der Symptomskala für Durchfall) eine niedrigere Lebensqualität im Vergleich zu Menschen ohne psychische Belastung.

**Fazit:** Psychische Belastung geht mit verminderter Lebensqualität in nahezu allen Bereichen einher und sollte daher in zukünftige Untersuchungen, welche die Lebensqualität betreffen, mit einbezogen werden.

Des Weiteren sollten klinisch tätige Ärzte sowie das Pflegepersonal grundlegend befähigt werden, die psychischen Belastungen ihrer Patienten zu erkennen, um gegebenenfalls eine Vermittlung an das professionelle psychosoziale Helfersystem zu realisieren und eine umfassende medizinische Versorgung während des Krankenhausaufenthaltes zu gewährleisten.

**Schlüsselwörter:** Onkologie, Prostata, Karzinom, Lebensqualität, psychische Belastung, Allgemeinbevölkerung

## Background

Quality of life (QoL) has become an important outcome in many fields of cancer research during the last decades [1]. To the extent that an exact definition of QoL is still missing, there is a consensual agreement that QoL is seen as a multidimensional construct defined by at least three sub-domains, including physical, emotional and social aspects of well-being [2]. The necessity of the measurement and evaluation of QoL for a better understanding of the impact of the disease and respective treatment on the patients' well-being is well documented [1], [3].

Besides the meaning of medical treatment options for QoL outcome in cancer patients, in recent years the focus of attention has also turned to psycho-social predictors, e.g., anxiety, depression and distress, which influence or at least correlate with the self-assessed QoL of the patients [4], [5], [6], [7], [8], [9], [10], [11], [12], [13]. Bloch et al. [14] and Weber et al. [15] give an overview about a wide range of different studies with prostate cancer patients. The results of the referred differ remarkably, which might be due to different settings, study designs and sample sizes. The limitations of well-being, psychological adjustment and QoL in prostate cancer patients were usually reported in relation to the occurrence of cancer and treatment related side effects, where urinary, bowel and sexual dysfunction are the most frequent [15]. Stark et al. [4] brought into focus the relation between anxiety and QoL. In a sample of 178 cancer patients of both sexes and with different cancer sites, they found clinically and statistically significant differences between the groups with and without probable anxiety disorder only in two dimensions of QoL: emotional function and insomnia, whereby patients with anxiety reported worse functioning and more insomnia. The results of Tsunoda et al. [5] and Skarstein et al. [6] pointed in the same dir-

ection, but only the QoL dimension of emotional functioning had been evaluated in relation to anxiety, depression and distress measured with the Hospital Anxiety and Depression Scale (HADS). Statistically significant differences in eight sub-scales of EORTC QLQ-C30, including physical, role, emotional and social functioning as well as health perception, were found by Namiki et al. [7] in men with prostate cancer, using a distress cut off of 10 points in the HADS. Similarly, Lue et al. [8] found significant differences in the majority of all functioning and symptom scales in dependence on anxiety or depression in a homogeneous cancer-specific sample. The same tendency emerged in a population of patients with mixed cancer sites [9]. Other studies reported significant correlations between specific sub-domains of QoL and anxiety, depression or psychological distress in patients with different cancer diagnoses [10], [11], [12], [13]. The correlation coefficients varied between .28 and .75. Other studies that employed questionnaires for anxiety, depression, distress and QoL had other foci of interests and did not put the results in relationship to each other [16], [17], [18], [19]. Concerning further predictor variables, the findings are inconsistent. While some researchers found older age of patients to be a predictor of better functioning and less symptoms in several sub-domains of QoL [18], [20], others did not detect such differences [8], [11]. In the study of Lintz [18] et al., the only significant difference in QoL between cancer patients diagnosed less than one year ago and those diagnosed more than one year ago was in the symptom of fatigue, with patients diagnosed more recently reporting more fatigue.

Some researchers examined questionnaires of QoL and distress in the general population to make the results of cancer patients comparable with those of a representative sample [21], [22], [23]. Conclusively, they recommend a more detailed consideration of the results, adjusted at least for gender and age. It has been reported that several

domains of QoL in cancer patients with carcinoid tumors were negatively affected in comparison to the general population [19], [24]. Role function, fatigue and diarrhea are the sub-scales that were affected consistently in both studies. Another study yielded differences in more sub-domains of QoL, but only in a descriptive way, leaving reliability and validity of the results vague [20]. In summary, findings about the relationship between psychological distress and QoL on the one hand and the comparison of the results with a representative sample on the other hand point in the same direction while remaining inconsistent. Thus, a systematic examination of these relations is required. Furthermore, many studies included only small groups of patients [8], [12], [17], [19], [24], so the generalizability of the results is limited. Therefore the question is, to what extent is the relation between QoL and psychological distress a cancer specific phenomenon or rather a general relationship among human beings?

The aim of this study is two-fold. The first part compares EORTC QLQ-C30 data in a large and homogeneous group of prostate cancer patients with the general population and analyzes the influence of cancer related as well as socio-demographic parameters. Secondly, differences in QoL in dependence on the experienced psychological distress will be shown both in prostate cancer patients and in the general population.

## Material and methods

### Study design

Between July 2007 and September 2008, 340 prostate cancer inpatients were eligible for this study in the University Hospital Leipzig – Department of Urology (Germany). Patients were invited to participate in this study and to answer the questionnaires if they had histologically proven carcinoma, were able to understand and read German well enough to answer the questionnaires, were at least 18 years old and had given informed consent.

### Questionnaires

Beside the socio-demographic and cancer related parameters, the core questionnaires used were the cancer-specific EORTC QLQ-C30 and the HADS. These questionnaires have been validated both in the general population [21], [22], [23], [25] and in cancer populations [26], [27]. The EORTC QLQ-C30 was designed for quality of life evaluation in cancer patients [26]. It consists of 30 items and incorporates five functioning scales (physical, role, emotional, social and cognitive), three symptom scales (fatigue, pain and nausea/vomiting), a global health status/QoL scale and six single items (dyspnoea, appetite loss, insomnia, constipation, diarrhea and financial difficulties). The scoring of the EORTC QLQ-C30 was performed according to the EORTC scoring manual [28]. All scores were linearly transformed into a 0–100 scale.

Higher functioning scores represent better functioning/QoL, whereas higher symptom scores represent more severe symptoms. In case of missing items, the value was replaced with the rounded mean of the remaining items of the corresponding sub-scale when at least half the items of the scale were answered. In addition to the different functioning scales, a general functioning score was calculated by the mean of all functioning scales. Corresponding to that, a general symptom score was calculated too. According to Osoba [1], differences of 5–10 points are considered to be clinically meaningful, indicating a small change, whereas differences of 10–20 points indicate a moderate change.

The Hospital Anxiety and Depression Scale (HADS) [29] is one of the most commonly used instruments worldwide for screening clinically significant anxiety, depression and distress in patients with somatic illness. The self-administered scale consists of two sub-scales, anxiety and depression, with seven items each which are rated on a four-point Likert scale. The scores of each sub-scale range from 0 to 21. It has been shown that a total score  $\geq 15$  is indicative of clinically significant distress [25], [30], [31], [32].

### External comparison with reference data

To compare the results of the study population with the German general population, the age- and gender-matched EORTC QLQ-C30 data published by Schwarz and Hinz [23] as well as the age- and gender-matched HADS data published by Hinz and Schwarz [25] were used. From the original samples of the representative surveys (N=889 [23], N=895 [25]), which were obtained using the random-route-technique, a partial sample (N=444) was selected in such a way that the mean age (63.76 years, SD=7.9, range 51–90) corresponds to that of the study population (63.82 years, SD=6.4, range 50–79). In addition, only complete data sets of both of these questionnaires were taken into further consideration. Furthermore, both populations and their EORTC QLQ-C30 results were split into two groups depending on the HADS sum score cut off ( $< 15$  or  $\geq 15$ ).

### Statistical methods

The statistical analysis of the data was conducted with the SPSS 15.0 software.

Mean scores as descriptive measures were used to enable comparisons between prostate cancer patients and the German general population. To examine differences for statistical significance, the t-test was used. To reduce the risk of spurious significant associations in multiple comparisons, we adjusted the level of significance according to Bonferroni. Referring to the 15 sub-scales of the EORTC QLQ-C30, the adjusted p-value for statistical significance was set to  $0.05/15=0.003$ . Additionally, an analysis of variances with two factors was employed to provide information on the independent associations of prostate cancer status and distress with quality of life.

**Table 1: Socio-demographic and cancer-related characteristics of the study population**

	Respondents (N=265)		Non-respondents (N=75)		Total (N=340)	
<b>Socio-demographic variables</b>						
<i>Age (years)</i>						
≤65	137	(51.7%)	29	(38.7%)	166	(48.8%)
>65	128	(48.3%)	46	(61.3%)	174	(51.2%)
Mean (SD)	63.8	(6.4)	65.7	(6.7)	64.3	(6.5)
<i>Living with partner</i>						
Yes	242	(91.3%)				
No	18	(6.8%)				
Missing	5	(1.9%)				
<i>Education</i>						
8 years	52	(19.6%)				
10 years	59	(22.3%)				
12 years	139	(52.4%)				
Missing	15	(5.7%)				
<b>Clinical variables</b>						
<i>Tumor stage</i>						
I	0	(0.0%)	1	(1.3%)	1	(0.3%)
II	195	(73.6%)	51	(68.0%)	246	(72.4%)
III	50	(18.9%)	12	(16.0%)	62	(18.2%)
IV	19	(7.1%)	11	(14.7%)	30	(8.8%)
Missing	1	(0.4%)	0	(0.0%)	1	(0.3%)
<i>Therapy</i>						
Surgery	251	(94.7%)				
Radiation Therapy	4	(1.5%)				
Chemotherapy	5	(1.9%)				
Hormone Therapy	19	(7.2%)				
<i>Time since diagnosis (days)</i>						
Mean (SD)	64.7	(49.5)				
Median		52				
Range		13–455				
Missing		3 (1.1%)				

For this procedure the same algorithm of Bonferroni correction was used. Only patients with complete data sets of both of these questionnaires were included in the statistical procedure.

## Results

### Patients

Finally, 265 (77.9%) out of 340 eligible inpatients took part in this study. The group of non-respondents consisted of 36 patients (10.6%) refusing to take part; 9 patients (2.7%) refused to take part because they felt too much distress and 30 patients (8.8%) had too many missing values (more than half the items of a scale) in at least one of the questionnaires. The group of non-respondents was on average two years older and included more patients with tumor stage IV compared to the participants of the study. Further socio-demographic and oncological characteristics of participants and non-respondents are summarized in Table 1.

### Quality of life of patients compared to the general population

Data show significantly diminished values in the domains of emotional and social functioning in the range of 13–15 points for the prostate cancer patients compared to the general population. Results are shown in Table 2.

Regarding the level of experienced symptoms, prostate cancer patients reported more insomnia, constipation and diarrhea as well as financial difficulties. Differences range from 5 to 7 points. There is an inverse difference in pain, where prostate cancer patients reported significantly less pain with a discrepancy of 5 points.

**Table 2: EORTC results compared to the general population and dependent on age, tumor stage, education and time since diagnosis (standard deviations in parentheses)**

EORTC-subscores	Sample		Age		Tumor Stage		Education		Time since diagnosis		p
	Gen. Pop.	Patients	≤65 y.	>65 y.	I	II+IV	≤10 y.	>10 y.	≤2 months	>2 months	
N (%)	444 (100)	265 (100)	137 (51.7)	128 (48.3)	195 (73.6)	69 (26.0)	111 (41.9)	139 (52.5)	161 (60.8)	103 (38.9)	
Physical functioning	86.7 (19.4)	87.5 (20.0)	86.5 (22.0)	88.6 (17.8)	88.1 (19.4)	85.6 (21.8)	86.4 (19.5)	89.7 (19.1)	86.5 (21.4)	89.2 (17.9)	n.s.
Role functioning	84.7 (26.0)	80.6 (33.1)	81.3 (32.6)	79.9 (33.7)	79.9 (33.2)	82.4 (32.9)	84.1 (28.9)	80.8 (35.4)	77.1 (35.4)	86.9 (27.3)	n.s.
Emotional functioning	80.4 (19.2)	65.3 (25.3)	65.0 (26.4)	65.6 (24.2)	66.7 (25.3)	61.0 (25.3)	64.8 (25.4)	66.5 (25.3)	62.9 (26.8)	69.1 (22.5)	n.s.
Cognitive functioning	89.1 (17.9)	84.8 (20.4)	85.4 (22.2)	84.1 (18.5)	84.8 (20.2)	84.5 (21.3)	86.8 (20.2)	83.6 (20.0)	82.4 (22.3)	88.7 (16.5)	n.s.
Social functioning	87.6 (22.0)	74.2 (30.2)	75.2 (29.4)	73.2 (31.2)	73.4 (30.8)	76.1 (28.8)	76.1 (28.7)	73.4 (31.1)	73.5 (31.4)	76.1 (27.5)	n.s.
Global health/QoL	66.5 (22.2)	63.5 (24.3)	64.7 (24.3)	62.2 (24.4)	63.6 (24.9)	62.8 (22.9)	61.2 (24.8)	66.5 (23.4)	61.3 (24.5)	67.0 (23.9)	n.s.
Fatigue	19.4 (23.6)	20.3 (24.9)	19.4 (25.3)	21.4 (24.5)	20.8 (25.6)	19.2 (22.9)	19.7 (24.2)	20.1 (25.2)	21.9 (27.1)	17.6 (20.8)	n.s.
Pain	20.3 (27.4)	15.3 (26.4)	14.6 (26.3)	16.1 (26.5)	15.8 (26.1)	14.3 (27.3)	15.8 (27.0)	14.0 (25.6)	18.1 (28.0)	10.7 (22.8)	n.s.
Nausea/Vomiting	2.1 (8.2)	2.5 (8.9)	2.3 (8.9)	2.6 (9.0)	2.6 (9.4)	1.9 (7.3)	2.3 (8.6)	2.6 (9.5)	2.9 (9.4)	1.8 (8.1)	n.s.
Dyspnea	12.0 (23.6)	10.1 (19.7)	10.9 (21.0)	9.1 (18.1)	9.7 (19.5)	11.1 (20.3)	10.8 (20.7)	9.4 (18.4)	10.6 (20.6)	9.1 (18.2)	n.s.
Appetite loss	5.5 (15.6)	7.7 (20.6)	9.7 (24.6)	5.5 (15.0)	8.0 (21.1)	6.8 (19.5)	8.1 (23.0)	7.0 (18.2)	8.3 (21.7)	6.8 (18.9)	n.s.
Insomnia	19.0 (28.5)	26.0 (32.9)	25.1 (33.0)	27.1 (32.9)	26.0 (32.6)	26.6 (34.1)	25.5 (34.5)	26.9 (31.8)	28.0 (33.9)	23.0 (31.3)	n.s.
Constipation	4.4 (15.6)	9.1 (21.8)	7.3 (20.1)	10.9 (23.3)	10.4 (22.9)	5.3 (17.7)	7.5 (19.4)	7.2 (18.3)	9.9 (23.2)	7.8 (19.4)	n.s.
Diarrhea	2.7 (10.4)	9.7 (21.8)	9.7 (21.8)	9.6 (21.8)	9.9 (23.0)	9.2 (18.0)	9.6 (21.3)	9.4 (22.0)	10.1 (22.1)	9.1 (21.5)	n.s.
Financial difficulties	8.5 (21.7)	14.6 (25.7)	20.0 (30.1)	8.9 (18.5)	15.2 (25.8)	13.0 (25.7)	20.7 (31.2)	8.6 (18.1)	11.6 (22.1)	19.4 (30.1)	n.s.

p: Bonferroni corrected significance level; \* p<0.05; \*\* p<0.01; n.s. = non significant

## Predictors of QoL in prostate cancer patients

### Age

The study population was divided into two age groups by the cut off of the approximate median, which was 65 years. Table 2 presents mean scores for both age groups. The only significant difference emerged in the domain of financial difficulties, with a discrepancy of 11 points, with more financial concerns for the patients ≤65 years old.

### Tumor stage

Four tumor stages were defined on the basis of the TNM classification system [33], using the complete information of Tumor size, Nodes and Metastases in this categorization. Each group within the same tumor stage is as homogeneous as possible concerning the survival rate. In the group of the study population there was no patient with tumor stage I, and the number of patients with tumor stage III and IV was very small in comparison to stage II. Therefore, tumor stages III and IV were classified into one group and compared to stage II. No statistically significant differences were found between the groups of different tumor stages in all scales of the EORTC QLQ-C30.

### Education

Two subgroups were constituted based on years of education, specifically 10 years or less and more than 10 years. No statistically significant differences were found in the sub-scales except financial difficulties. Patients with an education time of 10 years or less scored on average 12 points higher than patients with more than 10 years of education (Table 2).

### Time since diagnosis

The study group was split into two groups. One group of patients was informed about the diagnosis up to two months prior. The other group was informed more than two months prior. No significant differences emerged in the sub-scales.

## Differences in QoL depending on experienced psychological distress

Mean HADS values were 9.8 (SD 7.1) for prostate cancer patients and 10.3 (SD 6.5) for the general population. The t-test revealed no significant difference (T=-1.05, p=.29). A HADS cut off score of 15 was chosen to select patients and men in the representative sample with clinically significant distress. A total of 56 patients (21.1%) and 108 men of the general population (24.3%) had a HADS score ≥15. Differences in the distribution of HADS cases versus non-cases in both samples were examined with a  $\chi^2$ -test and revealed no significance ( $\chi^2$ =.93, p=.34).

**Table 3: EORTC means of different subgroups and analysis of variances with two independent factors**

EORTC	Patients		Gen.Pop.		Main effect Sample		Main effect Distress		Interaction Sample X Distress	
	HADS <15	HADS ≥15	HADS <15	HADS ≥15	F	p	F	p	F	p
Physical functioning	89.2 (18.6)	81.7 (23.6)	90.8 (15.3)	74.1 (24.7)	3.011	n.s.	<b>47.683</b>	**	6.795	n.s.
Role functioning	85.9 (28.3)	63.0 (41.4)	90.3 (20.5)	67.4 (32.8)	2.967	n.s.	<b>81.072</b>	**	.000	n.s.
Emotional functioning	72.0 (21.2)	40.6 (24.6)	85.6 (15.1)	64.4 (21.6)	<b>110.053</b>	**	<b>219.352</b>	**	8.209	n.s.
Cognitive functioning	89.8 (15.4)	66.7 (25.5)	92.7 (14.0)	77.9 (23.4)	<b>18.910</b>	**	<b>136.860</b>	**	6.795	n.s.
Social functioning	80.6 (26.5)	52.7 (31.9)	93.3 (14.8)	69.8 (29.9)	<b>47.871</b>	**	<b>142.756</b>	**	.995	n.s.
Global health/QoL	69.3 (22.0)	44.4 (20.4)	72.6 (19.0)	47.5 (20.8)	2.897	n.s.	<b>171.817</b>	**	.003	n.s.
Fatigue	15.2 (20.9)	38.6 (29.8)	14.5 (19.9)	34.6 (27.4)	1.239	n.s.	<b>107.015</b>	**	.639	n.s.
Pain	11.5 (22.9)	28.5 (33.1)	13.4 (20.5)	42.0 (34.3)	<b>10.901</b>	*	<b>95.345</b>	**	6.128	n.s.
Nausea/ Vomiting	1.3 (6.7)	7.0 (13.9)	1.1 (4.9)	5.2 (13.8)	1.550	n.s.	<b>40.069</b>	**	.951	n.s.
Dyspnea	8.3 (17.8)	16.4 (24.7)	9.0 (20.8)	21.3 (29.0)	1.916	n.s.	<b>24.669</b>	**	1.051	n.s.
Appetite loss	3.6 (12.7)	21.8 (33.5)	3.2 (12.5)	12.7 (21.2)	<b>9.363</b>	*	<b>78.619</b>	**	7.853	n.s.
Insomnia	19.8 (28.1)	48.5 (38.4)	14.1 (24.6)	34.3 (33.9)	<b>13.967</b>	**	<b>83.424</b>	**	2.514	n.s.
Constipation	7.5 (21.1)	13.9 (22.9)	2.9 (12.9)	9.3 (21.3)	7.644	n.s.	<b>14.629</b>	**	.001	n.s.
Diarrhea	7.5 (18.9)	17.6 (29.3)	2.4 (9.7)	3.7 (12.3)	<b>42.729</b>	**	<b>15.481</b>	**	<b>9.139</b>	*
Financial difficulties	11.7 (23.4)	23.6 (31.2)	3.8 (14.1)	23.1 (32.4)	4.105	n.s.	<b>56.678</b>	**	3.209	n.s.

p: Bonferroni corrected significance level; \* p<0.05; \*\* p<0.01; n.s.= non significant

To provide information on the independent associations of prostate cancer status and distress with the different quality of life domains of the EORTC, ANOVAs with two factors were conducted. QoL was compared between the corresponding subgroups with and without experienced distress. Results are shown in Table 3.

The distress factor had the strongest main effect on all EORTC sub-scales. Men of both samples with a HADS score  $\geq 15$  showed decreased levels of functioning and Global health/QoL and increased symptom scores in all domains except for diarrhea. These differences were clinically meaningful in most sub-scales. The main effect of the second factor (patients versus general population) was significant in three functioning and four symptom scales. Patients reported lower functioning and more symptoms except for the pain scale. The impact of the interaction term (sample X distress) is significant only for the diarrhea sub-scale. Compared with the main effects on the level of diarrhea, this interaction effect is quite small.

Means of cumulated functioning and symptom scores depending on HADS category and sample are presented in Figure 1 and Figure 2.

Parallel lines indicate that there is no interaction between sample and distress concerning functioning and symptom scales. However, the main effects of the single factors are evident. Differences between distressed and non-distressed persons are greater (functioning score: crude difference=diff=20-23; symptom score: diff=14) than between prostate cancer patients and the general population (functioning score: diff=7-10; symptom score: diff=2-3).

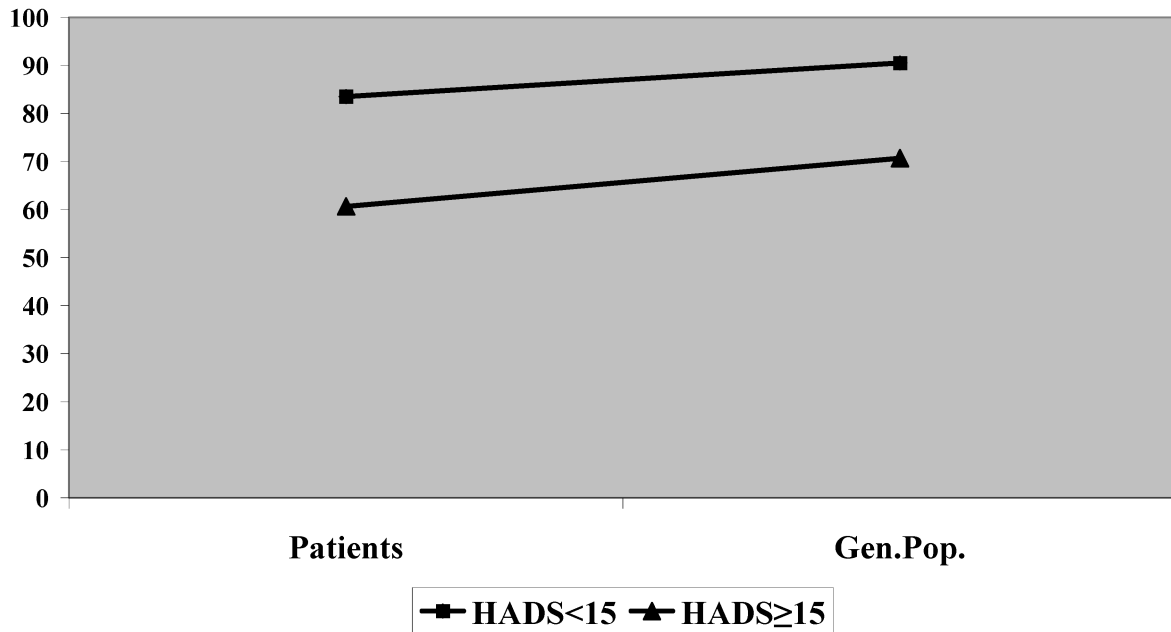
## Discussion

To our knowledge, this is the first study that compares QoL of a large homogeneous sample of prostate cancer patients with the general population in relation to the psychological distress experienced in both groups. The aim of this study was two-fold. Firstly, our results indicate that there is a substantial decrease in several aspects of

QoL of prostate cancer patients compared to the general population. This concerns the domains of emotional and social functioning as well as symptoms like insomnia, diarrhea and constipation – and financial difficulties, if only mean values are considered. These results differ from those of Frojd et al. [19] and Larsson et al. [24], regarding the specific sub-scales that are affected. Nevertheless we confirm a general decline in QoL. Secondly, if we take into account the influence of psychological distress, a more sophisticated overall picture emerges. In general, prostate cancer patients did not report higher levels of psychological distress compared to the general population. This is in line with other studies and possibly due to a less invasive treatment and a relative good prognosis [34], [35]. In this study, we provide evidence that the experienced psychological distress is strongly associated with the self-rated QoL. Prostate cancer patients and men of the general population that are distressed reported worse functioning and more severe symptoms than both groups without distress. This regards all sub-scales of the EORTC QLQ-C30 except for diarrhea. The differences between these groups increase to more than 20 points in the different sub-scales, e.g. the Global health/QoL, role functioning, fatigue and insomnia, whereby especially the enhanced level of insomnia might reflect individual psycho-social concerns. In general, the findings of our study provide support for previous results [4], [5], [6], [8], [9]. Furthermore, there are greater differences between patients and the general population in the group of distressed men. Namiki et al. [7] found restrictions in more sub-domains of QoL of prostate cancer patients. This might be due to the lower distress cut off they used.

In summary, the analysis of variances with two dichotomous factors, namely the sample group (patients versus general population) and the distress group (yes versus no), leads to the following conclusion. Self-rated QoL is to a greater extent associated with the experienced distress and to a lesser extent associated with the existence of a prostate cancer diagnosis. Thus, the reported significant associations in the literature between psychological distress and QoL [4], [5], [6], [7], [8], [9], [10],

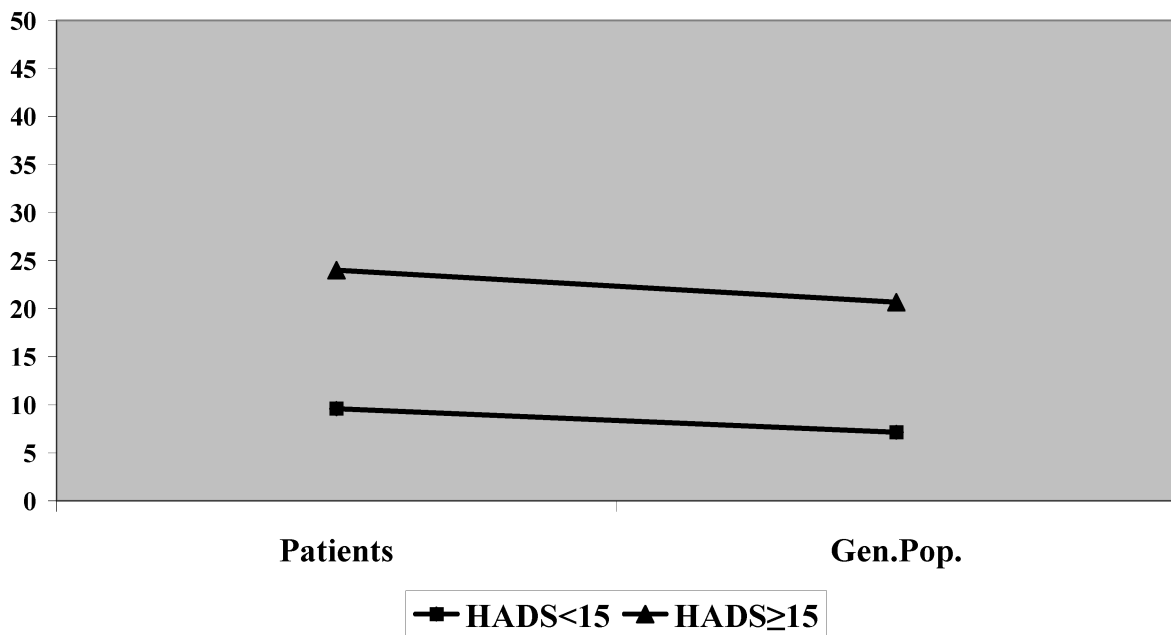
**Functioning score**



HADS <15: patients M=83.52 (SD=15.3); general population M=90.52 (SD=11.6)  
 HADS ≥15: patients M=60.95 (SD=22.5); general population M=70.71 (SD=20.2)

Figure 1: Means of functioning scores depending on HADS score and sample

**Symptom score**



HADS <15: patients M=9.59 (SD=11.6); general population M=7.15 (SD=9.8)  
 HADS ≥15: patients M=24.0 (SD=18.9); general population M=20.68 (SD=15.8)

Figure 2: Means of symptom scores depending on HADS score and sample

[11], [12], [13] in different cancer population are in line with the results of this study. However, these associations are not specific for cancer patients. In the general population the associations are similar. This might be due to a partial overlapping of the constructs measured in this study. Furthermore, due to the cross-sectional study design, we cannot constitute conclusive evidence whether distress causes lower QoL or vice versa. Nevertheless, some domains of QoL in prostate cancer patients are negatively affected compared to the general population.

Contrary to that, prostate cancer patients who are distressed reported substantially less pain than the corresponding sample of the general population. The reason for that remains vague. On the one hand prostate cancer in the first stages is not very painful. On the other hand we have to act on the assumption that patients were under appropriate pain medication. But why this difference emerges only in the group of the distressed is not clear.

Among the potential predictors of QoL, the results of this study indicate that neither education and age nor the tumor stage predict QoL, with the exception of financial difficulties. Cancer patients in general are faced with a higher risk for financial difficulties than the general population, especially later in the course of the treatment, when they are younger than 65 and had less than 10 years of education. This is probably due to the higher socio-economic status of the better educated people and to the discontinuation of their salary during the acute phase of cancer and treatment in the group of active population. These findings on the predictors support the results of Lue et al. [8] and Bang et al. [11].

The main limitation of this study is its cross-sectional design. A longitudinal design might be better suited to explore indications of causal relationships and would help to display changes of distress and QoL over time. In addition, the Bonferroni correction of the  $\alpha$ -level for multiple comparisons among the potential predictors of QoL is very conservative and might have caused spuriously non-significant results. Thus, it is possible that some of the mean differences really exist but did not reach the level of significance. Another limitation refers to the generalizability of the study results. The sample mostly consisted of patients that have had surgery as the main intervention. On the one hand this reflects a homogeneous sub-group of prostate cancer patients. On the other hand the sample is not representative of all prostate cancer patients. Further studies could also include the prostate-specific module of the EORTC questionnaire to obtain more detailed results.

In summary, we have to state that QoL in prostate cancer patients is associated to a greater extent with the experienced distress and emotional concerns and to a lesser extent by the physical impairment from the cancer itself. The results support this perspective, because prostate cancer patients without distress have better functioning scores and lower symptom levels than men of the general population with distress except for the scores in

the diarrhea scale. Thus, the well documented relationship of distress and QoL [4], [5], [6], [7], [8], [9], [10], [11], [12], [13] is not only cancer-specific, but also valid for the general population, and should therefore be taken into account when QoL in general is considered.

In the future, clinicians should be trained by professionals to detect distress in their patients and to pay more attention to their emotional concerns, which are closely connected with the patients' well-being and QoL during their stay in hospital. The realization of screening tests, followed by offers of psycho-social consultations in the case of positive results, an adequate preparation for the treatment and a trustful relationship between patients and the medical staff can help reduce the distress of patients. Further studies including psychological parameters in the research of QoL are required.

## Notes

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## Conflicts of Interest

None declared.

## Ethical standard

This study has been approved by the appropriate ethics committee of the University of Leipzig and has therefore been executed in accordance with the ethical standards.

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