Changes in the Health-Related Quality of Life of Patients with Prostate Cancer and Their Spouses

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Absract:

The purpose of this study was to determine how the health-related quality of life (HRQoL) of patients with prostate cancer and their spouses change during the 6 months after diagnosis and which factors explain the changes. Patients with prostate cancer and their spouses have reported a decrease in HRQoL, but simultaneous follow-up of the HRQoL of patients with prostate cancer and their spouses is rare. The sample consisted of 186 couples. The participants personally filled in the RAND-36-Item Health Survey, both at the time of diagnosis and 6 months later. Changes in the HRQoL were analysed statistically using descriptive statistics and non-parametric tests. Linear regression models were used to identify the factors associated with the changes in HRQoL in the patients and their spouses. The HRQoL of patients with prostate cancer and their spouses did not change significantly during the first 6 months after diagnosis. Changes in the patients' bodily pain and physical functioning were explained by their background variables. The spouses' background variables did not explain the changes in HRQoL during the follow-up period. In addition, the changes in the HRQoL of patients and their spouses are very similar. There is a need for long-term assessment of changes in the HRQoL of patients with prostate cancer and their spouses. The findings indicate that attention should be paid to spouses with regard to the nursing of patients with prostate cancer, as spouses seem to be an important resource for patients with prostate cancer.

Background for the study

The incidence of prostate cancer has been rapidly increasing in parts of the developing world, and it is currently the most common non-cutaneous cancer in men (Torre et al. 2015). The causative factors of prostate cancer remain unclear (Ferlay et al. 2015). The known risk factors are age, race and familial predisposition (Crawford 2009). Annually, over 4700 Finnish men are diagnosed with prostate cancer, 80% of whom live with their spouses (Lehto et al. 2015, Engholm et al. 2015). Several treatment options are available for prostate cancer, and the treatment decisions are made jointly by the physician and the patient during treatment visits (Heidenreich et al. 2011). Each treatment option might be associated with persistent or transient side effects such as hormonal, sexual, urinary and bowel symptoms; emotional distress and general symptoms; fatigue, pain and sleep disturbance (Heidenreich et al. 2011). These side effects have been shown to decrease the quality of life (QoL) of patients and also negatively affect the QoL of their spouses (Song et al. 2015, Song et al. 2011).

Health-related of quality of life (HRQoL) can be defined in many ways, and it is composed of physical, psychological, social and emotional functional domains. It is also considered to be a person's subjective and individual assessment of his or her situation. In addition, individual values and cultural context also affect HRQoL (Albaugh and Hacker 2008, Ferrans et al. 2005, Ware and Sherbourne 1992). Several studies have established that cancer and its treatment can have a significant effect on the QoL of both people with cancer and their family members (Hawkins et al. 2009, Hodges et al. 2005, Resnick et al. 2013, Kornblith et al. 1994). In particular, the distress level of male patients is most closely associated with that of their female carers (Hodges et al. 2005). Moreover, research has shown that spouses' beliefs about their partner's illness influence the beliefs related to QOL in patients with prostate cancer (Wu et al. 2013).

The QoL of patients with prostate cancer has been studied from the perspective of treatment methods in the long term. Three to four years after radical prostatectomy or radical external beam radiation therapy, affected men found that their QoL had decreased, particularly in the sexual domain, according to measurements with a disease-specific instrument; however, no differences were found between the treatment methods, according to the measurements of a general instrument (Nicolaisen et al. 2014). In another study, over a four-year follow-up period, the patients who were in the watchful waiting group reported lower QoL than those who underwent conventional or low-dose mixed-beam radiation treatment (Galbraith et al. 2005). However, three of the eight QoL dimensions—physical functioning, vitality and general health—significantly declined during the follow-up period (Galbraith et al. 2005). Watchful waiting is a prostate cancer management option for older men with well-differentiated low-volume prostate cancer and a life expectancy of less than 10 years (Wallace et al. 2004). Although there are studies on the HRQoL of patients with prostate cancer, the HRQoL of the spouses of these patients has not received much attention in studies. In one such study, Harden et al. (2013) have reported that younger (<65 years) spouses had lower QoL than older spouses two years after prostate cancer treatment.

Changes in QoL have been reported over short follow-up periods too. For example, in one study, six months after prostate cancer treatment, no significant differences were observed in the eight dimensions of QoL between patients who had undergone surgery and brachytherapy (Hashine et al. 2009). Further, patients with prostate cancer who were treated with hormonal treatment and radiation therapy reported that their physical function significantly decreased at six months (Paterson et al. 2015). However, there were no significant changes in the other dimensions of QoL (Paterson et al. 2015). Similar results have been reported by Ward-Smith and Kapitan (2005) in patients with prostate cancer who underwent external beam radiation therapy. However, the negative changes in the social dimension of QoL appeared within three months after treatment

(War-Smith and Kapitan 2005.) Previous studies have shown associations between QoL and background variables. For example, in a longitudinal, randomized clinical trial study, better QOL was associated with lower education level of the patients, older age of their partners, higher family income and localized cancer at the baseline (Song et al. 2011). Further, the QoL of patients and their partners was moderately correlated with each other (Song et al. 2011).

Although there is much information about HRQoL in patients with prostate cancer, little is known about their spouses' perspectives on HRQoL. Simultaneous follow-up of patients and their spouses is worthy of investigation, as this information will help identify the needs of patients and their spouses and develop evidence-based interventions for patients with prostate cancer and their spouses.

Research questions

The aim of this study was to monitor changes in HRQoL and identify the associated factors in patients with prostate cancer and their spouses. The following research questions were set:

1. How does the HRQoL of patients with prostate cancer and their spouses change during the six months after diagnosis of prostate cancer?

2. Which factors are associated with changes in the HRQoL of patients with prostate cancer and their spouses during the six-month follow-up period?

Sample

Study Design and Participants

The data for this longitudinal study were collected using questionnaires administered to patients with prostate cancer (N= 350) and their spouses (N= 350) at the time of diagnosis and the six–month period that followed. At the time of diagnosis, all patients were aware of the prostate cancer, but the treatment did not have an effect on their HRQoL. At the timepoint of six months, the invasive treatments were finished in all patients and the recovery time had begun. The selection of timepoints is also supported by previous literature (Street et al 2010, Paterson et al 2015). The data were analyzed using a paired-samples *t*-test, based on the assumption that a ten-point change in HRQoL is clinically significant (Osoba et al. 2005). Based on the sample calculation method recommended by Osoba et al. (2005) to achieve a power of 0.8 with a standard deviation of 20 and an alpha value of 0.05, a total of 33 participants are required. Thus, the target number of participants for this study was 33. Because there was more than one point of measurement, at least four types of treatment and five different hospitals, the questionnaire was distributed to 350 couples. The original power calculation was performed as described above. In practice, it was found that the changes were smaller than expected, so the original plan of analyzing hospitals separately was rejected. The local ethics committee approved of the study design. Permission for conducting the study was obtained from the directors of the five participating hospitals. All participants were informed of the purpose of the study, the longitudinal research design and the principle of voluntary, anonymous participation.

The data for the first stage were collected between October 2013 and January 2016 at the outpatient urology clinics of five Finnish central hospitals. The nurses asked patients with prostate cancer who wished to participate for their written informed consent during their treatment visits. The study included (1) patients diagnosed with prostate cancer who were at the pre-treatment stage, (2)

patients who described their relationship with their spouse as being permanent, and (3) patients who provided their written informed consent and additional contact information for their spouses. All treatment modalities were included in the study. Each patient was asked to provide the name of their spouse. If a patient agreed to participate in the study, he was given a letter containing the required information with the questionnaire and an envelope addressed to himself and his spouse. The questionnaires were returned by 232 patients and 229 spouses. No follow-up reminder was sent to the participants out of respect for their autonomy. In the second stage, questionnaires were sent to patients or spouses who had answered the questionnaires in the first stage and were willing to continue with the study. The data for the second stage were collected between April 2014 and July 2016 from patients (n = 199) and their spouses (n = 195). Only the data of couples (n = 186) who participated in the study at both measuring points were included in the analysis. The study samples are presented in Table 1.

Data collection methods

Data related to the patients' and their spouses' HRQoL were collected with the help of identical questionnaires. The general HRQoL instrument was chosen to measure HRQoL so that it was easy to compare the HRQoL of patients and their spouses. The RAND 36-item health survey (RAND-36) was used to measure HRQoL based on eight separate dimensions: physical functioning, role functioning/physical, role functioning/emotional, energy, emotional well-being, social functioning, bodily pain and general health (Aalto et al. 1999, Ware and Sherbourne 1992). The Finnish version of RAND-36 (Aalto et al. 1999) contains exactly the same questions as MOS SF-36 (Ware and Sherbourne 1992) but the scoring system for bodily pain and the general health scales differs slightly (Aalto et al. 1999). The items were scored on a 2- to 6-point Likert-type scales. Each dimension of HRQoL is separately scored from 0 to 100, where a higher score indicates a better HRQoL. MOS SF-36 is an internationally known, validated and used instrument for measuring HRQoL in prostate cancer patients (Dieperink et al. 2012, Treiyer et al. 2011) and their spouses (Harden et al. 2013). The reliability and construct validity of RAND-36 as a measure of HRQoL in the Finnish general population (Aalto et al. 1999) and Finnish patients with prostate cancer and their spouses have been found to be good (Vasarainen et al. 2013, Authors 2017).

The demographic background characteristics include self-reported age, duration of marital relationship, basic and vocational education, employment status and chronic diseases. In addition to these questions, the patients were asked about the hospital where the cancer was treated and the treatment methods for prostate cancer. The treatment methods were divided into four groups: surgery (all forms of radical prostatectomy), radiation therapy (brachytherapy and external beam radiation), hormonal treatment and non-invasive care (active and passive follow-up care).

Data analysis

Data were described using frequencies, percentages, means and standard deviations. The RAND-36 items were scored in accordance with the manual (Aalto et al. 1999). The resulting subscale scores were on a 0–100 scale, with higher values representing a better HRQoL. Differences between patients and their spouses with regard to changes in HRQoL were analyzed using the Wilcoxon signed-rank test because the distribution was skewed. A ten-point change was considered to be clinically significant on the RAND-36 scale (Aalto et al. 1999, Osoba et al. 2005) The patients and their spouses were divided into three groups: those in whom the HRQoL increased by ten or more points, those in whom the HRQoL decreased by ten points or more, and those in whom the HRQoL did not change. Cross-tabulations with the χ^2 test and ANOVA were used for testing dependencies between grouped HRQoL and background variables. Linear regression models were used to identify the factors associated with the changes in HRQoL in the patients and their spouses (Munro 2005). The residuals were examined and considered to be normally distributed (Munro 2005). Models were created separately for the patients and their spouses. The IBM SPSS statistics version 23 (IBM Corp., Armonk, NY, USA) was used to analyze the data. The level of statistical significance was set at $P < 0.05$.

Results

Demographic characteristics of the sample

Table 2 describes the demographic characteristics of patients with prostate cancer and their spouses six months after diagnosis. The mean age of the patients was 68 years (±8.1). The spouses were on average 3 years younger (65 ± 8.4 years). The respondents' marital relationship had been ongoing for an average of 36 years (±15.4, range: 1–60 years). Two-thirds of the patients and nearly half of the spouses had finished elementary school or civic school. More than one-third of the patients and their spouses had initial vocational qualifications. More than two-thirds of the respondents were not employed. Chronic disease, such as cardiovascular diseases, diabetes, chronic lung diseases and musculoskeletal disorders, was reported by 70% of the 186 patients and 66% of the 186 spouses. More than one-third of the patients had undergone surgical treatment for their prostate cancer; less than a third had undergone radiation therapy; less than a fourth had undergone non-invasive care; and 13% had undergone hormonal treatment during the follow-up period.

Changes in HRQoL in the patients and their spouses within six months

The mean HRQoL scores at the time of diagnosis and six months after diagnosis are presented in Table 3. On average, the HRQoL of the patients with prostate cancer and their spouses did not change significantly over the six-month study period. The data for participants for whom the HRQoL changed by ten points or more on the RAND-36 scale have also been described in Table 3. More than one-fifth of the patients and their spouses reported at least a ten-point increase or decrease during the six-month study period. The changes were very similar in patients and their spouses. Statistically significant differences were not observed between the groups.

Factors associated with changes in HRQoL in the patients and their spouses

Patients' age, basic education, vocational qualifications, employment status, chronic diseases and treatment method for prostate cancer explained 13.1% of the variance in bodily pain (Table 4.). The background variables did not significantly explain the variance in the other dimensions of the patients' HRQoL. Six months after prostate cancer diagnosis, basic education explained 4% of the variance in physical functioning. The patients who had higher basic education presented with a greater change in physical functioning (Table 4). Only the statistically significant results have been reported in Table 4.

Six months after prostate cancer was diagnosed, the background variables of the spouses did not significantly explain the variance of the dimensions of the spouses' HRQoL. The spouses' background variables did not explain the changes in the patients' HRQoL in a statistically significantly way, and vice versa (data are not shown in a table).

Conclusions, implications for practice

This study examined changes in the HRQoL of patients with prostate cancer and their spouses at the time of diagnosis and six months later. The study also identified the factors associated with changes in the HRQoL of participants. Our main finding was that the HRQoL of patients with prostate cancer and their spouses did not change significantly during the follow-up period. Nonetheless, the changes observed in the HRQoL of the patients were explained by their background variables.

A surprising discovery in this study was that that the changes in the HRQoL of patients and their spouses six months after prostate cancer diagnosis were on average minor. One of the reasons may be that the HRQoL of the patients and their spouses at the time of diagnosis was already high. On the other hand, one could assume that the side effects of treatments, such as surgery and radiation therapy, would show up at six months after diagnosis. In addition, the instrument used may have had some effect on the results of HRQoL. QoL is generally measured using both disease-specific instruments and generic instruments. A study by Paterson et al (2015) found that the HRQoL of patients with prostate cancer significantly decreased, according to a prostate cancer-specific instrument, at the six-month follow-up. However, although this study included all the treatment modalities, information about the marital relationship of the patients was not reported (Paterson et al. 2015). In a similar study, War-Smith and Kapitan (2005) also showed that the physical and social well-being of patients changed significantly after external beam radiation therapy, according to a disease-specific instrument. In contrast to these findings, Harden et al. (2013) reported that the QoL of spouses was generally good with a generic QoL instrument in a longitudinal, two-year follow-up study. In our study, the participants were in a long-term marital relationship, which may explain the high HRQoL. However, it is difficult to confirm such an effect, as the significance of marital relationship in the HRQoL of patients with prostate cancer and their spouses is not clearly understood.

According to the results of this study, the HRQoL of the patients had decreased with regard to six dimensions of HRQoL (physical functioning, physical/emotional role functioning, energy, social functioning and general health). In contrast, the HRQoL of their spouses had reduced for the following four dimensions: physical functioning, physical role functioning, bodily pain, and general health dimensions. Previous research has also found that patients with prostate cancer show negative changes with regard to the social and physical dimensions of HRQoL after prostate cancer diagnosis and treatment (War-Smith and Kapitan 2005, Galbraith et al. 2005) The findings from a follow-up study (Segrin et al. 2012) show that the spouses' psychological QoL at four months after treatment was predictive of the patients' psychological QoL at six months after treatment. We have not found similar associations in our study, but Segrin and colleagues (2012) used a prostate-specific instrument for HRQoL and we used a general HRQoL instrument, so this may explain the difference in the findings. The decrease in the physical dimension score of HRQoL in our study could be explained by the age of the participants. The decrease in the physical dimension score may also have been caused by the prostate cancer treatment itself. In a randomized, controlled trial study of primary prostate cancer patients, intervention was observed to be beneficial in improving the physical QoL (Dieperink et al. 2013). Another factor that affects HRQoL may be how patients and their spouses deal with the illness. Recent empirical evidence indicated that at the time of diagnosis, the spouses of patients with prostate cancer were more socially active than the men, but three and twelve months later, their involvement in social activities was more similar (Ezer et al. 2011). Our results followed a similar trend, as the decrease in social functioning of the patient corresponded to an increase in their spouses' social functioning during the follow-up period; however, the changes were not statistically significant.

Findings from this study show that the background variables of the patients with prostate cancer (age, basic education, vocational qualifications, employment status, chronic diseases and treatment method) explained some of the changes in bodily pain and physical functioning. According to a previous study (Song et al. 2011), patients and partners with a lower education level, older age, higher family income and localized cancer at the baseline were associated with better QoL. The findings of the present study also indicate the effect of age on changes in physical functioning. Moreover, in our study, the treatment method may have also partly influenced the changes in the bodily pain scores of the patients. Street et al. (2010) reported in a semi-structured qualitative study that a fifth of the spouses assessed themselves to be distressed, and that at six months after prostate cancer treatment, the majority of spouses reported that they had emotionally adapted and were not distressed anymore. With regard to our study, the six-month period following prostate cancer diagnosis may have been too short a time to discover the changes in HRQoL.

Strengths and Limitations

This study has some limitations. First, confounding factors such as family relationships or economic status might have affected the results. Furthermore, the patients were not asked about their first symptom of prostate cancer or the degree of the cancer. Second, the sample could have been selective, and there is a possibility that the study only included participants who felt that their HRQoL was better who non-responded. Third, the use of one QOL scale simplifies the complex concept of QoL. However, RAND-36 was chosen so as to allow for comparisons with spouses. Even though the sample size was quite small, the strength of this study is that the HRQoL of the same patients and their spouses was followed up at two different stages of the prostate cancer. The response rate was also excellent, especially at the second measurement point. On the other hand, this may have caused a bias, too, because it is probable that it was the participants who felt that their HRQoL was better who responded to the second survey. On the other hand, the non-response

analysis demonstrated that the demographic characteristics of the non-responders did not differ from that of the respondents in the second stage.

Implications for Practice

The present study findings indicate that in the case of patients with prostate cancer, care should be extended to their spouses as well. In practice, this means that healthcare professionals should pay attention to the spouses of patients, and that the spouses should be encouraged to participate actively in the care of patients with prostate cancer. The information presented in this study can help nurses plan the care of patients with prostate cancer from the perspective of the couples. Future research should use a longer follow-up period to study the changes in the HRQoL of patients with prostate cancer and their spouses, in addition to the factors associated with changes in HRQoL.

Conflict of interest

The authors declare no conflict of interest.

WHAT IS KNOWN ABOUT THIS TOPIC

Prostate cancer and side effects of treatments have been shown to decrease the quality of life of patients and also negatively affect the QoL of their spouses. Simultaneous follow-up of patients and their spouses is worthy of investigation.

WHAT THIS PAPER ADDS

The findings from this study add knowledge about the HRQoL of patients with prostate cancer and their spouses over a six-month follow-up period. Our results show that the HRQoL of patients with prostate cancer and their spouses did not change, on average, during the six months after diagnosis. Although there was some variation in individual HRQoL scores, this variation was quite similar

between the patients and their spouses. The background variables of the patients with prostate cancer explained the changes in bodily pain scores, and their basic education level explained the changes in the physical functioning scores.

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Table 1. Response rates of the study participants at the time of diagnosis and six months later

Time	Patient		Spouse	
	n	response rate	n	response rate
At the time of diagnosis				
Number of questionnaires sent	350		350	
Number of returned questionnaires	234	67%	230	66%
Number of rejected questionnaires	2		1	
Number of samples analyzed	232		229	
Number of respondents who did not continue with the study	1		1	
Six months				
Number of questionnaires sent	231		228	
Number of returned questionnaires	199	86%	195	86%
Number of questionnaires rejected	13		9	
Number of samples analyzed	186		186	

Table 2. Demographic characteristics of the prostate cancer patients and their spouses 6 months after diagnosis (patients [n = 186], spouses [n = 186])

Variable	Patients n	(%)	Spouses n	(%)
6 mo				
Age (y), mean (SD)	68.0 (8.1)		65.1 (8.4)	
Duration of marital relationship (y)				
Mean (SD)	36.2 (15.6)			
Basic education				
Elementary school/civic school	112	60	86	46
Comprehensive school/lower Secondary school	44	24	49	26
Upper secondary school	30	16	51	28
Vocational qualifications				
Initial vocational qualification	58	31	62	33
Further vocational qualification	46	25	53	29
Polytechnic/university degree	22	12	28	15
No vocational qualification	56	30	42	23
Missing	4	2		
Employment status				
Working	63	34	70	38
Not working	122	66	115	62
Chronic diseases				

Yes	131	70	123	66
No	55	30	63	34

Treatment method

Surgery	64	35
Radiation therapy	51	28
Hormonal treatment	24	13
Non-invasive care	45	24

Table 3. Changes in patients' (n = 186) and their spouses' (n = 186) health-related quality of life (RAND-36)

Quality of life dimension		At the time of diagnosis (baseline)		After 6 months (follow-up)		Change		p value for the difference between the baseline and follow-up[2]	HRQoL increased by ≥10 points		HRQoL decreased by ≥10 points	
		M[1]	SD	M[1]	SD	M	SD		n	%	n	%
Physical functioning	Patients	82.1	19.6	80.6	20.9	-1.5	12.6	0.052	25	14	37	20
	Spouses	80.1	19.4	78.8	21.2	-1.3	10.3	0.105	40	22	27	15
Role functioning/physical	Patients	66.0	40.1	62.9	40.9	-3.2	37.3	0.186	37	20	45	25
	Spouses	69.9	37.8	67.4	40.0	-2.5	32.6	0.312	34	19	42	23
Role functioning/emotional	Patients	72.4	37.1	71.2	38.0	-0.8	42.2	0.881	42	23	45	24
	Spouses	75.3	35.1	76.6	34.8	2.0	35.4	0.462	40	22	36	20

Energy	Patients	68.9	20.1	67.2	20.2	-1.6	15.3	0.136	44	24	63	34
	Spouses	68.2	19.3	68.5	19.1	0.3	14.5	0.957	42	23	45	24
Emotional well-being	Patients	77.4	15.1	78.3	15.2	0.9	14.3	0.569	44	24	43	23
	Spouses	76.8	14.9	78.0	16.0	1.3	13.5	0.319	38	20	26	14
Social functioning	Patients	83.5	21.5	81.9	20.7	-1.6	20.5	0.205	49	26	65	35
	Spouses	85.4	18.5	85.5	20.0	0.1	16.3	0.860	51	27	48	26
Bodily pain	Patients	76.3	22.2	76.6	23.6	1.8	31.0	0.859	77	42	65	35
	Spouses	75.1	23.4	73.4	24.1	-1.8	18.9	0.434	68	37	54	29
General health	Patients	59.8	17.9	57.7	19.1	-2.0	13.8	0.071	39	21	57	31
	Spouses	62.5	17.6	61.5	18.8	-1.0	11.8	0.129	41	22	58	31

[1]Scale: 0: poor health and quality of life, 100: good health and quality of life

[2]Wilcoxon signed-rank test

Table 4. Factors (n = 186) associated with the changes in health-related quality of life according to the linear regression model with the enter method

Variable	Physical functioning		Role functioning/physical		Role functioning/ emotional		Energy		Emotional well-being		Social functioning		Bodily pain		General health	
	p-value	R^2	p-value	R^2	p-value	R^2	p-value	R^2	p-value	R^2	p-value	R^2	p-value	R^2	p-value	R^2
Background variables[1]	0.103	0.095	0.172	0.085	0.336	0.069	0.887	0.033	0.815	0.039	0.839	0.037	**0.012**	**0.131**	0.589	0.053
Basic Education	**0.007**	**0.040**	0.081	0.027	0.819	0.002	0.668	0.004	0.983	0.004	0.321	0.012	0.083	0.027	0.682	0.004

Significant p-value for R^2 ($p < 0.05$)

[1]Age, basic education, vocational qualifications, employment status, chronic diseases, treatment method