

Fear of cancer recurrence in prostate cancer survivors

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ABSTRACT

Background High fear of cancer recurrence (FCR) is an understudied topic in prostate cancer (PCa) survivors. This study aimed to detect the prevalence, consequences and characteristics associated with high FCR in PCa survivors.

Material and methods This cross-sectional study included patients diagnosed with localized PCa and treated with curative radical prostatectomy between 1992 and 2012. We administered the Cancer Worry Scale (CWS) to assess FCR severity (primary outcome measure). Secondary outcomes included distress, quality of life (QOL), post-traumatic symptoms, and multidimensional aspects of FCR. χ^2 -tests, *t*-tests and Pearson's correlations examined the relationship between FCR and medical/demographic characteristics. MANOVA analyses and χ^2 -tests identified differences between PCa survivors with high and low FCR.

Results Two hundred eighty-three PCa survivors (median age of 70.0 years) completed the questionnaires a median time of 7.1 years after surgery. About a third (36%) of all PCa survivors experienced high FCR. High FCR was associated with lower QOL, more physical problems, higher distress and more post-traumatic stress symptoms. PCa survivors with high FCR reported disease-related triggers (especially medical examinations), felt helpless and experienced problems in social relationships. High FCR was associated with a younger age and having received adjuvant radiotherapy.

Conclusions Results illustrate that FCR is a significant problem in PCa survivors. Younger men and those treated with adjuvant radiotherapy are especially at risk. Those with high FCR experience worse QOL and higher symptom burden. Health care providers should pay specific attention to this problem and provide appropriate psychosocial care when needed.

ARTICLE HISTORY

Received 13 November 2015
Revised 28 January 2016
Accepted 30 January 2016

Fear of cancer recurrence (FCR) is the fear or worry that the disease will return or progress in the same organ or in another part of the body [1,2]. It is hypothesized that normal levels of FCR promote adequate threat monitoring behavior [3] whereas studies found that high FCR is associated with functional impairment [4], lower quality of life (QOL), distress and reassurance seeking behavior (e.g. extra medical examinations) [5–7]. Due to the use of different assessment instruments, reported prevalence of FCR amongst cancer survivors ranges between 39% and 97% [6].

FCR in PCa survivors has been described in some studies [6,8–12], but only one study has reported the prevalence of high FCR using a validated cutoff score [12]. While mean levels of FCR were found to be lower in PCa survivors compared to those with breast, colorectal or lung cancer [2,6]; the prevalence of high FCR was higher in PCa survivors (32%, $n = 23$) than colorectal cancer survivors (24%, $n = 10$), but lower than in breast cancer survivors (40%, $n = 23$) (significance testing was not conducted). Larger scale studies are needed to provide more insight in the prevalence and factors associated with high FCR in PCa survivors.

One might expect a lower prevalence of high FCR in PCa survivors than in other cancer types as PCa is considered as

one of the most curable forms of cancer: most PCa patients present with early stage disease (I–II), the five-year relative survival rate in this group is nearly 100% and the prognosis following a recurrence is still relatively good [13]. In contrast to the PCa population, high FCR is associated with female gender and younger age [6,14].

Clinical practice suggests that PCa specific factors might contribute to FCR. For example, the regular monitoring of prostate-specific antigen (PSA) levels in the blood. From the patient perspective, rising levels signals increasing PCa activity. PSA testing is therefore both clinically and psychologically meaningful for survivors and the uncertainty that comes with rising PSA might trigger FCR.

Greater knowledge of factors associated with FCR in PCa survivors can be used to inform intervention development and improve care. Currently, there is little data on the antecedents, triggers and consequences of FCR, or factors associated with high FCR in the PCa population. The aims of this study were to identify: 1) the prevalence (and characteristics) of FCR; 2) the consequences of clinical FCR; 3) medical characteristics and demographics associated with FCR; and 4) to explore the relationship between PSA testing and FCR amongst PCa survivors who underwent curative treatment.

Material and methods

Patient selection

Eligible patients were: 1) diagnosed with localized prostate adenocarcinoma; and 2) treated with curative radical prostatectomy (RP) [optional: radiotherapy (RT)] between 1992 and 2012. Patients were excluded if they received hormone therapy. Eligible patients were identified by a urologist (lvO) between June and August 2013 from a patient database managed by the Department of Urology, Radboudumc. Deceased patients were identified and removed by Dutch Cancer Registry data linkage. Eligible patients received a mailed study information and invitation to participate from the Department of Urology. Consenting patients returned a written informed consent form and completed either an online or paper and pencil questionnaire. Ethical approval was given by the Medical Ethics Committee, Radboudumc.

Instruments

Demographic and medical characteristics

Demographics, number of comorbid conditions and months until next medical follow-up were gathered by self-report. Treatment modality, PSA level, time since last PSA test were obtained from medical records. We were not able to specify patients with a disease recurrence. Due to length of time since diagnosis (up to 20 years), data on recurrence status was unavailable in the hospital database used to identify participants.

Fear of cancer recurrence: severity

Cancer Worry Scale: FCR severity was measured with the Cancer Worry Scale (CWS). The CWS consists of eight items ranging from 1 ('never') to 4 ('almost always'). Scores range from 8 to 32, a higher score indicating more FCR. A score of ≥ 14 is optimal for differentiating between high and low FCR in breast cancer survivors [15]. To determine the optimal cut-off point, and to evaluate the accuracy of the CWS in identifying PCa survivors with low versus high FCR, a receiver operating characteristic (ROC) analysis with the eight-item CWS and the Fear of Cancer Recurrence Inventory – Severity subscale (FCRI-Severity) was performed (using the clinical cut-off score of ≥ 16 to indicate high FCR) [12]. The area under the curve was 0.93 ($p < 0.001$; 95% CI 0.89–0.96) (Appendix 1, available online at <http://www.informahealthcare.com>), which represents a good level of discrimination. In order to correctly differentiate PCa survivors with high FCR, from those with low FCR, a cutoff which optimizes sensitivity and specificity was selected. To differentiate between high FCR and low FCR a cutoff point of 12 versus 13 (low: ≤ 12 , high ≥ 13) had the best performance with a sensitivity of 86%, a specificity of 84%, a positive predictive value of 71% and a negative predictive value of 93% (Appendix 2, available online at <http://www.informahealthcare.com>). The internal consistency of the CWS was high (Cronbach's $\alpha = 0.88$). The correlation between the CWS and the FCRI-Severity subscale was $r = 0.83$ and in

87% of the cases both the CWS and FCRI-Severity subscale agreed on the presence or absence of FCR. Cohen's kappa was 0.67 (SE 0.05), which corresponds to a substantial degree of agreement between measures.

Fear of cancer recurrence: Multidimensional aspects

The 42-item *Fear of Cancer Recurrence Inventory* (FCRI) is a psychometrically sound questionnaire used to assess multidimensional aspects of FCR [2,12]. Seven subscales were used: Triggers (8-items), Severity (9-items), Psychological Distress (4-items), Functioning Impairments (6-items), Insight (3-items), Reassurance seeking (3-items) and Coping (9-items). All items were scored on a scale from 0 ('not at all' or 'never') to 4 ('a great deal' or 'all the time') [2,12].

PSA-related anxiety

The three-item PSA Anxiety Scale of the *Memorial Anxiety Scale for Prostate Cancer (MAX-PC)* was selected to measure anxiety related to PSA [16]. All items were answerable on a 0 ('not at all') to 3 ('often') scale ($\alpha = 0.56$).

Distress

The *Hospital Anxiety and Depression Scale (HADS)* is a 14-item self-report questionnaire frequently used to screen for distress. The HADS has a 7-item anxiety and a 7-item depression subscale, all items are scored on a 0 ('never') to 3 ('almost always') scale; with a HADS total score ranging from 0 (no distress) – 42 (maximal distress) [17].

The *Impact of Events Scale (IES)* measures cancer-related distress and the extent to which patients experience intrusive thoughts about cancer (7-items) and avoid thinking about cancer (8-items). Total scores range from 0 to 75 (severe distress) [18].

Quality of life

QoL was assessed with the 30-item European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and PCa specific module (EORTC QLQ-PR25) [19,20]. The EORTC QLQ-C30 provides one global health status/QoL scale score and five functional scale scores. The QLQ-PR25 assesses sexual functioning and disease and treatment-related symptoms [19]. All scale scores were transformed to a 0–100 scale. A higher functional scale score reflects a better level of functioning, a higher symptom score indicates more severe symptoms [21].

Data analyses

SPSS20 was used for analyses. Relevant data were screened for normality and outliers. Descriptive statistics were used to describe the medical and demographic characteristics of the sample. Incomplete data for the CWS were recorded as missing and excluded from analysis. Unless otherwise specified, all analyses were done at an $\alpha \leq 0.05$ level of significance. χ^2 -tests, t -tests and Pearson's correlations were performed to

test the relationship between FCR (continuous score) and demographic (age at diagnosis, age at survey, partner status, children, education) and medical characteristics (years since diagnosis, years since surgery, treatment received, number of comorbidity, familiar PCa, PSA level, days since PSA-test and days until next medical appointment). For subsequent analyses the CWS cutoff score was used to group patients according to low or high FCR (low: ≤ 12 ; high ≥ 13 ; see measurements CWS). Multidimensional aspects of FCR (measured with the FCRI) and psychological variables (Distress, QoL) were compared between the high versus low FCR group with MANOVAs. For a descriptive analysis of the FCRI and MAX-PC PSA anxiety scores, percentages of responses to the individual questions were calculated and compared between the two groups.

Results

Response

In total, 740 men met eligibility criteria and were asked to participate (see Figure 1). In total 504 responded (68%) of whom 391 agreed to participate (53%). Reasons for non-participation are displayed in Figure 1. Questionnaires were completed and returned by 318 survivors (43%). Twenty-eight falsely included PCa survivors were excluded because they received hormone therapy ($n=24$) or were diagnosed prior to 1992 ($n=4$). Five PCa survivors did not complete the CWS and two questionnaires were completed by someone other than the patient. Eventually, data of 283 patients were analyzed (38%). Data on non-responders, decliners or non-completers were unavailable.

Patient characteristics

Information about demographic, disease and treatment characteristics of the participants are listed in Table 1. All PCa survivors received curative RP treatment with a median time since diagnosis of 7.9 years (range 0.9–20). Twenty-seven percent received additional RT (with curative intent). Median age at survey was 70.0 years (range 54–89).

Prevalence of high FCR

Mean CWS score of the total sample was 12.0 (SD = 3.7) and 104 PCa survivors (36%) met the cutoff criterion for high FCR. Mean CWS score for high fearful survivors was 15.8 (SD = 3.3), and 9.8 (SD = 1.4) for low fearful survivors [$t(281) = -21.44$; $p < 0.001$].

Multidimensional aspects of FCR

PCa survivors with high FCR reported significantly more triggers, distress and functional impairments, insight and reassurance seeking behavior than those with low FCR (Table 2). Item analysis of the FCRI subscales between low and high fearful survivors is shown in Table 3.

Psychosocial characteristics associated with high and low FCR

Distress: PCa survivors with high FCR reported significantly higher distress, depression, anxiety, intrusive thoughts and signs of avoidance ($p < 0.001$).

QoL: PCa survivors with high FCR reported significantly worse emotional functioning, global health and social functioning (all $p < 0.05$). Furthermore, those with high FCR reported more urinary symptoms ($p = 0.007$), more bowel symptoms ($p < 0.001$) and more treatment-related problems ($p = 0.003$) (Table 2). All differences were small in magnitude (<10 points) and thereby of minimal clinical significance.

Medical and demographic characteristics associated with high and low FCR

A younger age was significantly associated with higher FCR ($p = 0.03$) (Table 1). In addition, PCa survivors with high FCR had more often received adjuvant RT than those reporting low FCR (37% vs. 21%; $\chi^2 = 8.18$; $p = 0.004$). No significant associations were observed concerning the other demographics/medical characteristics.

PSA testing and FCR

Last measured PSA level, number of days since last PSA test and number of days to next medical follow-up, were not significantly associated with FCR (Table 1). PCa survivors with high FCR reported significantly more PSA-related anxiety ($p < 0.001$). Individual items of the three-item *PSA-Anxiety Scale* indicated that 6% of the high fearful compared with 1% of the low fearful survivors had considered delaying their PSA test due to FCR ($\chi^2 = 7.255$; $p = 0.007$). Four percent of high FCR survivors considered having the test repeated at another laboratory compared with 2% of the low fearful survivors ($\chi^2 = 1.230$; $p = 0.267$). Finally, 6% thought about having their own doctor repeat the test, compared with 2% of survivors with low FCR ($\chi^2 = 3.47$; $p = 0.06$).

Discussion

The first aim of this study was to investigate the prevalence of FCR in a large sample of PCa survivors. Approximately one-third (36%) of the sample displayed high FCR as defined by a score of 13 or higher on the CWS. This prevalence is similar to that reported in studies of breast (31%) and colorectal cancer survivors (38%) also using the CWS [15,22], and supports the findings of Simard et al. (2015) (32% of PCa survivors) who used the FCRI [12]. Despite the relatively favorable prognosis, high FCR remains a significant problem in a substantial minority of PCa survivors even years after diagnosis.

QoL differed significantly between participants who experienced high and low FCR, those with high FCR having a lower global health, poorer emotional functioning and social functioning. Furthermore, they experienced more problems with urinary, bowel and treatment-related symptoms. Findings were similar for psychological measures; those with high FCR

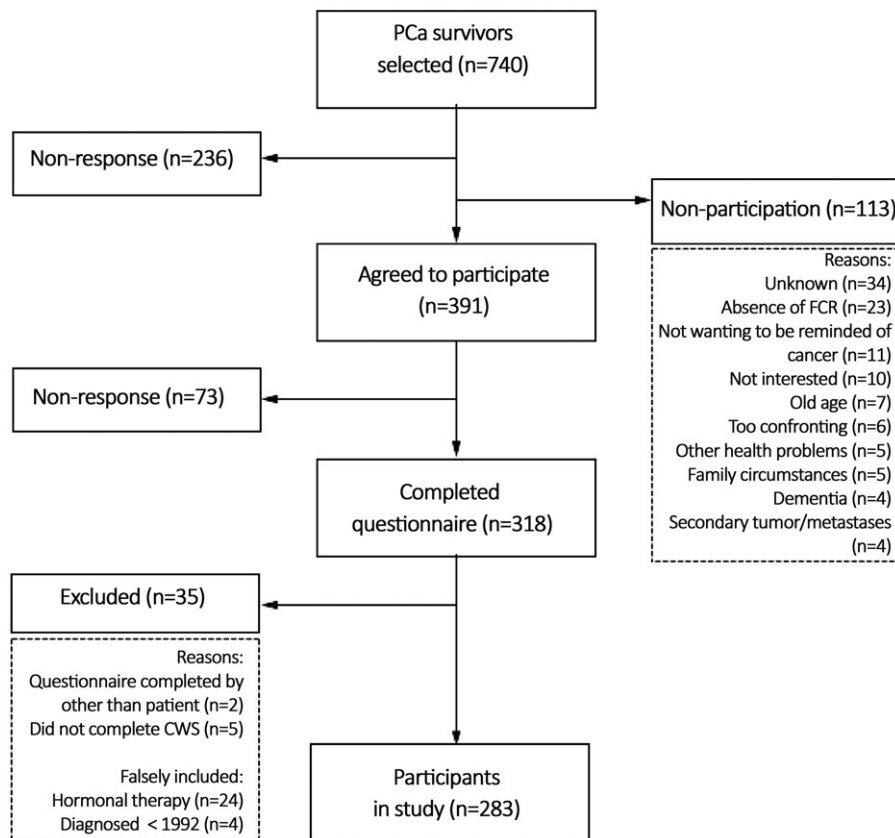


Figure 1. Patient recruitment flowchart.

Table 1. Demographic, medical characteristics and their association with FCR ($n = 283$).

	<i>N</i> (%)	Mean CWS (range 8–32)	Test statistic; <i>p</i> -value
Age at diagnosis (years)	Median 62.5 (range 39–76)	–	$r = -0.09$; $p = 0.146$
Age at survey (years)	Median 70.0 (range 54–89)	–	$r = -0.13$; $p = 0.025^*$
Partner			
Yes	255 (91%)	11.9 (3.6)	$t = 1.374$; $p = 0.171$
No	25 (9%)	13.0 (4.8)	
Children			
Yes	259 (92%)	12.0 (3.7)	$t = 0.465$; $p = 0.642$
No	23 (8%)	12.4 (3.8)	
Education			
Low	69 (27%)	12.1 (3.4)	$F = 0.233$; $p = 0.793$
Middle	75 (28%)	11.8 (4.0)	
High	121 (45%)	12.2 (3.8)	
Years since diagnosis	Median 7.9 (range 0.9–20)	–	$r = -0.10$; $p = 0.102$
Years since surgery	Median 7.1 (range 0.7–20)	–	$r = -0.11$; $p = 0.086$
Treatment			
Surgery only	206 (73%)	11.8 (3.7)	$t = -2.033$; $p = 0.043^*$
Surgery + RT	75 (27%)	12.8 (3.7)	
Comorbidity			
none	65 (23%)	11.6 (3.2)	$F = 0.591$; $p = 0.621$
1–2	160 (56%)	12.1 (3.4)	
3–4	49 (18%)	12.5 (4.8)	
>4	8 (3%)	11.9 (4.6)	
Familiar PCa			
No relatives with PCa	205 (73%)	12.0 (3.9)	$t = 0.729$; $p = 0.467$
Father, brother or both with PCa	77 (27%)	11.7 (3.0)	
PSA level			
0 or ≤ 0.1	247 (90%)	11.8 (3.7)	$F = 1.061$; $p = 0.348$
>0.1– ≤ 0.2	11 (4%)	13.5 (3.4)	
>0.2	17 (6%)	12.2 (3.4)	
Days since PSA test	Median 118.0 (range 4–3249)		$r = -0.05$; $p = 0.475$
Days until next medical appointment ^a	Median 79.0 (range 0–365)		$r = -0.04$; $p = 0.579$

FU, follow-up; PCa, prostate cancer; PSA test, prostate-specific antigen test; RT, radiotherapy.

^a $n = 174$: not all PCa survivors had already scheduled their next appointment. * $p \leq 0.05$

Table 2. Differences in psychosocial functioning by low versus high FCR.

	Low FCR (n = 179)	High FCR (n = 104)	p-value
EORTC QLQ-C30			
Global health/QoL	Mean (SD) 83.5 (15.1)	Mean (SD) 75.6 (17.4)	<0.001**
Physical functioning	89.3 (14.9)	88.1 (15.0)	0.528
Role functioning	89.2 (19.3)	84.0 (24.0)	0.050
Emotional functioning	92.7 (12.3)	85.5 (16.2)	<0.001**
Cognitive functioning	88.7 (17.0)	84.7 (19.1)	0.069
Social functioning	92.8 (15.4)	86.8 (21.9)	0.009**
EORTC QLQ-PR25			
Sexual activity	55.5 (17.4)	59.3 (17.6)	0.248
Sexual functioning	49.6 (24.7)	53.5 (24.7)	0.407
Urinary symptoms	12.6 (11.1)	19.4 (15.2)	0.007**
Bowel symptoms	1.9 (4.7)	7.5 (10.5)	<0.001**
Hormonal/treatment	7.3 (6.3)	11.5 (8.8)	0.003**
Incontinence aid	19.1 (16.6)	23.7 (15.2)	0.310
HADS			
Total	3.9 (4.2)	8.6 (6.2)	<0.001**
Anxiety	1.8 (2.2)	4.4 (3.3)	<0.001**
Depression	2.1 (2.6)	4.3 (3.6)	<0.001**
FCRI			
Severity	7.2 (4.8)	19.9 (7.8)	<0.001**
Triggers	6.1 (5.1)	14.2 (6.3)	<0.001**
Distress	1.8 (2.3)	5.4 (3.5)	<0.001**
Impairments	0.7 (1.7)	4.9 (5.4)	<0.001**
Insight	0.1 (0.3)	1.4 (2.0)	<0.001**
Reassurance	1.0 (2.3)	1.9 (2.3)	0.002**
IES			
Total	2.0 (5.3)	11.5 (13.9)	<0.001**
Avoidance	1.1 (3.1)	6.1 (8.3)	<0.001**
Intrusion	0.9 (3.0)	5.2 (6.3)	<0.001**
MAX-PC			
PSA-Anxiety Scale	0.2 (0.8)	0.7 (1.7)	<0.001**

Differences in QLQ-C30 and QLQ-PR25 scores of 5–10, >10–20 and >20 were defined as 'minimally', 'moderately' and 'largely' clinically significant.

** $p < 0.01$. MANOVA was used to test for significant differences.

experienced more depression, anxiety, post-traumatic symptoms (intrusive thoughts, avoidance) and were significantly more distressed than those with low fear. Although directionality of the relationship cannot be determined, healthcare professionals should be aware of high FCR in clinical practice, as it is associated with adverse outcomes in terms of both physical and emotional well being.

Interestingly, of those with high FCR only a small proportion reported disturbances in functioning (11–12%) and most survivors did not feel that they worried excessively about a possible recurrence (87%). So, despite the association of high FCR with negative health outcomes (QoL, treatment-related symptoms), item analysis seems to indicate that FCR is considered a manageable concern for most fearful PCa survivors. However, compared with low fearful survivors those with high FCR reported significantly higher percentages of disturbances in functioning or distress due to FCR.

In line with earlier studies, involving other cancer types, medical examinations were identified as an important trigger of FCR by high fearful PCa survivors (41%) [4,22,23]. Despite that high FCR has also often been associated with bodily checking and self-monitoring of symptoms [3,14], this was not the case in our study. Bodily checking did not occur frequently in high fearful PCa survivors. A possible explanation for this finding is that rising PSA levels are typically the first sign of a recurrence, well before any clinical signs are present. Bodily checking is therefore less relevant for PCa survivors than for other cancer

types (e.g. breast cancer). Time since diagnosis, last PSA test, and time until next medical follow-up were not associated with FCR. Nor was last measured PSA level associated with FCR. Our results imply that high FCR is stable over time and is not necessarily influenced by disease-specific events, such as PSA testing. However, due to the cross-sectional study design, longitudinal, prospective studies are needed in order to establish trajectories of FCR before and after PSA testing.

Demographics and medical variables significantly associated with higher FCR were a younger age and adjuvant RT. A younger age has more often been associated with high FCR in other cancer types [6,7,14]. For PCa survivors, it could be that those who are younger experience more life disruption caused by cancer (e.g. concerning employment problems, financial responsibility), which may increase their vulnerability to FCR. However, reasons for the association with age are still speculative and lend themselves to further exploration in qualitative studies.

PCa survivors who received adjuvant RT following surgery reported higher FCR than those treated with surgery only. This is consistent with two other studies where RT or brachytherapy was associated with higher FCR in a sample of mixed cancer types [2] and PCa survivors [10]. A possible explanation for the association between FCR and treatment modality is that the relationship between RT and FCR is mediated by recurrence status. In the academic center where our sample was recruited RT is only considered for treatment when PCa shows a recurrence and medical intervention is needed. Thus, those patients who were treated with RT have all experienced a (biochemical) disease recurrence prior to completion of questionnaire. It has previously been shown that having had a disease recurrence is in itself an independent risk factor for developing high FCR [24]. Unfortunately, due to absence of data it was not possible to specify recurrence status as an explicit variable in current study.

Some limitations of this study should be noted. First, due to the cross-sectional nature of this study our results do not imply causation. Longitudinal studies are needed to ascertain causality. Second, 6% of the PSA levels were >0.2: which is indicative of a current biochemical disease recurrence. At time of inclusion these individuals did not receive any medical intervention and were included. However, due to the relatively low number of those with heightened PSA levels we believe this had only a negligible impact on our findings. Third, all PCa survivors were selected from a database in an academic center and the response rate was low (38%). Literature shows that patients in non-academic medical centers differ from those who visit academic medical centers (the latter are often younger and have a better socioeconomic status) [25] and results might not be representative of all PCa survivors. Additionally, even though the study information made it clear the study was for everyone regardless of level of FCR, the main reason for non-participation in this study was the self-reported absence of FCR ($n = 23$). Our aim was to include all eligible survivors and not only those bothered by high FCR. Therefore, the percentage of PCa survivors experiencing high FCR could be overestimated due to self-selection bias. Fourth, as in most other self-report questionnaire studies, there is no guarantee that all returned

Table 3. Multidimensional aspects of FCR in high and low fearful PCa survivors (items).

Subscale Items (summed percentage 'most of the time' and 'all of the time')	High FCR (n = 104)	Low FCR (n = 179)
<i>Triggers</i>		
Medical examinations	41%	10%*
Seeing or hearing about cancer	28%	5%*
Appointments with the general practitioner or health professional	27%	5%*
<i>Psychological distress</i>		
Feelings of helplessness or resignation	17%	2%*
Feelings of worry, fear and anxiety	13%	2%*
<i>Functioning Impairments</i>		
Social relationships	12%	1%*
Quality of life	11%	2%*
Future planning	11%	0%*
<i>Reassurance</i>		
Calling a doctor/other health professional	7%	6%
Going to the hospital/clinical for examination	7%	6%
Self-examination for physical signs of a recurrence	4%	3%
<i>Coping</i>		
Trying to think positively	33%	30%
Trying to understand what is happening and how to deal with it	30%	23%
Trying to replace the thought with a more pleasant one	28%	17%
<i>Severity^a</i>		
Unpleasant thoughts or images (e.g. death, suffering) when thinking about a recurrence	33%	5%*
The belief that it is normal to be anxious or worried about potential cancer recurrence	28%	10%*
<i>Insight^b</i>		
The extent to which you feel that you worry excessively about a potential recurrence	87%	100%*
The extent to which other people think you worry excessively about a potential recurrence	91%	100%*

^aSeverity: answer categories 'Often/Very often';

^binsight: answer categories 'Not at all/A little'.

*To correct for multiple testing $p < 0.001$ was classified as indicating a significant difference between scores.

questionnaires were completed by the addressed patient and not someone else. An introductory letter was attached to the questionnaire booklet asking the patient to fill-out the questionnaire themselves and it was assumed that the patient completed the questionnaire unless otherwise specified. Finally, the CWS was used to differentiate between high and low fearful PCa survivors. Only estimates of reliability and criterion validity were established in this study and other aspects of validity were beyond the scope of this study.

This study showed that high FCR is a significant problem in more than a third of all PCa survivors. Younger patients and those treated with adjuvant RT are most vulnerable to high FCR. While medical examinations are triggers of FCR in themselves, FCR was not found to be influenced by PSA level, time since last PSA test, or time until next medical follow-up. PCa survivors with high FCR reported worse emotional well being and experienced more disease- and treatment-related symptoms even years after completion of treatment.

Compliance with ethical standards

Ethical approval: All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Written informed consent was obtained from all individual participants included in the study.

Acknowledgements

The authors wish to thank José Custers for her advice on methodology in validating the Cancer Worry Scale.

Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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