Determining Issues of Importance for Patients with Prostate Cancer: Results of a Web-Based Study in 2128 Patients with Prostate Cancer for the Development of a Quality of Life Instrument, the Prostate Cancer Symptom Scale (PCSS-QL)

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Abstract

Background: Identifying key issues for patients with malignancy is central to assessing QL and related reported outcomes. This aids in evaluating the effectiveness of treatment programs for those with the disease. The immediate aim of this study was to determine content validity using a large patient panel for the PCSS, a QL measure for patients with prostate cancer. The PCSS also uses an inexpensive hand-held pocket PC to enhance feasibility. The PCSS concept is based on the LCSS (a validated lung cancer instrument).

Methods: We used the established patient base of the web-based NexCura® patient information resource to survey registered patients with prostate cancer. Demographic stratifications included stage of disease, prior radical prostatectomy, and current treatment (none, hormonal, non-hormonal). 2128 patients completed the anonymous web-conducted survey, performed over a 3-day period. Patients were asked to rank 18 issues on a 5-point scale assessing the importance of each item. Issues included general, prostate-specific, and summative items.

Results: The 10 highest (and 2 lowest) ranked items are seen below; results are described by the percent of patients choosing the top category (very important) and the top 2 rating categories of importance:

	Very Important	Very Important + Important
Good QL	76%	98%
Maintaining independence	74%	97%
Perform normal activities	66%	97%
Being a burden to others	65%	90%
Urinary incontinence	61%	90%
Able to sleep	51%	94%
Depression	46%	82%
Difficulty with sexuality / erection	43%	80%
Being fatigued	40%	89%
Having pain	36%	78%
Maintaining an appetite	13%	64%
Having hot flashes	10%	35%

Ratings by disease subsets (such as NED or metastatic disease; hormonal or non-hormonal treatment) were quite similar to results found for the whole group, as listed in the table.

Conclusions: These results represent the largest survey of patient concerns in prostate cancer and support using computer-assisted survey technology to assess such information in all malignancies to obtain patient input rapidly from large patient samples. Strong support seek content validity for the PCSS was obtained.

Background

- Prostate cancer is often highly symptomatic with many issues that can affect all dimensions of quality of life. Both health care professionals and patients recognize the importance of quality of life and symptom control. Even with this recognition, formal evaluation of quality of life using well-validated instruments is unusual in clinical trials and rare in typical patient management.

- In a survey of oncologists concerning the frequency of quality of life evaluation, reasons stated as barriers to performing such assessments were [1]:
  - A perceived lack of validated instruments
  - Insufficient time and resources for carrying out the evaluation

- Several instruments for evaluating quality of life (QL) and symptoms in patients with prostate cancer are available, including the following: QLQ-C30 + Prostate Module, FACIT, EPIC, PC-QoL, PROSOOL, UCLA-PCI, and UCLA-PCI-SF. These instruments vary in length (10 to 52 questions), content, format, and psychometric properties.

- Due to the infrequent use of these instruments and stated barriers our group began the development of a new instrument for prostate cancer (the "**PCSS-QL**") based on the structure, outcomes, and model of the validated lung cancer instrument, the LCSS. [2, 3]

- To address the issues of insufficient time and resources for performing the QL and patient reported outcome (PRO) evaluations, the PCSS-QL was designed to be used with an inexpensive handheld pocket pc. In the experience with this format in lung cancer, less than 2 minutes of patient time was needed; no extra physician time was required. [4]

- *Content validity* is usually supported by a panel of experts (in this case 16 urologists, medical oncologists and oncology nurses) involved in the particular construct of interest. [5,6] Additionally, a review of the literature serves to help in establishing the list of items to be rated by the patients. After both a literature review and results were obtained from the expert panel, the survey was constructed for submission to patients.

- The current study was undertaken as a new online method for obtaining patient input from a large sample as part of the validation process.

Study Objectives

1. To determine which quality of life issues in prostate cancer are of importance to patients with this malignancy.

2. To obtain information from a large sample of patients, thus allowing subgroup analysis representing treatment status.

3. To determine among the issues, which are ranked as having the greatest importance.

4. To use this information for establishing content validity in a quality of life and patient reported outcomes questionnaire for patients with prostate cancer.

Methods

Design and Patient Recruitment

- This methodological study used an online survey approach.

- The established patient base of the web-based NexCura® patient information resource was used to survey patients with prostate cancer. Patients who had previously visited this website (www.nexcura.com), and had registered, are routinely asked if it is agreeable to contact them in the future. Such patients were then sent an invitation to participate anonymously in this survey. If a patient agreed, he was then sent a survey form for completion. No patient identifier was collected at anytime.

- Selection criteria included any patient with current or a history of prostate cancer. Caregivers were excluded. Demographic stratifications included stage of disease, prior radical prostatectomy, and current treatment (none, hormonal, non-hormonal).

- Over a 3-day period, 2128 patients completed the anonymous web-conducted survey. With this large response, no further recruitment of patients was conducted.

- In addition to a patient information form to obtain demographics and health-related variables, patients were asked to rank 18 issues on a 5-point scale assessing the importance of each item. Issues included general, prostate-specific, psychosocial and summative items.

Instruments and Scoring

Two instruments were used in this computer-assisted survey:

- **Patient Information Form** – The investigators developed a 10-item form to obtain self-reported demographic and health-related information for the following: age, time since diagnosis, stage at diagnosis, recurrence since completion of treatment, and presence of metastatic prostate cancer disease. Demographic stratifications included stage of disease, prior radical prostatectomy, and current treatment (none, hormonal, and non-hormonal).

- **Prostate Cancer Symptom Scale (PCSS-QL)** – The investigators developed a 18-item quality of life measure. The initial content validity was based on a literature review and on the results of deliberations of an expert panel of 5 health care professionals. The final step in the content validity process was the survey of patients with prostate cancer. The plan is then to use an inexpensive hand-held pocket PC to enhance feasibility. The PCSS-QL is based on the LCSS (a validated lung cancer quality of life and symptom assessment instrument). Further information on the LCSS can be found at www.lcss-ql.com and in references quoted in this poster. [2,3,4] In the instructions, patients were asked to rank 18 issues on a 5-point scale assessing the importance of each item (ranging from "Most Important" to "Not Important at All"). The items were in the following categories: general, prostate-specific, psychosocial, and three summative items (global symptomatic distress, global activity status, and global quality of life).

- **Scoring of the results.** The results were scored in several ways to allow different uses of the information. First, a scoring system ranging from 0 to 400 was created, with the highest score indicating the greatest importance as assessed by the patients. The highest weighting was given to the "Most Important" category in calculating the total score. The total scores for all patients are listed in the results Tables 1 – 4, and the individual issues are ranged from 1st to 18th according to the weighted total score. Another demonstration of the results is by the ranking in the "Most Important" category only; this too is listed in results Tables 1 – 4. Results Table 5 lists the findings by the percentage of patients who rated each item to be in the "Most Important" category, or in the combined "Most Important" plus "Important" (the second highest response) categories.

TABLE 1. Patient Characteristics (Available on 98% of the 2128 Patients)

AGE:	
< 45	1%
45 – 54	16%
55 – 64	44%
65 – 74	31%
> 74	8%

TABLE 1. Patient Characteristics *Continued* (Available on 98% of the 2128 Patients)

TIME SINCE DIAGNOSIS:	
< 1 Year	42%
1 – 2 Years	41%
3 – 7 Years	13%
> 7 Years	4%

TREATMENT (all that apply):	
Radical Prostatectomy	48%
Radiotherapy: External Beam	28%
Brachytherapy	18%
Hormonal Therapy	24%
Chemotherapy	3%
None	10%

EXTENT OF DISEASE AT DIAGNOSIS:	PERCENT / (Number of Patients)
Localized to Prostate	82% / 1725
Metastatic or Locally Advanced	15% / 304
Do not know	3% / 67

Results

TABLE 2. The 12 Top Ranked Items
By: All Patients and by Subgroups (no recurrent disease, and by status-post radical prostatectomy)

ITEM	ALL PATIENTS (N = 2128)		NO RECURRENT DISEASE (n = 1385)	RADICAL PROSTECTOMY (n = 1010)
	Rank by: Total Score	Rank by: "Most Important"	Rank by: "Most Important"	Rank by: "Most Important"
Quality of Life	1 (371)	1	1	1
Maintaining Independence	2 (369)	2	2	2
Perform Normal Activities	3 (360)	3	3	3
Burden to Others	4 (347)	4	4	4
Urinary Incontinence	5 (345)	5	5	5
Able to Sleep	6 (341)	6	6	6
Being Fatigued	7 (324)	10	10	10
Being Depressed	8 (315)	7	7	7
Erectile Dysfunction	9 (314)	8	7	7
Problems with Urination	10 (305)	12	11	11
Distress from Symptoms	11 (304)	14	14	14
Having Pain	12 (302)	11	13	11

TABLE 3. The 12 Top Ranked Items
By: All Patients and by Subgroups (metastatic disease, and by receiving hormonal treatment for recurrent disease)

ITEM	ALL PATIENTS (N = 2128)		METASTATIC DISEASE (n = 117)	HORMONAL TREATMENT (n = 128)
	Rank by: Total Score	Rank by: "Most Important"	Rank by: "Most Important"	Rank by: "Most Important"
Quality of Life	1	1	1	1
Maintaining Independence	2	2	2	2
Perform Normal Activities	3	3	3	3
Burden to Others	4	4	3	4
Urinary Incontinence	5	5	5	5
Able to Sleep	6	6	4	3
Being Fatigued	7	10	7	6
Being Depressed	8	7	6	7
Erectile Dysfunction	9	8	15	15
Problems with Urination	10	12	14	13
Distress from Symptoms	11	14	12	11
Having Pain	12	11	8	9

TABLE 4. The 6 Lowest Ranked Items
By: All Patients and by Subgroups (no recurrent disease, and by status-post radical prostatectomy)

ITEM	ALL PATIENTS (N = 2128)		NO RECURRENT DISEASE (n = 1385)	RADICAL PROSTECTOMY (n = 1010)
	Rank by: Total Score	Rank by: "Most Important"	Rank by: "Most Important"	Rank by: "Most Important"
Having Anxiety	13 (302)	12	11	11
Difficulty with Sexuality	14 (301)	9	9	9
Having Diarrhea	15 (275)	15	15	15
Having Constipation	16 (274)	16	16	16
Having a Good Appetite	17 (265)	17	17	17
Having a Hot Flashes	18 (238)	18	18	18

TABLE 5. The 6 Lowest Ranked Items
By: All Patients and by Subgroups (metastatic disease, and by receiving hormonal treatment for recurrent disease)

ITEM	ALL PATIENTS (N = 2128)		METASTATIC DISEASE (n = 117)	HORMONAL TREATMENT (n = 128)
	Rank by: Total Score	Rank by: "Most Important"	Rank by: "Most Important"	Rank by: "Most Important"
Having Anxiety	13	12	10	10
Difficulty with Sexuality	14	9	14	14
Having Diarrhea	15	15	11	12
Having Constipation	16	16	13	16
Having a Good Appetite	17	17	17	18
Having a Hot Flashes	18	18	18	17

TABLE 6. Percentage of the 2128 Patients Rating the Items in the Top 2 Categories of Importance
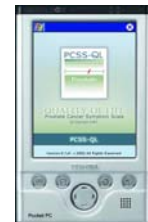
ITEM	RESPONSE CATEGORY	
	Very Important	Very Important + Important
Quality of Life	76%	98%
Maintaining Independence	74%	97%
Perform Normal Activities	66%	97%
Burden to Others	65%	90%
Urinary Incontinence	61%	90%
Able to Sleep	51%	94%
Being Depressed	46%	82%
Erectile Dysfunction	44%	80%
Difficulty with Sexuality	41%	79%
Being Fatigued	40%	89%
Having Pain	36%	78%
Problems with Urination	35%	81%
Having Anxiety	35%	78%
Distress from Symptoms	32%	80%
Having Diarrhea	30%	71%
Being Constipated	23%	67%
Maintaining an Appetite	13%	64%
Having Hot Flashes	10%	35%

Conclusions

- These results represent the largest survey of self-reported patient issues and concerns for prostate cancer. Several subgroups by treatment status and extent of disease were easily identified and provide useful comparisons to the full sample. Even when a subgroup represented a small percentage of the total, the number of patients in the subgroup was generally > 100.
  - In general, responses were fairly similar among subgroups with functional issues being rated as among the most important by all
  - Some differences appeared for those with metastatic disease who rated sexual and urinary issues lower than patients without recurrent prostate cancer, and not unexpectedly rated pain control as more important
  - Perhaps surprisingly, appetite and hot flashes (the latter even in those receiving hormonal treatment) were seen as less important issues, and the ability to sleep was rated highly by all

- Strong support for content validity for the PCSS-QL was obtained through a large panel of patients (2000+) with prostate cancer who ranked their quality of life concerns. These data are similar to those of a 16-member panel of health professionals in a previous survey conducted for this content validity process.
  - A prospective trial completing the psychometric evaluation of the PCSS-QL is now in progress
  - This trial uses the pocket pc assistance to aid in feasibility as was previously confirmed with the LCSS-QL in patients with lung cancer (high patient and staff acceptability, requirement of only 2 minutes of patient time and no additional physician time). [4]

- This approach of using a computer-assisted survey for patients already registered on a site-specific web address may serve as a model for rapidly assessing large patient samples with other malignancies. Based on the large response over just 3 days, it appears that patients are willing to provide input about their cancer experience. Brevity of the scale and avoiding patient identifiers may have helped this large and rapid response.
  - While it is most helpful to have a large patient sample, there are limitations to be considered with this approach. As a web-based methodology, it clearly tends to select those patients with computer availability and familiarity. In using patients who have previously registered with the Nexcura® website, there could be a selection bias for those who seek out information. This may partially explain why the issue of maintaining independence was so highly rated by all patient subgroups.

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