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Symptomatology of cancer patients in palliative care: content validation of self-assessment questionnaires against medical records

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Abstract

To elucidate which symptoms or problems to measure when evaluating palliative care, we assessed the content validity of selected patient self-assessment questionnaires used to evaluate palliative care: the European Organization for Research and Treatment of Cancer-Quality of Life-Core 30 (EORTC QLQ-C30), the Edmonton Symptom Assessment System (ESAS), the Palliative Care Outcome Scale (POS), the McGill Quality of Life Questionnaire (MQOL) and the Memorial Symptom Assessment Scale (MSAS). The content of the questionnaires was compared against the symptoms and problems noted in the medical records of 171 consecutive cancer patients on their first admission to a department of palliative medicine. From the records, 63 different symptoms were listed. Two questionnaires covered almost all of the prevalent symptoms/problems: the EORTC QLQ-C30 covered 10 and the MSAS 11 of the 12 most frequent problems. Researchers selecting instruments for evaluating palliative care may use the present study and other reviews to examine to what degree a given selection of instruments cover the symptoms/problems targeted by palliative care physicians. © 2002 Elsevier Science Ltd. All rights reserved.

Keywords: Palliative care; Advanced cancer; Symptomatology; Self-assessment questionnaire; Quality of life

1. Introduction

In recent years, attention on palliative medicine has increased considerably, thus increasing the need for evaluation of the effect and quality of treatment. However, results from palliative studies are often difficult to compare, as many different evaluation tools are used. There is no consensus as to which instruments are most appropriate.

The patient's physical symptoms, as well as psychological, social and spiritual problems may be described as 'the palliative needs', i.e. symptoms and problems for which the patient might expect intervention on arrival in a department of palliative medicine. A mapping of the patient's palliative needs forms the basis for the selection of questionnaires to assess the outcome of palliative care.

Many different questionnaires are used in palliative care [1–3], but no selection of questionnaires can cover all of the palliative needs of all patients. To minimise the burden on patients, questionnaires should be brief and manageable. The choice of questionnaires must therefore be made weighing feasibility with the demand for accurate and detailed information.

The aims of the present study were (1) to map the 'symptoms' of patients referred to a department of palliative medicine, and (2) to compare the resulting list of symptoms with five well-known questionnaires used to evaluate palliative care, in order to examine the extent to which the palliative needs described in the records can be measured by means of the questionnaires.

2. Patients and methods

2.1. Patients

From its opening on 17 May 1997 to 28 April 1999, 193 cancer patients were referred to the Department of Palliative Medicine at Bispebjerg Hospital, Copenhagen. Patients admitted must have advanced cancer for which no curative or life-prolonging treatment can be offered, as well as pronounced palliative needs. Inclusion criteria for this study were age $\geqslant 18$ years and an

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inpatient status. On referral, 1 patient was less than 18 years old, and 21 patients had an outpatient status. Thus, the medical records of 171 consecutive adult inpatients could be reviewed.

2.2. Data collection

We preferred to use the medical record instead of nurses' records for this review of symptomatology as the nurses' records were written by a large number of nurses with very different levels of experience in palliative care. The medical records were all written by the department's two consultants or by the senior registrar and were believed to be more systematic, homogeneous, and thus more reliable.

The data source was the medical records on first admission. The records were examined for 'palliative needs': for each patient, all information on subjective symptoms and problems was transferred to a symptom list. As a starting point, a list of symptoms and problems covered by the European Organization for Research and Treatment of Cancer-Quality of Life-Core 30 (EORTC QLQ-C30) [4] and the Edmonton Symptom Assessment System (ESAS) [5] was constructed. These questionnaires were selected because we used them in a prospective study and wanted to evaluate their comprehensiveness. Any symptom not present on the symptom list was added. Thus, the length of the list increased throughout the study as more symptoms were added. A symptom or problem was recorded only if it was evidently the patient's problem and not just an observation made by the doctor (e.g. many cases of jaundice, cachexia and dehydration). In the case of an ulcerating tumour or oedematous leg, we registered the pain, the reduction in physical activity, or the psychological problems caused by the disease process (and only if these were listed explicitly). This delineation was necessary to maintain the focus on the subjective aspects ('which questions should patients be asked?'), rather than on a mapping of the clinical conditions caused by cancer (tumour burden, ulcers, oedema, jaundice, etc.).

We compared the results of the review of medical records with the contents of the two instruments used in our prospective study and with the contents of three other questionnaires chosen because they are frequently recommended for the evaluation of palliative care: the Palliative Care Outcome Scale (POS) [6], the McGill Quality of Life Questionnaire (MQOL) [7], and the Memorial Symptom Assessment Scale (MSAS) [8].

3. Results

The demographic data and sites of primary malignancy in the patients are listed in Table 1. The survival from the day of first admission (when the medical record was written) ranged from 1 to 641 days after admission (median 28 days, mean 54.5 days).

Table 1
Demographic data and primary malignancies in 171 patients with advanced cancer

Demographic data ($n = 171$)	
Sex (F/M): 104/67	
Age (years): mean 63.3	range 32–91
Primary malignancy	*n* (%)
Lung	32 (19)
Breast	25 (15)
Colorectal	21 (12)
Pancreas	22 (13)
Other gastrointestinal	11 (6)
Gynaecological	16 (9)
Prostate	11 (6)
Other urogenital	8 (5)
Sarcoma	7 (4)
Head and neck	7 (4)
Unknown primary	7 (4)
Melanoma	2 (1)
Lymphoma	2 (1)

F, female; M, male.

From the 171 patient records, 867 cases of symptoms were recorded, of 63 different symptoms/problems. 35 of these symptoms were represented in one or more of the questionnaires. Pain was recorded most frequently (92%), followed by fatigue (43%), loss of appetite (36%), nausea (35%), depression/sadness (32%), poor physical function (30%), and impaired concentration or memory (29%).

The QLQ-C30 covered the most frequent symptoms (Table 2), but not drowsiness (unless it is understood as an aspect of 'fatigue') and anxiety (unless it is covered by the two items 'worry' and 'feeling tense'). The ESAS includes seven of the 12 most frequent symptoms, but not fatigue, poor physical function, impaired concentration or memory, constipation or vomiting (fatigue is included in a revised version of the ESAS). However, drowsiness and anxiety are both covered by ESAS (Table 2). Thus, the 12 most frequent problems were covered by our combination of questionnaires. The highest-ranking problems not included in any of these two questionnaires were vertigo (10%) and cough (7%). The MSAS covered 11 of the 12 most frequent symptoms from the list and several symptoms not covered by any of the other instruments. The POS and the MQOL questionnaire, however, did not cover many of the issues noted in the medical records (but covered other aspects).

4. Discussion

The symptom list (Table 2) reflects the existence of a large variety of symptoms in patients with advanced cancer. The most frequent problems found here did not

Table 2
Prevalence of palliative needs in 171 patients with advanced cancer: symptoms are ranked by prevalence (n)

Symptom/problem	n (%)	lit.%	ESAS	EORTC	POS	MQOL	MSAS
Pain	157 (92)	42–99	+	+	+	(+)	+
Fatigue	74 (43)	13–91		+	+	(+)	+
Loss of appetite	62 (36)	8–85	+	+		(+)	+
Nausea	60 (35)	8–71	+	+	(+)	(+)	+
Depression/sadness	55 (32)	31–38	+	+		+	+
Poor physical function	51 (30)	NA		+			
Concentration or memory	49 (29)	10–58		+			+
Constipation	41 (24)	33–65		+	(+)	(+)	+
Breathlessness	32 (19)	12–75	+	+		(+)	+
Vomiting	28 (16)	4–25		+			+
Drowsiness	19 (11)	NA	+			+	+
Anxiety	19 (11)	39–57	+		(+)	(+)	+
Vertigo	17 (10)	NA					+
Impaired economy	14 (8)	NA		+			
Cough	12 (7)	NA			(+)		+
Diarrhoea	12 (7)	NA		+		(+)	+
Inadequate housing	11 (6)	NA					
Impaired role functioning	10 (6)	NA		+			
Cachexia/weight loss	10 (6)	NA				+	+
Paraestesia	10 (6)	NA				+	+
Insomnia	9 (5)	NA		+		(+)	+
Aphasia	8 (5)	NA					
Impaired family contact	8 (5)	NA		+	+		
Inactivity	7 (4)	NA	+	+			
Difficulty swallowing	6 (4)	3–43					+
Hallucinations	6 (4)	NA					
Worry	5 (3)	NA		+	(+)	(+)	+
Abdominal distention	5 (2)	NA					+
Poor family resources	5 (3)	NA					
Impaired well-being	5 (3)	NA	+	+			
Heartburn	4 (2)	NA					
Pruritus	4 (2)	5–12					+
Relatives' reaction	3 (2)	NA					
Faecal incontinence	3 (2)	NA					
Sore mouth	3 (2)	NA					+
Dry mouth	3 (2)	8–25					+
Tremor	3 (2)	NA					
Anger	3 (2)	NA					
Nightmares	2 (1)	NA					+
Pulmonary secretion	2 (1)	NA					
Weakness	2 (1)	36–54		+		(+)	
Hoarseness	2 (1)	NA					
Muscle tension	2 (1)	NA					
Physical unrest	2 (1)	NA					
Altered vision	2 (1)	NA					
Altered taste	2 (1)	NA					+
Feeling tense	2 (1)	NA		+			
Loneliness	1 (1)	NA					
Dependence	1 (1)	NA					
Thirst	1 (1)	NA					
Salivation	1 (1)	NA					
Feels poorly informed	1 (1)	NA			+		
Adjusting to illness	1 (1)	NA					
Fainting	1 (1)	NA					
Guilt	1 (1)	NA					
Cramps	1 (1)	NA					
Restlessness	1 (1)	NA					
Hiccups	1 (1)	NA					
Irritation	1 (1)	NA		+			+
Light hypersensitivity	1 (1)	NA					
Sound hypersensitivity	1 (1)	NA					

(*continued on next page*)

Table 2 (*continued*)

Symptom/problem	*n* (%)	lit.%	ESAS	EORTC	POS	MQOL	MSAS
Tinnitus	1 (1)	NA					
Haemoptysis	1 (1)	NA					
Family worried					+		
Life not worthwhile					+	+	
Time wasted					+		
Existence meaningless						+	
Fear of future						+	
Achieving life goals						+	
Poor control over life						+	
Feeling distant from people						+	
Not feeling good about self						+	
Every day a burden						+	
World impersonal place						+	
Altered body image							+
Sweats							+
Swelling of arms/legs							+
Weight gain							+
Sexual problems							+
Hair loss							+
Problems with urination							+
Changes in skin							+

lit%, range of prevalence from the literature; ESAS, Edmonton Symptom Assessment System; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer-Quality of life-Core; POS, Palliative Care Outcome Scale; MQOL, McGill Quality of Life Questionnaire; MSAS, Memorial Symptom Assessment Scale. Italics: symptoms/problems not obtainable from the symptom list based on EORTC and ESAS; **bold**: symptoms/problems from POS, MQOL, or MSAS not chosen for the original symptom list; (+): one of at least two issues covered by one item; NA, not available.

differ strongly from what can be found in other reports (but most reports deal with much fewer symptoms). Several authors have found pain to be the most frequent symptom [9–12]; in some studies, fatigue/weakness was rated higher [13–16], in others breathlessness [17], and in some poor appetite [18,19]. In one study, 'psychological distress' had the highest prevalence [20]. Such rankings depend on the patient population examined, but primarily, they reflect the way problems are measured: for example, impaired well-being was infrequently mentioned in the records (Table 2), but if patients were systematically asked, this issue would probably be a problem to almost all. Terms like 'feeling tense' and 'weakness' rarely appear in the present medical records, although it seems evident that they must be common in palliative patients. It is quite possible that the medical records would reveal other symptoms as even more frequent and severe if patients were interviewed systematically.

An aspect left practically untouched by the medical records, as well as by four of the questionnaires, is the presence or absence of existential and spiritual problems. The MQOL Questionnaire has nine items covering these issues [7]. According to the medical records, 2 patients were reported as 'thinking of death', but it was not apparent whether this represented a problem to the patient. The medical records as well as most 'quality of life questionnaires' tend to focus mainly on medical problems, and in general, it is unusual for Danish doctors to discuss spiritual or religious matters with their patients at their admission to the department, although one might argue that this ought to be done. The lack of reported spiritual concerns is probably caused by the lack of doctor recognition in the records rather than indifference in the patients. It may be more natural to discuss such matters when the patient and the physician know each other better. However, the findings clearly reflect that the medical record—and thus probably the doctor–patient communication—is more focused on physical and psychological symptoms than existential issues.

The POS addresses pain directly [6], whereas all other physical symptoms are summarised in one item: 'Over the last 3 days, have other symptoms, e.g. nausea, coughing or constipation affecting how you feel?' This explains the seeming lack of concordance with our symptom list. The MQOL asks the patient to first list and then grade the three most troublesome physical symptoms without addressing any of these directly [7]. Therefore, our method for evaluating content validity of these questionnaires (Table 2) may seem a bit unfair.

Pain is a distressing symptom, which is impossible for the patient to ignore or neglect. Furthermore, the treatment of pain has received increasing attention. It would therefore be almost unthinkable in a palliative care department not to discuss the extent of pain with a patient. Pain was twice as frequent as the next symptom on the list (fatigue) and few patients (8%) were reported to have no pain at all. Ng and von Gunten [14] found pain and confusion to be recorded more frequently in the medical records than when recorded by patients themselves. These patients, however, reported weakness, fatigue, weight loss, anorexia, dyspnoea, etc., more often than did their physicians.

In practice, the medical record is based on a semi-structured interview. Ideally, the patient spontaneously reveals his concerns and problems, and the doctor asks additional questions if necessary, the doctor's role being simply to log this symptomatology in the medical records [21]. The large variation between records in different specialities, however, shows that the doctor also plays an active role. The medical record reflects those symptoms perceived as important by the doctor. Viewed as a description of the patient's 'palliative needs', the record may be inaccurate for several reasons:

1. The doctor might tend to emphasise symptoms, for which it is simple to take relevant action.
2. Symptoms may be so obvious that they are not mentioned at all (e.g. fatigue, sadness, inactivity).
3. The doctor might not report a problem, if he finds that the solution lies with another staff member and/or person (nurse, social worker, priest, etc.)
4. The patient's most important symptom can be so distressing to him that he forgets or leaves out other symptoms.
5. Communication theory has taught us that the communication between the patient and the professional is not a simple transmission of information, but rather a complicated psychological process [22]. The process is affected by a range of factors associated with both the patient and the professional. The insight obtained by a physician about a patient's palliative needs is dependent on this process.

For these reasons, we do not see the medical record as a 'golden standard' for validation of questionnaires. This is empirically confirmed by a large literature showing that observers (professionals and others) are not able to precisely describe the symptoms experienced by patients [23]. The medical record is clearly the doctor's view, not the patient's. However, the medical record represents an important source of information when determining the issues relevant to measure in the evaluation of palliative care. Thus, the medical records are relevant although not exhaustive.

Another point to make here refers to the possibilities of 'mapping' palliative needs. Such needs vary with time and place and thus, any attempt to 'map' palliative needs will at best be relevcant for that point in time.

At present, there is no consensus on how to describe the palliative patient's physical, psychological, social and spiritual symptoms and problems in research on palliative care. An abundance of patient self-assessment questionnaires exist, each covering selected aspects of 'the palliative needs'. Thus, a careful selection must be made, counterbalancing feasibility with the need for accurate information.

Among other measures, we used the questionnaires EORTC QLQ-C30 and ESAS for evaluation of palliative care. The present study shows that these questionnaires together cover the 12 most frequent problems written in the medical records. If we would want to expand the number of questionnaires, items covering vertigo, cough and cachexia/weight loss could be added, as these problems are not infrequent in patients with a terminal disease. These items are covered by the MSAS, which, however, did not cover 'poor physical function'.

Other relevant instruments for palliative care include the Support Team Assessment Scale (STAS), McMaster Quality of Life Scale (MQLS) [24], Symptom Distress Scale (SDS) [25], and many others. Extensive reviews of available measures are published elsewhere in Refs. [1,3].

The main finding is that much of the symptomatology noted in patients admitted to our unit was in fact covered by the questionnaires we are currently using. Of these questionnaires, the 30-item EORTC QLQ-C30 clearly is the most comprehensive to cover the most frequent symptoms. However, the short, nine-item ESAS also covers many of the frequent issues and the more recent version includes fatigue [26]. The ESAS questionnaire is practical due to its brevity, but the visual analogue scales are more complicated for the patients to fill out, at least initially: it requires more thought to respond on a continuous axis than to choose one out of four response categories in the EORTC QLQ-C30 [3,27]. Another important consideration when choosing between questionnaires is the extent to which the instruments have been validated. There is relatively little published evidence for the validity of ESAS, whereas the EORTC QLQ-C30 has been subjected to extensive validation in numerous cancer populations (including patients with advanced disease) in different countries, and its psychometric properties have been investigated in great detail [28–33]. Furthermore, the fact that the EORTC QLQ-C30 uses multi-item scales for some of the most important dimensions must be expected to give more reliable and thus more responsive measurement [27]. The MSAS provides a more comprehensive description of symptoms by not only measuring severity, but also distress/bother caused by the symptoms. The POS is quite comprehensive in describing psychosocial problems caused by the patient's disease.

Using questionnaires as a research method represents a compromise between the wish for quick, practical instruments consisting of easily understood, simple questions and, on the other hand, our recognition that such simple methods will never give us an in-depth understanding of the individual patient's unique situation. Results of questionnaire-based research should be viewed with these limitations in mind. However, when simple measures of the most frequent and distressing symptoms and problems in palliative care have been subjected to assessment of their validity and reliability (elucidating their limitations), they can be useful for medical research.

As in any research setting, the most important considerations are the extent to which the selected instruments adequately cover the research questions, have adequate measurement properties, and whether they are feasible for use [34]. Researchers selecting instruments for palliative studies may use the present study of symptomatology and other reviews to examine to what degree a given selection of instruments cover the important issues for their study. Clearly, the medical records should be viewed as one source only: a review of their content is useful in order to achieve content validity in the assessment of symptoms, but other sources (patient interviews, etc.) should be used as well in order to make sure that all aspects of palliative care (including social, psychological and spiritual problems) are assessed.

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