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Original Research

Developing a core set of patient-reported outcomes in pancreatic cancer: A Delphi survey☆

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Abstract ***Background:*** Patient-reported outcomes (PROs) are amongst the most relevant outcome measures in pancreatic cancer care and research. However, it is unknown which out of the numerous PROs are most important to patients and health care professionals (HCPs) in this setting. The aim of this study was to identify a core set of PROs to be incorporated in a nationwide prospective multidisciplinary pancreatic cancer registry.

Patients and methods: We performed a two-round Delphi survey among 150 patients diagnosed with pancreatic or periampullary cancer (treated either with curative intent or in palliative setting) and 78 HCPs (surgeons, medical oncologists, gastroenterologists, radiotherapists, nurses, and dietitians) in The Netherlands. In round 1, participants were invited to rate the importance of 53 PROs, which were extracted from 17 different PRO measures and grouped into global domains, on a 1–9 Likert scale. PROs rated as very important

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(score 7–9) by the majority ($\geq$80%) of curative and/or palliative patients as well as HCPs were considered sufficiently important to be incorporated in the core set. PROs not fulfilling these criteria in round 1 were presented again to the participants in round 2 along with individual and group feedback.

Results: A total of 97 patients (94%) in curative-intent setting, 38 patients (81%) in palliative setting and 73 HCPs (94%) completed both rounds 1 and 2. After the first round, 7 PROs were included in the core set: general quality of life, general health, physical ability, satisfaction with caregivers, satisfaction with services and care organisation, coping and defecation. After the second round, 10 additional PROs were added: appetite, ability to work/do usual activities, medication use, weight changes, fatigue, negative feelings, positive feelings, fear of recurrence, relationship with partner/family, and pancreatic enzyme replacement therapy use.

Conclusion: This study provides a core set of PROs selected by patients and HCPs, which may be incorporated in pancreatic cancer care and research. Validation outside the Dutch context is recommended for generalisation and use in international studies.

1. Introduction

Pancreatic cancer is associated with a very poor prognosis. The overall 5-year survival rate of patients with pancreatic cancer is approximately 5%[1,2]. Intervention studies on pancreatic and other cancers have traditionally focussed on clinical outcomes and survival. In recent years, however, patient-reported outcomes (PROs), referred to as 'any report coming directly from patients about a health condition and its treatment'[3], are of increasing importance in health care, in particular cancer care [4,5]. PROs can be used by clinicians and researchers to measure the impact of treatment on several domains of a patient's health status and might also enhance patient–provider communication. Also industry and policy makers can use PROs to evaluate and improve quality of care. Given the poor prognosis of patients diagnosed with pancreatic cancer, it becomes critical to accurately monitor and possibly improve health status and quality of life. PROs are, therefore, amongst the most relevant outcome measures in pancreatic cancer care and research, including disease-specific registries.

To date, it is unknown which PROs are the most relevant in the pancreatic cancer setting. PROs include a wide range of concepts, ranging from multidimensional constructs such as quality of life to more specific one-dimensional symptom aspects such as pain or fatigue. PROs are collected through the use of questionnaires or other type of patient-rating scales and can be collected through a variety of patient-reported outcome measures (PROMs). PROMs are usually extensive and cover a broad spectrum of health domains which are of varying relevance to the patient [6]. Also, PROMs are generally selected by health care professionals (HCPs) and it might well be that health domains contained in the selected PROMs are not highly relevant for patients.

The Delphi methodology is commonly used to systematically gather input from relevant experts on a topic [7,8]. In a Delphi survey, a panel of experts are asked for their opinion on a question and subsequently re-polled with controlled feedback regarding the polled opinions, to encourage consensus between the (groups of) experts [9].

The aim of this study was to identify a core set of PROs, selected by patients and HCPs, to be incorporated in a nationwide prospective multidisciplinary pancreatic cancer registry, using a two-round Delphi survey.

2. Methods

2.1. Participants

We performed a two-round Delphi survey, similar to the DATECAN projects [10,11], among patients diagnosed with pancreatic or periampullary cancer and HCPs in The Netherlands (see Fig. 1 for the study flow chart). The Medical Ethics Committee of the Academic Medical Center, Amsterdam, granted an exemption from ethical review of the full protocol for this study (W14_117 # 14.17.0152).

Patients with histo- or cytopathologically proven pancreatic or periampullary cancer diagnosed between January 2011 and July 2014 in the Academic Medical Center in Amsterdam, University Medical Center Utrecht in Utrecht (both academic hospitals) and the Catharina Hospital in Eindhoven (teaching hospital) were identified from prospectively maintained databases of all patients treated in curative-intent or palliative setting. Patients with a life expectancy of less than 3 months were excluded to ensure completion of both rounds. All patients meeting the criteria were contacted by telephone and asked whether they would be willing to participate in the survey. Additional participants were recruited via a call on the website of the nationwide multidisciplinary Dutch Pancreatic Cancer Group (DPCG, www.dpcg.nl).

HCPs were identified from the participant list of the DPCG and the national network of dietitians in surgery