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Short Report

Developing a core set of patient-reported outcomes and patient-reported experience measures for peritoneal surface malignancies (COMETE)

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Members of the COMETE study group are co-authors of this study and are listed under the heading Collaborators.

Introduction

Cytoreductive surgery alongside systemic and intraperitoneal chemotherapy allows improved disease control and chronic management of patients with primary or secondary peritoneal surface malignancies (PSMs)[1]. Most studies have focused on disease-free or overall survival, with little emphasis on the adverse effects of cancer treatment or its impact on quality of life, which can itself accelerate progression of disease[2].

Only recently have patient-reported outcomes (PROs) started to play some role in the assessment of oncological therapeutics[3–6]. Before this, PSM clinical trials focused on clinical outcomes and improvements in disease management, with no evaluation of PROs or patient-reported experience measures (PREMs)[7,8]. In contrast to other metastatic sites, no specific PRO or PREM instruments are available to assess patients with PSM for clinical and research practice[9].

Shared decision-making between patients and clinicians has been advocated[3], and patients' willingness to be involved in their care pathway is pivotal. Many patients are also eager to be involved in health services research, and to be active partners and co-designers of the research process, referred to as patient partners. The aim of this study was to elaborate a core set of specific PROs and PREMs for PSM through a Delphi process with patient partners and healthcare professionals.

Methods

A two-round Delphi process was proposed to healthcare professionals/researchers and trained French-speaking patient partners from five centres in France and Switzerland, according to COS-STAD recommendations[10] (*Appendix S1*). Further details of patient partners and the expert panel are available in *Appendix S2*[6,11–13].

PRO and PREM selection

A core group of healthcare professionals selected available PROs and PREMs based on studies relevant to abdominal cancer. To facilitate this, a PubMed and MEDLINE search was undertaken using the following keywords and Medical Subject Heading (MeSH) terms: 'patient reported outcomes' OR 'quality of life' OR 'patient reported experience measure' AND 'digestive cancer' OR 'peritoneum' OR 'peritoneal metastasis'. The reference lists of retrieved articles were searched manually to identify additional relevant studies.

Overlapping PROs and PREMs, and those deemed too unusual or too specific to other disease sites, were excluded. Items identified for inclusion were assigned to health domains (general health; physical health; social health; emotional health; financial health) and each PRO and PREM was formulated as an item or sentence respectively. Understanding of the sentences/items was checked by the remaining authors and a selected patient partner.

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Delphi consensus

The PROs and PREMs were sent electronically (Survey Monkey, San Mateo, CA, USA) or, upon request by patients, in paper format. Participants were asked to return both questionnaires within 2 weeks. Non-respondents received a maximum of three electronic reminders. Sociodemographic and cancer diagnostic details (from patient partners) were collected for all respondents. Participants were asked to rate the importance of each PRO and PREM on a Likert scale from 1 (not important) to 9 (very important). The first round provided free-text boxes, allowing respondents to suggest a maximum of three additional PROs or PREMs that had not already been considered in the questionnaire. The second round was conducted 8 weeks after the first round and included all respondents. The second-round survey included the original list of PROs and PREMs with rating results from round 1, in addition to the PROs and PREMs that were added in the first round through the free-text option.

Items scored from 1 to 3 by at least 20 per cent of respondents were considered as not important. Those rated very important[8,9] by at least 70 per cent of the group were retained for the final PRO/PREM instruments. Results in the first and second rounds were presented as the overall percentage of the group that rated the criterion as very important. Items meeting the threshold for inclusion in round 1 had to be confirmed by the group in round 2.

Results

PRO and PREM selection

A flow chart for selection of PROs and PREMs is shown in *Fig. 1*. Forty-eight PROs and 30 PREMs (*Appendix S3*) were selected for initial inclusion in the Delphi process.

Patient partners and healthcare professionals

Thirty-five eligible patients were contacted and received verbal information in addition to a video presentation of the project. Twenty-five patients agreed to participate and were trained by the Union Francophone des Patients Partenaires to be patient partners. *Table 1* summarizes the characteristics of the included patient partners and healthcare professionals (medical doctors and researchers). Both rounds of the Delphi process were completed by 21 of 25 patient partners and all 35 healthcare professionals. The rate of complete questionnaires was 95 per cent for PRO and 90 per cent for PREM questionnaires.

Results of Delphi consensus

In the first round, 10 PROs and 6 PREMs were rated very important and none were rated not important (*Appendix S4*). Three additional PROs were added (by patient partners) in the first round and included in the second-round questionnaire: skin or scratch lesions, fear at end of life/fear of death, and information given to the family by the medical team. Mean Likert scores for each of the PROs are detailed in *Appendix S5*, and the overall percentage of the group that rated the PROs criteria as very important is shown in *Appendix S6*. PREMs results are detailed in *Appendix S7 and Appendix S8*. *Figure 1* provides on overview of the nine PROs and eight PREMs that were finally retained.

Discrepancies between respondents

Minor discrepancies were noted between healthcare professionals and patient partners. Among the final outcome set, five of nine PROs and all eight PREMs were approved by both cohorts. General health, anxiety, and fear of recurrence were rated very important (score 8 or 9 by at least 70 per cent) only by patient partners, and abdominal pain only by healthcare professionals.

Discussion

A core set of items for patients with PSM (9 PROs and 8 PREMs) was elaborated by patient partners and healthcare professionals. The PRO items retained were: general quality of life, general health, physical ability, ability to work or perform usual activities, physical fatigue, anxiety, abdominal pain, fear of recurrence, and satisfaction with the medical team. The PREM items retained were: satisfaction with the care pathway, information about cancer given in an appropriate way, information on diagnosis/treatment/complications, an understanding by the medical team of what was important to the patient, knowing how to contact the hospital, and contact details of the hospital or healthcare professional.

It has been shown that routine PRO and PREM surveys improve patient compliance with personalized care plans, communication between the patient and the medical team, monitoring of treatment response, and detection of complications[14,15]. Integration of these PROs and PREMs into routine care can therefore improve outcomes and survival of patients with metastatic cancer[3,16].

In this study, patient partners and healthcare professionals did not include specific abdominal symptoms (for example nausea, vomiting, diarrhoea, constipation) in the final consensus, focusing more on general notions such as work, well-being, and physical ability. Although these notions are linked directly to symptoms of PSM, it is difficult to understand why abdominal symptoms as such were not selected by experts.

To the best of the authors' knowledge, these are the first PROs and PREMs instruments guided by patient partners specifically designed for patients with primary or secondary PSMs. Inclusion of patient partners is essential to avoid development of a questionnaire by specialists, who often have a monopoly on research owing to their training, specialized skills, and knowledge[17,18]. Patient participation in the conception and conduct of research has become increasingly important because of their experiential knowledge, which is as important as scientific knowledge[19,20].

PREMs are commonly used to explore patient satisfaction with health services, patient journeys, and patient experiences with treatment or care plans[14]. In this study, the PREMs considered as very important by patient partners and/or healthcare professionals focused principally on patient information in terms of diagnosis, treatment, and complications. This suggests that, although multiple sources of information are available, patients prefer to receive information about their disease and treatment through direct communication with their medical team[21].

The main limitation of this study is the selection and composition of the initial study panel. To limit the impact of this, patients with various peritoneal diseases in curative and palliative situations were included, as well as physicians from various specialties. Although it would have been easier to develop a core set for each specific clinical situation from a methodological point of view, the lack of external validity would have made it difficult to implement in clinical or research practice.

As suggested by Basch *et al.*[15], PRO and PREM instruments may help achieve better symptom control with an early response by the clinical team, preventing downstream adverse events and

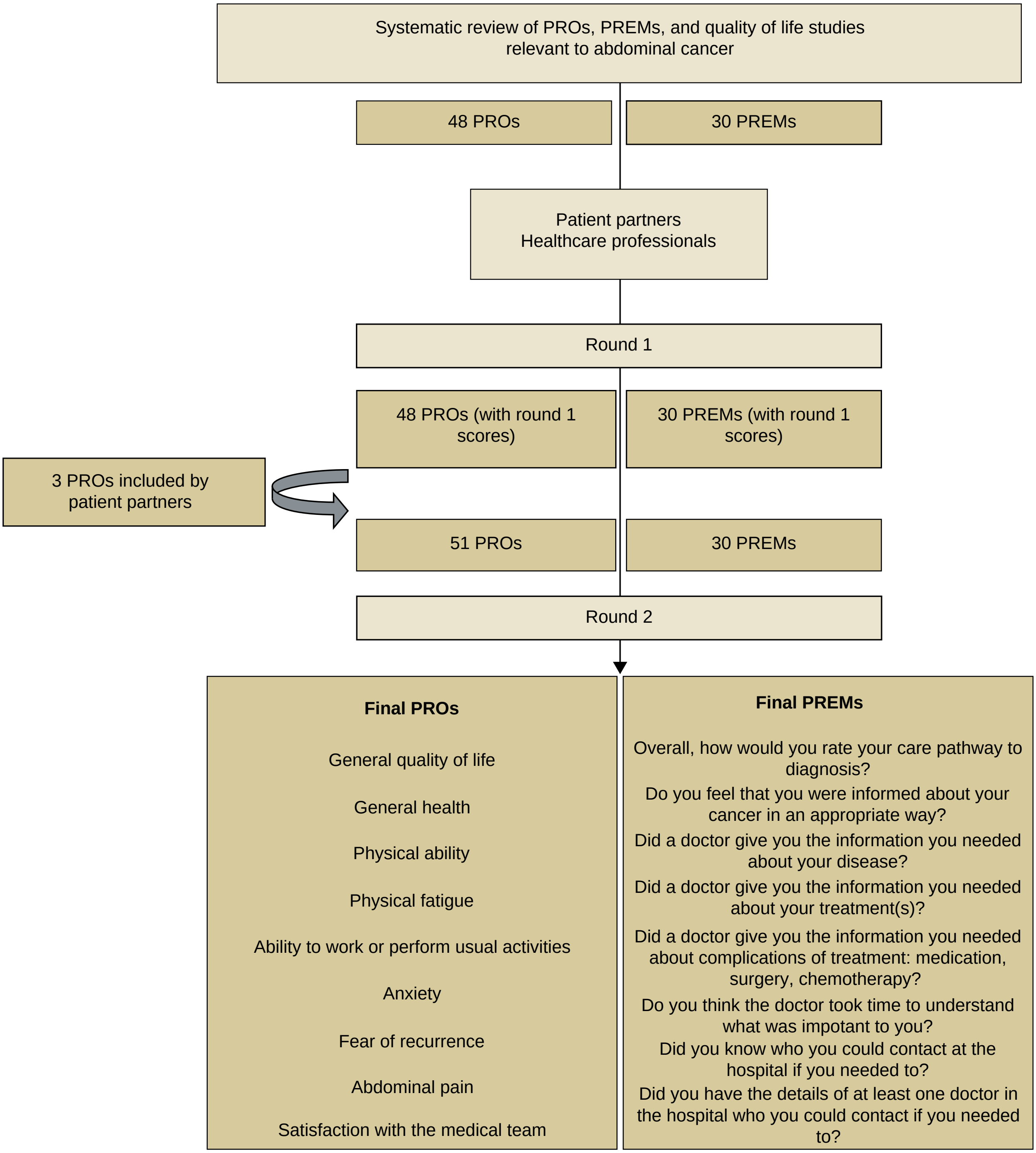

Fig. 1 Flow chart showing consensus obtained in COMETE study

PRO, patient-reported outcome; PREM, patient-reported experience measure.

allowing better tolerance of systemic or intraperitoneal chemotherapy or surgery. PROs and PREMs must therefore be brought into the clinical and research routine in a way that is easy for patients to use and easy for the medical team to analyse[22].

This study developed the first PRO and PREM instruments specific to primary and secondary PSMs, with nine and eight items respectively. This consensus between patient partners and various specialists will encourage conversations between patients and their medical team, lead to shared decision-making, allow the detection of neglected problems, personalize follow-up, and ensure individualized quality care. The next step is to validate the instruments in a population of patients with primary or secondary cancer of the peritoneum, with the ultimate aim of using them in clinical practice and evaluating the effects of their implementation on patients' health.

Collaborators

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Table 1 Characteristics of healthcare and patient participants

	No. of participants
Patient partners	
Mesothelioma	4
Pseudomyxoma peritonei	5
Peritoneal metastases from gastrointestinal cancer	7
Peritoneal metastases from gynaecological cancer	5
Healthcare professionals	
Digestive surgeon	12
Gynaecologist	5
Oncologist	7
Palliative care physician	11

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Author contributions

Abdelkader TAIBI : Conceptualization, Investigation, Methodology, Writing—original draft, and Writing – review & editing; Olivia SGARBURA : : Conceptualization, Investigation, Methodology, Writing—original draft, and Writing – review & editing; Laurent VILLENEUVE : Investigation, Writing—original draft, and Writing – review & editing; Clarisse EVENO : Investigation, Writing—original draft, and Writing – review & editing; Marc POCARD : Investigation, Writing—original draft, and Writing – review & editing; Naoual BAKRIN : Investigation, Writing—original draft, and Writing – review & editing; Guillaume ECONOMOS : Investigation, Writing—original draft, and Writing – review & editing; Cecile ODIN : Investigation, Data curation, Resources; Sylvaine DURAND FONTANIER : Investigation, Writing—original draft, and review; Sylvia M Bardet : Investigation, Software, Writing—original draft, and review; Olivier GLEHEN : Investigation, Writing—original draft, and Writing – review & editing and Martin HÜBNER : Conceptualization, Data Base, Methodology, Writing—original draft, and Writing – review & editing.

Disclosure

The authors and patient partners declare no conflict of interest.

Supplementary material

Supplementary material is available at *BJS* online.

Data availability

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available as they contain information that could compromise research participant privacy/consent.

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