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REVIEW

Development of a Patient-Reported Symptom Item Bank for Patients with Hepatobiliary or Pancreatic Malignancies: A Systematic Review

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Background: Patients with hepatobiliary or pancreatic cancers often experience severe symptoms, resulting in a sharp decline in functioning, poor quality of life, and increased mortality risk. Early and effective management of symptoms allows a better quality of life and reduced mortality, depending on the selection of appropriate assessment of specific symptoms for a defined purpose. We aimed to develop a symptom measurement item bank for hepatobiliary or pancreatic cancers.

Methods: The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement was applied to organize this systematic review. The articles validated patient-reported outcome measures (PROMs) for hepatobiliary or pancreatic cancer and published before December 2021 were retrieved from the Web of Science, PubMed, Embase databases and Cochrane Library. Items from the existing PROMs were selected and classified into different patient-reported symptoms based on the concepts and specific underlying constructs of the objects measured.

Results: Sixteen unique PROMs were identified across the 29 eligible studies included in our analysis. Items from the literature review (14 PROMs with 421 items for which information was obtained) were selected and classified. As a result of this study, we developed a symptom item bank with 40 patient-reported symptoms and 229 assessment items for hepatobiliary or pancreatic cancer, and fatigue, pain and nausea were the most common symptom items.

Conclusion: We developed an item bank to assess the patient-reported symptoms of hepatobiliary or pancreatic cancer. This item bank could allow researchers to select appropriate measures of symptom and provide a basis for the development of a single-item symptom-measurement system.

Keywords: patient-reported outcome measures, symptom, item bank, pancreatic carcinoma, hepatocellular carcinoma, cholangiocarcinoma, systematic review

Introduction

Patient-reported outcome measures (PROMs) have been given increasing attention over the past three decades after the groundbreaking endeavors undertaken by the Medical Outcomes Study and the Food and Drug Administration's patient-reported outcome (PRO) guidance for industry.[1] Regarding symptoms, PROMs reveal the patients' perspectives without interpretation by anyone else.[2] It has become increasingly common to use PROMs to assess symptoms to support treatment decisions or evaluate treatment effect.[2]

Patients with hepatobiliary or pancreatic cancers often experience severe symptoms, including pain, fatigue, and anorexia, because of the advanced disease stage at diagnosis, various necessary anticancer treatment modalities, and poor

Received: 22 November 2022
Accepted: 12 January 2023
Published: 19 January 2023

prognostic outcomes.[3–5] The occurrence of multiple symptoms results in a sharp decline in functioning, poor quality of life, and increased mortality risks.[4] Early and effective symptom management is expected to allow an increased quality of life and reduced mortality risks in many patients, depending on the selection of an appropriate PROM tool for a well-defined purpose.[1] However, owing to the often poor physical condition of patients with hepatobiliary or pancreatic cancer, low compliance with lengthy measurement tools is an insurmountable obstacle which impedes effective patient management. For these more severely ill individuals, a single-item measure has the advantage of being easy to understand, rapidly administered, and having a low response burden.[6] In addition, symptom measurement is usually unidimensional in symptom monitoring and screening, such as pain, fatigue, vomiting, etc., and a single-item measure is likely more suitable than multifaceted measures for the purpose of high-frequency screening.[6]

However, PRO instruments validated in patients with hepatobiliary or pancreatic malignancies are still lacking compared to other common types of cancer,[1,7] and the symptom items included in different PRO instruments vary. Therefore, it is difficult for researchers to select an appropriate symptom assessment tool for a specific purpose.[8] To list a symptom measurement item bank through a comprehensive summary and provide basis for the development of single item measurement system, the Chinese Anti-Cancer Association Geriatric Cancer Committee organized a PRO Symptom Rating Subcommittee to systematically review the validated PROMs in patients with hepatobiliary or pancreatic cancer.

Methods

Search Strategy

Articles were retrieved from the Web of Science, PubMed, Embase databases and Cochrane Library if they were published before December 2021. A search strategy (Appendix 1) for the three components was used as follows: "population", "instrument", and "measurement properties". The searches focused on patient-reported outcome measurements (PROMs) which were validated in patients with hepatobiliary or pancreatic cancer. The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement was used to organize this systematic review.[9] Duplicate entries were eliminated after importing the search records into Endnote X9.

Article Selection

Two subcommittee members, who arrived at a consensus on the final list of the included articles, screened all titles and abstracts independently. When there was a difference of opinion between the two reviewers, a third subcommittee member was consulted. Regarding potentially pertinent articles, two subcommittee members independently reviewed the full text to decide on inclusion or exclusion. The included articles' references were manually checked to identify additional references.

The inclusion criteria were as follows: articles that (1) were full-text original publications in English, (2) presented the psychometric characteristics of the PROMs, and (3) targeted patients with hepatobiliary or pancreatic cancer. Expert opinions, animal and case studies, conference abstracts, narrative reviews, and publications that were not peer-reviewed were excluded.

Identification of Existing Validated Patient-Reported Outcome Measures

The names of the PROMs were extracted and consolidated based on the above mentioned steps. When several versions of the same PROM were identified across the included studies, the most recent and comprehensive version was included to optimize the amount of pertinent items for review. Copies of shortlisted PROMs were obtained either from publicly accessible sources (such as official websites or research publications) or upon the permission of their developers or study investigators.

Data Extraction and Analysis

Measurement properties (items, recall period, response scale, and assessment content) and the validation population characteristics (sample size, cancer type, country, validation language, and publication year) were extracted from previous PROMs and the corresponding validation articles. Patient-reported symptom items were then selected and

classified based on consensus among members of the PRO Symptom Rating Subcommittee. Frequency counts of these identified symptom items were extracted from previous PROMs by two trained PRO symptom researchers.

The selection and classification were qualitative studies, and each item was independently judged by two trained PRO symptom researchers. When disagreements arise, decisions are made by senior PRO symptom researcher. The selection followed the principle that the item measured symptoms obtained directly from the patients, without any interpretation by the clinicians or others.[2] The measurements of psychological and social support dimensions were excluded. Classification was based on the meaning and specific underlying constructs of the objects measured by the item.[10]

Results

Search Results and Characteristics of the Included Articles

The database search yielded 53,096 studies in total, of which 15,544 duplicate entries were excluded. A total of 37,414 studies were eliminated after a careful review of titles and abstracts. Subsequently, 119 studies were excluded upon full-text review, the reasons for which are provided in Figure 1. A manual, thorough check of the reference lists revealed an additional 10 studies, leading to 29 pertinent studies validating PROMs in patients with hepatobiliary or pancreatic cancer. Appendix 2 presents the characteristics of the relevant studies.

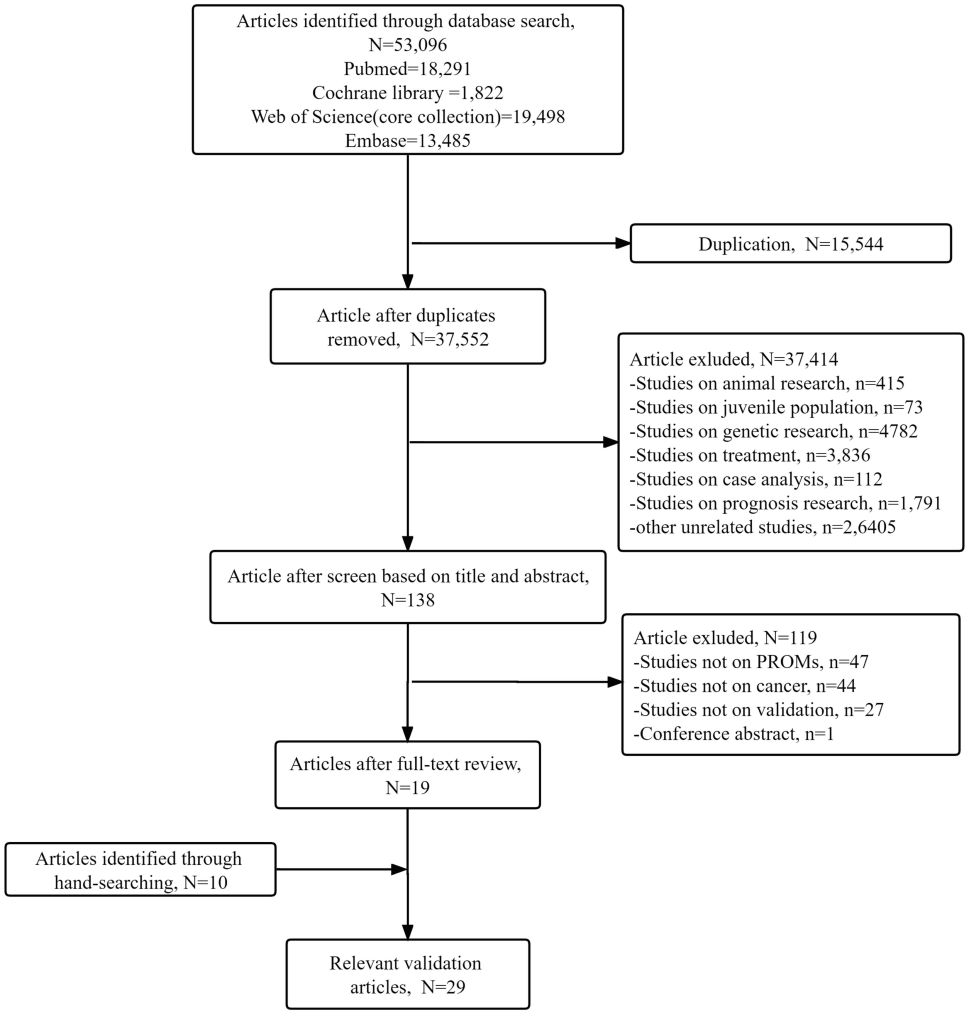

Figure 1 Flow chart of the systematic literature review.

Identification of Existing Validated Patient-Reported Outcome Measures

An analysis of the included articles identified 16 unique PROMs that were validated for hepatobiliary or pancreatic cancer, as presented in Box 1. Among the 16 PROMs, eight were validated in patients with cancer, including hepatobiliary or pancreatic cancer, and eight PROMs were validated in patients with hepatobiliary or pancreatic cancer.

In disease-specific PROMs, The European Organization for Research and Treatment of Cancer questionnaire module for hepatocellular carcinoma (EORTC QLQ-HCC18) was validated in patients with hepatocellular carcinoma alone, the European Organization for Research and Treatment of Cancer Quality of Life questionnaire liver metastases module (EORTC QLQ-LMC21) was validated in liver metastasis from colorectal cancer alone, and the European Organization for Research and Treatment of Cancer Quality of Life questionnaire in patients with cholangiocarcinoma and gallbladder cancer (EORTC QLQ-BIL21) was validated in cholangiocarcinoma or gallbladder cancer alone. The PROMs included (except the Quality of Life Instrument for Patients With Liver Cancer, QOL-LC, which developed in Chinese Mandarin) were developed in English, and eight PROMs were verified in languages other than English. A total of 15 languages were used in these validations: Arabic, Brazilian, Chinese Cantonese (Hong Kong), Chinese Mandarin (Mainland), Chinese Mandarin (Taiwan), Dutch, English, French, German, Haitian, Italian, Japanese, Korean, Polish, and Spanish.

Box 1 List of the Patient-Reported Outcome Measures That Were Validated in Hepatobiliary or Pancreatic Malignancies

Generic PROMs*
Functional Assessment of Cancer Therapy-General Scale (FACT-G) (27 items)[20,21]
The M.D. Anderson Symptom Inventory (MDASI-core) (19 items)**;[22]
World Health Organization Quality of Life Scale Brief Version (WHOQOL-BREF)** (26 items);[23]
EuroQol-5D(EQ-5D)**(5+1 items);[24,25]
Edmonton Symptom Assessment System-revised (ESAS-r)** (9 items);[26–30]
The Memorial Symptom Assessment Scale (MSAS)**(88 items);[31]
The Brief Fatigue Inventory (BFI)** (9 items);[32]
The Brief Pain Inventory (BPI)**(15 items);[33]
Disease-Specific PROMs
The European Organization for Research and Treatment of Cancer questionnaire module for hepatocellular carcinoma (EORTC QLQ-HCC18) (30 +18 items);[34–38]
The European Organization for Research and Treatment of Cancer Quality of Life questionnaire liver metastases module (EORTC QLQ-LMC21) (30+21 items);[39–41]
The European Organization for Research and Treatment of Cancer Quality of Life questionnaire in patients with cholangiocarcinoma and gallbladder cancer (EORTC QLQ-BIL21) (30+21 items)[42]
Functional Assessment of Cancer Therapy-Hepatobiliary Questionnaire (FACT-Hep) (45 items)[12,43]
Functional Assessment of Cancer Therapy-Hepatobiliary Symptom Index (FHSI-8) (8 items)[11]
The National Comprehensive Cancer Network-The functional Assessment of Cancer Therapy–Hepatobiliary-Pancreatic Symptom Index (FHSI-18) (18 items);[44]
The MD. Anderson Symptom Inventory for hepatectomy perioperative care (MDASI-PeriOp-Hep)(18 items);[45]
The Quality of Life Instrument for Patients With Liver Cancer (QOL-LC)(22 items).[46]

Notes: *Generic PROMs: Instruments were validated in generic patients with cancer, which included hepatobiliary or pancreatic cancer; **Instruments validated in non-English but have an existing English version.

Symptom Item Selection and Classification

Fourteen PROMs from 27 studies were retrieved and included in the symptom measure item analysis, and 2 PROMs (MD Anderson Symptom Inventory for hepatectomy perioperative care, MDASI-PeriOp-Hep and QOL-LC) were excluded because of failure to obtain item information. A total of 421 items were extracted from the PROMs. At the selection stage, 192 items that were inconsistent with the definitions of PRO symptom measures were removed. Two independent PRO symptom researchers achieved 95.01% agreement on the items for removal. Ultimately, 229 patient-reported symptom items were included and grouped into 40 patient-reported symptoms based on the measurement dimension. Finally, the patient-reported symptom item list was constructed according to the symptom classification (Appendix 3). Most eliminated items were measures of the psychological dimension (eg, "I worry about dying"). And social support dimension (eg, "I get emotional support from my family").

Measurement Properties of the Patient-Reported Symptom Items

There were 229 patient-reported symptom items and 40 patient-reported symptoms that were validated in patients with hepatobiliary or pancreatic cancer. The top three symptoms with the most items were fatigue (34), pain (28), and nausea (10). The number of items for each symptom is summarized in Table 1.

Table 1 Number of Patient-Reported Symptom Items on Each Symptom

NO.	Symptom	Number of Items	NO.	Symptom	Number of Items
1	Fatigue	34	21	Body image	4
2	Pain	28	22	Constipation	4
3	Nausea	10	23	Cough	3
4	Sleep disturbance	9	24	Difficulty swallowing	3
5	Lack of appetite	8	25	Dizziness	3
6	Sexual interest	8	26	Early satiety	3
7	Weight loss	8	27	Feel ill	3
8	Discomfort or pain in stomach	7	28	Problems with urination	3
9	Dry mouth	7	29	Sore mouth	3
10	Jaundice	7	30	Sweats	3
11	Itching	6	31	Chill	2
12	Shortness of breath	6	32	Difficulty remembering	2
13	Taste changes	6	33	Digest function	2
14	Back pain	5	34	Fever	2
15	Bloating	5	35	Hair loss	2
16	Diarrhea	5	36	Skin change	2
17	Difficulty concentrating	5	37	Swelling of arms or legs	2
18	Drowsiness	5	38	Trouble with eating	2
19	Numbness or tingling	5	39	Abdominal pain	1
20	Vomiting	5	40	Shoulder pain	1

Table 2 Measurement Properties of the Validated Patient-Reported Symptom Items

Measurement Properties (n = 229)	Number of Items	%
Recall period		
Now	8	3.49
Today	3	1.31
Last 24 hours	30	13.10
Past 7 days	48	20.96
Past week	132	57.64
Last 2 weeks	6	2.62
Last 4 weeks	2	0.87
Response scale		
Binary (Yes/No)	2	0.87
VRS_1-3	1	0.44
VRS_1-4	106	46.29
VRS_0-4	75	32.75
VRS_1-5	7	3.06
NRS_0-10	38	16.59
Assessment		
Frequency	22	9.61
Intensity	143	62.45
Interference	63	27.51
Relief	1	0.44
Instrument		
Generic PROMs	142	62.00
Disease-Specific PROMs	87	38.00
Validation disease		
Hepatobiliary cancer	189	82.53
Pancreatic cancer	162	70.74
Cholangiocarcinoma or gallbladder cancer	65	28.38
Liver metastasis from colorectal cancer	29	12.66

These symptom measurements included seven recall periods (now, today, past 24 hours, past week, past 7 days, past 2 weeks, and past 4 weeks) and six response scales (verbal rating scale (1–3) [VRS_1-3], VRS_1-4, VRS_0-4, VRS_1-5, numerical rating scale (0–10) [NRS_0-10]and binary), as well as four assessment contents (frequency, intensity, interference and symptom relief). "Past week" recall time, "4-points VRS" response scale and "intensity" symptom assessments were the most widely used measures of symptoms. The measurement properties of the patient-reported symptom items are summarized in Table 2, and the breakdown of the number of items for each symptom is presented in Appendix 4.

Discussion

This systematic review established a symptom item bank for hepatobiliary or pancreatic cancer, labeled by their measurement properties. Considering anatomical associations, we integrated symptoms of hepatobiliary or pancreatic malignancies into the same item bank, consistent with the development of most PROM tools.[11,12] To raise the comprehensiveness of the symptom item bank, items from PROMs that were validated in patients with hepatobiliary or pancreatic cancer, including both disease-specific and non-disease-specific PROMs, were taken into consideration and reviewed for inclusion. To the best of our knowledge, this systematic review is the first to compile symptom measurement items from various PROMs into a symptom item bank for hepatobiliary or pancreatic malignancies. Given that the

developed system of PROMs has been validated for measuring hepatobiliary or pancreatic malignancies, the symptom item bank summarizes all symptoms and their measurement characteristics, and identifies the most reported items. This will assist researchers in making rapid decisions regarding symptom measurement.

An expert consensus underscored pain intensity as a single construct and advised using a unidimensional assessment tool to assess pain intensity in 2011.[13] This approach allows for the prevalent practice of employing single-item pain measures in clinical and research contexts.[14] Subsequently, the validity and feasibility of more symptoms were verified using single-item measures such as back or leg pain,[15] fatigue[16] and headache.[17] When patients with cancer are under a symptom monitoring project, it is difficult for them to complete lengthy symptom measurements because of their poor physical condition.[6] Meanwhile, it is difficult for medical staff to supervise high-frequency monitoring or screening owing to busy clinical work.[18] Therefore, the advantages of simplicity and low burden of the single-item symptom scale would make it a feasible tool for assessing patient symptom intensity in routine clinical practice. The symptom item bank established in this study provides a basis for the development of a single-item measurement system for hepatobiliary or pancreatic malignancies.

We summarized 40 PRO symptoms from 14 PROMs validated for hepatobiliary or pancreatic cancer, of which fatigue, pain, and nausea were the most concerning. Within these symptom items, their measurement properties include recall times, response scales, and assessment content. It remains unclear how to select the best-performing item for a specific purpose and build a single-item measurement system. A comparative validation of the performance of items with different recall periods and response scales for each symptom is a future research plan.

This systematic review is subject to certain limitations. First, we included only full-text articles that were published in English and peer-reviewed.[19] Second, the symptom item library did not include the MDASI-PeriOp-Hep and QOL-LC items, because of the failure to obtain their item information from publicly available sources. Third, due to the well-validated PROMs allow for the accurate and reliable assessment of symptoms, this systematic review only included PROMs validated in patients with hepatobiliary or pancreatic cancer. This approach was regarded appropriate, considering the utmost value of validation in justifying the specificity of the instrument. Fourth, for a more comprehensive symptom item bank, generic PROMs including patients with hepatobiliary or pancreatic cancer in the validation population were reviewed for inclusion, but we did not limit the sample size of patients with hepatobiliary and pancreatic cancer in the verified population; therefore, few generic PROMs have the problem of a low proportion of patients with hepatobiliary or pancreatic cancer for validation, resulting in an underestimation of the reported frequency of specific items for hepatobiliary and pancreatic cancer. Besides, more information about symptoms, such as the incidence, correlation and influencing factors, need to be verified in the future development of single-item symptom measurement system.

In conclusion, this study applied a systematic review to identify and collate symptom items from 14 distinct validated PROMs into an item bank, from which researchers are enabled to select appropriate items for symptom assessment. Future research should consider population validation to compare the performance of different symptom measurement items to construct a single-item measurement system by selecting the best performing item for each symptom.

Abbreviations

PRO, patient-reported outcome; PROMs, patient-reported outcome measures; VRS, verbal rating scale; NRS, numerical rating scale.

Acknowledgments

JYZ and YXZ contributed equally as co-first authors. We would like to thank Editage for English language editing.

Funding

This research was supported by Natural Science Foundation of Chongqing, China (CSTB2022NSCQ-MSX0118).

Disclosure

The authors report no conflicts of interest in this work.

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