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Review Article

Patient-reported outcome measures (PROMs) used to assess sexual functioning in prostate cancer patients: a systematic review of psychometric properties

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Abstract

Background: Prostate cancer (PCa) significantly impacts patients' sexual functioning and quality of life. Patient-reported outcome measures (PROMs) are essential for accurately assessing these issues, yet a comprehensive evaluation of their psychometric properties in PCa patients is lacking.
Aims: This systematic review aimed to provide a comprehensive evaluation of all generic and specific PROMs used to assess sexual functioning in PCa patients and make recommendations the application of PROMs in this patient group.
Methods: Six electronic databases were searched from up to May 5, 2024. Studies reporting the development and/or validation of PROMs for PCa patients or generic instruments administered to this population were included. The COSMIN risk of bias checklist was adopted to assess the methodological quality and psychometric properties of included PROMs. Psychometric properties of the PROM in each included study were rated against the criteria for good measurement properties based on the COSMIN guideline.
Outcomes: The main outcome was to identify the appropriate PROM that can be adopted and used for assessing sexual functioning in PCa patients in clinical setting.
Results: A total of 10 PROMs were identified across 32 studies, primarily focusing on localized PCa patients after radical prostatectomy. The Expanded Prostate Cancer Index Composite (EPIC-26) was the most frequently evaluated and widely used PROM in clinical practice. EPIC-26 (Spanish, Italian, Chinese versions) and UCLA Prostate Cancer Index (UCLA-PCI) demonstrated better psychometric properties compared to other scales. However, no PROM met all COSMIN standards.
Clinical Implications: In a clinical setting, it is crucial to utilize well-validated PROMs with good psychometric properties to effectively identify patients with PCa experiencing sexual difficulties who may require additional support.
Strengths and Limitations: We applied strict inclusion criteria related to study design and study population, ensuring the assumption of transitivity and the consistency of the analysis.
Conclusion: Although EPIC-26 is a shortened version with strong psychometric properties, it may still be too lengthy for patients with significant health issues. Furthermore, the included PROMs do not address issues related to partner relationships, or the psychological impact of sexual dysfunction in sufficient detail. Future research should aim to develop and validate new PROMs that fill these gaps. These tools should be both psychometrically robust and practical for routine use, enabling real-time monitoring and improved care delivery.

Keywords: patient-reported outcome measures; prostate cancer; psychometric properties; sexual functioning; systematic review.

Introduction

Prostate cancer (PCa) is the second most common cancer and the fifth leading cause of death among men globally.[1] Advances in cancer treatment strategies have increased the life expectancy of PCa patients from 73% to 82% over the past decades.[2,3] Nevertheless, living longer does not always equate to living well, as well as the disease and its treatments impact not only the physical health of patients but also their psychological, emotional and social well-being. Research indicates that PCa patients experience a multitude of sexual problems, including erectile dysfunction, reduced sexual function and desires, ejaculation issues, and problems with orgasm, which can occur before and/or after treatment.[4,5] These sexual problems can significantly affect PCa patients' quality of life (QOL), psychological status, treatment outcome, and even survival.[6]

The effects of PCa extend beyond erectile dysfunction caused by the disease itself to include psychological disorders induced by PCa or its treatments.[6] PCa reduces sexual desire and the frequency of sexual intercourse.[6] A reduction in sexual function in PCa patients is often linked to psychological instability caused by the cancer diagnosis, particularly depression.[6] PCa also often has a negative impact on the partner's mental state, leading to decreased sexual function.[6] The diagnosis of PCa induces fear and anxiety in married couples regarding the disease's impact on their lives, creating

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an unstable mental state in their sex lives and reducing sexual activity.[6] Therefore, preserving sexual function is crucial in managing PCa patients, and clinicians need to focus more on ensuring better QOL for patients and their partners.[7]

Given the significance of sexual problems in PCa patients' health, accurately identifying those who need substantial support is crucial in managing PCa, as a substantial proportion of patients die from causes other than the disease itself.[8] While the use of clinician-reported outcomes is crucial in the management of patients with PCa, managing PCa patients, relying solely on these clinical parameters may underestimate the disease's and its treatment's impact on patients' health outcomes.[9,10] Evidence has highlighted discrepancies between patient and clinician estimation of the prevalence and severity of symptoms and functional impairments, underscoring the importance of direct patient reporting.[11,12] A patient-reported outcome (PRO) is defined as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else"[13] (P.2). Self-reported questionnaires, known as PRO measures (PROMs), are standardized tools designed to capture PRO information.[14] PROM data can complement clinical parameters and inform the management of patients with cancer.

Various PROMs are available to assess sexual problems in the general population.[15,16] However, due to the multifactorial nature of sexual dysfunction in PCa patients, which often involves neurological, circulatory and psychological components,[17] it is recommended that specific PROMs be used for this particular patient group. Some studies have utilized available PROMs, including the University of California, Los Angeles Prostate Cancer Index (UCLA-PCI) and Expanded Prostate Index Composite-26 (EPIC-26) to assess sexual problems in PCa patients[18,19]; however, the validity of these measures has been poorly addressed, and limited data are available on the properties of PROMs that should be used and adopted in routine practice. There is still limited guidance to support healthcare professionals in choosing the most valid and reliable PROMs for assessing sexual problems in clinical settings. To our knowledge, a comprehensive systematic review assessing the psychometric properties and uses of PROMs for assessing sexual problems in PCa patients is still lacking. Thus, this review aimed to identify and evaluate the suitability of published measures of sexual problems for use in PCa patients and to make recommendations for best clinical practices. This paper seeks to answer the following questions: (1) Which PRO sexual measures have been used in people with PCa? (2) What instruments have been developed and validated specifically for people with PCa? (3) What is the evidence for the reliability and validity of sexual instruments in PCa patients? (4) What currently available PROM can be recommended in clinical practice? Understanding the available PROMs and their effectiveness in this context is essential for improving patient care and treatment outcomes and for aiding healthcare professionals and researchers in selecting the most appropriate PROMs for sexual assessment in PCa patients.

Methods

Design

A systematic review was conducted to provide a comprehensive evaluation of all PROMs related to sexual problems experienced by PCa patients. This review included instruments developed for other diseases but administered to adult PCa patients, regardless of their disease stage or treatment regimen. The review adhered to the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) guidelines for systematic reviews of measurement properties[20] and was reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[21]

Search strategy

A comprehensive electronic search was systematically conducted in Scopus, Web of Science, PubMed, Embase (Ovid), CINAHL Plus (EBSCOhost), and PsycINFO (ProQuest) to identify sexual outcome measures that have been utilized in PCa. Search terms included a combination of appropriate Medical Subject Headings (MeSH) terms, subject headings, and keywords for the concepts of "*prostate cancer*" AND "*sexual dysfunction**" AND "*PROM**". The search strategy was developed with the assistance of university library staff. Detailed search strategies for all included databases can be found in Supplementary Table 1.

Eligibility criteria

Inclusion criteria

1) Articles investigating the validation or development of subjective assessments of sexual problems/functioning, regardless of study design.
2) Articles describing PROMs specifically designed and validated for PCa patients or generic instruments administered to PCa patients.
3) Articles that developed, validated, evaluated, or tested the psychometric properties of sexual PROMs for PCa patients.
4) Articles providing evidence of measurement and/or practical properties (validity, reliability, interpretability, acceptability, and feasibility).
5) Articles considering adults clinically diagnosed with PCa.
6) Articles published in journals from inception to May 5, 2024.
7) Articles published in English.

Exclusion criteria

1) Articles focused on cancers other than PCa.
2) Articles with mixed study samples where results from PCa patients were not reported separately.
3) Qualitative research without validated metrics.
4) Abstracts, conference proceedings, dissertations/theses, study protocols, expert opinions, and review articles.

Study selection

The retrieved articles from the electronic search were exported into Endnote version X21, which afterward was used to remove duplicates. Two authors (HAO and KL) independently reviewed all titles and abstracts to assess eligibility. Full texts of the potentially eligible articles were further screened against the eligibility criteria. The reference lists of eligible studies were also reviewed to identify any additional studies missed in the electronic searches. The author (JY) was approached to resolve conflicts not agreed upon by discussion. The results

of the database searches and the study selection process are depicted in Supplementary Table 2.

Data extraction

For the included articles, the first author (HAO) extracted the following data: basic information (author(s), year of publication, setting/country); study design/type; population characteristics (sample size, inclusion criteria, age); PROM details (name and type, development method, items, mode of administration and PROM language); and measurement properties according to the COSMIN guidelines. Data extractions were checked, reviewed, and verified by KL. Discrepancies were discussed and resolved by consensus among the authors.

Evaluation of the methodological quality of each study

The methodological quality of included studies was independently evaluated and ranked by two authors (HAO and KL) using the COSMIN Risk of Bias checklists.[20] The checklists assess the measurement properties of instruments in terms of content validity, structural validity, internal consistency, cross-cultural validity/measurement invariance, reliability, measurement error, criterion validity, hypotheses testing for construct validity, and responsiveness. The measurement properties and definitions are presented in Supplementary Table 3.[22]

Eligible studies were rated based on the checklists, which include items rated as "very good," "adequate," "doubtful," "inadequate," and "not applicable".[23] The overall rating of each study was determined based on "the worst score counts" principle, where the lowest rating for any item was the rating for the study.[24]

Evaluation of the quality of psychometric properties and level of evidence of each measurement property

The psychometric properties of the PROMs in each included study were rated against criteria for good measurement properties.[23] The measurement properties and criteria are presented in Supplementary Table 4.[25] Each property was rated as sufficient (+), insufficient (−), or indeterminate (?).[26] After evaluating the quality of the psychometric properties of the PROM in different studies, a levels-of-evidence appraisal was conducted to determine the overall quality of each measurement property. Each PROM was given a final rating for each measurement property. The quality of each psychometric property of the PROM was rated as either sufficient (+), insufficient (-), inconsistent (±), or indeterminate (?). Subsequently, a modified Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach, as outlined in the COSMIN guideline, was used to grade the level of evidence of each psychometric property of the PROM as "high," "moderate," "low," or "very low" (Supplementary Table 5). This grading considered factors such as risk of bias, inconsistency, imprecision, and indirectness.[25] Afterwards, PROMs were grouped into three categories to enable evidence-based recommendations[27]: Category A includes PROMs with sufficient content validity (any level) and at least low-quality evidence for sufficient internal consistency. PROMs ranked as A can be recommended for use, and their outcomes can be relied upon. PROMs ranked as B, are not categorized in A or C category; and this category has the potential for recommendation to be used but need additional validation. PROMs ranked as C have high-quality evidence for an insufficient measurement property and should not be recommended for use.[27]

Results

Study selection

The initial literature search yielded 7453 articles. After removing duplicates, the title and abstract of the remaining articles ($n = 4473$) were screened, and a total of 204 articles' full texts were evaluated. Of these, 166 articles were excluded for the following reasons: no validation paper ($n = 121$), abstract only ($n = 11$), review paper ($n = 16$), conference proceeding ($n = 5$), thesis ($n = 6$), and no validated PROM of sexual problems ($n = 7$). Finally, 26 articles met the eligibility criteria and were included in the final analysis. Additionally, the reference lists of the included articles were checked to see if there were any relevant articles. Through this, three articles were added; three articles were also added through manual searching, and consequently, 32 articles were included in the analysis (Figure 1).

Characteristics of included studies

In recent years, there has been a growing validation of PROMs in PCa patients; out of the 32 identified studies, 17 were published from 2017 to 2023.[28-44] The majority of studies ($n = 27$) were methodological cross-sectional studies[28-36,39,41-57]; two were mixed method studies,[37,58] two were a longitudinal population-based study,[38,40] one was a retrospective study,[59] and one a secondary data analysis study.[34] Seven studies were conducted in the USA,[36,38,40,47,48,56,57] four in Canada,[34,37,53,54] three in China,[41,43,49] three in Germany,[31,39,59] two in Norway,[44,50] two in Spain,[28,46] two in Italy,[35,51] and one in the Philippines,[30] Brazil,[33] Australia,[29] Korea,[32] Japan,[52] Netherlands,[58] and Iran.[55] One international validation study was conducted in Northern and Southern Europe and from the United Kingdom.[42]

The number of participants included in the studies ranged from 10[30] to 3094,[31] with mean ages ranging from 62.7[57] to 75 years.[42] Most of the studies ($n = 20$) focused on patients with localized PCa treated with radical prostatectomy or radiotherapy.[28,30,31,33-36,38-40,45-48,50,52-54,57,58] Only two studies focused on PCa survivors.[42,56] Detailed characteristics of the included studies are presented in Table 2.

Patient-reported outcome measures

A total of 10 different PROMs were identified across the studies: four PCa-specific PROMs (Expanded Prostate Cancer Index Composite [EPIC], EPIC for Clinical Practice [EPIC-CP], UCLA-PCI, and Patient-Oriented Prostate Utility Scale [PORPUS]); three generic PROMs (Short-Form Health Survey-36 [SF-36], Short-Form Health Survey-12 [SF-12], and Patient-Reported Outcomes Measurement Information System Sexual Function and Satisfaction [PROMIS SexFS]); two specific to erectile function (International Index of Erectile Function [IIEF] and Premature Ejaculation Diagnostic Tool [PEDT]); and one cancer-generic PROM (European Organisation for Research and Treatment of Cancer Quality of Life, 30-item core questionnaire [EORTC QLQ-C30]).

The PCa-specific PROM (EPIC) was the most frequently evaluated in validation studies ($n = 14$),[28-31,34-36,39,41,43-45,50,57] followed by the UCLA-PCI ($n = 6$)[47,51,52,54,56,58] and

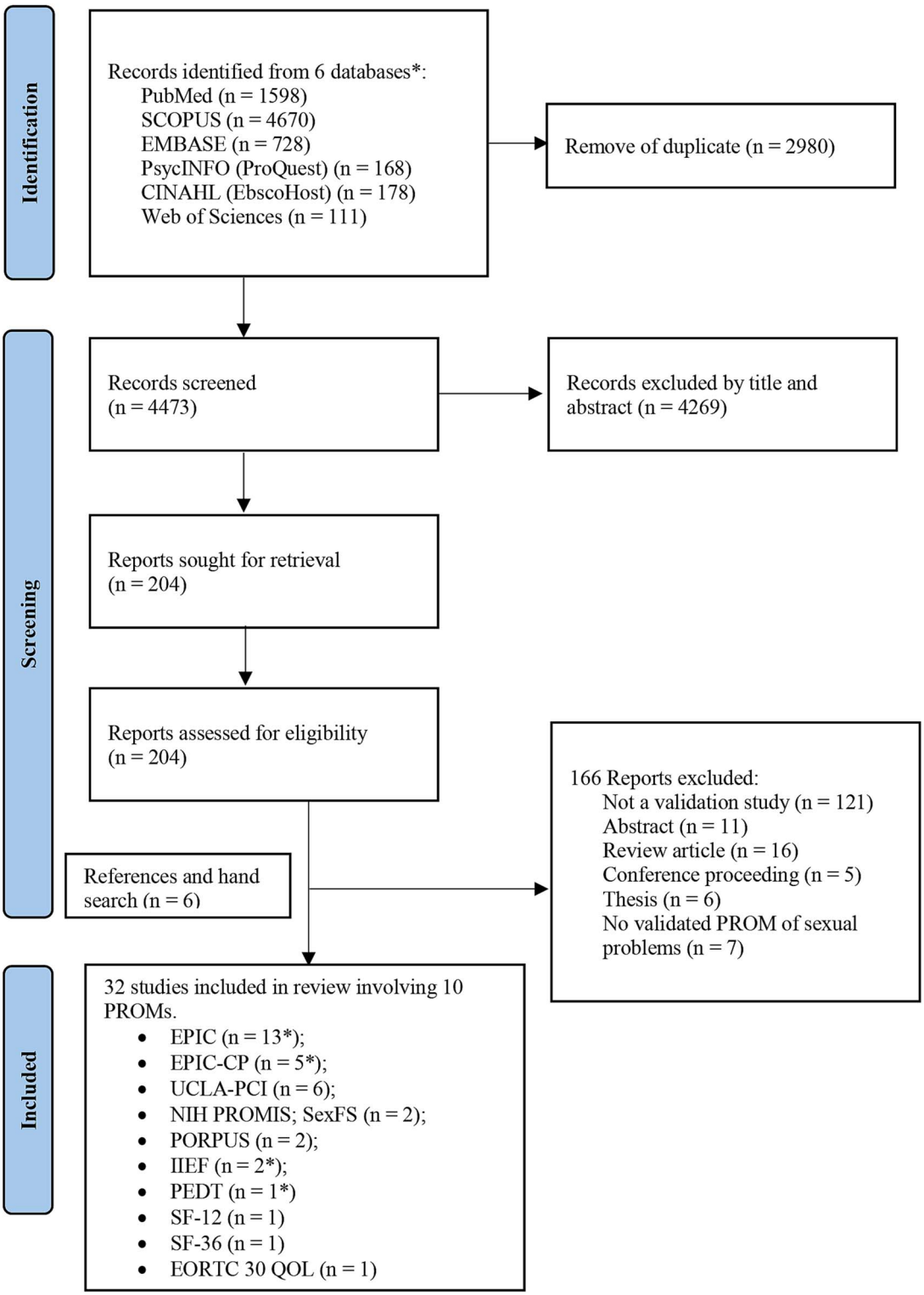

Figure 1. Flow diagram of articles identified for use in the review. ∗ Two validated studies evaluated 4 included patients reported outcome measures. EORTC 30 QOL = the EORTC Core quality of life questionnaire; EPIC = expanded prostate cancer index composite; EPIC-CP = expanded prostate cancer index composite-clinical practice; UCLA-PCI = University of California, Los Angeles prostate cancer index; IIEF = international index of erectile function; PORPUS = patient-oriented prostate utility scale; PEDT = premature ejaculation diagnostic tool; PROMIS SexFS = patient-reported outcomes measurement information system sexual function and satisfaction; SF-12 = short form-12 health survey; SF-36 = short form-36 health survey.

EPIC-CP ($n = 5$).[32,33,37,43,48] Among the EPIC versions, EPIC-26 was the most frequently utilized ($n = 8$)[28,29,31,34-36,43,50] compared with EPIC-50 ($n = 5$)[39,41,44,45,57] and EPIC 32 ($n = 1$).[30]

The number of items in each PROM ranged from five items in IIEF-5 and PEDT[55] to 56 items in PROMIS SexFS.[40] All PROMs were multidimensional, including domains ranging from four to 11, except for the unidimensional IIEF

and PEDT with five items.[55] The most common specific domains measured were urinary incontinence, urinary irritative, bowel symptoms, sexual symptoms and hormonal symptoms. Generic PROMs (SF-12, SF-36, and PROMIS SexFS) focused more on measuring sexual desire, pain, social support, and physical and emotional function. A summary of the number of items and domains assessed for each PROM is presented in Table 1 and Supplementary Table 6.

Methodological quality of the included studies

The methodological quality of the measurement properties in the included articles varied across different PROMs (Table 2). Some PROMs exhibited very good methodological quality across multiple measurement properties, while others showed varying levels of adequacy and doubtfulness. For instance, 15 studies conducted hypothesis testing for construct validity, with their methodological qualities rated as very good or adequate.[29,38-46,52,54,56,58,59] Although internal consistency was the most frequently reported property (24 studies), most studies were rated as doubtful due to a lack of information on structural validity or unidimensionality of PROMs.[36,39-42,48,51,52,54,55,57,58] Among the studies that evaluated structural validity ($n = 11$), ten studies were rated as very good or adequate, except for the EPIC-26-English-Canadian study,[34] which was rated as inadequate due to confirmatory factor analysis (CFA) not meeting the threshold for adequate fit. Four studies evaluated criterion validity, all rated as very good,[28,45,48,50] and ten studies evaluated responsiveness, with their methodological qualities rated as very good or adequate.[28,29,31,38-40,47-49,58] Regarding cross-cultural validity, 13 studies were rated as doubtful due to unclear approaches and whether the samples were similar for relevant characteristics.[28,30,33,38,39,41,43,44,46,50-52,54,58] Five of the 15 studies that evaluated content validity were rated as doubtful[31,35,36,48,50,51] due to unclear patient feedback on item relevance.

Quality of psychometric properties

Psychometric properties of the PROMs in the individual studies are presented in Table 3, with details in Supplementary Table 6. Internal consistency was evaluated in 24 studies, with 12 rated as indeterminate due to insufficient evidence for structural validity or unidimensionality.[36,39-42,48,51,52,54,55,57,58] Thirteen studies evaluated test–retest reliability, with ten rated as sufficient.[28,35,36,39,46,52-54,56,57] Content validity was evaluated in 15 studies, with seven rated as sufficient.[28,30,32,35,43,45,52] Structural validity, including CFA and EFA, was assessed in 10 studies, all rated as sufficient.[28,31,33,35,43-45,55,56,59] Only four studies reported criterion validity and two of them were rated as sufficient.[28,50] Thirteen of the 15 studies that conducted hypothesis testing for construct validity were rated as sufficient.[29,31,38,40,41,43-46,54,56,58]

Summarizing the evidence and grading the quality of the evidence

Summarized evidence of the included PROMs is presented in Table 4, and details psychometric statistics in Supplementary Table 7. The levels of evidence varied among the different psychometric properties of the PROMs. For specific PCa scales, the French version of EPIC-50 had a high level of evidence for internal consistency and a moderate level of evidence for test–retest reliability, content validity, structural validity, and hypothesis testing for construct validity, all rated as sufficient, which categorized as A; can be recommended for use and result can be trusted.[44] The EPIC-50 (Norway) had a moderate level of evidence for internal consistency, structural validity, and hypothesis testing for construct validity, all rated as sufficient[44] and the EPIC-50 (English USA and Germany) had a moderate level of evidence for sufficient test–retest reliability,[39,57] they were categorized as B; have the potential for recommendation to be used but need additional validation.

The EPIC-26 (Italian) had a moderate level of evidence for internal consistency, test–retest reliability, content validity, and structural validity, all rated as sufficient.[35] The Spanish version of EPIC-26 had a moderate level of evidence for internal consistency, test–retest reliability, content validity, structural validity, criterion validity, and responsiveness, all rated as sufficient.[28] The Chinese version of EPIC-26 also had a moderate level of evidence for internal consistency, content validity, and structural validity, all rated as sufficient.[43] These EPIC-26 versions (Italian, Spanish, Chinese) were categorized as A. For the EPIC-CP, it was found that almost all of the studies had a low level of evidence of in most of the properties, except the Chinese version[43] that had moderate content validity and internal consistency, which categorized as A; can be recommended for use and result can be trusted.

For UCLA-PCI, the English-USA, Italian, French, and Dutch versions had a moderate level of evidence for test–retest reliability and hypothesis testing for construct validity, all rated as sufficient.[47,51,54,58] The English version of UCLA-PCI by Litwin et al. (1998)[56] had a high level of evidence for internal consistency, test–retest reliability and hypothesis testing for construct validity and a moderate level of evidence of structural validity, and these psychometric properties were all rated as sufficient. However, the only UCLA-PCI- Japanese version[60] had categorized as A because it had sufficient content validity (any level) and low-quality evidence for sufficient internal consistency and can be recommended for use and result can be trusted. The PORPUS Spanish version had a low level of evidence for test–retest reliability and hypothesis testing for construct validity, and a very low level of evidence for indeterminate internal consistency and cross-cultural validity.[46]

For specific erectile function, the IIEF-English Canadian version had a moderate level of evidence for test–retest reliability,[53] while the Persian version had a low level of evidence for structural validity.[55] For generic scales, the NIH PROMIS SexFS (English USA version) had a high level of evidence for responsiveness and a moderate level of evidence for hypothesis testing for construct validity, both rated as sufficient. However, it had a low level of evidence for indeterminate internal consistency.[38,40] The SF-12-Chinese had a high level of evidence for responsiveness.[49] While the SF-36 (English) had a moderate level of evidence for sufficient hypothesis testing for construct validity and a low level of evidence for indeterminate internal consistency.[42] The EORTC QLQ-C30 (German) had a moderate or high level of evidence for internal consistency, structural validity, and hypothesis testing for construct validity, all rated as sufficient.[61] Despite the high psychometric properties of some priorities of generic scales, they categorized as B, indicating need further validation.

Table 1. Characteristics of the included articles and PROMs

Author, year publication	Study title	• *PROMs-full name* • Items, (n) • Mode of administration • (PROM Language)	PROM Content/domains	Study design	Study location	• Study participant • Inclusion criteria	Age, years
Studies adopted EPIC (specific for PCa)							
We et al., (2000)[57]	Development and validation of the Expanded Prostate Cancer Index Composite (EPIC) for comprehensive assessment of health-related quality of life in men with prostate cancer	*EPIC: Expanded Prostate Cancer Index Composite.* • 50 items • Self-administered • English	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel symptoms • Sexual symptoms • Vitality/Hormonal symptoms	• Methodology study	• USA	• Localized PCa patients (n = 252) • Patients treated with radical prostatectomy, external beam radiation, or brachytherapy (with or without adjuvant hormonal therapy).	67.2 ± 8.1
Anota et al., (2016)[45]	Cross-cultural adaptation and validation of the French version of the Expanded Prostate cancer Index Composite questionnaire for health-related quality of life in prostate cancer patients	• *EPIC* • 50 items • Self-administered • French	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel • Sexual • Vitality/Hormonal	• Methodology study	• France	• Localized PCa patients (n = 187)	70.0 ± 6.5
Axcrona et al., (2017)[44]	Psychometric properties of the expanded prostate cancer index composite – 26 instruments in a cohort of radical prostatectomy patients: theoretical and practical examinations.	*EPIC* • 50 & 26 items • Self-administered • Norwegian	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel • Sexual • Vitality/Hormonal	• Methodology study	• Norway	• PCa patients (n = 651) • Norwegian males treated with robot-assisted laparoscopic prostatectomy (RALP).	NR
Umbehr et al., (2018)[39]	The German version of the Expanded Prostate Cancer Index Composite (EPIC): translation, validation and minimal important difference estimation	EPIC • 50 items • Self-administered • German	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel • Sexual • Vitality/Hormonal	• Methodology study	• Germany	• Localized PCa patients (n = 92) • Patients had a 3robotic radical prostatectomy	NR
Lee et al., (2018)[41]	Cultural adaptation and validation of the Chinese version of the expanded prostate cancer index composite	• *EPIC* • 50 items • Self-administered • Chinese (Hong Kong)	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel • Sexual • Vitality/Hormonal	• Methodology study	• China	• Prostate cancer patients (n = 50) • Patients had a history of biopsy-proven PCa and the ability to understand the spoken Chinese (Cantonese dialect) and traditional Chinese characters.	72.2 ± 6.44

(*Continued*)

Table 1. Continued

Author, year publication	Study title	• *PROMs-full name* • Items, (n) • Mode of administration • (PROM Language)	PROM Content/domains	Study design	Study location	• Study participant • Inclusion criteria	Age, years
Bacorro et al., (2023)[30]	Development and pilot-testing of the expanded prostate index composite – Filipino version (EPIC-F)	*EPIC-F: Expanded prostate index composite—Filipino version* • 32 items • Self-administered • Filipino	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel symptoms • Sexual symptoms • Vitality/Hormonal symptoms	• Methodology study	• Filipin	• Localized PCa patients (n = 10) • Patients, regardless of stage, disease status, or treatment received, and without cognitive or psychological dysfunction	66
Fosså et al., (2016)[50]	Psychometric testing of the Norwegian version of the Expanded Prostate Cancer Index Composite 26-item version (EPIC-26)	*EPIC* • 26 items • Self-administered • Norwegian	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel symptoms • Sexual symptoms • Vitality/Hormonal symptoms	• Methodology study	• Norway	• Localized PCa patients (n = 471) • Patients who were treated with radical prostatectomy (RP), or high-dose radiotherapy (RAD)	64 ± 6
Lam et al., (2017)[43]	Psychometric assessment of the Chinese version of the abbreviated Expanded Prostate Cancer Index Composite (EPIC-26) and the Clinical Practice Version (EPIC-CP) in Chinese men with prostate cancer	*EPIC* • 26 items • Self-administered • Chinese (Hong Kong)	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel symptoms • Sexual symptoms • Vitality/Hormonal symptoms	• Methodology study	• China	• Prostate cancer patients (n = 252) • Patients diagnosed with PCa were native Cantonese or Mandarin speakers.	69.32 ± 7.9
Einstein et al., (2019)[36]	Expanded Prostate Cancer Index Composite-26 (EPIC-26) Online: Validation of an Internet-Based Instrument for Assessment of Health-Related Quality of Life After Treatment for Localized Prostate Cancer	*EPIC* • 26 items • Phone interviews/Internet self-administered • English	• Urinary incontinence • Urinary irritation • Bowel function • Sexual function • Hormonal function	• Methodology study	• USA	• Localized PCa patients (n = 133) • Patients previously untreated stage T1 to T2 PCa who had elected prostatectomy, brachytherapy, or external-beam radiotherapy as primary treatment.	61.8 ± 7.4
Marzorati et al., (2019)[35]	Validation of the Italian version of the abbreviated expanded prostate cancer index composite (EPIC-26) in men with prostate Cancer.	*EPIC* • 26 items • Self-administered • Italian	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel • Sexual • Vitality/Hormonal	• Methodology study	• Italy	• Localized PCa patients (n = 284) • Patients undergone robot-assisted radical prostatectomy.	63.4 ± 7.12

(*Continued*)

Table 1. Continued

Author, year publication	Study title	• *PROMs-full name* • Items, (n) • Mode of administration • (PROM Language)	PROM Content/domains	Study design	Study location	• Study participant • Inclusion criteria	Age, years
Crump et al., (2020)[34]	Evaluating the measurement properties of the 26-item Expanded Prostate Cancer Index Composite (EPIC-26) with a multicenter cohort.	*EPIC* • 26 items • Self-administered • English	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel • Sexual • Vitality/Hormonal	• A secondary analysis of data prospectively	• Canada	• Localized PCa patients (n = 205) • Patients treated with either radical prostatectomy or radiation therapy.	NR
Sibert et al., (2021)[31]	Psychometric validation of the German version of the EPIC-26 questionnaire for patients with localized and locally advanced prostate cancer.	*EPIC* • 26 items • Self-administered • German	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel • Sexual • Vitality/Hormonal	• Methodology study	• Germany	• Localized or locally advanced PCa (n = 3094) • Patients with localized or locally advanced PCa (any T, any N, M0) treated with active surveillance, surgery, external radiotherapy, or brachytherapy.	66.0 ± 7.4
Bulamu et al., (2023)[29]	Responsiveness and construct validity of EPIC-26, AQoL-6D and SF-6D following treatment in prostate cancer	*EPIC* • 26 items • Self-administered • English	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel symptoms • Sexual symptoms • Vitality/Hormonal symptoms	• Methodology study	• Australia	• PCa patients (n = 1915)	65.3 ± 6.9
Zamora et al., (2023)[28]	Psychometric validation of the Spanish version of the Expanded Prostate Cancer Index Composite-26	*EPIC* • 26 items • Self-administered • Spanish	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel symptoms • Sexual symptoms • Vitality/Hormonal symptoms	• Methodology study	• Spain	• Localized or locally advanced prostate cancer (n = 534) • Patients diagnosed with localized or locally advanced prostate cancer (any T, any N, M0) treated with active surveillance, surgery, external radiotherapy, or brachytherapy.	68.1 (8.0)
EPIC-CP (specific for PCa)							
Chang et al., (2011)[48]	Expanded prostate cancer index composite for clinical practice: development and validation of a practical health related quality of life instrument for use in the routine clinical care of patients with prostate cancer.	*EPIC-CP: EPIC for Clinical Practice* • 16 items • Self-administered • English	• Urinary Incontinence • Urinary Irritative • Bowel • Sexual • Hormonal	• Methodology study	• USA	• Localized primary or systemic PCa patients (n = 307) • Patients who had undergone brachytherapy, external radiotherapy, and radical prostatectomy.	65

(*Continued*)

Table 1. Continued

Author, year publication	Study title	• *PROMs-full name* • Items, (n) • Mode of administration • (PROM Language)	PROM Content/domains	Study design	Study location	• Study participant • Inclusion criteria	Age, years
Lam et al., (2017)[43]	Psychometric assessment of the Chinese version of the abbreviated Expanded Prostate Cancer Index Composite (EPIC-26) and the Clinical Practice Version (EPIC-CP) in Chinese men with prostate cancer	*EPIC-CP* • 16 items • Self-administered • Chinese (Hong Kong)	• Urinary Incontinence • Urinary Irritative/Obstruction • Bowel symptoms • Sexual symptoms • Vitality/Hormonal symptoms	• Methodology study	• China	• Prostate cancer patients (n = 252) • Patients diagnosed with prostate cancer were native Cantonese or Mandarin speakers.	69.32 ± 7.9
Brundage et al., (2019)[37]	A pilot evaluation of the expanded prostate cancer index composite for clinical practice (EPIC-CP) tool in Ontario	*EPIC-CP* • 16 items • Self-administered • English	• Urinary Incontinence • Urinary Irritative • Bowel • Sexual • Hormonal	• Mixed method; cross sectional followed by qualitative	• Canada	• Prostate cancer patients (n = 287) • Patients had not received palliative chemotherapy or radiotherapy (hormonal therapy was permitted).	NR
Lourenço et al., (2020)[33]	Portuguese version of the Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP): psychometric validation and prospective application for early functional outcomes at a single institution	*EPIC-CP* • 16 items • Self-administered • Portuguese	• Urinary Incontinence • Urinary Irritative • Bowel • Sexual • Hormonal	• Methodology study	• Brazil	• Localized PCa patients (n = 152) • Patients who had preoperatively, these patients after robotic radical prostatectomy, and those 12 months after undergoing that surgery.	62.7 ± 8.5
Hwang et al., (2021)[32]	Translation and Linguistic Validation of Korean Version of the Expanded Prostate Cancer Index Composite for Clinical Practice for patients with prostate cancer	*EPIC-CP* • 16 items • Self-administered • Korean	• Urinary Incontinence • Urinary Irritative • Bowel • Sexual • Hormonal	• Methodology study	• Korea	• Prostate cancer patients (n = 10)	-
UCLA-PCI (specific for PCa)							
Litwin et al., 1998[56]	The UCLA Prostate Cancer Index: development, reliability, and validity of a health-related quality of life measure	*UCLA-PCI: University of California, Los Angeles Prostate Cancer Index*. • 20 items • Self-administered • English	• Urinary Function • Urinary Bother • Sexual Function, • Sexual Bother • Bowel Function, • Bowel Bother	• Methodology study	• USA	• PCa survivors (n = 528) • Patients with early-stage prostate cancer	72.7

(*Continued*)

Table 1. Continued

Author, year publication	Study title	• *PROMs-full name* • Items, (n) • Mode of administration • (PROM Language)	PROM Content/domains	Study design	Study location	• Study participant • Inclusion criteria	Age, years
Kakehi et al., (2002)[52]	Development of Japanese version of the UCLA Prostate Cancer Index: A pilot validation study	*UCLA-PCI* • 20 items • Self-administered • Japanese	• Urinary Function • Urinary Bother • Sexual Function, • Sexual Bother • Bowel Function, • Bowel Bother	• Methodology study	• Japan	• Localized PCa patients (n = 125) • Patients who had undergone radical retropubic prostatectomy or 3-D conformal external-beam irradiation	69.8
Karakiewicz et al., (2003)[54]	Cross-cultural validation of the UCLA prostate cancer index	*UCLA-PCI* • 20 items • Self-administered • French	• Urinary Function • Urinary Bother • Sexual Function, • Sexual Bother • Bowel Function, • Bowel Bother	• Methodology study	• Canada	• Localized PCa patients (n = 2415) • Patients treated with the radical prostatectomy.	63.6
Korfage et al., (2003)[58]	Measuring disease specific quality of life in localized prostate cancer: the Dutch experience	*UCLA-PCI* • 20 items • Self-administered • Dutch	• Urinary Function • Urinary Bother • Sexual Function, • Sexual Bother • Bowel Function, • Bowel Bother	• Mixed method: Qualitative followed by quantitative cross sectional	• Netherlands	• Localized PCa patients (n = 389)	67 ± 7
Gacci et al., (2005)[51]	Quality of life after radical treatment of prostate cancer: validation of the Italian version of the University of California-Los Angeles Prostate Cancer Index	*UCLA-PCI* • 20 items • Self-administered • Italian	• Urinary Function • Urinary Bother • Sexual Function, • Sexual Bother • Bowel Function, • Bowel Bother	• Methodology study	• Italy	• PCa patients (n = 595) • Patients treated with radical retropubic prostatectomy (RRP) or external beam radiation (EBR)	63.5 ± 11.6
Bergman et al., (2010)[47]	Responsiveness of the University of California-Los Angeles Prostate Cancer Index	*UCLA-PCI* • 20 items • Self-administered • English	• Urinary Function • Urinary Bother • Sexual Function, • Sexual Bother • Bowel Function, • Bowel Bother	• Methodology study	• USA	• Localized PCa patients (n = 475) • Patients underwent radical prostatectomy, external beam radiotherapy, or interstitial seed brachytherapy.	63.8 ± 8.3

(*Continued*)

Table 1. Continued

Author, year publication	Study title	• *PROMs-full name* • Items, (n) • Mode of administration • (PROM Language)	PROM Content/domains	Study design	Study location	• Study participant • Inclusion criteria	Age, years
PORPUS: (specific for PCa)							
Ávila et al., (2014)[46]	Adaptation and validation of the Spanish version of the Patient-Oriented Prostate Utility Scale (PORPUS)	*PORPUS: Patient-Oriented Prostate Utility Scale.* • 10 items • Self-administered • Spanish	• Pain • Energy • Social support • Communication with doctor • Emotional well-being • Urinary frequency • Urinary leakage • Sexual function • Sexual interest • Bowel Function	• Methodology study	• Spain	• Localized PCa patients (n = 480) • Patients treated with radical prostatectomy or radiotherapy.	66.8 ± 6.4
IIEF (specific for erectile function)							
Karakiewicz et al., (2005)[53]	Reliability of remembered International Index of Erectile Function domain scores in men with localized prostate cancer	*IIEF: International Index of Erectile Function.* • 15 items • Self-administered • English	• Erectile Function • Orgasmic Function • Sexual Desire • Intercourse Satisfaction • Overall Satisfaction	• Methodology study	• Canada	• Localized PCa patients (n = 39) • Patients diagnosed and treated with radical retropubic prostatectomy	55
Lin et al., (2016)[55]	Rasch analysis of the premature ejaculation diagnostic tool (PEDT) and the International index of erectile function (IIEF) in an Iranian sample of prostate cancer patients	• *IIEF-5* • 5 items • self-administered • Persian	• Five items	• Methodology study	• Iran	• Prostate cancer patients (n = 1058) • Patients aged 18 years and above, being in a stable sexual relationship with a female partner for at least 6 months, good cognitive function,	64.07 ± 6.84
PEDT (specific for erectile function)							
Lin et al., (2016)[55]	Rasch analysis of the premature ejaculation diagnostic tool (PEDT) and the International index of erectile function (IIEF) in an Iranian sample of prostate cancer patients	*PEDT: Premature Ejaculation Diagnostic Tool* • 5 items • Self-administered • Persian	• 5 items	• Methodology study	• Iran	• Prostate cancer patients (n = 1058) • Patients aged 18 years and above, being in a stable sexual relationship with a female partner for at least 6 months, good cognitive function.	64.07 ± 6.84
PROMIS SexFS: (generic)							
Reeve et al., (2018)[40]	Psychometric Evaluation of PROMIS Sexual Function and Satisfaction measures in a longitudinal population-based cohort of men with localized prostate cancer	*PROMIS SexFS: Patient-Reported Outcomes Measurement Information System Sexual Function and Satisfaction (version 2).* • 56 items • Self-administered/ Interviews • English	• Fatigue • Pain, • Depression • Anxiety • Physical functioning • Interest in sexual activity • Erectile function • Orgasm • Global satisfaction	• A longitudinal, population-based, observational study	• USA	• Localized PCa patients (n = 1449) • Newly diagnosed prostate cancer	-NR

(*Continued*)

Table 1. Continued

Author, year publication	Study title	• *PROMs-full name* • Items, (n) • Mode of administration • (PROM Language)	PROM Content/domains	Study design	Study location	• Study participant • Inclusion criteria	Age, years
Agochukwu et al., (2019)[38]	Validity of the Patient-Reported Outcome Measurement Information System (PROMIS) Sexual Interest and Satisfaction Measures in Men Following Radical Prostatectomy	PROMIS SexFS: Patient-Reported Outcomes Measurement Information System Sexual Function and Satisfaction. • 2items • Self-administered/Interviews • English	• A single item from the PROMIS Global Satisfaction with Sex Life subdomain • A single item from the PROMIS Interest in Sexual Activity subdomain	• A prospective longitudinal study.	• USA	• Localized PCa patients (n = 1604) • Patients had radical prostatectomy.	63.2 (7.3)
SF-12 (generic) Choi et al., (2016)[49]	The internal and external responsiveness of Functional Assessment of Cancer Therapy-Prostate (FACT-P) and Short Form-12 Health Survey version 2 (SF-12 v2) in patients with prostate cancer	*SF-12: Short Form-12 Health Survey (version 2).* • 12 items • Self-administered/Interviews • Cantonese	• Physical • Mental	• Methodology study	• Hong Kong/China	• PCa patients (n = 168)	72.9 (8.0)
SF-36 (generic) Van Leewen et al., (2017)[42]	International evaluation of the psychometrics of health-related quality of life questionnaires for use among long-term survivors of testicular and prostate cancer	*SF-36: Short Form-36 Health Survey.* • 36 items • Self-administered/Interviews • English	• Physical • Mental	• Methodology study	• Northern/-Southern Europe and UK	• PCa survivors (n = 116)	75.0 (5.8)
EORTC 30 QOL (cancer generic) Bestmann et al., (2006)[59]	Validation of the German prostate-specific module	*EORTC 30 QOL: The EORTC Core Quality of Life questionnaire* • 30 items • Self-administered/Interviews • German	• Physical • Emotional • Cognitive • Social • Global health status/QOL • Fatigue • Pain • Nausea and vomiting • Dyspnea • Insomnia • Appetite loss • Constipation • Financial difficulties	• Retrospective study	• Germany	• PCa patients (n = 950)	68.4 ± 6.4

Table 2. Methodological quality of the measurement properties in included articles

PROM	Internal consistency	Test–retest reliability	Content validity	Structure validity	Criterion validity	Hypothesis testing for construct validity		Responsiveness	Cross-cultural validity	Overall methodology
						Hypothesis testing	Measurement error			
EPIC-50-English 60]	Doubtful	Doubtful	0	0	0	0	0	0	0	Doubtful
EPIC-50-Frensh[44]	Very good	Very good	Adequate	Adequate	Very good	Very good	0	0	Doubtful	Doubtful
EPIC-50-Norway[44]	Adequate	0	0	Adequate	0	Adequate	0	0	0	Adequate
EPIC-50-Germnay[39]	Doubtful	Adequate	Adequate	0	0	Very good	0	Inadequate	Doubtful	Doubtful
EPIC-50-Chinese[41]	Doubtful	Adequate	Adequate	0	0	Adequate	0	0	Doubtful	Doubtful
EPIC-32- Filipino[30]	0	0	Very good	0	0	0	0	0	Doubtful	Doubtful
EPIC-26-Norway[50]	Adequate	0	Doubtful	0	Very good	0	0	0	Doubtful	Doubtful
EPIC-26-Chinese[43*]	Very good	0	Very good	Very good	0	Very good	0	0	Doubtful	Doubtful
EPIC-26-Englsih[36]	Doubtful	Adequate	Doubtful	0	0	0	0	0	0	Doubtful
EPIC-26-Italian[35]	Very good	Very good	Doubtful	Very good	0	0	0	0	0	Doubtful
EPIC-26-English[34]	Adequate	0	0	Inadequate	0	0	0	0	0	Inadequate
EPIC-26-German[31]	Very good	0	Doubtful	Very good	0	0	0	Adequate	0	Doubtful
EPIC-26-Englsih[29]	0	0	0	0	0	Very good	0	Very good	0	Very good
EPIC-26-Spanish[28]	Very good	Very good	Very good	Very good	Very good	0	0	Very good	Doubtful	Doubtful
EPIC-CP-English[48]	Doubtful	0	Doubtful	0	Very good	0	0	Adequate	0	Doubtful
EPIC-CP-Chinese[43*]	Very good	0	Very good	Very good	0	Very good	0	0	Doubtful	Doubtful
EPIC-CP-Englsih[37]	0	Doubtful	0	0	0	0	0	0	0	Doubtful
EPIC-CP- Portougese[33]	Very good	0	0	Very good	0	0	0	0	Doubtful	Doubtful
EPIC-CP-Korean[32]	0	0	Very good	0	0	0	0	0	0	Very good
UCLA-PCI- English[56]	Very good	Adequate	0	Adequate	0	Very good	0	0	0	Adequate
UCLA-PCI- Japanese[60]	Doubtful	Adequate	Adequate	0	0	Adequate	0	0	Doubtful	Doubtful
UCLA-PCI- Frensh[54]	Doubtful	Very good	0	0	0	Very good	0	0	Doubtful	Doubtful
UCLA-PCI- Dutch[58]	Doubtful	0	0	0	0	Adequate	0	Very good	Doubtful	Doubtful
UCLA-PCI- Italian[51]	Doubtful	0	Doubtful	0	0	0	0	0	Doubtful	Doubtful
UCLA-PCI- Englsih[47]	0	0	0	0	0	0	0	Very good	0	Very good
IIEF-English[53]	0	Adequate	0	0	0	0	0	0	0	Adequate
IIEF-Persian[55*]	Doubtful	Adequate	0	Adequate	0	0	0	0	0	Doubtful
PORPUS-Spanish[46]	Very good	Very good	Very good	0	0	Very good	0	0	Doubtful	Doubtful
PEDT- Persian[55*]	Adequate	Adequate	0	Adequate	0	0	0	0	0	Adequate
PROMIS SexFS- English[40]	Doubtful	0	0	0	0	Very good	0	Adequate	0	Inadequate
PROMIS SexFS- English[38]	0	0	0	0	0	Very good	0	Very good	0	Very good
SF-12-Chinese[49]	0	0	0	0	0	0	0	Very good	0	Very good
SF-36-Englsih[42]	Doubtful	0	0	0	0	Adequate	0	0	0	Doubtful
EORTC QLQ-C30-German[61]	Very good	0	0	Adequate	0	Very good	0	0	0	Adequate

Each study is rated as very good, adequate, doubtful or inadequate quality. 0 = not available data Overall methodology reported according to COSMIN risk of bias checklist using a "worst score count" principle and evaluation related to measurement property assessed. *One study evaluated two PROMs.

Table 3. Psychometric properties of the included PROMs in each study

PROM	Internal consistency	Test–retest reliability	Content validity	Structure validity	Criterion validity	Hypothesis testing for construct validity		Responsiveness	Cross-cultural validity
						Hypothesis testing	Measurement error		
EPIC-50-English 60]	?	+	0	0	0	0	0	0	0
EPIC-50-Frensh[44]	+	?	+	+	-	+	0	0	?
EPIC-50-Norway[44]	+	0	0	+	0	+	0	0	0
EPIC-50-Germnay[39]	?	+	?	0	0	+	0	+	?
EPIC-50-Chinese[41]	?	?	-	0	0	+	0	0	?
EPIC-32- Filipino[30]	0	0	+	0	0	0	0	0	?
EPIC-26-Norway[50]	?	0	?	0	+	0	0	0	?
EPIC-26-Chinese[43]*	+	0	+	+	0	-	0	0	-
EPIC-26-Englsih[36]	?	+	0	0	0	0	0	0	0
EPIC-26-Italian[35]	+	+	+	+	0	0	0	0	0
EPIC-26-English[34]	+	0	0	-	0	0	0	0	0
EPIC-26-German[31]	+	0	?	+	0	0	0	+	0
EPIC-26-Englsih[29]	0	0	0	0	0	+	0	+	0
EPIC-26-Spanish[28]	+	+	+	+	+	0	0	+	?
EPIC-CP-English[48]	?	0	?	0	?	0	0	+	0
EPIC-CP-Chinese[43]*	-	0	+	+	0	+	0	0	?
EPIC-CP-Englsih[37]	0	?	0	0	0	0	0	0	0
EPIC-CP- Portougese[33]	+	0	0	+	0	0	0	0	?
EPIC-CP-Korean[32]	0	0	+	0	0	0	0	0	0
UCLA-PCI- English[56]	+	+	0	+	0	+	0	0	0
UCLA-PCI- Japanese[60]	?	+	+	0	0	-	0	0	?
UCLA-PCI- Frensh[54]	?	+	0	0	0	+	0	0	?
UCLA-PCI- Dutch[58]	?	0	0	0	0	+	0	+	?
UCLA-PCI- Italian[51]	?	0	?	0	0	0	0	0	?
UCLA-PCI- Englsih[47]	0	0	0	0	0	0	0	+	0
IIEF-English[53]	0	+	0	0	0	0	0	0	0
IIEF-Persian[55]*	-	?	0	+	0	0	0	0	0
PORPUS-Spanish[46]	?	+	?	0	0	+	0	0	?
PEDT- Persian[55]*	-	?	0	+	0	0	0	0	0
PROMIS SexFS- English[40]	?	0	0	0	0	+	0	+	0
PROMIS SexFS- English[38]	0	0	0	0	0	+	0	+	0
SF-12-Chinese[49]	0	0	0	0	0	0	0	+	0
SF-36-Englsih[42]	?	0	0	0	0	+	0	0	0
EORTC QLQ-C30-German[61]	+	0	0	+	0	+	0	0	0

Hypothesis testing of construct validity was evaluated using convergent validity, which was considered as sufficient if a correlation between the PROM under study and the comparator instrument measuring the similar construct was ≥0.50.[62] The hypothesis testing for evaluating discriminant validity and responsiveness were in accordance with that in individual studies. + = sufficient; –= insufficient; ? = indeterminate; 0 = no data available.

Table 4. Evidence synthesis of the included PROMs

PROMs	Internal consistency	Test–retest reliability	Content validity	Structure validity	Criterion validity	Hypothesis testing for construct validity		Responsiveness	Cross-cultural validity	Category/ Recommendation
						Hypothesis testing	Measurement error			
EPIC-50 (English, Germany)[39,57]	?	+	0	0	0	0	0	0	0	B
Level of evidence	Low	Moderate								
EPIC-50-Frensh[44]	+	?	+	+	-	+	0	0	?	A
Level of evidence	Low	Moderate	Moderate	Moderate		Moderate			Low	
EPIC-50-Norway[44]	+	0	0	+	0	+	0	0	0	B
Level of evidence	Moderate			Moderate		Moderate				
EPIC-50-Chinese[41]	?	?	-	0	0	+	0	0	?	B
Level of evidence	Low	Moderate	Low			Moderate			Low	
EPIC-32- Filipino[30]	0	0	+	0	0	0	0	0	?	B
Level of evidence			Moderate						Low	
EPIC-26 (English, Norway)[29,36,50]	?	0	?	0	+	0	0	0	?	B
Level of evidence	Low		Low		Low				Low	
EPIC-26-Chinese[43]*	+	0	+	+	0	0	0	0	0	A
Level of evidence	Moderate		Moderate	Moderate						
EPIC-26-Italian[35]	+	+	+	+	0	0	0	0	0	A
Level of evidence	Moderate	Moderate	Moderate	Moderate			0			
EPIC-26-English[34]	+	0	0	0	0	0	0	0	0	B
Level of evidence	Low									
EPIC-26-German[31]	+	0	?	+	0	0	0	+	0	B
Level of evidence	Moderate		Low	Moderate				Moderate		
EPIC-26-Spanish[28]	+	+	+	+	+	0	0	+	?	A
Level of evidence	Moderate	Moderate	Moderate	Moderate	Moderate			Moderate	Low	
EPIC-CP-English[48]	?	0	?	0	?	0	0	+	0	B
Level of evidence	Low		Low		Low			High		
EPIC-CP-Chinese[43]*	+	0	+	+	0	+	0	0	?	A
Level of evidence	Low		Moderate	Low		Low			Low	
EPIC-CP (English, Korean, Portougese)[32,33,37]	0	?	0	0	0	0	0	0	0	B
Level of evidence		Moderate								
UCLA-PCI- English[56]	+	+	0	+	0	+	0	0	0	B
Level of evidence	High	High		Moderate		High				
UCLA-PCI- Japanese[60]	?	+	+	0	0	-	0	0	?	A
Level of evidence	Low	Moderate	Low			Low			Low	
UCLA-PCI (Englsih, Italian, French, Dutch)[47,51,54,58]	?	+	0	0	0	+	0	0	?	B
Level of evidence	Low	Moderate				Moderate			Low	
IIEF-English[53]	0	+	0	0	0	0	0	0	0	B
Level of evidence		Moderate								
IIEF-Persian[55]*	-	?	0	+	0	0	0	0	0	B
Level of evidence	Low	Low		Low						
PORPUS-Spanish[46]	?	+	?	0	0	+	0	0	?	B
Level of evidence	Very low	Low	Low			Low			Very low	
PEDT- Persian[55]*	-	?	0	+	0	0	0	0	0	B
Level of evidence	Low	Low		Moderate						
PROMIS SexFS (Englsih)[38,40]	?	0	0	0	0	+	0	+	0	B
Level of evidence	Low					Moderate		High		
SF-12-Chinese[49]	0	0	0	0	0	0	0	+	0	B
Level of evidence								Very good		
SF-36-Englsih[42]	?	0	0	0	0	+	0	0	0	B
Level of evidence	Low					Very good				
EORTC QLQ-C30-German[61]	+	0	0	+	0	+	0	0	0	B
Level of evidence	Moderate			Moderate		Moderate				

+ = sufficient; − = insufficient; ? = indeterminate; 0 = no data available. A = PROMs with evidence for sufficient content validity (any level) and at least low-quality evidence for sufficient internal consistency. B = PROMs categorized not in A or C. C = PROMs with high-quality evidence for an insufficient measurement property.

Discussion

This is the first systematic review that has assessed the methodological quality and psychometric properties of PROMs for evaluating sexual issues in PCa patients, both in research and, ideally, in clinical practice. Overall, ten PROMs were identified across 32 studies, indicating an increasing focus on validating these measures in this specific population, particularly in recent times. This study highlighted that half of the studies on this topic were conducted in the United States and European countries, including Canada, Germany, and Norway. These findings align with earlier research indicating the United States is one of the leading nations in implementing PROMs at the national level. In Asia, China has three validated PROMS, including EPIC-26, EPIC-CP, and IIEF,[41,43,49] indicating the increasing interest in assessing sexual problems of PCa since 2016. This significant interest in China is attributed to the high incidence of PCa diagnosis between 2015 and 2030,[63] increased disease awareness and the use of prostate-specific antigen screening.[61] The variety of geographical areas emphasizes the worldwide significance of this issue. However, the predominance of studies from high-income countries suggests a potential gap in research from low- and middle-income countries, where the burden of PCa is also significant.

This review showed that almost all the PROMs assessed sexual issues in PCa patients after radical prostatectomy or radiotherapy. This aligns with recent evidence indicating that these groups are a priority in survivorship care, which aims to improve men's lives after PCa treatment.[38] The high focus on these groups is attributed to the fact that sexual dysfunction after radical prostatectomy is directly related to treatment regret, feelings of loss, and distress.[38] PROMs after radical prostatectomy are primarily focusing on erectile function.[38,64] Despite these findings, little validated PROM has focused on patients undergoing other active treatments to assess the influence of treatments on their QOL. There is a notable imbalance in PROMs participants, with many studies predominantly focusing on specific demographic groups, including USA and Europe, with a focus on localized PCa. This lack of diversity can lead to a limited understanding of how various factors such as age, ethnicity, socioeconomic status, and cultural background influence PROs. Future research should include more diverse populations to enhance the generalizability of the findings. Expanding the scope of PROMs to cover different stages of treatment and diverse patient demographics will contribute to a more comprehensive understanding of patient experiences and outcomes in PCa care.

Although the generic preference-based measures, such as SF-12, and SF-36 are the most common preference-based PROMs identified in this review that provide information about patient QOL in general, they are not comprehensively addressed the core domains of urinary, bowel, and sexual functioning. The SF-12 andSF-36 scales are recognized as being sensitive, valid and reliable for a wide range of health issues.[65,66] These generic PROMs may lack sensitivity in measuring PCa-specific issues,[67] and they tend to be used in the general population and are perhaps more relevant at the system level. Thus, they can be used alongside other more specific PROMs, but clinicians and researchers have to consider the following feasibility measures of theses generic PROMs as part of their decision-making process: the scope and number of items of the generic PROM, ease of administration, and permissions and costs. Furthermore, these generic PROMs have high-quality evidence for insufficient measurement properties and thus cannot be recommended for routine practice or research.

Disease-specific PROMs are focused on assessing health aspects particular to a specific disease.[68] Our review revealed various disease-specific measures used for PCa patients, with the EPIC and the UCLA-PCI being the most frequently evaluated. Findings using these more specific PROMs may inform PCa treatment regimens, policy, and patient support. The EPIC-26 version was particularly prominent, reflecting its widespread use and acceptance in clinical practice. The EPIC-26 had a moderate level of evidence for internal consistency, test–retest reliability, content validity, and structural validity, all rated as sufficient for the Spanish, Italian, and Chinese versions.[28,35,43] The frequent adoption of EPIC-26 is based on the recommendation of the International Consortium for Health Outcomes Measurements (ICHOM) in 2015 for its use in clinical settings.[69] The frequent use of EPIC-26 suggests it is a well-accepted tool for assessing sexual health in PCa patients. Its multidimensional nature allows for a comprehensive assessment of various aspects of sexual health, which is crucial for understanding the full impact of PCa and its treatments. Additionally, The UCLA Prostate Cancer Index (UCLA-PCI) performed well and has the most positive COSMIN rating. It is a comprehensive measure of QOL for men with localized PCa patients in routine clinical practice, including six disease-targeted domains that measure function and bother in the urinary, sexual, and bowel domains. However, it is important to note that the ICHOM recommended that EPIC-26 can be used in men with localized PCa.[69] The pilot Chinese study by Lee et al (2018)[41] used EPIC-26 for assessing of all PCa patients, including those undergoing active surveillance and focal therapy. Despite the good validity and reliability of Lee et al,[41] it may overlook certain aspects, necessitating a re-evaluation to verify its robustness. UCLA-PCI also does not directly assess hormonal symptoms.[69] Therefore, considering that hormonal symptoms are one of the core outcomes,[70] we do not recommend the UCLA-PCI to be utilized in assessing sexual functioning in PCa. Therefore, EPIC-26 and UCLA-PCI have the potential to be recommended and used in clinical practice, but they require further research. Further robust validation studies are needed to assess the EPIC-26 among PCa patients' beyond during survival journey. Survival and time to PCa progression are common primary outcomes in oncology.[71] There is a need for a scale that can be utilized throughout the long-term journey of patients, starting from diagnosis, through treatment, and into recovery. Such a scale will help with real-time assessment and allow for comparisons of the effects of PCa diagnosis at all life stages. In addition, Although EPIC-26 is a shortened version of the original EPIC-50, it can still be considered lengthy for some PCa, especially those who are experiencing significant health issues or fatigue. Moreover, EPIC-26 covers several important domains, it may not capture all aspects of a patient's experience, particularly those related to mental health, social support, and other psychosocial factors. This limitation means that some important areas of patient well-being might be overlooked. EPIC-26 also does not address issues related to partner relationships, or the psychological impact of sexual dysfunction in sufficient detail. Adding more items related to partner relationships, or the psychological

impact may make the scale too long; however, to address these concerns, the Rasch analysis, a robust statistical technique that allows us to evaluate the measurement properties of the questionnaire items,[72] will be employed. Using Rasch analysis will help ensure that the questionnaire remains both concise and comprehensive. Rasch analysis will help us identify and retain only the most informative and relevant items, thereby reducing redundancy and ensuring that the questionnaire is as efficient as possible.

Furthermore, although, 13 studies evaluated the cross-cultural validity of the PROMs, they only conducted forward–backward translation.[28,30,33,38,39,41,43,44,46,50-52,54,58] It is insufficient to evaluate cross-cultural validity by merely performing forward-backward translation or conducting a pilot study on a sample with a different culture without proper statistical analysis. Cross-cultural validity for PROMs have to be assessed in culturally different populations than those in which the scale was originally developed.[73] It is important to note that most PROMs are developed in English and thus need to be validated in different languages. Furthermore, the term "culturally different population" should not be restricted to considering only different ethnic or language groups; it should also include other groups such as different gender or age groups, as well as various patient populations, with different health status. The concept of culturally different populations must be interpreted broadly.[73] For instance, lacks cross-cultural validity may lead the responses may not accurately reflect the patients' health states, leading to potential biases and misinterpretations of the data.[74] Cultural differences can influence how patients perceive and report their health, and their understanding of specific terms used in the PROM. To assess cross-cultural validity of PROMs in future studies, regression analyses or CFAs using classical test theory (CTT) methods, and differential item functioning (DIF) analyses using item response theory (IRT) methods are recommended.

Responsiveness propriety was assessed only in ten studies[28,29,31,38-40,47-49,58] by measuring effect size and standardized response mean values and using paired t-test and ANOVA for measuring mean difference; other studies missed the ability to detect clinically important changes. Responsiveness is defined as "the ability to detect clinically important change" or as "the ability to detect a change in the construct to be measured".[20] Therefore, further studies should be conducted to evaluate the responsiveness of PROMs. In addition to effect size and standardized response mean, Norman's responsiveness coefficient (σ^2 change/σ^2 change + σ^2 error), and relative efficacy statistics ((t-statistic$_1$/t-statistic$_2$)^2)[75] are appropriate statistical methods to evaluate responsiveness. In contrast, use of paired t-test is not appropriate for this purpose.[76] Content validity was only evaluated in 15 of the 32 studies included in the present review, and only five of these PROMs have a high level of evidence on content validity. Content validity is defined as the degree to which the content of a PROM is an adequate reflection of the construct to be measured,[20] is widely recognized as one of the most important type of validity for PROMs.[20] Asking the PCa patients about comprehensiveness, comprehensibility and the relevance of the scale, and obtaining the views the professionals' views about the relevance and comprehensiveness of a PROM, are essential when designing a PROM with sufficient content validity and strong level of evidence.[20] Future research is strongly recommended considering COSMIN guideline to develop all PROMs that have sufficient validity with a strong level of evidence.

Use of sexual-related PROMs for PCa in routine clinical care and recommendations

Integrating sexual-related PROMs into routine clinical care for PCa patients is critical for addressing the significant impact of sexual dysfunction on their health outcomes. PROMs serve as a bridge between clinical outcomes and patient experiences, offering a comprehensive view of the impact of PCa and its treatments on sexual functioning. Thus, the accurate assessment of these issues using PROMs can provide valuable insights into the patient's sexual health, allowing healthcare professionals to tailor interventions more effectively. Although the EPIC-26 and the UCLA-PCI provide valuable insights into patients' sexual health, enabling personalized interventions, their challenges such as the length of these instruments, lack of comprehensive validation, and cultural sensitivity hinder their widespread adoption.

To enhance the use of sexual-related PROMs in routine clinical care, it is recommended to develop shorter, yet comprehensive versions of existing PROMs that can reduce patient burden and improve response rates. New PROMs should encompass a broader range of issues, including partner relationships, and the psychological impact of sexual dysfunction as this holistic approach ensures that all aspects of a patient's sexual health are considered. Furthermore, leveraging electronic health records and digital platforms can facilitate the routine collection and analysis of PROMs. Automated systems can prompt patients to complete PROMs at specific intervals, ensuring consistent data collection without adding to the clinical workload.

Conclusion

This systematic review provides a comprehensive evaluation of the methodological quality and psychometric properties of PROMs used to assess sexual problems in patients with PCa. The findings highlight the widespread use and validation of the EPIC, particularly the EPIC-26 version, in this patient population. While the overall methodological quality of the studies was adequate, there were notable gaps in cross-cultural and content validity, suggesting areas for future research. Further research is needed to address existing gaps and enhance the robustness of these tools. This will ultimately improve the assessment and management of sexual health outcomes in this patient population, contributing to a better overall QOL. Future research should also aim to include more diverse populations and develop new tools that can capture other relevant dimensions of sexual health. There is a need to apply sexual-related PROMs for PCa in routine clinical care for real-time monitoring and improved care delivery.

Author contributions

H.A-O.: Conceptualization-Equal, Data curation-Equal, Investigation-Equal, Methodology-Equal, Project administration-Equal, Supervision-Equal, Visualization-Equal, Writing—original draft-Equal, Writing—review & editing-Equal. K-Y.H.: Data curation-Equal, Investigation-Equal, Methodology-Equal, Writing—review & editing-Equal. C-F.N.: Supervision-Equal, Validation-Equal, Visualization-Equal, Writing—review & editing-Equal. S.W.: Investigation-Equal, Validation-Equal, Visualization-Equal, Writing—review & editing-Equal. K-K-W.L.: Investigation-Equal, Validation-Equal, Visualization-Equal, Writing—review & editing-Equal. J.Y.: Conceptualization-Equal, Investigation-Equal, Methodology-Equal, Supervision-Equal, Validation-Equal,

Visualization-Equal, Writing—original draft-Equal, Writing—review & editing-Equal.

Supplementary material

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Conflicts of interest

The authors declared no potential conflicts of interest concerning the research, authorship, and/or publication of this article.

Data availability

All the data used in the conduction of this study are publicly available through online databases, and no codes were generated. The data that support the findings of this study were retrieved from previously published materials and are available from the corresponding authors upon reasonable request.

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