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Review

Assessing outcome measures used after rib fracture: A COSMIN systematic review

Simon Craxford[a,*], Christopher Deacon[b], Yulanda Myint[b], Benjamin Ollivere[a]

[a] Trauma Outcomes Group, University of Nottingham, UK
[b] Department of Trauma and Orthopaedics, Queens Medical Centre, Nottingham, UK

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ABSTRACT

Purpose: The incidence of invasive treatment of rib fracture has increased significantly over the last decade however the evidence of improved patient outcomes to support this is lacking. A systematic review was performed to identify patient reported outcome measures (PROMs) used in the assessment of outcomes following chest wall injury. The quality of evidence for the psychometric properties of the identified PROMs was graded using the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) methodology.

Methods: Rib fracture studies measuring patient reported outcomes were identified using PubMed/Medline, EMBASE, AMED and PsycINFO. Methodological quality of measurement properties was evaluated with the COnsensus-based Standards for selection of health status Measurement INstruments (COSMIN) checklist.

Results: A total of 64 studies were identified including 19 different PROM instruments. Domains included in the reported PROMs included pain, breathlessness, general health quality of life, physical function and physiological health. No rib fracture specific PROM was identified. The most frequently reported instrument was the SF-36 reporting overall quality of life (HRQoL) although there was very low quality evidence for its content validity. There was low quality evidence to support good content validity for the Medical Research Council (MRC) dyspnoea scale, Brief Pain Index (BPI) and McGill Pain Questionnaire (MPQ). No PROM had undergone validation in a rib fracture population. The overall quality of the PROM development studies was poor. While we were unable to identify a clear "gold standard", based on the limited current evidence, we recommend that the EQ-5D-5L is used in combination with the MRC and BPI or MPQ for future rib fracture studies.

Conclusion: The lack of validated outcome measures for rib fracture patients is a significant limitation of the current literature. Further studies are needed to provide validated outcome measures to ensure accuracy of the reported results and conclusions. As interventions for rib fractures have become more common in both research and clinical practice this has become an urgent priority.

Contents

* Corresponding author at: University of Nottingham, Queens Medical Centre, Derby Road, Nottingham NG72UH, UK.
E-mail address: Simon.craxford@nhs.net (S. Craxford).

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Introduction

Rib fracture is a common occurrence after traumatic injury. 10% of blunt force trauma patients admitted to a major trauma centre sustaining one or more fractured ribs [1]. Rib fractures represent a spectrum of injury from simple isolated fractures that require only analgesia to life threatening injuries with a significant associated mortality [2]. The incidence of invasive treatment of rib fractures has increased significantly over the last decade; the evidence of improved patient outcomes to support this is lacking [3–6]. Of the three current RCTs of rib fracture fixation, only two used a patient reported outcome measure (PROM) [7].

PROMs provide unique information on the impact of a medical condition and its treatment from the patient's perspective. A PROM is usually self-completed by the patient allowing assessments to be quantified without interference from a clinician PROMs may be differentiated into disease-specific or generic [8]. Generic PROMS are broad in content and can be used across a variety of conditions. Some generic PROMS also enable cost-effectiveness analysis as part of a cost-utility analysis to examine the cost of an intervention in terms of the number of years lived in full health [9]. Disease specific PROMS identify specific symptoms of a disease process and therefore have greater content validity but many not allow such comparisons between different conditions [8].

Which PROM to use depends on the construct of interest, and the measurement properties of the PROM [10]. The quality of the studies providing this evidence is often overlooked. The COSMIN (COnsensus-based Standards for the selection of health status Measurement INstruments) initiative developed a consensus-based standard for assessing the quality of studies on measurement properties [11]. The validity of any outcome measure (including PROMs) is the extent to which the instrument in question is able to measure the disease and recovery state [12]. To be considered precise and reliable, an instrument must be both valid and responsive and sensitive to change when evaluating treatment differences. These measurement properties are assessed in clinimetric studies; these studies establish the measurement properties of any outcome measure including responsiveness to change, reliability, and assess ceiling and floor effects. They provide vital evidence when selecting the most appropriate PROM to use in both research and clinical practice. The methodological quality of these studies is often overlooked but is vital when assessing the evidence they provide.

Content validity is the degree to which the content of a PROM is an adequate reflection of the construct to be measured [8,13]. It is regarded as the most important measurement property of a PROM and the most challenging to assess [14]. It refers to the relevance, comprehensiveness, and comprehensibility of the PROM for the construct, target population, and context of use of interest. The content validity of PROMs is established through analysis of the instrument's content and the concept or domain that the test is designed to measure [14]. A key step of verifying content validity is assessment of the PROM from the patient's perspective. Due to the complex nature of their injuries, rib fracture patients experience a wide variety of symptoms and disability during their recovery [15]. Symptom domains previously identified as relevant to rib fracture survivors include pain, breathlessness, physical disability and depression or anxiety after surviving a major injury [16].

The purpose of this study was to systematically identify the PROMs used in the published literature used to measure outcomes following rib fracture and to evaluate the psychometric properties of the identified instruments using the COSMIN toolkit.

Methods

This systemic review is reported as per the Preferred Reporting Items for Systematic Review and Meta-Analyses guidelines [17]. The protocol for this review was registered on PROSPERO (2018 CRD42018096365) on 22 May 2018.

Literature search

We performed a search of Pubmed/MEDLINE, Embase, AMED and PsycINFO medical indices from inception to identify studies either using or validating a PROM in an adult rib fracture population. No restriction was placed on language; although only studies in English could be fully reviewed as no other language was fluently spoken by the research team. The electronic search was tailored to the individual database being searched and was based on the protocol suggested by the Cosmin group [18]. Index terms and free text words were combined with validated search filters for Pubmed and Embase to identify relevant studies containing PROMs and studies specifically validating PROMs within the target population [19,20]. A summary of the search strategy is shown in Table 1. The full PubMed search strategy is included as supplementary material. The final search was performed on 27 February 2019, following submission of the protocol to PROSPERO. Reference lists were hand-searched to identify potential additional relevant studies. In addition, the development study for each PROM, where available, was sourced and assessed as per the COSMIN checklist for content validity and quality of PROM development.

Table 1
Summary of search strategy.

Search Number	Definition (example search terms)
#1 Condition	**Adult patients with traumatic rib fracture** (rib fracture, flail chest, broken ribs, thoracic trauma)
#2 Construct of interest	**Patient reported healthcare related outcomes** ("quality of life" OR qol OR func* OR HR-PRO OR HRPRO OR HRQOL OR QL OR disab* OR wellbeing OR "well being" OR subjective OR utility OR utilities OR priorit* OR outcome* OR health).af
#3 Instrument	**PROMs** (score* OR measure* OR PROM OR index* OR indices OR scale* OR questionnaire* OR instrument* OR survey* OR profile* OR apprais* OR status OR reported OR reporting OR rated OR rating* OR assessment).af
#4 Measurement Properties	**Cosmin Validation Filter** **Oxford PROM filter**
#5 (#1 AND #2 AND #3 AND #4)	

Selection criteria for eligible studies

After removal of duplicate studies, two reviewers (SC and YM) independently assessed all titles and abstracts. We included all studies that detailed at least one PROM in adults after blunt chest wall trauma resulting in one or more acutely fractured rib. Clinical studies were eligible regardless of the presence or type of study intervention. Development and validation studies for PROMs were included, in addition to more clinically orientated research papers. Studies of mixed patients were eligible provided at least 75% had a rib fracture, or the rib fracture sub group was separately reported. When in doubt about the eligibility of a study the full text was retrieved and discussed by both authors. Further review by the senior author (BO) to gain consensus was not required as consensus was reached between the two reviewers for all studies.

Data extraction

Data were extracted by SC and CD. The following were extracted from each publication: the PROM, the intended construct for measurement, measurement properties, administration method, study population and diagnosis, number of patients, patient demographics, country, language and setting. The instrument authors were contacted when information was not reported in the report.

Assessment of the quality of studies

Two reviewers (SC and CD) and independently rated the methodological quality of the eligible studies using the COSMIN checklist [21]. The COSMIN criteria consist of 11 separate checklists. In nine checklists the quality of nine measurement properties is addressed; internal consistency, reliability, measurement error, content validity, structural validity, hypotheses testing, cross-cultural validity, criterion validity and responsiveness. Interpretability, while not strictly a measurement property, is a meaningful requirement for the applicability of PROMs in research. The generalisability of the results is determined with the final checklist. Each subsection is awarded a score of "excellent", "good", "poor" or not applicable. As per the COSMIN methodology the reported worst score counts, a PROM could only be awarded "excellent" if all subsections of that checklist were also rated "excellent" [21]. A copy of each PROM was reviewed by SC and CD. Content validity was scored on the relevance, comprehensibility and comprehensiveness of the PROM to a rib fracture patient. Each item of the identified PROM was coded using the ICF framework to guide the reviewers' score for comprehensiveness and relevance [22]. The overall level of evidence for each PROM was determined after assessment of the PROM development study.

Results

No studies were found with the COSMIN recommended search filter applied. To ensure that no relevant papers were being inappropriately missed by the filter the research was repeated using the Oxford PROM filter alone [20]. With the Oxford PROM filter applied 3042 unique articles were identified for screening. After screening, 76 full text articles were retrieved, of which 64 met the inclusion criteria for this review. 19 PROMs were identified, covering symptom domains of pain, breathlessness, general health quality of life, physical function and physiological health. The study selection flow chart is shown in Fig. 1.

The separate patient reported outcomes reported by the studies varied. In the 25 studies which used a PROM reporting general health-related quality of life as a separate study outcome [23–47]. 3 reported physical disability [25,48,49], 1 reported psychological health [50] and 6 reported respiratory symptoms [34,46,51–53]. Pain was an outcome in the majority (44) of studies [3,4,15,28–31,34–36,40,44,45,50,54–83]. 6 studies used a custom PROM that had not previously been published [15,34,70,73,76,81]. The SF-36 was the most frequently used generic quality of life PROM and was used in 12 studies. The characteristics of the identified PROMs are shown in Tables 2–4.

Despite widening the search terms by removing the COSMIN filter, no validation studies of any PROM performed in a rib fracture population were found, leaving only the development studies and the content validity of the PROMs available for further review. The quality of PROM development studies are shown in Table 5.

Content validity of the PROMs was assessed by the review team, the results are shown in Table 6. The lack of validation studies in a rib fracture population precluded further completion of the COSMIN checklist.

Summary of identified PROMS

Patient reported generic health related quality of life (HRQoL) measures

The SF-36 is the most widely evaluated generic patient assessed health outcome measure [84]. The instrument consists of a 36 item patient reported score measuring across eight domains and is available in over 170 languages. Each domain is scored independently between 0 and 100. The scores can be directly transformed into a scale between 0 and 100; a score of 0 is complete disability and 100 is no disability. These allow presentation of the sub-scale scores for each of the domains. The sub-scales can be combined to give the overall physical component summary (PCS) and mental component summary (MCS). Normal values for the PCS and MCS have been calculated with the average healthy adult scoring 50 and normalised scores facilitate direct comparisons across disease states in the average adult population. The SF-12 is a shorter 12 item scale and the measures replicate the SF-36 summary measures well [85]. However, a criticism of the SF-12 is that it allows only the calculation of the summary scales but not of the subscales, potentially concealing important and subtle disability [86]. Neither SF-36 or SF-12 have been validated for rib fracture patients. The SF-36 was the most frequently cited HRQoL instrument being used in 12 studies. The SF-12 was used in 6 studies.

The EuroQoL (EQ-5D) was used in three studies and describes five health domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression and includes a 20 cm VAS for self-reporting of the participants own "health state". The EQ-5D is a European quality of life measure that has been specifically developed with validity in mind. It is available in the majority of European languages and takes two forms with the 5 L providing five responses in each of the five domains and the 3 L version providing three. A total of 245 separate health states can be defined by the tool. Multiple valuation studies have been performed allowing for the calculation of quality-adjusted life years (QALYs). The wide use of the EQ-5D wide use and established country specific population norms make it a useful generic measurement tool. The EQ-5D-5L may have greater discriminatory power that the EQ-5D-3L although neither version have been validated in rib fracture they are widely used in prospective randomised trials and other studies to define general health status [87]. The content validity for rib fracture remains uncertain as the impact of respiratory symptoms is only indirectly measured in the EQ-5D. The EQ-5D has been used in two studies as a single outcome measure and in combination with another PROM and one study.

The Assessment of Quality of Life (AQoL) instrument covers the dimensions of "Independent Living", "Happiness", "Mental

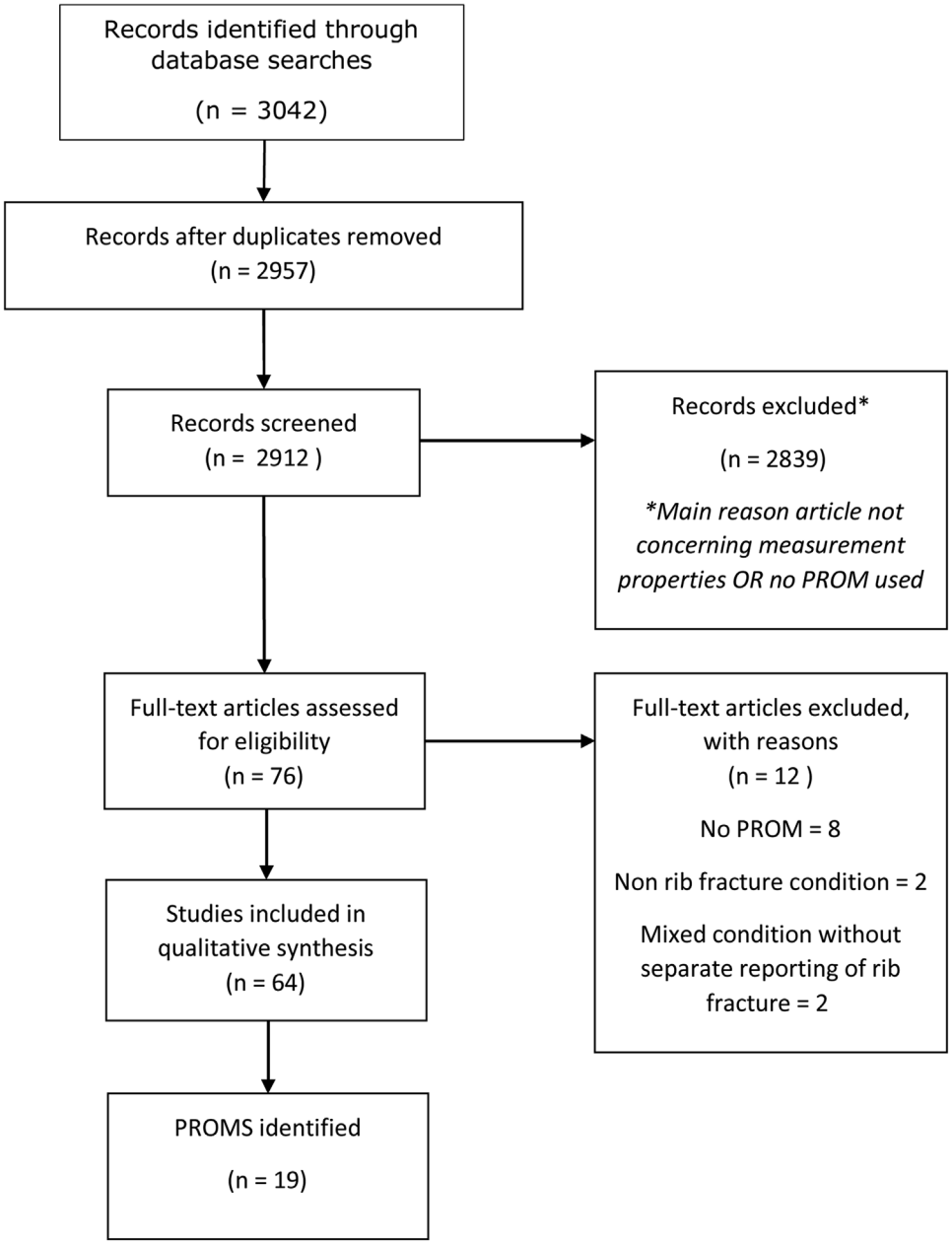

Fig. 1. Study flow chart.

Health", "Coping", "Relationships", "Self Worth", "Pain" and "Sense". It provides a descriptive system for a multi-attribute utility instrument (MAU) allowing scores to be used in cost-utility evaluations. Originally developed in an Australian population, it is available in four versions (4D, 6D, 7D and 8D) ranging from 12 to 35 items. It has been shown to respond in a broadly comparable way to the SF-36 and EQ-5D [88]. The AQoL has been used in one study cohort study of Australian patients undergoing rib fixation.

The American Chronic Pain Association Quality of Life Scale is a 0–10 scale of increasing disability due to chronic pain. Little evidence exists for its development or psychometric properties; it has been used in combination with the SF-36 to assess quality of life in one rib fracture study.

The Health Utilities Index (HUI) 2 and 3 and the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire version 3 (EORTC QLQ-C30) were both developed for assessing quality of life in cancer patients. The HUI 2 covers seven dimensions (sensation, mobility, pain, emotion, cognition, self-care and fertility) with three to five levels of ability while the HUI covers eight (vision, hearing, speech, ambulation, dexterity of the hands, emotion, cognition and pain) with five or six levels. The EORTC consists of 30 items to assess physical, role, emotional, cognitive and social functioning, global health status or QOL scales, fatigue, pain, nausea and vomiting, dyspnoea, insomnia, appetite loss, constipation, diarrhoea and financial difficulties.

As both PROMs were designed for a different target condition, some instrument items did not appear relevant to rib fracture patients. The EORTC QLQ-C30 includes one question on breathing however, questions about diarrhoea or nausea, are unlikely to be relevant in rib fracture. The HUI includes items on vision and

Table 2
Characteristics of identified generic HRQoL PROMs used in rib fracture.

PROM	Abbreviation	Year developed	Cited by	County of origin	Intended construct and domains	No. of items	Original target or development population
Health related quality of life							
Euroquol 5D-3L	EQ-5D-3L	1990 [83]	[24]	UK, The Netherlands, Finland, Norway, Sweden	HRQoL 1. Mobility 2. Self-care 3. Usual activities 4. Pain/discomfort 5. Anxiety/depression	6	General population
Euroquol 5D-5L	EQ-5D-5L	2011 [84]	[22,23]	UK, Spain (derived from EQ-5D-5L	Same as ED-5D-3L	6	General population
Short form 36	SF-36	1992 [85]	[25–35,45]	USA	HRQoL 1.physical functioning, 2.bodily pain, 3.role limitations due to physical health problems, 4.role limitations due to personal or emotional problems, 5. emotional well-being, 6.social functioning, 7.energy/fatigue, 8. general health perceptions.	36	General populaion
Short form 12	SF-12	1996 [86]	[36–41]	USA	Same as SF-36	12	General population
Health utilities index Mark 2 and 3	HUI 2 and 3	1992 [87]	[32,42,46]	Canada	HUI2 sensation, mobility, emotion, cognition, self-care, pain and fertility. HUI3 Hearing, Vision, Speech, Ambulation, Dexterity, Emotion, Cognition, Pain	15	Survivors of childhood cancer
European Organization for Research and Treatment of Cancer Quality of Life Questionnaire	EORTC QLQ-C30	1993 [88] Currently version 3 since 1995	[43]	Pan-European	HRQoL	30	Patients with cancer
Assessment of Quality of Life	AQoL	1998 [89]	[44]	Australia	HRQoL	15	General Australian population
American Chronic Pain Association Quality of Life Scale	ACPA	2017	[33]	USA	HRQoL	1	Patients with chronic pain

hearing which again appear less relevant in the context of rib fracture. The EORTC has been used in one rib study while the HUI has been used in three.

Measures of physical disability

The Constance Murley Score (CMS) is a widely used PROM to assess shoulder function regardless of underlying condition. It is part patient and part clinician assessed. There is sufficient evidence to support its use in subacromial pathologies and low quality evidence for other shoulder conditions [89]. No formal validation studies have been performed in a rib fracture population. As the score focuses on shoulder function, it is doubtful that all the items of the score are relevant to a rib fracture patient. The CMS was used in one study assessing surgical fixation of combined rib and clavicle fractures.

Table 3
Characteristics of PROMS measuring physical disability, respiratory function and psychological function.

PROM	Abbreviation	Year developed	Cited by	County of origin	Intended construct and domains	No. of items	Original target or development population
Physical disability							
Constant-Murley score	CM	1987 [90]	[47]	UK	Shoulder function pain (15 points), activities of daily living (20 points), strength (25 points) and range of motion	8	Shoulder function irrespective of diagnosis
Disability rating index	DRI	1994 [91]	[24,48]	Sweden	Physical Function dressing (without help); (2) outdoor walks; (3) climbing stairs; (4) sitting for a longer time; (5) standing bent over a sink; (6) carrying a bag; (7) making a bed; (8) running; (9) light work; (10) heavy work; (11) lifting heavy objects; (12) participating in exercise/sports.	12	Patients with pain in the back, neck or shoulders
Psychological							
Hospital anxiety and depression scale	HADS	1983 [92]	[49]	UK	Depression and anxiety	14	General hospital patients
Respiratory symptoms							
St George's respiratory questionnaire	SGRQ	1991 [93]	[45,50]	UK	Respiratory symptoms	50	Patients with obstructive airway disease
MRC Dyspnoea scale	MRC	1960 [94]	[33,45,51,52]	UK	Breathlessness	1	Patients with chronic respiratory conditions
COPD Assessment Test	CAT	2009 [95]	[33]	UK, USA	Health quality in COPD	8	Patients with COPD

Table 4
Characteristics of pain instruments used in rib fracture studies.

PROM	Abbreviation	Year developed	Cited by	County of origin	Intended construct and domains	No. of items	Original target or development population
Pain							
McGill Pain Questionnaire	MPQ	1975 [96]	[15,27–29,53]	Canada	Subjective quality and intensity of pain	15 (short form)	Any patient with pain
Brief Pain Inventory	BPI	1989 [97] (Short form released 1991)	[35]	USA	Severity of pain and impact on function	9 items (15 questions)	Pain in cancer
Visual Analogue Scale	VAS		[3,30,35,39,49,54–68,81]		Severity of pain	1	
Verbal Rating Scale	VRS		[4,39,70,78]			1	
Numeric rating scale	NRS		[33,34,43,44,69–77,79,80,82]		Severity of pain	1	

Ratings as defined by the COSMIN checklist: V = very good, D = doubtful, I = inadequate.

Table 5
Quality of PROM development and concept elicitation studies.

PROM	PROM design							Total PROM development
	General design requirements					Concept elicitation	Total PROM design	
	Clear construct	Clear origin of construct	Clear target population for which the PROM was developed	Clear context of use	PROM developed in sample representing the target population			
EQ-5D-3L	I	D	V	V	I		I	I
EQ-5D-5L	V	V	V	V	D	I	I	I
SF-36	V	V	V	V	I		I	I
SF-12	V	V	V	V	I		I	I
HUI 2 and 3	V	V	V	V	I		I	I
EORTC	V	V	V	V	I		I	I
AQoL	V	V	V	V	I		I	I
CPAQoL	I	D	I	D	I		I	I
CMS	I	D	V	V	I		I	I
DRI	I	D	V	V	I		I	I
HADS	V	D	V	V	I		I	I
SGRQ	V	V	V	V	I		I	I
MRC	V	D	I	I	I		I	I
COPD	V	V	V	V	V	D	D	D
MPQ	V	D	V	V	D	D	D	D
BPI	V	V	A	V	D	D	D	D

Table 6
Content validity of identified PROMs relevant to a rib fracture population.

PROM	Relevance		Comprehensiveness		Comprehensibility		Content Validity	
	Rating	Evidence	Rating	Evidence	Rating	Evidence	Rating	Evidence
AQoL	+/–	Very low	–	Very low	+	Very low	+/–	Very low
BPI	+	Low	+	Low	+	Low	+	low
CM	–	Very low	–	Very low	+–	Very low	+/–	Very low
CAT	+/–	Low	–	Low	+	low	+/–	low
CPAQoL	+/–	Very low	–	Very low	+/–	Very low	+/–	Very low
DRI	+	very low	+	Very low	+	Very low	+	Very low
EORTC	+/–	Very low	–	Very low	+	Very low	+/–	Very low
EQ-5D-3L	+	Very low	–	Very low	+	Very low	+/–	Very low
EQ-5D-5L	+	low	–	low	+	low	+/–	Low
HADS	+	Very low	+	Very low	+	Very low	+	Very low
HUI 2 3	+/–	Very low	–	Very low	+	Very low	+/–	Very low
MPQ	+	Low	+	Low	+	Low	+	low
MRC	+	Very low	+	Very low	+	Very low	+	Very low
SF-36	+	Very low	–	Very low	+	Very low	+/–	Very low
SF-12	+	Very low	–	Very low	+	Very low	+/–	Very low
SGRQ	+/–	Very low	+	Very low	+	Very low	+/–	Very low

COSMIN Rating definitions: "+" = sufficient, "+/– "= inconsistent, "– "= insufficient.

The Disability Rating Index (DRI) comprises of 12 items of physical disability measured using a visual analogue scale (0–100). Originally used in patients with back, neck or shoulder pain the DRI has since undergone validation in other musculoskeletal conditions, such as hip arthritis, but not in rib fracture [90]. The DRI has been used as the primary outcome in one rib study and used in combination with the EQ-5D-3L in another.

Psychological health measures

The Hospital Anxiety and Depression Scale (HADS) consists of 14 items; seven assess anxiety and seven assess depression. The instrument was developed to assess inpatients with psychological health problems. A score of over eight gives a specificity of 0.78 and a sensitivity of 0.9 for diagnosing anxiety and for 0.79 and a sensitivity of 0.83 depression [91]. Only one study reported psychological health as a primary outcome using the HADS.

Respiratory specific outcome tools

The COPD assessment tool (CAT) is a disease specific PROM assessing quality of health in patients with COPD. Symptoms covered by the CAT include cough, amount of sputum, breathlessness, chest tightness, confidence, activity, sleep and energy levels. Some aspects of the PROM, such as sputum and cough may be less relevant in rib fracture, limiting the relevance of the instrument. The CAT was used in one study.

The Medical Research Council Dyspnoea Scale (MRC) measures perceived respiratory disability during activities of daily living. It is scored from one (not troubled by breathlessness except on vigorous exercise) to five (too breathless to leave the house or breathless on dressing). The MRC was the most frequently used respiratory PROM, being used in four studies (two as the sole outcome and two used with other PROMS).

The St. Georges Respiratory Questionnaire (SGRQ) contains 50 items with 76 weighted responses. It was developed and validated for use in asthma and COPD. It has since been validated in other respiratory conditions [92]. Like the CAT, the SGRQ contains items less relevant to rib fracture patients, such as wheeze or sputum production. The recall period of three months may also be more appropriate to chronic rather than acute respiratory conditions. The SGRQ was used in two studies; one as a primary end point and one in combination with the SF-36 and MRC.

Measures of pain

The Brief Pain Inventory (BPI) details severity of pain (four items) and the impact of pain on daily activities. It was originally used in studies of cancer pain and has undergone validation for chronic non-malignant pain [93] and in other musculoskeletal conditions [94]. It is available in a short (nine items) and long (17 items) form. The BPI short form is more frequently used and is what is usually referred to when cited in research [95]. Only one study used the BPI where it was used in combination with the SF-36.

The McQill Pain Questionnaire (MPQ) consists of three major measures — pain-rating index, the number of words chosen to describe pain and the present pain intensity based on a 1–5 intensity scale. The pain-rating index is built by a numerical grading of words describing sensory, affective and evaluative aspects of pain. The affective subscale consists of five sets of words describing the pain affect. The MPQ has undergone psychometric assessment in acute back pain but not after rib fracture [96]. Five studies assessed pain using the MPQ.

The Numeric Rating Scale (NRS) uses an 11-point scale (0—'no pain' to 10—'worst pain', or 'pain as bad as it could be'). The Visual Analogue Scale (VAS) consists of a 100 mm unmarked line with standardised wording: 'no pain' on the left of the line, and 'worst pain imaginable' on the right—the patient then places a mark on the line corresponding to their level of pain. In a Verbal Rating Scale (VRS), adjectives are used to describe different levels of pain, forming an ordinal scale. The respondent is asked which adjective fits best to the pain intensity. As in the VAS, two endpoints such as 'no pain at all' and 'extremely intense pain' should be defined. The number of points on the VRS were poorly reported in the identified studies.

The VAS and NRS for assessment of pain intensity agree well and are equally sensitive in assessing acute pain [97]. Both correlate well with the VRS [98]. There is inadequate evidence to recommend one over another for use in rib fracture. No development studies were available for the VAS, VRS or NRS. Some pain PROMs, such as the BPI, contain several NRS and capture more information about the patient's pain than current pain intensity.

Discussion

This review had three aims: to identify which PROMs have been used in rib fracture research, to evaluate the methodological quality of the studies evaluating the available PROMs and to make recommendations for the selection of PROMs based on this evidence.

The review identified 19 PROMs covering a variety of symptom domains previously identified as being relevant to rib fracture patients [16]. There appears to be little consensus, however, as to which domains themselves should be assessed in a study or which PROM is most appropriate for measuring them. Generic quality of life PROMS were selected in 39% of studies; the SF-36 was the most the most frequently cited generic HRQoL PROM (12 out of 64 studies). Only 6 studies utilised a PROM covering respiratory symptoms which appear important for rib fracture patients [16]. There were 6 studies which used a custom PROM not previously published, which may introduce bias into a study [99] and make interpretation of results, systematic review and meta-analysis impossible. No study used a rib fracture or chest trauma specific PROM; the authors of this review are unaware of the existence of such a disease specific PROM. Disease-specific PROMs have greater face validity than generic PROMs [100,101]. The initial target population of some of the PROMs, such as the CMS (designed to assess shoulder disease) or CAT, score used also appeared far removed from a patient with rib fracture, making the relevance of the PROM to a rib fracture patient doubtful. The variety of PROMs used in rib fractures makes comparing results and effect sizes in different studies and interventions difficult [102]. Of the two RCTs assessing surgical intervention in rib fracture, one used the MRC [53] and one used the SF-36 [32].

We were unable to identify a validation study performed for rib fracture, making a full review using the COSMIN checklist difficult. Many of the PROMs identified in this review have undergone psychometric assessment, but in different populations to the population of interest in this review. Different instruments may perform differently in certain scenarios and may even underestimate the impact in trauma patients. The findings of this review do not mean that these and other PROMs have poor measurement properties and thus are of poor quality; only that insufficient evidence to support their use for rib patients currently exists. As none of the PROMS had undergone formal content validity studies in rib fracture patients the overall score for each PROM in this review was dependant on the judgement of the reviewers, downgrading the quality of evidence. The quality of life scores available were not deemed fully comprehensive as the respiratory component of HRQoL was at most only indirectly assessed. The greatest evidence was for the EQ-5D-5L with low quality evidence for inconsistent content validity. The MRC was judged to have the greatest content validity of the respiratory PROMs with very low quality evidence for sufficient content validity. There was low quality evidence of sufficient content validity for the BPI and MPQ and very low quality evidence of sufficient content validity for HADS and DRI.

There are strengths and limitations to this review. This is the first systematic review of PROMs used in rib fracture research to and the

first to apply the COSMIN checklist, which is a validated and accepted tool for the appraisal of study quality. The review demonstrates that the PROMs currently used in rib fracture research are heterogenic with no obvious "gold standard". However, it was not always clear if specific methodological aspects of the development studies were not performed or simply not reported. It was therefore not possible to distinguish between poor reporting and poor methodological quality. A significant number of PROM development studies were published before the COSMIN standards and therefore may have not been reported in a way to score highly using the standard.

Our review only identifies PROMS that have either been used in published research studies or undergone formal validation in a rib fracture setting. It is possible that other instruments currently used in clinical practice but not identified by the review, for example the World Health Organization Disability Assessment Schedule 2.0 [103], may be appropriate tools for assessing health status in rib fracture patients. In addition, several trauma registries now record patient outcomes using PROMs routinely, although these are registries of general trauma patients rather than specifically for rib trauma. Such PROMs would have been detected by the search strategy if the PROM had undergone formal validation within a rib fracture population. The lack of validation studies performed in a rib fracture population limits the evidence available in this review. There is an urgent need for these validation studies to be performed to provide further evidence for which PROM to use in rib fracture research and clinical practice.

Recommendations

The current lack of evidence makes it difficult to recommend using one particular PROM over another. The lack of a clear gold standard has presumably lead to a wide variety of PROMs being used by researchers, including those not originally intended for chest trauma use. In the absence of any validated scores to assess outcomes of rib fractures, the use of a generic HRQoL instrument in combination with a validated pain and respiratory score appears the most robust current approach. While the NRS was the most frequently used instrument in assessing pain and is commonly used in clinical practice, the BPI and MPQ capture more detailed information about the respondent's pain than pain intensity alone, giving potentially greater content validity. Based on the limited current evidence, we recommend that the EQ-5D-5L is used in combination with the MRC and BPI or MPQ for future rib fracture studies.

Conclusion

The lack of validated outcome measures for rib fracture patients is a significant limitation of the current literature. Further studies are needed to provide validated outcome measures to ensure the legitimacy of the reported results.

Declaration of Competing Interest

The authors of this manuscript have no conflicts of interest to declare.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.injury.2019.07.002.

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