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Reliability, validity and generalizability of multidimensional pain assessment tools used in postoperative adult patients: a systematic review protocol

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Reliability, validity and generalizability of multidimensional pain assessment tools used in postoperative adult patients: a systematic review protocol

Abstract

Objective: The objective of this review is to evaluate the measurement properties of multidimensional pain assessment tools for postoperative pain in adults. **Introduction:** Effective postoperative pain management increases patient safety and satisfaction, and reduces healthcare costs. The most commonly used postoperative pain assessment tools only evaluate pain intensity, which is only one aspect of the sensory dimension of pain. Pain is a subjective phenomenon, and variability exists among patients. Efforts are underway to incorporate multidimensional assessment tools for postoperative pain assessment in clinical practice. **Inclusion criteria:** Eligible studies will include postoperative patients aged 18 years and older from all surgical disciplines. Studies evaluating multidimensional assessment instruments for the measurement of postoperative pain during the first two weeks following surgery will be considered. Studies will include the following measurement properties of assessment tools as outcomes: reliability, validity and generalizability. **Methods:** MEDLINE, CINAHL, Embase, PsycINFO and Cochrane Trials (CENTRAL) will be searched, as well as ClinicalTrials.gov and multiple gray literature sources. There will be no limitations on publication date. Titles and abstracts will be screened by independent reviewers for inclusion. The full text of selected papers will be retrieved and assessed against the inclusion criteria. Two independent reviewers will assess papers for methodological quality using the COSMIN checklist, and papers with poor scores on relevant items will be excluded. Data will be extracted by two independent reviewers using a standardized data extraction tool. Statistical pooling will be performed, if possible.

Keywords

review, systematic, patients:, adult, postoperative, validity, protocol, used, reliability, tools, assessment, pain, multidimensional, generalizability

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1 **Reliability, validity and generalizability of multidimensional pain assessment tools used in**
2 **postoperative adult patients: A systematic review protocol of measurement properties**

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20 **Reliability, validity and generalizability of multidimensional pain assessment tools used in postoperative**
21 **adult patients: A systematic review protocol of measurement properties**

22

23 **Introduction**

24 Pain is a common occurrence among patients in the postoperative period.¹ While the prevalence rates
25 of acute post-operative pain have not been accurately established, available data suggests that
26 approximately 75 per cent of postoperative patients experience moderate to severe pain, resulting in
27 unnecessary suffering and discomfort.² Pain in the postoperative period is mainly as a result of tissue
28 damage or nociceptive pain, which subsequently manifests as an undesirable emotional and sensory
29 experience.²

30 Poorly managed postoperative pain can significantly delay ambulation which is associated with
31 potentially life threatening risks such as venous thromboembolism, severe respiratory illness and,
32 long term chronic pain and disability.¹ Healthcare services are also negatively impacted as persistent
33 pain can lengthen hospital stay, increase the number of unanticipated hospital readmission and the
34 need for outpatient chronic pain management services.³ Hence, effective postoperative pain
35 management is imperative in increasing patient safety and satisfaction, and reducing costs to the
36 health services.¹

37 The experience of postoperative pain is a complex multidimensional phenomena which comprises of
38 a range of physiological, psychological, sensory, cognitive, behavioral, and sociocultural dimensions.¹
39 ⁴ However, the most commonly used postoperative pain assessment tools are unidimensional and
40 assess only pain intensity which is one aspect of the sensory dimension of pain.⁵ Examples of these
41 unidimensional tools include versions of the Numerical Rating Scale (NRS) and the Visual Analog
42 Scale (VAS).⁶⁻⁹ These tools rely on a score based on the patients' self-report of the existence of pain
43 and its intensity. Whereas, pain is a subjective phenomenon and a large amount of inter-individual
44 variability exists in patients' pain experiences. For example, patients may experience severe pain in
45 the absence of physiologic or behavioral signs.¹⁰ In addition, patients have also reported difficulties in
46 describing complex nature of the experience of pain by only a single numbered value or a point on
47 linear scale.³

48 As a result, evidence-based guidelines, expert consensus reports and position statements from health
49 professional governing bodies have recommended comprehensive, multidimensional assessment as
50 an integral component of effective pain management.¹¹⁻¹³ Hence, efforts are being made to
51 incorporate multidimensional assessment tools for postoperative pain assessment in clinical practice.
52 The most frequently used multidimensional pain assessment tools are the McGill Pain Questionnaire
53 (MPQ)⁴ and the Brief Pain Inventory (BPI).^{14,15} The MPQ is used to measure the multidimensional
54 aspects of pain including the physical and emotional characteristics of pain. The MPQ includes
55 descriptive words to define pain, a diagram to indicate the exact location of the pain, a one to five
56 score to represent overall present pain intensity (PPI) and a section that considers the individual
57 context of the patient.⁴ The BPI is used to measure the complex pain experienced by patient with

58 cancer. The BPI includes a sensory and a reactive dimension, which measures both pain intensity
59 and the interference of pain with activities of daily living.¹⁴

60 Other, less commonly used multidimensional pain assessment tools include the Surgical Pain Scales
61 (SPS),¹⁶ the Pain Assessment in Advanced Dementia scale (PAINAD) and the Checklist of Nonverbal
62 Pain Indicators (CNPI).^{17,18} Despite the availability of several multidimensional tools there is no
63 evidence to inform the selection of the most reliable and valid tool that can be used to accurately
64 assess pain in postoperative adult patients.

65 A preliminary search in MEDLINE, CINAHL, JBI Database of Systematic Reviews and Implementation
66 Reports and the Cochrane Database of Systematic Reviews was performed to identify completed and
67 in-progress systematic reviews on multidimensional postoperative pain assessment tools when used
68 to assess post-operative pain in hospitalized adult patients. The search identified five existing,
69 quantitative systematic reviews investigating the psychometric properties of pain assessment tools.¹⁹⁻
70 ²³ However, there are a number of important limitations with the existing reviews. Three of the reviews
71 focused only on the use of unidimensional pain assessment tools.¹⁹⁻²¹ The fourth review was limited to
72 pain assessment tools used in pediatric settings,²² and the fifth review assessed multidimensional
73 pain assessment tools only in elderly patients with dementia.²³ While these reviews report important
74 findings for pediatric patients and patients with dementia, they do not provide evidence for the most
75 psychometrically reliable and valid multidimensional pain assessment tool for adult postoperative
76 patients. Therefore, there is a need to appraise the best available evidence in relation to the
77 measurement properties of multidimensional pain assessment tool when used to assess
78 postoperative pain in hospitalized adult patients.

79

80 **Review objective**

81 The objective of this review is to evaluate the measurement properties (reliability, validity and
82 generalizability) of the multidimensional pain assessment tools that are used to assess postoperative
83 pain in adults.

84 **Methods**

85 *Inclusion Criteria*

86 *Participants*

87 The review will consider studies that include postoperative patients aged 18 years and over from all
88 surgical disciplines.

89

90 *Instrument(s) or Construct*

91 This review will consider multidimensional pain instruments used to measure postoperative pain
92 during the first two weeks following surgery. The two week time frame has been chosen as it is
93 widely considered to be the period when patients experience the most amount of postoperative pain.²⁴

94

95 *Outcomes*

96 This review will consider studies that include the following measurement properties as outcomes:

- 97 • Reliability (internal consistency, test-retest reliability, inter-rater reliability and intra-rater
98 reliability)
- 99 • Validity (content validity, face validity, construct validity, structural validity, cross-cultural
100 validity, hypotheses testing, criterion validity, responsiveness, sensitivity to change)
- 101 • Generalizability (sample characteristics, setting(s), location, language, sampling methods,
102 response rate)

103 As not every study will provide data for all the measurement properties, studies that report sufficient
104 details pertaining to at least one outcome regarding reliability or validity will be considered.

105

106 *Study Types*

107 This review will consider only instrument development or instrument evaluation studies. Other types
108 of studies (in which needs assessment instruments are merely used) will be used to contact their
109 authors in search for unpublished psychometric studies or testing of the instrument.

110

111 *Search Strategy*

112 The search strategy will aim to find both published and unpublished studies. An initial limited search
113 of MEDLINE and CINAHL has been undertaken followed by analysis of the text words contained in
114 the title and abstract, and of the index terms used to describe articles. This informed the development
115 of a search strategy which will be tailored for each information source. A full search strategy for
116 MEDLINE is detailed in Appendix I. The reference list of all studies selected for critical appraisal will
117 be screened for additional studies.

118 The databases to be searched include: MEDLINE, CINAHL, EMBASE, PyscINFO and Cochrane
119 Trials (CENTRAL). The trial register to be searched includes clinicaltrials.gov. The search for
120 unpublished studies will include: Google Scholar, Dissertation Abstracts International, ProQuest
121 Dissertations and Theses, ProQuest Researchgate (contact with relevant researchers), and MedNar.
122 We will also identify relevant researchers during the literature research and contact them to obtain
123 information about unpublished psychometric studies or instrument testing of relevant instrument.

124 *Study Selection*

125 Following the search, all identified citations will be collated and uploaded into EndNote version X8 and
126 duplicates removed. Titles and abstracts will then be screened by two independent reviewers for
127 assessment against the inclusion criteria for the review. Studies that may meet the inclusion criteria
128 will be retrieved in full and their details imported into SUMARI. The full text of selected studies will be
129 retrieved and assessed in detail against the inclusion criteria. Full text studies that do not meet the
130 inclusion criteria will be excluded and reasons for exclusion will be provided in an appendix in the final
131 systematic review report. Included studies will undergo a process of critical appraisal. The results of
132 the search will be reported in full in the final report and presented in a PRISMA flow diagram. Any

133 disagreements that arise between the reviewers will be resolved through discussion, or with a third
134 reviewer.

135 *Assessment of Methodological Quality*

136 Papers selected for retrieval will be assessed by two independent reviewers for methodological
137 validity prior to inclusion in the review using the COSMIN checklist. The COSMIN checklist is a
138 standardized tool which is recommended to use in systematic reviews of measurement properties.²⁵
139 The checklist consists of a range of items that consider nine measurement properties namely internal
140 consistency, reliability, measurement error, content validity, structural validity, hypotheses testing,
141 cross-cultural validity, criterion validity and responsiveness. There are also four separate items that
142 are used to assess the methodological quality for studies that applied classical test theory (CTT) and
143 the item response theory (IRT). Studies with poor scores for all relevant items will be excluded from
144 the review. Any disagreements that arise between the reviewers will be resolved through discussion,
145 or with a third reviewer.

146

147 *Data Extraction*

148 Data will be extracted from papers by two reviewers independently using the standardized data
149 extraction tools from JBI-MAStARI and adapted to the specific elements of a psychometric review.
150 Any disagreements that arise between the reviewers will be resolved through discussion or with a
151 third reviewer. Authors of papers will be contacted to request missing or additional data where
152 required.

153

154 *Data Synthesis*

155 The main aim of the data synthesis is to compare outcomes to provide recommendations on the most
156 suitable instrument for research and clinical use. The pooled estimate and 95% confidence intervals
157 for the measurement properties of indices used to measure multidimensional pain will, where
158 possible, be performed using standard statistical techniques and JBI SUMARI. Heterogeneity will be
159 assessed statistically using the standard chi-square and also explored using subgroup analyses
160 based on the different study designs included in this review. Where statistical pooling is not possible,
161 the findings about reliability, validity and generalizability will be compared and presented in narrative
162 form including tables and figures to aid data presentation. A content comparison will give an overview
163 of the content of each instrument and the similarities and differences on an item level. To judge the
164 measurement properties of the different instruments the quality criteria from Terwee et al.²⁶ will be
165 used, these criteria allow to judge: reliability, validity and generalizability in terms of positive rating,
166 indeterminate rating, negative rating, no information available and doubtful design or method. The
167 results of this appraisal will be presented in a narrative form.

168 **Conflicts of Interest**

169 R.F. who is an author on this paper is also a member of the JBISRIR editorial board.

170 S.L. who is an author on this paper is the current Chair of the JBI Psychometric Methodology Group

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Appendix I: Search Strategy

| | |
|-----|--|
| 1. | surgical patient*.mp. |
| 2. | "post operative".mp. |
| 3. | postoperative.mp. |
| 4. | Critical Care/ or "acute care".mp. or Inpatients/ |
| 5. | GYNECOLOGIC SURGICAL PROCEDURES/ or SURGICAL ONCOLOGY/ or SURGICAL PROCEDURES, OPERATIVE/ or DECOMPRESSION, SURGICAL/ or ROBOTIC SURGICAL PROCEDURES/ or ARTERIOVENOUS SHUNT, SURGICAL/ or ORAL SURGICAL PROCEDURES/ or UROLOGIC SURGICAL PROCEDURES/ or PORTACAVAL SHUNT, SURGICAL/ or ANASTOMOSIS, SURGICAL/ or ORTHOGNATHIC SURGICAL PROCEDURES/ or AMBULATORY SURGICAL PROCEDURES/ or MINIMALLY INVASIVE SURGICAL PROCEDURES/ or OPHTHALMOLOGIC SURGICAL PROCEDURES/ or PROPHYLACTIC SURGICAL PROCEDURES/ or VASCULAR SURGICAL PROCEDURES/ or REFRACTIVE SURGICAL PROCEDURES/ or CYTOREDUCTION SURGICAL PROCEDURES/ or THORACIC SURGICAL PROCEDURES/ or DIGESTIVE SYSTEM SURGICAL PROCEDURES/ or UROGENITAL SURGICAL PROCEDURES/ or NASAL SURGICAL PROCEDURES/ or MINOR SURGICAL PROCEDURES/ or OTORHINOLARYNGOLOGIC SURGICAL PROCEDURES/ or DERMATOLOGIC SURGICAL PROCEDURES/ or CARDIAC SURGICAL PROCEDURES/ or surgical.mp. or RECONSTRUCTIVE SURGICAL PROCEDURES/ or OTOLOGIC SURGICAL PROCEDURES/ or ELECTIVE SURGICAL PROCEDURES/ or UROLOGIC SURGICAL PROCEDURES, MALE/ |
| 6. | 1 or 2 or 3 or 4 or 5 |
| 7. | Pain Measurement/ |
| 8. | "pain assessment".mp. |
| 9. | (checklist* adj5 pain) |
| 10. | pain scale* |
| 11. | ((rate OR rating) adj pain) |
| 12. | (pain adj3 questionnaire*) |
| 13. | pain and tool* |
| 14. | "pain questionnaire".mp. |
| 15. | "pain intensity".mp. |
| 16. | exp Pain/di [Diagnosis] |
| 17. | Pain Perception/ |
| 18. | 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 |
| 19. | PSYCHOMETRICS/ |
| 20. | "internal consistency".mp. |
| 21. | Reliability.mp. |
| 22. | "measurement error".mp. |

| | |
|-----|--|
| 23. | "hypotheses testing".mp. |
| 24. | responsiveness.mp. |
| 25. | validity.mp. |
| 26. | generalizability.mp. |
| 27. | Reproducibility of Results/ |
| 28. | Dimensional Measurement Accuracy/ |
| 29. | Validation Studies/ |
| 30. | Sensitivity and Specificity/ |
| 31. | Data Accuracy/ |
| 32. | Scientific Experimental Error/ |
| 33. | 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 |
| 34. | 6 and 18 and 33 |