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Development, validation and psychometric properties of a diagnostic/prognostic tool for breakthrough pain in mixed chronic-pain patients

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ABSTRACT

Background/Objective: Breakthrough pain (BTP) shows variable prevalence in different clinical contexts of cancer and non-cancer patients. BTP diagnostic tools with demonstrated reliability, validation and prognostic capability are lacking. We report the development, psychometric and validation properties of a diagnostic/prognostic tool, the IQ-BTP, for BTP recognition, its likelihood and clinical features among chronic-pain (CP) patients.

Methods. Patients: $n = 120$ consecutive mixed cancer/non-cancer CP in/outpatients. Development, psychometric analyses and formal validation included: Face/Content validity (by 'experts' opinion and assessing the relationship between the IQ-BTP classes and criteria derived from BTP operational-case-definition); Construct validity, by Principle Component Analysis (PCA); and the strength of Spearman correlation between IQ-BTP classes and the Brief Pain Inventory (BPI) items; Reliability, by Cronbach's alpha statistics. Associations with clinical/demographic moderators were assessed applying χ^2 analysis.

Results: Potential-BTP was found in 36.7% of patients (38.4% of non-cancer and 32.4% of cancer patients). Among these the likelihood for BTP diagnosis was 'high' in 25%, 'intermediate' in 41% and, 'low' 34% of patients. Analyses showed significant differences between IQ-BTP classes and between the latter BPI pain-item scores. Correlation between IQ-BTP classes and BPI items was moderate. PCA and scree test identified 3 components accounting for 62.3% of the variance. Cronbach's alpha was 0.71.

Conclusions: The IQ-BTP showed satisfactory psychometric and validation properties. With adequate feasibility it enabled the allocating of cancer/non-cancer CP patients in three prognostic classes. Results are sufficient to warrant a subsequent impact study of the IQ-BTP as prognostic model and screening tool for BTP in both CP populations.

1. Introduction

Breakthrough pain (BTP) definition [1] does not limit its occurrence to cancer patients. Prevalence of BTP varies in different clinical contexts and may reach as much as 93% among cancer patients and 74% among non-cancer patients [2–9]. BTP has been reported as an independent predictor for poor pain outcomes and to have negative impact on patients' quality of life (QoL) with physical, psychological and economic burden for both patients and caregivers [3,6,10–13]. Detection of BTP in either chronic-pain (CP) populations is fundamental for adequate pain management.

While the burden of BTP is generally recognized, available common pain assessment tools are insufficient for its identification [14–17]. Various instruments have been used to assess cancer BTP (BTcP) however, their general adequacy is undermined since there is no widely accepted definition, classification system or well-validated diagnostic tool for BTcP [16]. Indeed, currently there is no clinically and consistently used standardized diagnostic tool for BTcP (nor in non-cancer patients) with demonstrated reliability and formal validation [16]; nor are there any attempts to include BTP in prognosis research.

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Clinical prognosis refers to the risk of future outcomes in people with a given health condition; caregivers, patients, funders and policy makers necessitate reliable evidence about health conditions outcomes for decisions making [18]. Further, prognosis research seeks to recognize and ameliorate patients future outcomes and it provides evidence for translating findings from clinical research to practice. A useful prognostic model, using prognostic factors, provides accurate predictions that inform stakeholders, supports clinical research and allows for informed decisions to ameliorate patient outcomes [19].

To date, there is no validated prognostic/diagnostic measure for BTP among mixed (cancer/non-cancer) CP patients. Thus, we have developed an interview-administered, multi-dimensional prognostic/diagnostic tool, the Italian Questionnaire for BTP (IQ-BTP), for clinical and research purposes. This study was sought to explore the psychometric properties and to validate the IQ-BTP within a sample of consecutive mixed non-cancer/cancer CP in- and out-patients as a first step towards its application in a subsequent impact study.

2. Methods

2.1. Settings and patients

This prospective and observational study was held at the Acute and CP centre of Bologna's Teaching Hospital, Italy. The sample included $n = 120$ consecutive mixed CP in- and out-patients as general indications for exploratory validation studies recommend ≥ 10 patients per item.

2.2. Proceedings and instruments

A scientific panel (SP) of five clinicians implemented the development/validation process of the IQ-BTP. Following literature reviews and recommendations [14,16,20–22] BTP domains were identified and the adapted 11 corresponding items were chosen to match a BTP case-definition and to be comprehensive and feasible in clinical/research settings. For the final Italian/English version of the IQ-BTP, instructions, and item abbreviations used in this paper see Online Resource-1 (tables I-III).

Upon first visit, patients who signed informed consent completed three questionnaires: Short Portable Mental Status Questionnaire (SPMSQ), the Brief Pain Inventory (BPI) and the IQ-BTP. Inclusion criteria were: patients ≥ 18 years, competent with Italian language, with cancer/non-cancer CP that in the past 7 days were treated around the clock (ATC) with strong opioids and who signed informed consent; exclusion criterion was SPMSQ score <8.

2.3. Validation

Following the literature [23] the SP planned the corroboration of the following validity components (for details see Online Resource-2):

(1) The rationale for the introduction of the new measure by literature search for an existing similar validated International/Italian tool; and, by verifying its feasibility and practicability.
(2) For Content validity of the IQ-BTP we sought to verify whether its items are relevant and representative to criteria derived from an established hypothetical 'construct' [24,25]. Thus, we developed, following the literature [14,16,20–22] and based on our experience, an operational case-definition of BTP which enabled a set of hypotheses for formal testing. This case definition was: "a patient with BTP should have (a) 'prerequisite elements': persistent CP with an average intensity in the past 3-7 days of NRS$\leq$4, ATC strong opioids treatment, pain exacerbations (flares) with an intensity of NRS$\geq$6 and uncorrelated with the opioid administration schedule; (b) 'clinical descriptive elements': flares may be of variable localization, predictable or unpredictable, with known or unknown causes, and of nociceptive, neuropathic or both qualities; and (c), 'clinical discriminate characteristics': flares are limited in frequency ($\leq$5/24 h) and of short duration ($\leq$30–60 min)". As we were interested in the prognostic features of the IQ-BTP, we have assumed that patients that potentially experience BTP (potential-BTP) are those who possess all 'prerequisite elements'. In these patients the likelihood for the presence of BTP is 'high', when all 'prerequisite elements' and the clinical discriminates (frequency and duration) are present; 'intermediate', if all 'prerequisite elements' and only one of the 'clinical discriminates' are present; and, 'low', if all 'prerequisite elements' and none of the 'clinical discriminates' are present.

To assess face/content validity the BTP case-definition and IQ-BTP items were presented, after a BTP workshop, to fifteen senior anaesthesia residents and consultants with experience in CP management. Participants evaluated each item [using a five-level Likert-type scale (1 = Strongly agree – 5 = Strongly disagree)] for relevance to the BTP case-definition and adequacy of grammar, wording and items randomization; and, added observations/suggestions. An item was considered 'valid' if $\geq$90% of the participants responded Strongly agree/Agree for its relevance and adequacy. The SP resolved by consensus emerged divergences/suggestions.

To support the IQ-BTP content validity we hypothesized that there should be significant association between IQ-BTP items and the presence/absence of potential-BTP.

(3) Construct validity. Along with Principle Component Analysis (PCA) and scree test, evidence for construct validity may come from the strength of correlation with other measures of similar/dissimilar construct.[23] Thus we sought to assess whether patients with/without potential-BTP score differently at BPI pain items and the strength of Spearman correlation between potential-BTP presence/absence and BPI items.
(4) Reliability (Internal consistency) by applying Cronbach's alpha statistics. Reliability is considered acceptable when Cronbach's alpha exceeds 0.7 [26,27].

2.4. Psychosocial and clinical moderators

We sought to uncover possible relationships between *potential*-BTP and clinical/demographic moderators like: Gender: Male/female; Age groups (patients were divided into ~20 year interval subsets: 18–40; 41–60; 61–80 and >80 years); non-cancer pathology; primitive tumour site; presence of metastases; and settings (in- or out-patients).

2.5. Ethics

The study was authorized by the hospital Ethics Committee and conducted according to the Helsinki declaration and IASP's guidelines for pain research in animals and humans. All participants were personally and thoroughly informed by the investigators on the study's aims and structure. Patients were informed that participation was voluntary, anonymous and would not affect their care, hence, an informed consent was obtained.

2.6. Data presentation and statistical analysis

Continuous data were reported as the mean (± standard deviation); when appropriate the median and CI (95% upper and lower Confidence Intervals) were reported. Category data