American Pain Society
RESEARCH
EDUCATION
TREATMENT
ADVOCACY

PUBLISHED BY ELSEVIER

The Journal of Pain, Vol 17, No 9 (September), Suppl. 2, 2016: pp T118-T131
Available online at www.jpain.org and www.sciencedirect.com

Approaches to Demonstrating the Reliability and Validity of Core Diagnostic Criteria for Chronic Pain

Stephen Bruehl,* Richard Ohrbach,† Sonia Sharma,† Eva Widerstrom-Noga,‡ Robert H. Dworkin,§ Roger B. Fillingim,¶ and Dennis C. Turk‖

*Department of Anesthesiology, Vanderbilt University School of Medicine, Nashville, Tennessee.
†Department of Oral Diagnostic Sciences, University at Buffalo, Buffalo, New York.
‡Miami Project to Cure Paralysis, Miller School of Medicine, University of Miami, Miami, Florida.
§Department of Neurology in the Center for Human Experimental Therapeutics, University of Rochester School of Medicine and Dentistry; and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION), University of Rochester School of Medicine and Dentistry, Rochester, New York.
¶Pain Research and Intervention Center of Excellence, Gainesville, Florida.
‖Department of Anesthesiology and Pain Medicine, University of Washington, Seattle, Washington.

Abstract: The Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks-American Pain Society Pain Taxonomy (AAPT) is designed to be an evidence-based multidimensional chronic pain classification system that will facilitate more comprehensive and consistent chronic pain diagnoses, and thereby enhance research, clinical communication, and ultimately patient care. Core diagnostic criteria (dimension 1) for individual chronic pain conditions included in the initial version of AAPT will be the focus of subsequent empirical research to evaluate and provide evidence for their reliability and validity. Challenges to validating diagnostic criteria in the absence of clear and identifiable pathophysiological mechanisms are described. Based in part on previous experience regarding the development of evidence-based diagnostic criteria for psychiatric disorders, headache, and specific chronic pain conditions (fibromyalgia, complex regional pain syndrome, temporomandibular disorders, pain associated with spinal cord injuries), several potential approaches for documentation of the reliability and validity of the AAPT diagnostic criteria are summarized.

***Perspective:** The AAPT is designed to be an evidence-based multidimensional chronic pain classification system. Conceptual and methodological issues related to demonstrating the reliability and validity of the proposed AAPT chronic pain diagnostic criteria are discussed.*

***Key words:** Chronic pain, taxonomy, classification, diagnostic criteria, reliability, validity.*

The public-private partnership, Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks and the American Pain Society have jointly been working toward development of a comprehensive chronic pain taxonomy, the AAPT. The AAPT will provide diagnostic criteria for an array of chronic pain conditions using a consistent, multidimensional format. The 5 proposed diagnostic dimensions include: core diagnostic criteria (dimension 1); common features (dimension 2); common medical comorbidities (dimension 3); neurobiological, psychosocial, and functional consequences (dimension 4); and putative neurobiological and psychosocial mechanisms, risk factors, and protective factors (dimension 5).[24] An important aspect of the AAPT is its emphasis on having an adequate evidence base to support the diagnostic criteria included in the taxonomy.[24] Although this supporting evidence initially will be based primarily on clinical consensus as well as literature review and synthesis, the AAPT diagnostic categories and their associated

The views expressed in this article are those of the authors, none of whom has financial conflicts of interest relevant to the specific issues discussed. No official endorsement by the U.S. Food and Drug Administration (FDA) or the pharmaceutical and device companies that have provided unrestricted grants to support the activities of the ACTTION public-private partnership with the FDA should be inferred. Financial support for this supplement and for the development of the AAPT has been provided by the ACTTION public-private partnership, which has received research contracts, grants, or other revenue from the FDA, multiple pharmaceutical and device companies, and other sources. A complete list of current ACTTION sponsors is available at: http://www.acttion.org/partners.

Address reprint requests to Stephen Bruehl, PhD, Vanderbilt University Medical Center, 701 Medical Arts Building, 1211 Twenty-First Avenue South, Nashville, TN 37212. E-mail: Stephen.Bruehl@vanderbilt.edu

1526-5900/$36.00

http://dx.doi.org/10.1016/j.jpain.2015.10.014

criteria subsequently will be subjected to systematic empirical evaluation of their reliability and validity, and will be revised as appropriate.

The planned empirically-based, iterative process is designed to parallel similar successful efforts to develop valid and reliable diagnostic criteria for psychiatric disorders (the Diagnostic and Statistical Manual of Mental Disorders, first through fifth editions[1-5]) and headache disorders (the International Classification of Headache Disorders, first through third editions[32-34]). In both of these endeavors, initial criteria represented the consensus opinions of experts, followed by revisions increasingly driven by empirical studies of reliability and validity.[43,50,67,68]

The current article is intended to provide an overview of the conceptual and methodological issues involved in demonstrating the reliability and validity specifically of the AAPT Core Diagnostic Criteria (dimension 1). These core criteria include the subjective symptoms and objective signs (potentially including test results) that are considered the central, defining features of each specific chronic pain condition, and the decision rules (ie, diagnostic algorithm) for determining the threshold for when a patient meets criteria for being assigned a diagnosis.[24] Examples of chronic pain conditions for which systematic diagnostic research has already been conducted are described herein to demonstrate different approaches for development of evidence-based diagnostic criteria. Validation methods and limitations described in these examples are highly relevant to improvement of the diagnostic criteria for all common chronic pain disorders.

Definitions

Pain is inherently a subjective phenomenon, dependent on each individual's conscious experience of pain. Thus, there is no objective external reference standard against which the validity of a set of chronic pain diagnostic criteria can be conclusively determined, because of the centrality of pain as a core criterion in any chronic pain disorder. If a sufficient objective external reference standard for the symptom of pain were to emerge, this might permit demonstration of criterion validity for chronic pain diagnostic criteria with definitive validation methods. Although criteria might also be validated against underlying pathophysiology for each specific chronic pain condition, the existence of a definitive and complete pathophysiology for any chronic pain condition remains at best debatable. As a result, demonstrating criterion validity in a manner similar to many other medical diagnoses, for example, validating diagnostic criteria for dementia using autopsy results as the criterion (eg, Gold et al[27]), is impossible. Rather, each chronic pain condition described in the AAPT represents a presumably unique syndrome, that is, a set of clinical signs and symptoms that co-occur and define the condition.[53] Each chronic pain syndrome is therefore a construct and, as such, the type of validity most relevant to chronic pain diagnosis is construct validity. The construct validity of diagnostic criteria for a given pain condition reflects the extent to which the signs, symptoms, and diagnostic decision rules incorporated in the criteria correspond with the underlying chronic pain syndrome construct as it exists in the "real world." There are several subtypes of construct validity and multiple methods available for assessment of the construct validity of diagnostic criteria.

One relevant subtype of construct validity is content validity. In the diagnostic context, this refers to whether the domain of signs and symptoms that comprise the specific pain syndrome is adequately captured by the criteria. This is an area in which input not only from clinicians and researchers, but also from patients who experience the targeted syndrome (via focus groups or qualitative research methods) is particularly valuable.

Another subtype of construct validity is internal validity. We use this term not in the sense it is used in the experimental design literature, but, rather, to refer to the validity of the internal structure of the diagnostic criteria. Specifically, to what extent do the criteria as written correspond with the inter-relationships among the clinical features as they exist in patients with the condition? Using complex regional pain syndrome (CRPS) as an example, best evidence indicates that multiple mechanisms (eg, central sensitization, neurogenic inflammation, altered autonomic function, altered motor function) likely contribute to the condition. Although these different mechanisms might overlap and interact and thus are not entirely separable, each might be expected to be associated with somewhat different symptoms and signs (eg, central sensitization with allodynia, inflammation with edema). Hence, diagnostic criteria might display greater internal validity if they include as separate criteria the distinct groupings of inter-related signs and symptoms associated with each of the hypothesized underlying mechanisms. Clinical implications of internal validity issues are further highlighted in the more detailed CRPS example in the Validity Case studies section.

A third relevant subtype of construct validity is concurrent validity. For purposes of development of diagnostic criteria, this would typically refer to demonstration of associations between diagnoses made using new proposed criteria and diagnoses made using an existing diagnostic standard. This standard might reflect a previously published set of diagnostic criteria,[10] "expert clinician diagnoses,"[58,68] or even "usual method of diagnosis."[70]

Construct validity of diagnostic criteria can also be supported by demonstrating expected associations between meeting the diagnostic criteria and presence of clinical markers associated with the condition but not contained within the criteria themselves. This subtype of construct validity is typically referred to as convergent validity. For example, given the evidence for a role for central sensitization in fibromyalgia (FM), patients who meet diagnostic criteria for FM might be expected to exhibit enhanced temporal summation (an index reflecting central sensitization) on quantitative sensory testing