

Clinical Study

The selection of core International Classification of Functioning, Disability, and Health (ICF) categories for patient-reported outcome measurement in spine trauma patients—results of an international consensus process

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Abstract

BACKGROUND CONTEXT: There is no outcome instrument specifically designed and validated for spine trauma patients without complete paralysis, which makes it difficult to compare outcomes of different treatments of the spinal column injury within and between studies.

PURPOSE: The paper aimed to report on the evidence-based consensus process that resulted in the selection of core International Classification of Functioning, Disability, and Health (ICF) categories, as well as the response scale for use in a universal patient-reported outcome measure for patients with traumatic spinal column injury.

STUDY DESIGN/SETTING: The study used a formal decision-making and consensus process.

PATIENT SAMPLE: The sample includes patients with a primary diagnosis of traumatic spinal column injury, excluding completely paralyzed and polytrauma patients.

OUTCOME MEASURES: The wide array of function and health status of patients with traumatic spinal column injury was explored through the identification of all potentially meaningful ICF categories.

METHODS: A formal decision-making and consensus process integrated evidence from four preparatory studies. Three studies aimed to identify relevant ICF categories from three different perspectives. The research perspective was covered by a systematic literature review identifying outcome measures focusing on the functioning and health of spine trauma patients. The expert perspective was explored through an international web-based survey among spine surgeons from the five AOSpine International world regions. The patient perspective was investigated in an international empirical study. A fourth study investigated various response scales for their potential use in the future universal outcome instrument. This work was supported by AOSpine. AOSpine is a clinical division of the AO Foundation, an independent medically guided non-profit organization. The AOSpine Knowledge Forums are pathology-focused working groups acting on behalf of AOSpine in their domain of scientific expertise.

RESULTS: Combining the results of the preparatory studies, the list of ICF categories presented at the consensus conference included 159 different ICF categories. Based on voting and discussion, 11 experts from 6 countries selected a total of 25 ICF categories as core categories for patient-reported outcome measurement in adult traumatic spinal column injury patients (9 body functions, 14 activities and participation, and 2 environmental factors). The experts also agreed to use the Numeric Rating Scale 0–100 as response scale in the future universal outcome instrument.

CONCLUSIONS: A formal consensus process integrating evidence and expert opinion led to a set of 25 core ICF categories for patient-reported outcome measurement in adult traumatic spinal column injury patients, as well as the response scale for use in the future universal disease-specific outcome instrument. The adopted core ICF categories could also serve as a benchmark for assessing the content validity of existing and future outcome instruments used in this specific patient population. © 2016 Elsevier Inc. All rights reserved.

Keywords:

Consensus process; Core ICF categories; Functioning; ICF; Outcome instrument; Spine trauma

Introduction

Traumatic spinal column injuries remain a major public health concern. Although these injuries comprise only a minority of all traumatic injuries, they have a significant influence on the individual's social, functional, and financial situations [1,2]. A subset of these patients are dealing with an associated neurological injury, which contributes to substantial disability with long-term consequences and associated considerable health-care-related costs [3–5].

Currently, there is a lack of consensus on the evaluation and optimal treatment of many types of spinal column injuries [6,7]. Although a number of outcome instruments have been developed and validated for individuals with traumatic spinal cord injury, these tend to focus on the impact of paralysis [8]. In the absence of an outcome instrument specifically designed and validated for spine trauma patients without com-

plete paralysis, it is difficult to compare outcomes of different treatments of the spinal column injury within and between studies.

In reflection of this dilemma, the AOSpine Knowledge Forum Trauma initiated a project to develop and validate universal disease-specific outcome instruments for adult spine trauma patients that include both the patient's and the clinician's perspectives [9]. In the developmental phase and initial validation of the patient-reported part of this outcome instrument, completely paralyzed (American Spinal Injury Association (ASIA) impairment grade A or B) and polytrauma patients (Injury Severity Score >15) were excluded, in order to exclude confounding factors and to maintain the focus on a well-defined patient population with traumatic spinal column injury as primary diagnosis.

We have decided to use the systematic and comprehensive approach of the International Classification of Functioning,

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