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SPECIAL COMMUNICATION

Methodological Issues and Research Recommendations for Prognosis After Mild Traumatic Brain Injury: Results of the International Collaboration on Mild Traumatic Brain Injury Prognosis

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Abstract

The International Collaboration on Mild Traumatic Brain Injury (MTBI) Prognosis performed a comprehensive search and critical review of the literature from 2001 to 2012 to update the 2002 best-evidence synthesis conducted by the World Health Organization Collaborating Centre for Neurotrauma, Prevention, Management and Rehabilitation Task Force on the prognosis of MTBI. Of 299 relevant studies, 101 were accepted as scientifically admissible. The methodological quality of the research literature on MTBI prognosis has not improved since the 2002 Task Force report. There are still many methodological concerns and knowledge gaps in the literature. Here we report and make recommendations on how to avoid methodological flaws found in prognostic studies of MTBI. Additionally, we discuss issues of MTBI definition and identify topic areas in need of further research to advance the understanding of prognosis after MTBI. Priority research areas include but are not limited to the use of confirmatory designs, studies of measurement validity, focus on the elderly, attention to litigation/compensation issues, the development of validated clinical prediction rules, the use of MTBI populations other than hospital admissions, continued research on the effects of repeated concussions, longer follow-up times with more measurement periods in longitudinal studies, an assessment of the differences between adults and children, and an account for reverse causality and differential recall bias. Well-conducted studies in these areas will aid our understanding of MTBI prognosis and assist clinicians in educating and treating their patients with MTBI.

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In 2004, the World Health Organization (WHO) Collaborating Centre for Neurotrauma Prevention, Management and Rehabilitation Task Force on Mild Traumatic Brain Injury (WHO Task Force) found the mild traumatic brain injury (MTBI) literature to be large and of variable quality.[1] The purpose of the International Collaboration on MTBI Prognosis (ICoMP) was to update the WHO Task Force findings on prognosis and to comprehensively search and critically review the quality of the new literature on MTBI prognosis. Overall, we accepted and based our findings on 34% of the 299 eligible studies as having a low risk of bias.[2] The WHO Task Force accepted 28% of reviewed studies; thus, despite the proliferation of MTBI research over the past decade, virtually no improvement was seen in study quality.[1] These low acceptance rates indicate a literature plagued with poorly designed studies and, as a result, many unanswered important clinical and research questions. The objectives of this article are to discuss issues related to the definition and classification of MTBI; outline common flaws including sources of bias, problems with study design, and issues with reporting; provide recommendations for improvement; and identify priority areas of research on MTBI prognosis.

Definition of MTBI

The WHO Task Force report tabled 38 definitions from studies included in their best evidence synthesis.[1] Although many definitions had overlapping criteria, they also exhibited considerable differences and used varying terms for the condition including MTBI, concussion, and minor head injury. Most definitions (62%) included Glasgow Coma Scale (GCS) scores as one or the only criterion, but not all applied the same GCS spectrum to define MTBI. Others (38%) used varying criteria for loss of consciousness (LOC) and amnesia, or Abbreviated Injury Severity scores, or *International Classification of Diseases* (ICD) codes, or other criteria. Some definitions also allowed skull fractures or intracranial lesions.

Based on their findings, the WHO Task Force proposed an operational definition derived from the definition developed by the Mild Traumatic Brain Injury Committee of the Head Injury Interdisciplinary Special Interest Group of the American Congress of Rehabilitation Medicine (ACRM).[3] This definition reads as follows:

> "MTBI is an acute brain injury resulting from mechanical energy to the head from external physical forces. Operational criteria for clinical identification include: (1) 1 or more of the following: confusion or disorientation, LOC for 30 minutes or less, posttraumatic amnesia for less than 24 hours, and/or other transient neurologic abnormalities such as focal signs, seizure, and intracranial lesion not requiring surgery; (2) GCS score of 13−15 after 30 minutes post-injury or later upon presentation for health care. (3) These manifestations of MTBI must not be due to drugs, alcohol, medications, caused by other injuries or treatment for other injuries (eg, systemic injuries, facial injuries, or intubation), caused by other problems (eg, psychological trauma, language barrier, or coexisting medical conditions), or caused by penetrating craniocerebral injury."[1(p115)]

This operational definition has similarities with the conceptual definition produced by a panel of experts from the U.S. Centers for Disease Control and Prevention's MTBI Working Group in 2003.[4] While the ACRM definition suggests that the GCS score of 13 to 15 be assessed after 30 minutes postinjury, the WHO Task Force proposed the use of a GCS score after 30 minutes or later on presentation for health care, arguing that individuals with MTBI will rarely be assessed at an emergency department (ED) within 30 minutes. The proposed definition differed from the ACRM definition in 2 ways: (1) According to the ACRM criteria, disturbed mental status includes feeling "dazed," but this was not included in the WHO Task Force definition; and (2) In the ACRM definition, focal neurologic deficits "may or may not be transient," while the WHO Task Force definition states "other transient neurologic abnormalities." Ruff et al[5] correctly identify that "the rational by the WHO Task Force for making these two changes was not stated explicitly in their publication."[(p5)] However, the extent to which the term "dazed" truly refers to disturbed mental status could be debated.

Ruff[5] also points out that neither definition provides guidelines or specific recommendations for assessing the 4 key elements: LOC, posttraumatic amnesia (PTA), disorientation/confusion, and neurologic signs. This is a key issue, and we strongly recommend further study of the diagnostic accuracy of relevant measures.

The current review found a continuing lack of unity regarding MTBI definitions (table 1). While most studies include the GCS score as 1 component, others apply only LOC or PTA-based criteria. Although most recent studies apply criteria that are compatible with the ACRM and WHO Task Force criteria, in many cases authors have selected a subset of patients with MTBI who have a particular severity of injury, within the broader MTBI definition. The impact of different degrees of MTBI severity on the prognosis is not known, and the variation of study sample characteristics hinders comparison of the results. We recommend further studies comparing the prognosis for subgroups with well-defined but different severity degrees. A more nuanced severity grading based on GCS scores (GCS 15 vs 14 vs 13) or PTA levels, or both, may be promising. We need more information on the reliability of the GCS, especially in the 13 to 15 range.

List of abbreviations:

ACRM	**American Congress of Rehabilitation Medicine**
ED	**emergency department**
GCS	**Glasgow Coma Scale**
ICD	***International Classification of Diseases***
ICF	***International Classification of Functioning, Disability and Health***
ICoMP	**International Collaboration on MTBI Prognosis**
LOC	**loss of consciousness**
MTBI	**mild traumatic brain injury**
PTA	**posttraumatic amnesia**
RTW	**return to work**
WHO	**World Health Organization**
WHO Task Force	**WHO Collaborating Centre for Neurotrauma Prevention, Management and Rehabilitation Task Force on MTBI**

Upper and lower severity delimitations of MTBI

The distinctions of MTBI from moderate TBI and from trivial head injury are debated. Some authors have proposed that in patients where imaging demonstrates brain pathology, the diagnosis should be complicated mild or moderate TBI.[6] Since there is a higher frequency of brain pathology in patients with a presenting GCS score of 13, and the prognosis of these patients may be similar to that of patients with moderate TBI, GCS scores of 13 may be better classified as being indicative of moderate TBI. However, given the

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