

Randomized treatment trial in mild traumatic brain injury

Omar Ghaffar^a, Scott McCullagh^a, Donna Ouchterlony^b, Anthony Feinstein^{a,*}

^aDepartment of Psychiatry, Sunnybrook and Women's College Health Sciences Centre, University of Toronto, Toronto, Ontario, Canada M4N 3M5

^bDepartment of Rehabilitative Medicine, St. Michael's Hospital, University of Toronto, Toronto, Ontario, Canada

Received 30 June 2004; accepted 20 July 2005

Abstract

Objective: To determine whether multidisciplinary treatment of mild traumatic brain injury (MTBI) improves neurobehavioral outcome at 6 months postinjury. **Methods:** Subjects with MTBI were randomly assigned to treatment ($n=97$) or non-treatment (control, $n=94$) groups. Treated patients were assessed within 1 week of injury and thereafter managed by a multidisciplinary team according to clinical need for a further 6 months. Control subjects were not offered treatment. Six-month outcome measures included: severity of postconcussive symptoms (Rivermead Post-Concussion Disorder Questionnaire), psychosocial functioning (Rivermead Follow-up Questionnaire), psychological distress (General Health Questionnaire), and

cognition (neurocognitive battery). **Results:** Treatment and control subjects were well-matched for demographic and MTBI severity data. In addition, the two groups did not differ on any outcome measure. However, in individuals with preinjury psychiatric difficulties (22.9% of the entire sample), subjects in the treatment group had significantly fewer depressive symptoms 6 months postinjury compared with untreated controls ($P=.01$). **Conclusions:** These findings suggest that routine treatment of all MTBI patients offers little benefit; rather, targeting individuals with preinjury psychiatric problems may prove a more rational and cost-effective approach.

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Keywords: Traumatic brain injury (TBI); Closed head injury; Depression; Neuropsychiatry; Neuropsychological testing; Treatment

Introduction

Mild traumatic brain injury (MTBI) is a significant public health issue: 150 per 100,000 hospital admissions, four to five times as many outpatients, and a cost of 1 billion dollars per year in the United States [1–4]. MTBI gives rise to a constellation of symptoms termed the *postconcussion disorder* (PCD), of which complaints of headache, fatigue, depression, anxiety, irritability, and cognitive difficulties figure prominently [5–10]. The natural history of PCD is generally toward spontaneous resolution with time; however, 15% of patients continue to suffer disabling symptoms 1 year postinjury [11,12]. Given the large number of patients affected, studies have sought to better identify this so-called

miserable minority [13], with the hope that early intervention may improve their outcome.

To date, studies investigating whether routine treatment of all MTBI improves outcome have been few, with mixed results. Paniak et al. [14,15] found similar psychosocial outcomes at both 3 and 12 months post-MTBI regardless of whether additional intensive, “as-needed” treatment was given to supplement an initial education session for all patients. A treatment study by the Oxford Head Injury Service found that only in moderate and severe traumatic brain injury (TBI) did “treatment tailored according to clinical need” make a difference with respect to outcome at 6 months postinjury [16]. However, in two studies from the 1970s that lacked standardized outcome measures, *reassurance* and *education* were associated with a reduction in PCD symptom frequency 6 months postinjury and, in some cases, an earlier return to work after MTBI [17,18]. A more recent study found that individuals who were given an information booklet outlining MTBI symptoms

* Corresponding author. Department of Psychiatry, Sunnybrook and Women's College Health Sciences Centre, University of Toronto, Toronto, Ontario, Canada M4N 3M5. Tel.: +1 416 480 4216; fax: +1 416 480 6022.

E-mail address: ant.feinstein@utoronto.ca (A. Feinstein).

and coping strategies had significantly less anxiety, sleep difficulties, and psychological distress at 3 months after MTBI compared with patients who were not given the information booklet [19].

Given the clinical importance of the PCD entity and the equivocal treatment results to date, we undertook a randomized prospective treatment trial in a consecutive group of patients with MTBI to assess whether a multidisciplinary approach to management can improve outcome. Although clear clinical guidelines exist for the acute diagnosis of MTBI [20], the absence of consistent, empirical data on the possible benefits of treatment have left providers in a quandary. Most often, MTBI patients are discharged with no treatment or follow-up or told that they should see their primary care provider should they develop persisting symptoms. We hypothesize that multidisciplinary treatment addressing physical, emotional, and psychosocial sequelae in the acute phase of recovery may prevent or reduce morbidity following MTBI [3]. Our secondary hypothesis is that certain groups, by virtue of putative premorbid risk factors, may have worse outcomes. These groups include patients with a previous head injury, past psychiatric difficulties, and those pursuing litigation related to their injury [12,21,22].

Methods

Subjects and study design

Subjects were recruited from a consecutive group of patients with MTBI presenting to the emergency departments of two tertiary trauma centers associated with the University of Toronto. MTBI was defined according to the criteria of the American Congress of Rehabilitation Medicine—Head Injury Interdisciplinary Special Interest Group [23]. Patients with a major medical illness such as cardiac or cerebrovascular disease and those younger than 16 or older than 60 years were excluded. Sample size was predicated by the number of consecutive patients with MTBI meeting the above-specified criteria over an 18-month period. Subjects were assigned randomly to treatment or no treatment (control) groups:

- (a) Treatment group ($n=97$). Subjects were given an appointment in a multidisciplinary TBI clinic within 1 week of injury. They were encouraged to attend with their spouse, partner, or relative. Both the patient and spouse or relative were educated by an occupational therapist in a standardized manner with reference to a checklist of PCD symptoms and possible effects of MTBI. At each visit, subjects were assessed separately by an occupational therapist and two physicians experienced in managing patients with MTBI, namely a neurorehabilitation physician and a neuropsychiatrist. Physical

symptoms including pain, headache, and dizziness were addressed by the former, whereas emotional sequelae including depressive symptoms, anxiety symptoms, and sleep difficulties were managed by the neuropsychiatrist. Treatments were tailored according to each individual patient's need and included pharmacotherapy, supportive psychotherapy, physiotherapy, and occupational therapy if appropriate. Follow-up visits varied in frequency from weekly to monthly or bimonthly depending on clinical need. When required, patients were also offered assistance at home through the offices of the Community Occupational Therapy Association. In addition, where indicated, subjects in the treatment group were referred for consultation with other specialties, such as plastic surgery or orthopedics if required.

- (b) Control group ($n=94$). Patients in the control group were not offered follow-up visits or treatment. As with the treatment group, consent and inclusion criteria were ascertained during their initial Emergency Department visit. Their next contact with the study was when they were approached by a TBI research assistant 6 months after their head injury.

Data collection

1. The following baseline measures were compiled:
 - (a) Demographic variables such as age, sex, education, and employment status.
 - (b) Severity of the TBI documented by duration of loss of consciousness (LOC), length of posttraumatic amnesia (PTA), and Glasgow Coma Scale (GCS). Mechanism of accident and the presence or absence of other (non-TBI) injuries was also recorded. GCS recorded on arrival in the emergency department was used, and estimation of PTA duration was obtained retrospectively using the method of Russell and Smith [24,25].
 - (c) Putative risk factors for poor outcome identified from the MTBI literature [12,21,22]: history of prior head trauma, previous psychiatric history, and whether the patient was pursuing litigation. A previous psychiatric history was defined as contact with a psychiatrist, psychologist, or family physician for psychiatric difficulties. This information was obtained from detailed patient interviews.
2. Outcome measures at 6 months post-TBI included the following:
 - (a) Symptoms of PCD were quantified using the Rivermead Post-Concussion Disorder Questionnaire (RPCQ) [26]. The RPCQ is scored on a modified Likert Scale. It contains 18 questions probing symptoms of: headache, dizziness, nausea,

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