Investigating the variability in mild traumatic brain injury definitions: a prospective cohort study

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Abstract

Objective: To prospectively compare the proportion of traumatic brain injuries (TBIs) that would be classified as 'mild' using different published definitions by applying published definitions of mild TBI to a large prospectively collected dataset and to examine the variability in the proportions included by various definitions. High rates of mild TBI in children makes it a major public health issue, however, there is a wide variation in how mild TBI is defined in literature and guidelines.

Design: Prospective observational study.

Setting: Ten hospital emergency departments in the 'PREDICT' network based in Australia and New Zealand.

Participants: The sample included 11,907 children aged 3-16 years. The mean age was 8.2 years (SD = 3.9 years), 3,868 (32.5%) were female, and 7,374 (61.9%) of TBI were due to a fall. Median Glasgow Coma Score was 15.

Main outcome measure: We applied 17 different definitions of mild TBI, identified through a published systematic review, to children aged 3-16 years. Adjustments and clarifications were made to some definitions. The number and percentage identified for each definition is presented.

Results: Adjustments had to be made to the 17 definitions to apply to the dataset: none in 7, minor to substantial in 10. The percentage classified as mild TBI across definitions varied from 7.1% (n = 841) to 98.7% (n = 11,756) and varied by age group.

Conclusions: When applying the 17 definitions of mild TBI to a large prospective multicenter dataset of TBI there was wide variability in the number of cases

classified. Clinicians and researchers need to be aware of this variability when examining literature concerning children with mild TBI.

Keywords: Traumatic Brain Injury, Head Injuries, Child

Abbreviations: ACRM: American Congress of Rehabilitation Medicine; AIS: Abbreviated Injury Scale; BCRM: British Society of Rehabilitation Medicine**;** GCS: Glasgow Coma Score**;** LOC: Loss of consciousness**;** PTA: Post traumatic amnesia; TBI: traumatic brain injury; WHO: World Health Organization

Word count: 3196

Traumatic brain injury (TBI) frequently occurs in children, with the vast majority of these events considered 'mild' [1]. While once considered a benign injury, mild TBI (and its subset of concussion) have been linked to poor neurobehavioral outcomes in some children [2] and the relative burden of disability from TBI is predominately from mild injuries [3]. However, there is wide variation in the way 'mild' TBI is defined, which limits the interpretation of current studies and comparison across studies. A recent review by Lloyd Wilson, Tenovuo and Saarijärvi [4] and prior reviews of mild TBI outcomes [5] have highlighted the variability in mild TBI definitions across studies, leading to concern that injury groupings are not equivalent. The World Health Organization (WHO) Collaborating Centre Task Force on Mild TBI (WHO Task Force) compiled a best evidence synthesis by completing a systematic review on definitions of mild TBI used in the literature [6]. This information was then used to develop their operational definition of mild TBI.

The definition of mild TBI developed by the WHO Task Force is very similar to the definition developed by the American Congress of Rehabilitation Medicine (ACRM) in 1993 [7]. The WHO definition clarifies what constitutes a mild TBI combined with Glasgow Coma Score (GCS) [8], clinical symptoms such as loss of consciousness and strict exclusion criteria. The major difference is that the WHO definition does not use the term 'dazed' as in the ACRM definition [8]. Kristman and colleagues [9-10], building on earlier work of the WHO Task Force [6], conducted a review of definitions used in the literature to define mild TBI. They highlighted that only 28% of studies they reviewed were considered of acceptable research quality, and few studies utilized the WHO definition of mild TBI [8]. Most studies reviewed had developed their own definition of mild TBI.

The purpose of this study was to apply several different definitions of pediatric mild TBI that have been used in the literature to a single prospective dataset. In this paper, we have used Kristman et al. [9] review and searched for all definitions that included pediatric samples. We were interested in how the percentage of children classified as having a mild TBI would vary dependent on the definition used; this is critical information when comparing findings across published studies. We also were interested in whether rates would vary across age groups.

Method

This was a planned secondary analysis of a large prospective observational study of children presenting with an injury to the head of any severity to 10 emergency departments in Australia and New Zealand who are members of the PREDICT Network [11]. Recruitment for the Australian Paediatric Head Injury Rules Study (APHIRST) was between April 2011 and November 2014. The primary purpose of the original study was to assess and compare the accuracy of neuroimaging rules in TBI with details of the methodology and initial results published elsewhere [12-13]. However, it is important to know that in the primary study we included TBIs of all severities with GCS 3-15. Exclusion criteria included: patients with trivial facial injury only, patients referred from emergency department triage to a General Practitioner, those who underwent neuroimaging before transfer to a study site, and those who did not wait to be seen. Patients who were eligible but not approached for enrolment (missed patients) had similar characteristics to enrolled patients.

We examined each of the 101 definitions listed by Kristman et al. [9] based on a detailed systematic review previously conducted [10]. We aimed to include the definitions outlined in articles that included children. This was conducted by examining the original definitions using the article referenced by Kristman [9].

Definitions were reviewed by two authors (LC and FB) to determine inclusion. For the purposes of this study we included children aged from 3 to 16 years. Children under 3 years were excluded as they tend to present differently and post-traumatic amnesia (PTA) and disorientation are difficult to ascertain [14]. For the purposes of this study, adolescents over 16 years were excluded as this age group are generally seen at adult hospitals and the definitions identified for children tended to use an upper limit of 15 to 16 years.

Insert figure 1 here

Articles that did not specify an age range were excluded [15-16]. For example, Selassie appeared to include all age groups but this was not clearly defined in their method [16]. Adult studies were excluded as were studies focused on older adolescents (15 years +) as these definitions were not applicable for the majority of the sample based on their age range [15-26]. That is, although a percentage of our sample were applicable for the definition (15-16 year olds), these were predominately definitions developed for use on adult populations and unable to be applied to younger children. Definitions that used ICD codes only were excluded. Da Dalt et al. (2007) was excluded as the definition was unclear [29], refer to Figure 1. Applying all criteria resulted in 26 articles, which contained 17 definitions, as some studies utilized the same samples (Table 1). Fifteen out of 17 definitions (88.2%) included GCS as one criterion. Loss of consciousness (LOC) or alteration of consciousness was included as a criterion in 13 out of 17 (76.5%) definitions. The 17 definitions included over 35 different variables. Adjustments and clarifications were made to some definitions to accommodate the data we had available. Adjustments to the definitions were generally made because the definition had classified LOC using a different time format than recorded in the database [33-34]. Clarifications included how we interpreted variables in the definition, for example, we clarified that we considered ‘altered consciousness’ to include either LOC or drowsiness [50-53]. No adjustments were made to seven definitions and minor to substantial adjustments in the remaining ten.

We arranged Table 1 into four groupings: GCS alone; GCS and Clinical Symptoms; GCS, Clinical Symptoms and Neuroimaging; and Clinical Symptoms Only.

Insert Table 1 here

Definitions were then applied to the prospectively collected APHIRST dataset which included detailed demographic information, information on presenting signs and symptoms as well as information on neuroimaging and short-term outcomes with telephone follow up 14 to 90 days after ED visit as set out in the detailed protocol published elsewhere [11]. Review of records for representations and follow up calls were used to checks for adverse outcomes or potentially missed intracranial injury. Ethics was approved by each of the hospital ethics boards and consent was obtained from participants upon enrolment.

In the APHIRST database, LOC was defined as either <5 seconds, 5 seconds-5 minutes or >5 minutes. This was a decision made when developing the study, based on the neuroimaging rules studied in APHIRST. A specific duration of LOC was likely to be largely based on estimation, however, most witnesses to injuries would be able to rate between <5 seconds, 5 seconds-5 minutes and >5 minutes. GCS data was recorded for the time of arrival at triage in ED, on clinician assessment and 2 hours post-injury. Information was collected on whether injury was non-accidental or penetrating and admission was defined as admission to: the ED for >4 hours of observation, short stay unit, ward or pediatric intensive care unit. Time of PTA was defined as <5 minutes, >5 minutes, or unknown.

Analysis

We applied the 17 definitions with our assumptions to the APHIRST dataset and calculated the % with 95% confidence intervals (CIs) for key point estimates. Means and medians were also used for certain variables. To investigate how the definitions performed across the different age bands we divided the sample into three: preschool (3 years up to 6 years), middle childhood (6 years up to 12 years) and adolescence (12 years up to 16 years). We also have included the citations from PubMed for the articles used to assess whether they have been used in other studies (combined together when more than one article by same author).

Results

Of the total dataset of 20,137 children enrolled in the parent study, 11,907 children remained for analysis when limiting the sample to patients aged 3-16 years. Demographics of this sample are provided in Table 2. The majority of children in the study were male. The most commonly reported symptom was headache, followed by vomiting. Most TBIs were sustained from falls. Median GCS was 15. There were few penetrating TBIs (n = 20). Cranial CT rate was 12.7%, abnormal neuroimaging findings was 2.9% and neurosurgery rate was 0.5%. Less than 1% of children had a reported LOC >5 minutes.

Table 3 lists the number of children who would be defined as mild TBI using the different definitions. Percentages of the cohort covered by the definitions of “mild” TBI ranged from 7.1% (841) to 98.7% (11,756). The two definitions using GCS alone contributed to the largest group, covering 98.6- 98.7% of the sample. The lowest was Levin et al., [33] at 7.1% overall, using a combination of GCS and clinical symptoms. This appears to be because of the inclusion of LOC as a necessary. Applying the ACRM criteria utilized by Gagnon [46-48] meant that 32.5% of children were classified as having a mild TBI.

When the age group and the number classified by the definition was examined, it was noticed that the two definitions that used GCS as the only clinical feature [31-32], showed little variation across the age groups. This was also true for some other definitions with little variation (<15%) in the number defined across the different age groups [33, 49, 54, 56, 59]. When GCS was combined with clinical symptoms the trend was for mild TBI to be classified as greatest for the oldest age group (12-16 years) and lowest for the youngest age group (3-5 years) [33-48]. This was less so when neuroimaging results were included. For the definitions using clinical symptoms only, one definition [G2: 57-58] showed a reverse trend with younger age group (3-5 years) having the highest rate of mild TBI classifications.

Insert Table 3 about here

Discussion

This is the first study to apply multiple mild TBI definitions to a single dataset, derived from a large prospective observational study of children with TBIs of all severities. We found very wide variation in terms of which children would be defined as having a mild TBI from less than 10% of the sample to more than 90%.

Different age bands included a variable number of children within the same definition. This was most obvious for the group of definitions that combined GCS with clinical symptoms, with older children fitting the mild TBI definitions at much higher rates. It is possible that younger children exhibit different clinical symptoms after a TBI than older children, therefore are less likely to fit the definitions [14]. However, research available into differences in presentation across age groups is minimal.

The definitions highlight the difference between head trauma and a brain injury. For example, all children in the APHIRST study have injured their head and on presentation to the ED were medically evaluated with symptoms and typically a GCS value assigned. Two definitions that utilized GCS without clinical symptoms [31-32] identified >98% of the sample; these definitions were from studies that investigated late mortality and value of CTs. The nature of these studies meant that they were focused on all presentations of children with injuries to the head and were not attempting to select cases where the injury had resulted in a brain injury possibly impacting functional, cognitive or behavioral outcomes. Definitions that use the term TBI or concussion, tend to emphasize the physical, behavioral, psychiatric or neurocognitive outcomes. These definitions used clinical variables in addition to GCS most likely to indicate that the head trauma experienced by the child had resulted in an injury to the brain [33, 37, 40-44, 50-54, 56-57]. We used the term TBI to encompass all definitions. TBI was chosen as it was the most common term used by the definitions, and is the term used by both the WHO Task Force and Kristman's review [9].

Over 35 different descriptors of symptoms associated with mild TBI were identified. Many were related to LOC, with different time periods specified (i.e., LOC> 1 minute or 5 minutes, etc) or PTA. Descriptors related to PTA include: loss of memory, disorientation, confusion, and amnesia <5 minutes. Other related descriptors include feeling foggy, dazed, displaying an altered mental state, or asking repetitive questions. The lack of specificity of some variables is of concern, particularly when the definitions are applied retrospectively or obtained from medical records. For example, variables such as 'neuropsychological dysfunction' and 'behavior change in days following' and more uncommon symptoms may not be detailed in medical notes and are likely difficult for younger children to report (e.g., double vision, ringing in ears). A lack of clarity in time variables is another problem, with terms such as 'persistent', 'transient' or 'momentary' left undefined.

The duration of LOC was defined differently across articles. In some definitions, LOC was defined by a specific time such as <1 minute [59], <2 minutes [58], <5 minutes [36], <15 minutes [35, 49], <30 minutes [40-44], and <1 hour [38]. In another group of papers any period of LOC [39] or impaired consciousness or alteration in consciousness was used [45, 50-53]. It is unclear why the duration of LOC considered consistent with a mild TBI varies so widely. Duration of LOC is problematic as the injury may be unwitnessed or parents/carers can be distressed leading to inaccurate estimation of time. Isolated LOC has been related to a very low likelihood of intracranial injury on CT scan [60]. The presence of any LOC has been associated with poor neurobehavioral outcomes [61], however, the specific impact of longer periods of up to 1 hour is unclear. In this large dataset, <1% of children had LOC >5minutes. This emphasis on time or presence of LOC alone seems to be an unnecessary component of defining mild TBI. Neither the ACRM nor the WHO definitions have LOC as a necessary. Criteria that only identify children who experience LOC may be selecting for a particular and restrictive population.

Our findings show that the most common symptoms experienced by children after head trauma were vomiting and headache, consistent with prior research [62]. However, few definitions included these symptoms as criteria [40-44, 38, 54]. The APHIRST study also collected information on irritability and agitation as symptoms associated with increased risk of intracranial injury [11]. Yet, no definition included this as a symptom. A definition that is not specific enough includes everyone in the dataset and one that is overly specific would exclude more people than necessary or only include those with on the more severe end of the mild TBI spectrum. The consequence of both is that the wrong population is included and outcomes may appear better or worse than they actually are. In the future it is likely that definitions of mild TBI will evolve to include newly developed blood and neuroimaging biomarkers, these are however not currently considered standard practice [63]. The use of clinical exam findings such as balance assessments [64] or cognitive computerized testing [65] also holds promise.

Based on our findings any description of mild TBI will need to take into account that definitions in the literature are highly variable; precise definitions used will be critical to understand the sample population for any research study or analysis and comparison of clinical samples. In addition, any research findings or consensus based recommendations for care of children with mild TBI will need to precisely describe who the targeted population is. Also, in a research versus a clinical setting the use of definitions may need to be somewhat varied. For example, a research setting may have a very specific set of inclusion and exclusion criteria dependent on the goal of the study, while in clinical setting more of a screening definition/ criteria may be important, so that a "brain injury" is not missed.

Study limitations

Limitations of this study are the adjustments made to the definitions and applying them retrospectively. We did not have information on some symptoms included in definitions such as diplopia (double vision), ringing in the ears, seeing stars or nausea. However, emergency department physicians were asked to record any focal neurological signs, which typically includes vision and hearing difficulties. We did not collect information on nausea. This was a decision made early in the study as it was not part of any neuroimaging rules [66] and is perceived as more subjective than vomiting. We also did not ask children specifically if they felt 'dazed'. We felt it was unlikely to be understood and we followed the WHO Task Force decision to exclude it [6]. Amnesia was not assessed with a formal tool only physician judgement. The specific number of minutes of LOC were not collected, as previously discussed. From the database, less than 1% of cases had LOC >5 minutes, therefore even if we had collected information on LOC >5 minutes there would be very little difference in the number of children classified as mild TBI.

Children younger than 3 years where not included in the study and neither were adolescents over 16 years of age. Information on race, ethnicity and socioeconomic status was not collected, this is generally the case for Australian and New Zealand studies. This is an emergency department based study and there may be different considerations for outpatient, community care and rehabilitation settings.

Conclusions

When applying 17 common definitions of mild TBI to a large prospective multicenter dataset of TBI of any severity we demonstrated wide variability between the number of children defined as having a mild TBI. Although we had to make changes to 10 of the 17 definitions it is unlikely that this affected our major finding, as we found considerable variation alone in the sub-group of seven definitions where no changes were made. Clinicians and researchers need to be aware of this important variability when applying the published literature to children presenting to emergency departments with mild TBI. Based on our findings, any description of mild TBI will need to take into account that definitions in the literature are highly variable; and the definitions used will be critical to understand the sample population of research or clinical studies. From the analysis of the definitions in this article and including the

ACRM and the WHO Task Force definition as well as the NDIS common data elements for TBI [67], there are certain variables that should be included in a definition of mild TBI, these include symptoms such as loss or alteration of consciousness, confusion or disorientation, PTA and focal neurological signs as well as GCS and the presence of a penetrating injury. To enhance clinical and research understanding it is critical to move the field towards a more cohesive and standardized definition increased consistency and reliability. The definition by the WHO Task Force, developed from a large body of work and input from experts in the field, is possibly a valid definition to select. Alternatively, by incorporating elements of this definition into future studies would provide a common data metric allowing comparison. In cases where the use of a standardized definition is unachievable, there should be reasoning around the selection of the definition utilized.

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