Definitions, epidemiology and outcomes

Severe traumatic brain injury in high-income countries

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Summary

Severe traumatic brain injury (TBI) is a silent epidemic, and a medical, social and economic burden in high-income countries. Different diagnostic instruments are used to define severe TBI; all diagnostic instruments have limitations and may contribute to the heterogeneity in reported severe TBI populations. In high-income countries the incidence lies between 4 and 17/100 000/year, depending on the diagnostic instruments used for inclusion. In Switzerland, an incidence of 11/100 000/year was observed using the abbreviated injury scale of the head region (HAIS) >3 as inclusion criteria. In patients ≤65 years the incidence was 8/100 000/year and in patients >65 years the incidence was 22/100 000/year. For severe TBI the mortality lies between 30 and 45% in high-income countries. In Switzerland, the mortality was 30% (25% in patients ≤65 years, 41% in patients >65 years). The instruments used to estimate functional outcome differ across studies and clinical practice; in research the Glasgow Outcome Coma Scale Extended (GOSE) most often is the instrument of choice. In Switzerland median GOSE scores were 5 (interquartile range [IQR] 3–7) at 3 months and 6 (IQR 4–8) at 6 months post-injury. Health-related quality of life has rarely been investigated; these rare studies reported on improvement over the first year after TBI comparable to functional recovery. Neuropsychological outcome is assessed using test batteries that include cognitive, psychiatric and social aspects of functioning. Prolonged cognitive impairments and psychiatric disturbances, most prevalently affective disorders, were observed after severe TBI. A standardized data collection of patients after TBI may allow interdisciplinary quality improvement initiatives in Switzerland.

Key words: severe TBI; high-income countries, functional outcome, neurocognitive outcome, quality of life

Severe traumatic brain injury (TBI) is a critical public health issue and socioeconomic burden throughout the world. TBI may be considered a "silent epidemic" due to its high incidence of 4–17/100 000/year, and its high mortality rate of 30–70% in both low- and high-income countries [1–3]. A lifelong disability is common among the survivors. In the European Union, approximately 7.7 million people who have experienced a TBI report disabilities [4] of physical, mental, and cognitive nature. These reported lifelong disabilities not only cause lower life expectancy compared to the general population [5], but also substantial indirect costs [6, 7].

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In the present review we will summarize the different definitions of severe TBI, the estimated incidences in high-income countries, and the functional and neuropsychological outcomes. Swiss data will be presented whenever available.

Definitions of severe traumatic brain injury

The definition of severe TBI depends on the different instruments that are used (table 1). The heterogeneity of instruments in use is partially related to the difficulty to classify TBI. But potential treatments are based on diagnostics, thus, it is crucial that diagnostic instruments have proven to be reliable and valid; otherwise, treatments may be inadequate. We will, therefore, first describe the diagnostic scales most commonly used, and further report their reliability and validity.

Glasgow Coma Scale

The Glasgow Coma Scale (GCS) estimates the conscious states of patients after a TBI [8]. GCS is a predictor of mortality, together with pupil reaction and age [9, 10]. The scale consists of three domains in which a patient's functioning is rated: 1) response to stimuli by eye opening; 2) verbal response; and 3) motor response. The sum of scores across domains provides a total score (range from 3–15) that is further often categorized into mild (13–15), moderate (8 or 9–12 [controversial]), and severe (<8–9) [9, 10]. Some researchers suggest using only the motor component of the GCS in severe TBI patients because of great difficulties to assess all other components in emergency settings [9, 10].

Even though the GCS is widely used, inter-rater reliability has been shown to be moderate among physicians [11], marginal among healthcare staff [12, 13], and variable across other healthcare providers [12]. Apart from its inter-rater reliability, its validity has been criticized as well, most commonly because of its inability to accurately record verbal status in intubated and aphasic patients [14, 15]. Salottolo et al. further found that the GCS validity to predict severity changes as a

Table 1: Specific instruments used for diagnosis and prediction in severe traumatic brain injury (TBI) at acute hospital admission.

Instrument	Purpose
Glasgow Coma Scale GCS	Estimation of consciousness
Motor component of GCS	Estimation of consciousness in intubated patients
Pupil reaction to light	Estimation of integrity of the brainstem function, optical nerve and oculomotor nerve
Clinical global assessment	Comprehensive estimation of trauma lesions as part of the Injury Severity Score ISS
Cerebral computed tomography (CT)	Estimation of structural pathological abnormalities Result of CT assessment is used for the Marshall CT classification, Rotterdam CT score, or Helsinki CT Score Result of CT assessment contributes to the score of the Abbreviated Injury Scale of the head

function of age. In other words, GCS is most accurate at predicting outcome when combined with age and pupillary response. The authors hypothesize that elderly patients may show a blunted and/or delayed clinical response to injury compared with younger patients (e.g., decreased inflammatory response and slower brain swelling due to atrophy). Nevertheless, the GCS remains the scale that is most widely used for both research and clinical purposes (see online appendix: table 2).

The amount of time consciousness is lost immediately following the TBI has been used as a measure for injury severity (length of coma [LOC]). The ratings are mostly split into <30 minutes (mild), and <24 hours (severe). A positive association between time of lost consciousness, the severity of the injury and outcome has been observed [16]. Some research, however, showed that LOC was not related to TBI severity [17].

Abbreviated Injury Scale of the head region

The Abbreviated Injury Scale of the head region (HAIS) is an anatomical injury severity scoring system that is based on clinical and radiographic findings (computed tomography; CT), and is a part of the Abbreviated Injury Scale (AIS). The AIS includes six body regions (head [i.e., HAIS], face, chest, abdomen, extremities [including pelvis], external) that are rated on a 6-point Likert scale from *minor* [1] to *maximum* [6]. The scores from the three most severely injured body regions are then squared and summed up to produce the Injury Severity Score (ISS). HAIS has high predictive validity for mortality up to 2 weeks [18] and permanent disability [19].

HAIS suffers less from low inter-rater reliability than the GCS because the score is based on measurable and objective anatomic lesions. However, inter-rater reliability of ISS including HAIS has been shown to be low (0.49 [range 0.16–0.82]) based on results of 10 different coders [20]. HAIS and ISS are often used in epidemiological or in trauma register studies. For the epidemiological, multicenter study in Switzerland on severe TBI, HAIS was used as inclusion measure [21].

The International Classification of Diseases

The International Classification of Diseases (ICD) has been translated into 43 languages and is used in 117 countries (including Switzerland). ICD-10 codes of TBI (compliance deadline October 10, 2015) are S06 (intracranial injury), whereas ICD-9 codes are from 800+. A recent review of ICD-9 TBI surveillance codes showed that 89% of the codes were sensitive to the presence of any severe TBI. However, one fifth of patients were assigned to an unspecific injury code (S06.2X9S; diffuse traumatic brain injury with loss of consciousness of unspecified duration, sequela), which means that specific details about the head injury had gotten lost.

The ICD coding is used at the end of acute hospital admission in Switzerland, is a part of the hospital data in many countries and can therefore be useful for retrospective studies or studies starting after inpatient stay.

Posttraumatic amnesia

Posttraumatic amnesia (PTA) subsumes both anterograde and retrograde amnesia. PTA refers to a state of confusion that can occur after a TBI. PTA is rated on a 6-point Likert scale: *very mild* (<5 mins), *mild* (5–60 mins), *moderate* (1–24 hours), *severe* (1–7 days), *very severe* (1–4 weeks), *extremely severe* (>4 weeks). PTA is often used in combination with the GCS and LOC (see online appendix: table 3).

Research shows that oftentimes PTA is assessed retrospectively by self- or other report, due to missing data (especially in moderate to severe TBI cases). PTA is rarely used in large investigations on TBI (see online appendix: tables 2 and 3). This may potentially be related to the absent or weak relationship between self-reported PTA and TBI severity.

Demography of severe traumatic brain injury in high-income countries

There is a debate about the origin of the changing incidence of severe TBI in high-income countries. It may be decreasing due to improved road safety [22] and other

safety-related interventions [23], or it may be increasing due to an aging population related to more falls [24]. Incidence rates of severe TBI based on population-based investigations have been explored in only a few high-income countries [21, 25–28]. These incidences vary from 4 to 17/100 000/year due to different inclusion criteria [29].

Demography in Switzerland

In our prospective, nation-wide, cohort study in Switzerland, we observed a low incidence of severe TBI of 10.6 per 100 000 adults per year (7.90/100 000/year in individuals ≤65 years, 22.40/100 000/year in individuals >65 years) using HAIS >3 as inclusion criteria. A high median age of 55 years (interquartile range 33–71) was associated with a high number of falls (52.6%) [21]. Furthermore, we observed a higher GCS on scene and in the emergency department (ED) in patients >65 years (12 on scene, 8 in the ED) compared with patients ≤65 years (8 on scene, 3 on ED) with a comparable severity of TBI (using HAIS classification). The mortality was in the expected range for severe TBI (30.2% at 14 days), but higher in patients >65 years compared with patients ≤65 years (40.9% vs 24.5%). High rates of return to consciousness were observed at 14 days with no differences between age groups. In earlier studies conducted in three different geographical regions in Switzerland, the estimated incidence was 8/100 000/year using the combined criteria HAIS >3 and GCS <9 [30].

Demography in selected high-income countries

A French population-based study in a rural region estimated the incidence of severe TBI at 17/100 000/year using HAIS >3 as the inclusion criterion [27]. The distribution of HAIS was similar to that in the Swiss cohort (HAIS 4: 41.1%, HAIS 5: 58.9%), including the amount of multiple trauma (32.2%); the overall death rate was almost identical (30.0%). Additionally, there was a similarity in the death rates by HAIS category (HAIS 4: 7.7% in Aquitaine, France, 10.4% in Switzerland; HAIS 5: 46.0% in Aquitaine, 40.9% in Switzerland). The data for the two studies were collected 10 years apart (1997 in France, 2007 in Switzerland). In the Swiss study a median age of 55 years was observed, which is much higher than in the French study. Since age is one of the most important risk factors for poor post-TBI outcome [31], the mortality rate was similar in both studies but the age distribution was different, one may hypothesize that care has improved over the past years in Europe, thus counterbalancing the effects of age on mortality.

A recent study in Norway observed an incidence of 4 to 5/100 000/year on the basis of ICD-10 codes and a GCS <9 [25]. If only patients with a GCS ≤8 on scene are taken into account, the incidences in the investigation of Walder et al. [21] are similar to those of Andelic et al. [32] (5 per 100 000 individuals per year in Switzerland, 4 to 5 per 100 000 individuals per year in Norway), although comparisons need to be made with caution because of the use of different diagnostic systems (ICD-10 [33–40] vs HAIS [35, 41] vs GCS [38, 39, 42–48]). The Norwegian and the Swiss cohorts showed further similarities: similar cause distribution, similar age distribution and similar death rate (29%), including an increased early mortality rate (within 48 hours following injury). Therefore, even in high-income countries, mortality may be linked to (a) the severity of the injury and (b) to the age of the injured person [10, 49].

In all the presented investigations, "true" incidence is difficult to assess given that the deaths on scene (potentially related to severe TBI) may not have been detected because these data are not available to medical staff (i.e., are property of the police). Thus, the available incidences are most likely underestimates [50]. A summary for the frequency of severe TBI across countries is provided in table 4 (in the online appendix).

Outcomes after traumatic brain injury in high-income countries

Main outcomes after severe TBI are mortality, functional outcome, health-related quality of life and cognitive, social, and psychiatric outcomes. Mortality and functional outcome are typically short-term outcomes (~<1 year) and health-related quality of life and neuropsychological assessments more often long-term outcomes (~>1 year). We will therefore first describe some outcome assessment instruments most commonly used (see online appendix: table 5), and further report their reliability and validity.

Mortality

The most significant mortality is observed in the acute period and after severe TBI is between 30 and 45% [21, 27, 51]. It has been suspected that mortality after severe TBI could decrease over the decades; however, in a meta-regression no such trend could be observed since 1990 [52]. Based on the international, multicenter study CRASH, a prediction model for mortality at 14 days was developed: http://www.trialscoordinatingcentre.lshtm.ac.uk/Risk%20calculator/index.html.

Brooks et al. [53–55] reported poorer survival rates at long term than that of the general population (standardized mortality ratio = 2.1; 95% confidence interval = 1.9–2.3). The investigators found age, sex and func-

tional disability to be significant risk factors for mortality (p <.001), and these specific mortality rates after TBI reportedly have not significantly declined over the past 20 years [56]. Based on these findings Brooks et al. published a survival prognosis calculator online (http://www.LifeExpectancy.org/tbims.shtml).

Functional disability

Functional outcome or disability is most commonly referred to problems with independence in social integration, self-care, employment, and family burden. Different scales have been developed such as the Glasgow Outcome Scale (GOS), the Disability Rating Scale (DRS [57]) and the Functional Independence measure (FIM [58]). In this review we will focus on the GOS for the estimation of functional outcome after severe TBI.

The Glasgow Outcome Scale (GOS) was rapidly integrated in clinical outcome research and clinical practice after its creation in 1975 [59]. The short and easily usable scale consists of five items: death (one point), vegetative state (two points), severe disability (three points), moderate disability (four points) and good recovery (five points). The inter-rater reliability and validity have been moderate; which led to the development of more sensitive instruments based on the GOS: the Glasgow Outcome Scale Extended (GOSE [8, 60, 61]). The GOSE is one of the most frequently used scales to assess functional outcome (see online appendix: table 5) and includes items for lower (three points) and upper severe disability (four points), lower (five points) and upper moderate disability (six points), and lower (seven points) and upper good recovery (eight points). Patients or relatives (if the patient is not able in the current state) fill in the questionnaire that assesses daily functioning postinjury and compares those questions with preinjury functioning.

Different calculators based on large data bases were developed to predict GOS and GOSE at 6 months: http://www.tbi-impact.org/?p=impact/calc or http://www.trialscoordinatingcentre.lshtm.ac.uk/Risk%20calculator/index.html. All these calculators were established for prediction of a population with TBI and not for individual patients. The cooperative interpretation of functional outcome assessments is difficult because of the different starting times in data collection. Some investigators, for example, start data collection at acute hospital admission (with a high mortality) and others after acute hospital admission (with a low mortality). Average GOSE will be higher in the latter example and is most often referred to as GOSE of survivors. The average GOSE of survivors in Switzerland (data collection start at acute hospital admission) was 5 (IQR 3–7) at 3 months and 6 (IQR 4–8) at 6 months [21]. Functional outcome improves at least up to 1 year, thus a functional outcome report at 6 months may be too early to estimate functional outcome. Sigurdardottir, Andelic [62], for example, investigated the functional disability (GOSE) of 115 patients 1 year postinjury and found a good recovery for 30% out of the 41 individuals with a severe TBI (mean GCS 5.5, standard deviation 1.8). Dikmen, Machamer [63] investigated functional disability 3–5 years after TBI and found that for individuals with severe TBI (AIS >3; 210 patients), 75 (36%) showed a good recovery, 18 (9%) showed moderate disability, and 6 (3%) severe disability.

Health-related quality of life

Health-related quality of life (HRQoL) is a part of the outcome research after medical interventions and it is important to assess it in all investigation of patients with a complex disorder such as TBI. A patient's subjective well-being is related to functional and neuropsychological outcome and, therefore, may be important in the estimation of the quality of TBI care. Even in major scientific investigations, however, HRQoL has rarely been assessed (see online appendix: table 5). In general, two main types of HRQoL can be distinguished: generic and disorder-specific HRQoL. Generic HRQoL [64] has the advantage of comparability with the general population. However, generic HRQoL measures such as SF-12 or SF-36 (most frequently used [64–66]) may not be sensitive enough to capture HRQoL specifically after certain complex disorders such TBI [67]. In recent years the QOLIBRI (Quality Of LIfe after BRain Injury) was introduced as a HRQoL assessment that has been validated with patients after TBI (http://www.qolibrinet.com/). The QOLIBRI is a 37-item self-report covering six dimensions of HRQoL after TBI [68] with reportedly overall good reliability and validity [69, 70]. The questionnaire provides a profile of quality of life together with a total score (http://www.qolibrinet.com/).

Hawthorne et al. found scores on the SF-36 to be between 13 and 24% worse among patients with TBI than their matched counterparts [71], and Andelic et al. [72] found 46% of patients to report poor physical health, and 37% poor mental health. Soberg and Røe [73] found no particular pattern of reduction on the QOLIBRI subscales 1 year after injury, though fatigue seemed to be reported across severities, which in turn was linked to change in cognitive capacity, sleep disturbance, and depression. In Germany, an improvement of HRQoL over the first year after TBI was observed using a Generic HRQoL instrument [74]. Neither a generic HRQoL instrument nor the QOLIBRI have been used to assess HRQoL after TBI in Switzerland.

Back to work and leisure activities

Ponsford and Downing [75] assessed 141 individuals 2, 5, and 10 years postinjury using the Structured Outcome Questionnaire (SOQ). The investigators observed that 70% were able to drive, 40% required more support than before the injury, approximately 50% returned to work and/or leisure activities [76], and 30% reported problems in personal relationships (marital status remained stable). Hoofien et al. [77] reported the 10–20 year (mean 14.1 years) postinjury outcome of 76 individuals with severe TBI (17% females). Results showed an employment rate of 60.5%, whereas 73% out of the employed participants worked in low-level professions (sheltered settings or volunteers [39%] or technology [37%]).

Neuropsychological outcome

Neuropsychological outcome estimation includes cognitive, psychiatric and social functioning. Clinical neuropsychological testing is an integrative part of clinical practice and an important part of the outcome research after brain disorders. Neuropsychological data is crucial to link functional to structural deficits, and should be assessed after a complex disorder such as TBI. However, neuropsychological assessments are difficult in individuals with severe TBI, and are therefore often missing in scientific contributions (see online appendix: table 5). Cognitive dysfunction (especially working memory and processing speed) contribute to the (in)ability to go back to work [32], which in turn explains some of the variance in satisfaction with life [78], and may contribute to self-esteem [79]. Patients with severe TBI suffer from extensive disability compared with healthy controls. A limitation of neuropsychological testing in research settings is the heterogeneity of specific tests in use (see online appendix: table 5). For instance, different language regions will use different instruments, which decreases comparability. Furthermore, with more and more geriatric patients, tests may have to be adapted to this newer phenomenon. Studies that perform extensive and time-intensive neuropsychological test batteries are often limited by their small cohorts. This reduces statistical power, increases bias and thus decreases generalizability. In studies involving patients with TBI, preinjury neuropsychological testing is often not available but may be an important confounding factor to be assessed. In the Swiss cohort, for example, 13% of the patients had had a psychiatric diagnosis before the injury and 25% had consumed alcohol [21].

Neurocognitive functioning

Ruttan et al. [80] performed a meta-analysis in which they investigated 1380 individuals (694 people with moderate to severe TBI and 686 healthy controls) from 16 studies. They stratified cognitive tests into timed and untimed tests. Among the untimed measures were tests that assess learning and memory (recall), executive function (Wisconsin Card Sort Test), and the full Wechsler Adult Intelligence Scale (WAIS). Among the timed measures were tests that assess verbal fluency, psychomotor function, attention including split attention, and executive function (e.g., Trails B). They found that individuals with moderate to severe TBI showed reliably lower functioning in both timed and untimed tests 18+ months postinjury, with larger effect sizes when comparing timed tests. Thus, cognitive impairment depends on severity of TBI. Thornhill et al. [81] collected data on 2995 individuals with TBI out of whom 549 were followed-up; patients with severe TBI (GCS 3–8, 45 individuals) reported significant cognitive impairment (decision making, memory, concentration) compared with individuals with both mild TBI and moderate TBI.

Most researchers detect an improvement in neuro- and social cognitive functioning across time. Sigurdardottir et al. [62] for example reported improvement up to 1 year postinjury (3–12 months) on three factors (found by principal component analysis) among the 41 individuals with a severe TBI (total number: 115): memory/speed, verbal/reasoning, and visual/perception. Persistent cognitive dysfunction predicted functional outcome even when injury severity, demographics, and trauma variables were controlled for. Wood et al. [82] administered 15 neuropsychological tests (to test attention, language, memory, visuoperception and construction, psychomotor speed, and problem solving) to 141–182 individuals with TBI (analyses not stratified by severity) at 1 year and at 5 years postinjury. They observed that individuals with moderate and severe TBI exhibited statistically significant improvement on 6 of 15 neuropsychological tests: i.e., on Digits Forward (working memory, attention), Logical Memory I and II (verbal memory), Controlled Oral Word Association Test (verbal fluency), Symbol Digit, Block Design (visuoconstruction) of the Wechsler Adult Intelligence Scale (WAIS), Wisconsin Card Sorting Test (problem solving), and Trails B (split attention). However, statistical significance does not necessarily imply clinical relevance and the analysis concept of minimal clinically important difference may be more relevant [83]. Recovery in new learning and memory was not consistent across tests; some patients declined (i.e., 15 patients declined, 22 improved, and 62 exhibited no change).

Cognitive functioning is impaired after TBI [84–102], the degree of impairment is associated with the severity of TBI and cognitive functioning improves at least in the first year after TBI. A Swiss single center study showed that after rehabilitation three quarters of the patients had at least one neuropsychological deficit, even patients with favorable functional outcome measured with GOS [103].

Social cognitive and psychiatric functioning

Studies report different incidence and prevalence rates between studies (e.g., incidence of depression = 15.3% to 33%, prevalence for depression from 18.5% to 77%; [104]). Psychiatric disorders can emerge in the acute stages [105, 106], and findings concerning development of the disorder thereafter have been mixed [107–117].

Gould et al. [118] used the Structured Clinical Interview for DSM-IV Disorders to assess 44 (out of a total of 102) individuals with severe TBI at 3, 6, and 12 months postinjury. The 12-months postinjury rate was significantly different (p-values <0.001) among the TBI sample as compared with the general population for the following disorders: (a) any disorder (37%), (b) mood disorder (31%), (c) major depressive disorder (29%), (d) posttraumatic stress disorder (13%). Results revealed a significant association between pre- and postinjury psychiatric disorder in that out of 54 individuals with preinjury psychiatric history, 74% showed postinjury psychiatric disorders. Results further showed that out of the 48 individuals with no preinjury psychiatric history, 46% developed a psychiatric disorder in the first year postinjury.

Lecrubier used the Mini International Neuropsychiatric Interview (MINI; [119]); a brief structured diagnostic interview based on DSM-IV and ICD-10 criteria; and the Clinician-Administered PTSD Scale–IV (CAPS; [120]) to assess a total of 1084 patients with TBI during hospital admission and followed them up at 3 months (n = 932, 86%) and 12 months (n = 817, 75%). The investigators found 31% of individuals to be diagnosed with a disorder. Thornhill et al. [81] collected data on 2995 individuals with TBI out of whom 549 were followed-up. Individuals with severe TBI (GCS 3–8, n = 45) reported significant mood dysfunction (i.e., anxiety, pressure, depression, irritability, temper) compared with individuals with both mild TBI (GCS 13–15, n = 333) and moderate TBI (GCS 9–13, n = 81).

Psychiatric problems are often present after TBI, and may interrupt the sleep-wake cycle, as very recently observed in Switzerland [121]. Additionally, social functioning remains decreased, and patients as well as relatives report personality and self-identity changes [122–129] (see online appendix: table 5).

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Agenda of further investigations

National professional societies together with national authorities should invest into the possibility to create a standardized, minimal data set, which is openly accessible to clinicians and researchers, and to which all contribute their data. The dataset should include potential predictors for severe TBI, preinjury variables, patient characteristics including risk factors, and relevant outcomes after severe TBI up to 1 year after TBI. It is highly probable that improvement in care of patients with severe TBI will be associated with process-oriented interventions based on such a data base. It is crucial to integrate data from prehospital care to the end of rehabilitation. The high costs related to about 900 patients with severe TBI per year in Switzerland justify a national surveillance program identifying and implementing multidisciplinary quality improvement initiatives to further improve good clinical practice.

Based on the patient-centered outcome research identifying a high prevalence of depressed mood and cognitive impairment after TBI, adequately powered randomized controlled trials with psychological interventions in long-term rehabilitation are required.

Prevention programs including fall prophylaxis in the growing population of the elderly are clearly indicated if the incidence of severe TBI is to be decreased in Switzerland. Specific pathways after TBI for elderly patients with comorbidities may be indicated.

Conclusions

Definitions of severe TBI are heterogeneous and assessment instruments are different across studies. In clinical practice GCS and a HAIS should be assessed at different time points for each patient. The incidence of severe TBI in high-income countries depends on the chosen inclusion criteria and may vary therefore. Relevant outcome measures include mortality, functional outcome, HRQoL and neuro-psychological outcome. HRQoL and neuropsychological outcomes are rarely investigated in high-impact research. Neuropsychological assessments often differ across languages. A standardized minimal dataset of patients after TBI would rapidly allow interdisciplinary quality improvement initiatives and potentially decrease costs.

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The full list of references is included in the online version of the article on www.sanp.ch.

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