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Original Articles

Feasibility of the Neurological Outcome Scale for Traumatic Brain Injury (NOS-TBI) in Adults

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Abstract

This article describes the design and initial implementation of the Neurological Outcome Scale for Traumatic Brain Injury (NOS-TBI) as an adaptation of the National Institutes of Health Stroke Scale (NIHSS), specifically for clinical and research use in patients with TBI, including (1) the addition of items specific to TBI, (2) adjustment to the scoring algorithm to allow quantification of deficits in patients who are comatose/vegetative or agitated, and (3) the reassignment of items (i.e., limb ataxia) that are problematic in TBI as supplemental items. The feasibility of using the NOS-TBI is discussed and limitations of the scale are highlighted. This scale offers (1) a cost-effective, brief, practicable, standardized, and quantifiable method of communicating and analyzing neurological deficits in a way that traditional neurological assessment alone cannot currently provide, and (2) a measure that non-physicians can administer. The NOS-TBI may serve a role in clinical practice in patients with TBI similar to the way the NIHSS has functioned for patients following stroke, by serving as a tool for initial stratification of injury severity, and as an outcome measure in clinical trials.

Key words: neurological functioning; Neurological Outcome Scale for Traumatic Brain Injury; outcome; traumatic brain injury

Introduction

Neurological deficits are a common consequence of head trauma producing traumatic brain injury (TBI) (Annoni et al., 1992; Dimopoulou et al., 2004; Jennett et al., 1981), with hemiparesis, aphasia, and cranial nerve dysfunction contributing substantially to overall outcome of severe TBI. In fact, Jennett and Bond (Jennett and Bond, 1975), the creators of the most commonly used measure of outcome in TBI, the Glasgow Outcome Scale (GOS), indicated that neurological status via a neurophysical assessment should be considered in grading the GOS, since neurophysical deficits contributed significantly to disability in about a third of patients sustaining severe TBI. However, despite this recommendation, they did not present sufficient detail regarding administration, scoring procedures, and psychometric properties (i.e., validity and reliability) of their neurophysical scale to enable replication (Jennett et al., 1981). In the following years, this recommendation to take into account hemiparesis, ataxia, and other neurological disturbances has largely been overlooked by clinical researchers, and to date a well-standardized measure of neurological functioning in the TBI population still does not exist. Measures frequently utilized in TBI outcomes research and clinical trials, such as the Disability Rating Scale (DRS) and the Functional Independence Measure (FIM™), do measure aspects of physical functioning, yet neither of these measures highlights neurological functioning per se. Furthermore, with the exception of the DRS, few existing outcome measures developed for use in TBI populations can be meaningfully used throughout the entire spectrum of recovery. The lack of assessment of neurological functioning in this population, as well as the lack of outcome measures that can be applied to patients with acute severe injuries,

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represents a notable gap in TBI outcome research. This lack of sensitive outcome measures may be an impediment to progress in clinical trials for acute TBI interventions.

To address these needs, we identified a neurological assessment scale that has been successfully validated and used in another patient population for clinical trials: the National Institutes of Health Stroke Scale (NIHSS) (Brott et al., 1989; Goldstein, 1994, 1989; Heinemann et al., 1997; Josephson et al., 2006; Pallicino et al., 1992; Wityk et al., 1994). Using the original NIHSS as a model, we adapted the scale to more appropriately assess common neurological sequelae of TBI and validated the resultant measure, the Neurological Outcome Scale for Traumatic Brain Injury (NOS-TBI), in a sample of subjects with the full spectrum of TBI severity. Our adapted measure is a 15-item scale (some having sub-items, for a total of 23 items) that incorporates basic elements of a clinical neurological examination including, orientation, cranial nerve functioning, strength, sensation, language, and coordination. We attempted to preserve essential characteristics of the NIHSS, including its brevity (administration time of approximately 15 min), ease of administration by both physicians and non-physicians, and applicability to a wide range of recovery stages and levels of injury severity (i.e., mild to severe). However, consideration was given to adjustment of items that may require inclusion or exclusion due to injury differences in TBI as opposed to stroke. These changes also were made based on the known or suspected frequency of central nervous system and cranial nerve injuries associated with TBI, as well as neurological deficits likely to produce greater functional impairment for patients. Inclusion of additional items was limited to measurement of neurological phenomena that could be reasonably tested and scored by non-physician examiners without extensive training in neurology.

Content validity

In order to modify the NIHSS to be appropriate for use with patients with TBI, it was necessary to determine the most salient neurological indicators currently used in clinical practice with this population, thereby assessing the scale's content validity. To review, content validity is the systematic evaluation of test content to determine whether it covers a representative sample of the behavioral domain to be measured (Anastasi and Urbina, 1997). The content validity of the NOS-TBI was established by a panel of recognized experts from a wide range of relevant backgrounds (drawn from two Level 1 trauma centers in a large metropolitan area) who regularly treat patients with TBI at varying points in recovery, including two neurologists, a neurointensivist, a physiatrist specializing in TBI rehabilitation, two neurosurgeons, and four neuropsychologists specializing in TBI. This panel was canvassed and recommendations were implemented regarding changes to the original NIHSS to be more appropriate for patients with TBI. The set of items comprising the NOS-TBI was agreed upon by consensus of the expert panel to best sample the range of neurological indicators found most useful in clinically managing patients with the full spectrum of TBI severity and chronicity. A supplemental set of items (see the Appendix) was also proposed to determine if these items could be successfully administered to a majority of patients with TBI (including those in the acute recovery phase), and if abnormal scores would be found with sufficient frequency (over a wide range of recovery points post-TBI) to warrant inclusion in the final form of the NOS-TBI.

Alterations to the NIHSS

In adapting the NIHSS to better meet the needs of research in TBI, we made the following changes in the NOS-TBI.

Adjustment of test items specific to TBI. We retained items from the NIHSS that detect TBI-related deficits to a significant degree (e.g., neglect, aphasia, and dysarthria). We have included four additional items in our scale that reflect the higher frequency of injury to specific cranial nerves or patterns of intracranial injury in TBI as opposed to stroke (as described below). The incidence of injury to the trigeminal (cranial nerve [CN] V), glossopharyngeal (CN IX), and vagus (CN X) nerves are reportedly less than 2% (Keane, 1982; Keane and Baloh, 1992); accordingly, items assessing these particular cranial nerves were not added to the NOS-TBI.

Olfaction. Early estimates of olfactory nerve (CN I) injury were reported to occur in 7% of all patients with TBI (Jennett et al., 1981; Keane and Baloh, 1992; Rovit and Murali, 2000; Summer, 1962), though this has been considered an underestimate, given the inability to examine olfaction in unresponsive patients, and inconsistent seeking of medical attention after mild TBI. The incidence of injury to CN I is notably higher following moderate (19.4%) and severe (24.5%) head injury (Costanzo and Becker, 1986). In a recent study, Callahan and Hinkebein demonstrated impaired olfaction in 56% of patients with TBI, with 40% of these patients being unaware of their deficits (Callahan and Hinkebein, 2002). Therefore we added an item for olfaction testing. We selected a set of four distinct and easily identifiable odors (i.e., lemon/orange, cinnamon, vanilla, and licorice) that do not stimulate CN V through nociception (e.g., peppermint, camphor, and ammonia). We acknowledge that testing of olfaction is difficult or impossible in some patients (e.g., comatose patients, patients with endotracheal tubes, and patients with aphasia), but scoring of this item on the NOS-TBI was designed to accommodate these scenarios.

Pupillary response. Optic nerve (CN II) injury is estimated to occur in 5% of patients with TBI, (Rovit and Murali, 2000), and oculomotor nerve (CN III) injury may occur in as many as 17% of patients (Sabates et al., 1991), particularly those with subarachnoid hemorrhage or skull fracture (Tokuno et al., 1995). Though included in the early version of the NIHSS, this item was later deleted from abbreviated versions of the scale due to concerns about its validity (Brott et al., 1989). We have reinstated this item in the NOS-TBI since pupillary response has been associated with later recovery from TBI (Lannoo et al., 2000; Levin et al., 1992).

Hearing. The incidence of sensorineural hearing loss associated with nerve injury (CN VIII) has been reported to be as high as 85% in TBI (Podoshin and Fradis, 1975), necessitating the addition of an item to assess auditory functioning in this population. Administration of this item is done via light finger rub near each ear. Double simultaneous stimulation testing is also performed as part of this item, and the presence of extinction factors is in the "Neglect" test item. Although

auditory testing is also difficult to administer to certain patients, detailed instructions for scoring of this item have also been provided to accommodate these situations.

Lateralization. In addition to adding TBI-related items, we have altered scoring of certain items to reflect lateralization of the deficit (right or left side), such as visual field defects, facial movement, motor response, sensation, hearing, and limb ataxia. Addressing a criticism of the NIHSS, scoring of items on the NOS-TBI was altered to include upper/lower limbs and lateralization (e.g., sensory and motor items in all four quadrants) for greater sensitivity.

Supplemental test items. Two supplementary items have been added to the NOS-TBI. The NOS-TBI limb ataxia item was placed in this category due to the large percentage of patients with TBI who demonstrate greater frequency of orthopedic and multi-organ injuries resulting in pain, restricted mobility, non-weight-bearing status, and treatment orthotics (e.g., fixation and casting), that preclude the testing of either the finger-nose-finger or heel-knee-shin tests. We added an additional novel item to this section, which assesses gait ataxia via tandem gait testing (10 steps). These items are administered only to participants who are able to safely perform them, and scores for these items do not factor into the NOS-TBI total score.

Scoring of the NOS-TBI

The total score for the NOS-TBI is the sum of the scores for items 1–13 (based on 3-, 4-, and 5-level ratings, where 0 represents no impairment or deficit), except those scored as "UN." If an item is scored as untestable, it is not included in the total score. Items 14 and 15 are considered supplemental and do not factor into the total score; thus low scores reflect less severe neurological impairment. Please see the detailed appendix in the online supplementary materials for further instructions for administration and scoring, including complicated patient situations (Supplementary Table 1; see online supplementary material at http://www.liebertonline.com).

Experience using the NOS-TBI in outcomes research and clinical trials

Aside from a validation sample, which is described in Wilde and associates (Wilde et al., 2010) and McCauley and colleagues (McCauley et al., 2010), the NOS-TBI was first utilized in the National Acute Brain Injury Study: Hypothermia IIR, a multi-site clinical trial of moderate hypothermia in severe TBI. During the course of the trial, the scale was administered to participants at 3, 6, and 12 months post-injury. In a subset of participants, the scale was also successfully administered in the acute time frame (at acute hospital discharge, generally 4 weeks post-injury). Outcome investigators (primarily neuropsychologists) and their staff (e.g., nurses and neuropsychological technicians) at 11 sites were trained to administer the scale. Training included the use of the NIHSS certification training videos, as well as in-person training by the Outcome Monitor (EAW), and occasional consult by attending physicians at the site, including neurosurgeons or neurologists. Each examiner was provided with a testing kit that included standard items including incandescent penlights for pupillary testing, laminated stimulus cards from the Boston Diagnostic Aphasia Examination for the "Cookie Theft" picture and object naming, laminated stimulus cards of the words and sentences for aphasia and dysarthria testing, disposable safety pins for sensory testing, and essential oils for olfactory testing. The most common difficulties in administration of the scale are detailed below.

Difficulty administering the measure to severely-injured patients. In natural outcome studies, clinical trials, and the validation studies for the measure, it was more difficult for raters to complete administration of all items to severely-injured patients in the subacute phase of recovery. This may be particularly true for raters who are relatively inexperienced in dealing with acutely injured, non-responsive patients. However, similarly to the NIHSS, we included a scoring system that clearly details administration and scoring procedures in patients who are comatose, aphasic, or have an injury or physical barrier that prohibits assessment (Supplementary Table 1; see online supplementary material at http://www.liebertonline.com).

Difficulty administering the measure to agitated patients. In the validation studies it was difficult to administer items from the NOS-TBI or the neurological examination to participants who were agitated or uncooperative. However, we included a scoring system that clearly details administration and scoring procedures in these patients.

Recommended uses of the NOS-TBI

Use of the NOS-TBI in clinical research. The NOS-TBI could be used as (1) an initial stratification tool for injury severity, and (2) as an outcome measure in randomized clinical trials for novel interventions and rehabilitation treatments. The NOS-TBI is not intended to necessarily replace all other outcome measures, but rather to complement by them adding an additional critical element that, when used in conjunction with other well-established measures of cognitive and functional outcome and imaging, may increase sensitivity in detecting treatment effects and track neurological sequelae in greater detail.

Use of the NOS-TBI in clinical practice. In addition to its important role as an outcome measure in clinical trials, the NOS-TBI may serve a similar role in clinical practice to the way the NIHSS has functioned for patients following stroke. For example, the NIHSS has been used as a tool in the initial assessment of patients with stroke in emergency or prehospital settings, and is predictive of subsequent resource use and long-term outcome (Appelros and Terent, 2004; Kasner, 2006; Rundek et al., 2000; Schlegel et al., 2003). Although many hospitals continue to utilize the less-sensitive Glasgow Coma Scale score and pupillary examination for serial monitoring of patients with stroke who are at risk for neurological worsening, some institutions train nurses to use the NIHSS to monitor at-risk stroke patients to assess the need for further diagnostic studies or treatment (Kasner, 2006). The NIHSS has been used in stroke populations as a predictive tool in planning a patient's rehabilitation or long-term care needs, even as early as the date of admission (Schlegel et al., 2003). The NIHSS has also been extensively used to select and characterize stroke patients for clinical trials (Dromerick et al., 2000),

and provides a common metric for quantifying and communicating stroke severity. We anticipate that the NOS-TBI could be similarly used to assess and monitor patients with TBI in clinical as well as research settings. Family members of severely or moderately affected TBI patients, and mildly affected patients themselves, are generally acutely aware of the progress being made during the recovery process. However, they often struggle with the prediction of future recovery. Some of the most frequent questions encountered by physicians caring for TBI patients are centered on outcome prediction. Although a number of different measures can be used to predict outcome and to provide this information to the patients and their families, these measures are either insensitive or rarely used. The NOS-TBI could be implemented to quantify the progress made by patients from the admission to the emergency department to various stages of their acute hospitalization and the recovery process. The use of a unified scale would clearly facilitate the longitudinal assessment of functional status and outcome prediction.

Conclusions

In conclusion, in this article we described the design and initial implementation of the NOS-TBI as an adaption of the NIHSS, specifically for clinical and research use in patients with TBI, including the addition of items specific to TBI, adjustment of the scoring algorithm (lateralization), and the reassignment of items (i.e., limb ataxia) that are problematic in TBI, as supplemental items. This experience, although limited, demonstrates the feasibility of the NOS-TBI and highlights some of the limitations of using this scale. While formal serial neurological testing performed by a neurologist would certainly provide the most accurate assessment of neurological deficits, this scale offers a cost-effective, brief, practicable, standardized, and quantifiable method of communicating and analyzing neurological deficits in a way that traditional neurological assessment alone cannot currently provide. An additional important advantage of the NOS-TBI is the fact that non-physicians can administer it, as demonstrated by our own initial experience with it and the analogous experience with the NIHSS. The NOS-TBI is envisioned to serve as a tool for initial stratification of injury severity, and as an outcome measure in randomized clinical trials. The NOS-TBI may serve a role in clinical practice in patients with TBI similarly to the way the NIHSS has functioned for patients following stroke.

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Appendix. NOS-TBI Summary Sheet

Subject number_____ Date____/____/____

1a. Level of consciousness (LOC) (observation through examination and testing of level of arousal)

0 Alert
1 Not alert, but arousable with minimal stimulation
2 Not alert, requires repeated stimulation to attend
3 Coma—responds only with reflex motor or autonomic effects, or totally unresponsive

1b. LOC questions (current month and age)

0 Answers both correctly
1 Answers one correctly
2 Both incorrect

1c. LOC commands (open and close eyes, make a fist)

0 Obeys both correctly
1 Obeys one correctly
2 Both incorrect

2. Gaze (only horizontal eye movements; check for abnormal spontaneous movements and ability to look right and left to command)

0 Normal
1 Partial gaze palsy (unable to move one or both eyes completely to at least one direction)
2 Forced deviation or total gaze paresis (conjugate deviation of eyes to right or left)

3a. Visual fields: R side (count fingers in all four quadrants of the visual field of each eye separately)

0 No visual loss
1 Partial hemianopia (partial field defect in both eyes; quadrantic or sector defect)
2 Complete hemianopia (dense visual field defect in both eyes; homonymous hemianopia)

3b. Visual fields: L side (count fingers in all four quadrants of the visual field of each eye separately)

0 No visual loss
1 Partial hemianopia (partial field defect in both eyes; quadrantic or sector defect)
2 Complete hemianopia (dense visual field defect in both eyes; homonymous hemianopia)

4. Pupillary response: (observe pupil shape; test direct pupillary reactivity with penlight; test accommodation)

0 No deficits (pupils are round, equally reactive, responsive to light and accommodation)
1 Abnormal but incomplete response (one eye compared to the other); abnormal pupil shape
2 Abnormal and complete absence of pupillary response in at least one pupil.

5a. Hearing: R side (finger rub)
0 No deficits
1 Mild deficits (inconsistent detection of the stimulus or need to increase volume)
2 Severe or complete hearing deficit in right ear (cannot detect the stimulus at all)

5b. Hearing: L side (finger rub)
0 No deficits
1 Mild deficits (inconsistent detection of the stimulus or need to increase volume)
2 Severe or complete hearing deficit in left ear (cannot detect the stimulus at all)

6a. Facial paresis: R side (look for symmetry at rest and during spontaneous facial movements observe activation during commands such as smile, show teeth, puff out cheeks, pucker, close eyes forcefully, raise eyebrows)
0 Normal facial movements; no abnormal asymmetry
1 Minor paresis (asymmetry at rest or during spontaneous facial movements)
2 Partial paresis (unilateral, "central" facial paresis: decreased spontaneous and forced movements with changes most prominent at the mouth; orbital and forehead are normal)
3 Complete palsy (involves forehead, orbital, and circumoral muscles)

6b. Facial paresis: L side (look for symmetry at rest and during spontaneous facial movements; observe activation during commands such as smile, show teeth, puff out cheeks, pucker, close eyes forcefully, raise eyebrows)
0 Normal facial movements; no abnormal asymmetry
1 Minor paresis (asymmetry at rest or during spontaneous facial movements)
2 Partial paresis (unilateral, "central" facial paresis; decreased spontaneous and forced movements with changes most prominent at the mouth; orbital and forehead are normal
3 Complete palsy (involves forehead, orbital, and circumoral muscles)

7a. Motor function: R arm (patient extends arm at 90-degree angle for 10 sec)
0 No drift
1 Drift (able to hold for 10 sec, but there is drift; limb falls to intermediate position)
2 Some effort against gravity (unable to hold for 10 sec, but some effort against gravity)
3 No effort against gravity (unable to raise to angle, but some effort against gravity; patient is unable to sustain the position if the examiner raises the limb to the correct angle)
4 No movement (unable to move the limb, no movement against gravity)
UN Untestable (use if limb is missing or amputated or shoulder joint is fused)
Reason:_____

7b. Motor function: L arm (patient extends arm at 90-degree angle for 10 sec)
0 No drift
1 Drift (able to hold for 10 sec, but there is drift; limb falls to intermediate position)
2 Some effort against gravity (unable to hold for 10 sec, but some effort against gravity)
3 No effort against gravity (unable to raise to angle, but some effort against gravity; patient is unable to sustain the position if the examiner raises the limb to the correct angle)
4 No movement (unable to move the limb, no movement against gravity)
UN Untestable (use if limb is missing or amputated or shoulder joint is fused)
Reason:_____

8a. Motor function: R leg (patient extends leg at 30- to 45-degree angle for 5 sec)
0 No drift
1 Drift (able to hold for 5 sec, but there is drift or unsteadiness)
2 Some effort against gravity (unable to hold for 5 sec, but some effort against gravity)
3 No effort against gravity (unable to raise to angle, but some effort against gravity; patient is unable to sustain the position if the examiner raises the limb to the correct angle)
4 No movement (unable to move the limb, no movement against gravity)
UN Untestable (use if limb is missing or amputated or hip joint is fused)
Reason:_____

8b. Motor function: L leg (patient extends leg at 30- to 45-degree angle for 5 sec)
0 No drift
1 Drift (able to hold for 5 sec, but there is drift or unsteadiness)
2 Some effort against gravity (unable to hold for 5 sec, but some effort against gravity)
3 No effort against gravity (unable to raise to angle, but some effort against gravity; patient is unable to sustain the position if the examiner raises the limb to the correct angle)
4 No movement (unable to move the limb, no movement against gravity)
UN Untestable (use if limb is missing or amputated or hip joint is fused)
Reason:_____

9a. Sensory: Right upper extremity (examine with sharp and dull ends of a pin on the proximal ends of all four limbs)
0 Normal (no sensory loss)
1 Partial loss (mild to moderate diminution in perception)
2 Dense loss (severe sensory loss so that the patient is unaware of being touched)

9b. Sensory: Left upper extremity (examine with sharp and dull ends of a pin on proximal ends of all four limbs)
0 Normal (no sensory loss)
1 Partial loss (mild to moderate diminution in perception)
2 Dense loss (severe sensory loss so that the patient is unaware of being touched)

9c. Sensory: Right lower extremity (examine with sharp and dull ends of a pin on proximal ends of all four limbs)
0 Normal (no sensory loss)
1 Partial loss (mild to moderate diminution in perception)
2 Dense loss (severe sensory loss so that the patient is unaware of being touched)

9d. Sensory: Left lower extremity (examine with sharp and dull ends of a pin on proximal ends of all four limbs)
0 Normal (no sensory loss)
1 Partial loss (mild to moderate diminution in perception)
2 Dense loss (severe sensory loss so that patient is unaware of being touched)

10. Best language (naming objects and reading sentences from stimulus card, comprehension of language through entire exam)
0 No aphasia (reading sentences, naming and comprehension are intact)
1 Mild to moderate aphasia (mild to moderate naming errors, word-finding errors, paraphasia, mild impairment in comprehension or expression)
2 Severe aphasia (difficulty in reading as well as naming objects; Broca's or Wernicke's aphasia)
3 Mute

11. Dysarthria (pronounce standard list of words from stimulus card; observation through examination)
0 Normal articulation (clear and without articulation difficulty)
1 Mild to moderate dysarthria (slurring; can be understood but with some difficulty)
2 Near unintelligible or worse (patient's speech so slurred that it is unintelligible)
UN Untestable (use only if patient has endotracheal tube or Best Language = 3)

12. Neglect (visual, auditory, and sensory extinction or inattention: "Cookie theft" card is used for visual; finger rub for auditory; bilateral simultaneous stimulation to the hands)
0 No neglect (no evidence of inattention or neglect on any modality: able to recognize bilateral simultaneous cutaneous stimulation on the right and left, no evidence of visual neglect on the stimulus card, and no evidence of auditory extinction or inattention)
1 Partial neglect (evidence of inattention or neglect in one of three modalities)
2 Complete neglect (profound hemi-inattention or hemi-inattention to more than one modality; the patient does not recognize his or her own hand or orients only to one side of space)

13. Smell (identify four different odors)
0 No observed or reported change in sense of smell
1 Decreased sense of smell by observation or report (at least one error in identifying stimuli)
2 Absent sense of smell by observation
UN Untestable
Reason:_____

14. Gait ataxia (tandem gait)—SUPPLEMENTAL
0 Normal tandem gait
1 Occasional lateral missteps (two or less within 10 consecutive steps)
2 Frequent lateral missteps (more than two within 10 consecutive steps)
UN Untestable (patient is unable to ambulate safely)
Reason:_____

15. Limb ataxia (examined by finger-to-nose and heel-to shin tests) —SUPPLEMENTAL
0 No ataxia (movements are accurate, smooth, and precise)
1 Ataxia present in either arm or leg (one of the two tests is performed well)
2 Ataxia present in both arm and leg or bilaterally (Movements are inaccurate, clumsy, or poorly done on both tasks)
UN Untestable (use if complete paralysis of the limb or limb is missing, or if this item would create significant pain or possible injury)
Reason:_____

NOS-TBI score (without Supplemental Items) _____ (sum of the scores for items 1–13 except those scored as "UN"; if an item is scored as "UN," do not include in the total)
Score for Supplemental Items_____ (sum of items 14–15 except those scored as "UN")