RESEARCH ARTICLE

Severe Traumatic Brain Injury outcome assessed by a novel scale: a pilot study.

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Abstract

Background: Valid and reliable assessment of long term outcome in traumatic brain injury (TBI) survivors is a prerequisite for the evaluation of functional disability and appropriateness of healthcare provision and rehabilitation support.
Aim: The aim of the present study was to design a new, time-sparring and relatively simple outcome measurement scale for the evaluation of severe TBI, on aspects of functionality, mobility, psychocognitive status as well as overall quality of life.
Method and Material: The present is a retrospective study that was carried out from February to June 2010. The cohort consisted of 96 patients that were hospitalized due to severe TBI at the University Neurosurgery Clinic of β€Evaggelismos Hospitalβ€, from February 1999 until June 2009. The proposed β€Athens Disability Scaleβ€ (ADS) - which combines selected elements of commonly used outcome scales β€“ allows, as a pilot research, the quick (5-7 minutes) assessment of TBI outcome on motor, psycho-cognitive and social aspects by evaluating ten elements. The scale was applied on the cohort by telephone interview. The statistical analysis of the data was accomplished with the SPSS 16.0 for Windows.
Results: The study highlighted statistically significant associations between the total ADS score and the following parameters: GCS score, physiotherapy duration, physiotherapy treatment, presence of post-traumatic epileptic seizures and use of antiepileptic medication. No statistically significant relations between the total ADS score and gender, age, injury mechanism or the elapsed time between admission and interviews, were identified. Multivariate linear regression method showed that increased GCS score, decreased physiotherapy duration and absence of post-traumatic epileptic seizures were independently associated with increased total ADS score. A statistically significant association was found between the ability to work and verbal expression, verbal comprehension, mobility, physiotherapy as well as presence of epileptic seizures.
Conclusion: The present findings indicate that

ADS, as a pilot, represents a useful outcome measurement tool that allows for the rapid assessment of functional disability and quality of life in TBI survivors, in which nurses should also take part.

Keywords: Traumatic brain injury, outcome, rehabilitation, outcome measurement scales

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Introduction

Traumatic brain injury (TBI) represents a leading cause of mortality and disability and thus a highly significant public health issue. The incidence of TBI in the U.S.A. is an estimated 175-200/100.000 injuries / year,[1] while even higher incidence rate estimates have been previously obtained for several European countries such as France (281 / 100 000 injuries/ year)[2] and Sweden (546/100.000 injuries / year).[3] Recent data derived from the Greek National Statistics Agency, indicate that TBI-associated road traffic accident mortality is as high as 146/1.000.000/year and thus significantly higher than the corresponding rates of 57/1.000.000/year for the U.K or 53/1.000.000/year for Sweden. Nevertheless, given the paucity of available epidemiological data on TBI in Greece, its overall economic and social impact remains unknown.[4-6]

Valid and reliable assessment of long term outcome in TBI survivors is a prerequisite for the evaluation of functional disability and appropriateness of healthcare and rehabilitation provision.[7] In this context, several scales have been previously used to evaluate outcome of TBI patients.[8]

The present study **aimed** in designing a simple outcome measurement scale for the evaluation of TBI on aspects of functionality, mobility, psychocognitive status as well as overall quality of life, in a time-sparing manner. The proposed scale incorporates selected elements of commonly used outcome scales[8] and was tested on a cohort of 96 severe TBI patients, previously hospitalized in our department.

Methodology:

Scale design

The proposed outcome scale questionnaire, named «Athens Disability Scale» (ADS; Appendix 1) was generated by selecting and combining items incorporated in the following internationally recognized outcome scales: the Glasgow Outcome Scale (GOS), the Functional Independence Measure + Functional Assessment Measure (system FIM + FAM), the Disability Rating Scale (DRS) and The Barthel Index (Barthel scale).[9-11] Feeding, personal hygiene, dressing, sphincter control, mobility, car transfer (not necessarily as the driver), verbal comprehension, verbal expression, emotional status and ability to work or study, are the 10 items that are examined with the new scale. Each of the 10 items incorporates 3 subcategories indicating total dependency (score =1), moderate dependency (score=2) or independency (score=3) with overall scale score ranging between 10-30 points. An ADS overall score of 26-30 indicates that the patient is independent, 15-25 indicates moderate dependency and 10-14 indicates total dependency.

Application of ADS on Traumatic Brain Injury (TBI) patients-Inclusion criteria

A search on the departmental electronic database incorporating records of all previously hospitalized patients between February 1999 to June 2009, identified a total of 231 adult individuals that had suffered severe TBI (GCS ≤ 8 / 15), were aged ≤ 65 years and had left the hospital alive to either rehabilitation clinics or their homes. ADS was applied by means of telephone interviews involving patients (whenever possible), family members or

caregivers that were in contact with the patients on a daily basis. Of the original 231 identified cases, 96 patients/family members/caregivers were contactable; 123 persons (53.2%) were not contactable due to no longer valid telephone numbers, whereas 12 of the contacted families indicated patient death. Prior to the application of ADS, descriptive data on demographic characteristics, mechanisms of injury, physiotherapy treatment, current accommodation standards, presence and treatment of seizures and continuous medical follow-up were gathered from our electronic database and/or during interviews (Appendix 2). Interviews were timed and were conducted by three authors-examiners.

Statistical analysis

Continuous variables are presented as mean (± standard deviation; SD) and median (interquartile range), while categorical variables are presented as absolute and relative frequencies. Kolmogorov-Smirnov test and histograms were used to evaluate normality for continuous variables. Continuous variables followed normal distribution and therefore parametric methods were used.

To investigate the relationship between categorical variables chi-square test was used, while the relationship between continuous and categorical variables was estimated with Student's t-test. Pearson's correlation coefficient was used to explore the relationship between continuous variables. A correlation matrix was assessed prior to conducting the multivariate linear regression analysis to check for collinearity among the independent variables. Pearson's correlation coefficient was used to estimate correlations between variables. Variables with a value of $p < 0.25$ in the bivariate analysis were included in a multivariate linear regression model with backward stepwise selection method and adjusted beta coefficients with corresponding 95% confidence intervals were estimated.

One way analysis of variance (ANOVA) was used to compare mean values of interview completion times between examiners.

The reliability of the questionnaire was tested following previously described methods (test-retest reliability).[12] A correlation analysis (Pearson's r) was performed to evaluate the reliability of each question. On the results of the correlation analysis of the pilot study, the correlation rate was very high for all the questions included in the final version of the questionnaire (Pearson's r = 0.85–1.00). Cronbach's alpha coefficient was 0.9 which indicates a high internal reliability of the questionnaire. A two-sided $p < 0.05$ was considered statistically significant. Statistical analysis was performed with SPSS 19.0 (Chicago, Illinois, USA).

Results

Mean scale and initial questionnaire application times did not significantly differ between the three individual examiners (Examiner 1 = 6.637 ± 0.995 min; Examiner 2 = 6.756 ± 1.057; Examiner 3 = 6.303 ± 0.889). The overall mean ± SD application time was 6,565 ± 0.235 min.

Demographic and clinical data of the participants are presented in Table 1. The mean ADS score was 24.5 (± 6.7), while median score was 27 (interquartile range 20). On the basis of the proposed ADS classification scheme (scores 26-30 = independent, scores 15-25 = moderately dependent and 10-14 = totally dependent), 58.5% (n = 56) of the sample was shown to be independent, 27.1% (n = 26) moderately dependent and 14.6% (n = 14) totally dependent. The absolute and relative frequencies of individuals within each of the ten ADS items are shown in Table 2.

Bivariate analysis, identified statistically significant relations between the total ADS score and the following parameters: GCS score (r = 0.4; p<0.001), physiotherapy duration (r = - 0.5; p<0,001), physiotherapy treatment (t = -6.3, p <

0.001), presence of post-traumatic epileptic seizures (t = -3.2, p = 0.002) and use of antiepileptic medication (t = -3,7, p < 0.001). No statistically significant relations between the total ADS score and gender, age, injury mechanism or the elapsed time between admission and interviews, were identified. A correlation matrix was assessed prior to conducting the multivariate linear regression analysis to check for collinearity among the independent variables. Since the presence of post-traumatic epileptic seizures and the use of antiepileptic medication were strongly correlated (r = 0.66, p < 0.001), we chose to include only presence of post-traumatic epileptic seizures in the multivariate model. Multivariate linear regression method showed that increased GCS score, decreased physiotherapy duration and absence of post-traumatic epileptic seizures were independently associated with increased total ADS score (Table 3).

A statistically significant relation was found between the ability to work and verbal expression (x^2=44, p<0.001), verbal comprehension (x^2=27, p<0.001), mobility (x^2=51, p<0.001), physiotherapy (x^2=13.4, p<0.001) as well as presence of epileptic seizures (x^2=11, p=0.001), as shown in Table 4.

Discussion

Valid and reliable assessment of long term outcome in TBI survivors is a prerequisite for the evaluation of functional disability and appropriateness of healthcare and rehabilitation provision. At present, assessment of TBI outcome is largely based on various well-established measurement scales, including GOS, FIM+FAM, DRS and the Barthel index. Nevertheless, the aforementioned outcome scales exhibit certain drawbacks in terms of usability and scope. Thus, GOS represents a crude functional assessment tool that does not examine aspects of disability-associated social burden.[8, 9] While providing a more detailed investigation into various aspects of the patient's motor, cognitive and psycosocial functions, FIM + FAM remains very time consuming to complete (approximately 35 min).[10] Similarly, while DRS represents a relatively thorough assessment tool, its application is time consuming (15-30 min) and the examiner's familiarity with this scale is a prerequisite for timely completion.[11] The Barthel's index scale while quick to administer, lacks sensitivity and focuses mainly on daily living aspects but excludes those related to cognition, emotionality and social functionality.[13-16]

In the present study a novel and relatively simple outcome measurement scale for the evaluation of TBI was designed and its suitability and usability was tested on a cohort of 96 severe TBI patients, previously hospitalized in our neurosurgery clinic. The proposed "Athens Disability Scale" (ADS) was generated by combining selected items from the aforementioned, well-established scales in a way that allows for the assessment of patient's motor, psychocognitive as well as social abilities in a time sparing manner (< 7 min), thus representing a suitable tool for the needs of a neurosurgery clinic. Each of the 10 items in ADS incorporates 3 subcategories indicating total dependency (score =1), moderate dependency (score=2) or independency (score=3) with overall scale score ranging between 10-30 points. An ADS overall score of 26-30 indicates that the patient is independent, 15-25 indicates moderate dependency and 10-14 indicates total dependency. The classification scheme was derived following thorough examination of the ADS questionnaire and all possible score combinations. In this context, the classification "moderately dependent" is derived on the basis of the largest scoring range, since individuals that fall within this range, could neither be characterized as "fully dependent" even when they presented an ADS score of 15 points, nor "independent" even when they presented an ADS score of 25 points.

In the present study, putative correlations

between overall ADS outcome scores and demographic/clinical data were investigated in order to test the prognostic value of the latter factors. Our analysis indicated that increased GCS scores, decreased physiotherapy duration and absence of post-traumatic epileptic seizures were independently associated with increased total ADS score. Ability to work or study was also shown to be associated with physiotherapy, presence of posttraumatic epileptic seizures, mobility levels, and psychocognitive status.

The predictive value of GCS scores in short and long-term TBI functional or occupational outcome assessed using various tools, is supported by the results of some early studies.[17-19] Interestingly, Balesteri et al. suggest that changing practices in TBI treatment over the past decade (incorporating aggressive early treatment) may impede GCS assessment on admission, leading to the loss of its predictive value. In this context it is noteworthy that several more recent studies indicate that GCS alone has limited prognostic value in long-term TBI functional and occupational outcome, which can be nevertheless improved when GCS score measures are combined together with pupillary reaction assessment as well as other injury severity scales and certain demographic data.[20-22]

Our results showed that decreased physiotherapy duration is independently associated with increased total ADS score. While this relationship is counterintuitive, a likely explanation for this finding is that severe disability following TBI does not improve with prolonged physical therapy, as indicated previously.[23]

Post-traumatic epilepsy (PTE) is a well-described consequence of TBI. Its incidence varies according to both TBI and PTE case definitions as well as the time elapsed between TBI and assessment.[24, 25] The high frequency of PTE (26%) in the studied cohort appears consistent with previous epidemiological evidence indicating higher rates of PTE following severe, compared to mild and moderate TBI.[26-28] Moreover, the present results indicating poorer overall functional outcome in TBI survivors with PTE are in agreement with previous findings indicating a negative impact of early or late seizures on TBI functional outcome, assessed using various outcome scales.[29-32]

In the present study, while a trend towards decreased total ADS score with increasing age was apparent, this relationship did not reach statistical significance. Moreover, no apparent relation between gender and outcome was established. Evidence supporting an effect of age on severe TBI outcome has been previously obtained by numerous studies.[33-36] In contrast, an effect of gender on TBI outcome has been less well-characterized, with various studies presenting contradicting findings.[37-40] The extent to which the size and the uneven gender distribution of the studied sample influenced the present findings in relation to the putative effects of age and/or gender on outcome, warrants further investigation.

Return to work (or study) represents an important outcome index for severe TBI survivors.[41] The present findings indicated that 43.8% of the studied cohort returned to prior full-time occupation, 15.6% returned to work under specific conditions (part-time, supervisor or specialized device-assisted occupations or within a modified occupational/study environment), while 40.6% was unable to return to work/study. The relatively high rates of return to work/study following severe TBI shown herein appear in accord with the results of a recent meta-analysis.[42]

Previous studies indicate that several factors, including demographic characteristics,[43, 44] TBI severity,[44, 45] as well as cognitive and motor status[46-48] can influence return to work/study. As a corollary, the results presented herein show a significant relation between return to work/study and verbal expression, verbal comprehension, mobility, physiotherapy treatment and presence

of epileptic seizures. Moreover, consistent with previous findings,[49,50] the present study highlights several impeding factors for return to work/study, including motor deficits, tremor, fatigue and difficulties in verbal expression and comprehension.

A limitation of the present pilot study concerns its retrospective nature and the small number of participants. Further studies on larger cohorts incorporating survivors of varying TBI severity or other neurological injuries, as well as comparative studies using other well-established scales are warranted to extend the present findings and provide indices of sensitivity, usefulness and reliability of the proposed novel scale.

Conclusions

The present study investigated the suitability and usability of a novel and simple outcome measurement scale on a cohort of 96 severe TBI patients, previously hospitalized in our department. The proposed "Athens Disability Scale" (ADS) combines selected elements of commonly used outcome scales and allows for the assessment of TBI outcome on motor, psychocognitive and social aspects, in a time-sparing manner (<7min). Outcome scores were correlated with demographic and clinical data. The analysis indicated that increased GCS score, decreased physiotherapy duration and absence of posttraumatic epileptic seizures were independently associated with increased total ADS score. Ability to work or study was also shown to be associated with physiotherapy, presence of posttraumatic epileptic seizures, mobility levels, cognitive and psychosocial status. The present results indicate that our novel and relatively simple scale (ADS) may represent a useful outcome assessment tool that allows for the rapid evaluation of functional disability and quality of life following TBI.

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ANNEX

Table 1. Demographic, clinical and other relevant data of the studied cohort.

Cohort data	N (%) or mean ± SD
Gender	
Male	83 (8.5)
Female	13 (13.5)
Injury mechanism	
Car accident	86 (89.6)
Fall	10 (10.4)
Condition on discharge	
Stable	28 (29.2)
Improvement	68 (70.8)
Physiotherapy treatment	
Yes	79 (82.3)
No	17 (17.7)
Physiotherapy location	
Institution	39 (40.6)
Home	27 (28.1)
Institution and home	13 (13.5)
Current accommodation	
Home	90 (93.8)
Rehabilitation center	3 (3.1)
Clinic/hospital	3 (3.1)
Epileptic seizures	
Yes	25 (26.0)
No	71 (74.0)
Antiepileptic medication	
Yes	43 (44.8)
No	53 (55.2)
Continuous medical follow-up	
Yes	49 (51.0)
No	47 (49.0)
Age (years)	29.5±10.6
Physiotherapy duration (months)	22±28.2
Time elapse from injury to interview	5.6±3.5
GCS score on admission	
3	2 (2.1)
4	14 (14.6)
5	9 (9.4)
6	13 (13.5)
7	33 (34.4)
8	25 (26.0)

Table 2. Absolute and relative frequencies of the individuals within each of the 10 ADS items

Category	N (%)
Feeding	
Fully dependent	11 (11.5)
Moderately dependent	8 (8.3)
Independent	77 (80.2)
Personal hygiene	
Fully dependent	17 (17.7)
Moderately dependent	18 (18.8)
Independent	61 (63.5)
Dressing	
Fully dependent	15 (15.6)
Moderately dependent	19 (19.8)
Independent	62 (64.6)
Sphincter management	
Fully dependent	12 (12.5)
Moderately dependent	12 (12.5)
Independent	72 (75.0)
Mobility	
Fully dependent	13 (13.5)
Moderately dependent	21 (21.9)
Independent	62 (64.6)
Car transfer	
Fully dependent	13 (13.5)
Moderately dependent	14 (14.6)
Independent	69 (71.9)
Verbal comprehension	
Unable	6 (6.3)
Moderately able	15 (15.6)
Able	75 (78.1)
Verbal expression	
Unable	9 (9.4)
Moderately able	26 (27.1)
Able	61 (63.5)
Emotional status	
Bad	20 (20.8)
Moderate	33 (34.4)
Good	43 (44.8)
Ability to work-study	
Unable	39 (40.6)
Moderately able	15 (15.6)
Able	42 (43.8)

Table 3. Multivariate linear regression analysis with total ADS score as the dependent variable.

	Beta coefficient	**95% confidence interval for beta coefficient**	**P value**
GCS score	1.6	0.67 to 2.52	0.001
Physiotherapy duration	-0.1	-0.13 to -0.04	0.001
Absence of post-traumatic epileptic seizures	4.5	0.18 to 7.3	0.002

R^2 =37%

Table 4. Absolute and relative frequencies of individuals with varying capacity to work or study in relation to verbal expression, verbal comprehension, mobility, physiotherapy treatment and presence of epileptic seizures.

	Ability to work-study				
	Unable	Moderately able	Able	Total	P value
Verbal expression					<0.001
Unable	9 (100%)	0 (.0%)	0 (.0%)	9 (100%)	
Moderately able	17 (65.4%)	8 (30.8%)	1 (3.8%)	26 (100%)	
Able	13 (21.3%)	7 (11.5%)	41 (67.2%)	61 (100%)	
Total	39 (40.6%)	15 (15.6%)	42 (43.8%)	96 (100%)	
Verbal comprehension					<0.001
Unable	6 (100%)	0 (.0%)	0 (.0%)	6 (100%)	
Moderately able	9 (60.0%)	6 (40.0%)	0 (.0%)	15 (100%)	
Able	24 (21.3%)	9 (11.5%)	42 (67.2%)	75 (100%)	
Total	39 (40.6%)	15 (15.6%)	42 (43.8%)	96 (100%)	
Mobility					<0.001
Fully dependent	13 (100%)	0 (.0%)	0 (.0%)	13 (100%)	
Moderately dependent	14 (66.7%)	7 (33.3%)	0 (.0%)	21 (100%)	
Independent	12 (19.4%)	8 (12.9%)	42 (67.7%)	62 (100%)	
Total	39 (40.6%)	15 (15.6%)	42 (43.8%)	96 (100%)	
Physiotherapy treatment					<0.001
Yes	38 (48.1%)	13 (16.5%)	28 (35.4%)	79 (100%)	
No	1 (5.9%)	2 (11.7%)	14 (82.4)%	17 (100%)	
Epileptic seizures					0.001
Yes	16 (64%)	5 (20%)	4 (16%)	25 (100%)	
No	23 (32.4%)	10 (14.1%)	38 (53.5%)	71 (100%)	

APPENDIX 1

ATHENS DISABILITY SCALE (ADS)

1. FEEDING

a) Able to eat on his/her own by mouth, even if extra time needed □

b) Able to eat by mouth with minimal assistance □

c) Unable to eat by mouth (presence of feeding tube/gastrostomy).
Maximal assistance needed □ **2. PERSONAL HYGIENE**

a) Does it on his/her own, even if extra time needed □

b) Does it with minimal assistance □

c) Unable to do it on his/her own. Maximal assistance needed □

3. DRESSING

a) Dresses on his/her own, even if extra time needed □

b) Dresses with minimal assistance □

c) Unable to dress on his/her own. Maximal assistance needed □

4. SPHINCTER MANAGEMENT

a) Sphincter control / manages to go to the toilet on his/her own □

b) Urine/stool loss sometimes. Minimal assistance needed □

c) No sphincter control (continuous use of catheter/diaper).
Maximal assistance needed □

5. MOBILITY

a) Walking on his/her own, even if difficulties in walking (spasticity/paretic)
or extra time needed □

b) Walking with minimal assist/uses mobility devices or
unable to cover long distances □

c) Unable of walking, constant use of wheelchair. Maximal assistance needed □

6. CAR TRANSFER (NOT NECESSARILY AS THE DRIVER)

a) Gets in and out of the car on his/her own, even if extra time needed.
Not tired by long distances □

b) Needs minimal assistance, gets tired by long distances □

c) No self transportation (bed-dependent/use of stretcher).
Maximal assistance needed □

7. VERBAL COMPREHENSION

a) Comprehends easily simple and complex commands most of the time □

b) Confused at various times, comprehends only simple commands or

needs repetition □

c) Unable to comprehend commands □

8. VERBAL EXPRESSION

a) Expresses himself/herself easily with simple and complex words most of the time /tracheostomy □

b) Has difficulty in expression at various times (voice disruptions, dysphasia facial paresis), uses only simple words □

c) has incomprehensible expression or is unable to speak, sighs or gestures /tracheostomy □

9. EMOTIONAL STATUS

a) Participates in daily life with adjustable emotional reactions. Has complete control over his/her behavior □

b) Occasionally presents anxiety / depression / agitation / frustration, controlled by medication. Does not display dangerous behavior □

c) Frequently or constantly presents with anxiety / depression / agitation / frustration / displays dangerous behavior or has suicidal tendencies. Needs constant medication and supervision □

10. ABILITY TO WORK-STUDY

a) - Has returned to prior occupation. Full time job
- Students continue their studies with satisfactory performance □

b) - Is able to carry out only specific jobs, requires the use of ancillary devices or works in a specially equipped environment / assistant required / part time job
- Students attend special schools and learning programs □

c) - Unable to work
-Students unable to attend special schools and learning programs □

APPENDIX 2
QUESTIONNAIRE

NAME: ……
GENDER: ……
AGE: ……
TELEPHONE NUMBER: ……
DATE OF HOSPITAL ADMISSION: ……
DATE OF INTERVIEW: …….
INJURY MECHANISM:

1. Car accident □
2. Fall □
3. Brawl □
4. Other □

GCS ON ADMISSION: .....
DIAGNOSIS ……
PATIENT CONDITION ON DISCHARGE :

1. Stagnant □
2. Improvement □

PRESENT CONDITION:

1. Alive □
2. Dead □
3. Date of Death: .....

PHYSIOTHERAPY TREATMENT:

1. Continued right after discharge □
2. Else when □
   a) Time: ……..
   b) Duration: ……...
   c) Place:
      - Institution □
      - Home □

CURRENT ACCOMMODATION:

1. Home □
2. Rehabilitation Center □
3. Clinic / Hospital □

EPILEPTIC SEIZURES:

1. Yes □
2. No □

ANTIEPILEPTIC MEDICATION:

- Miorel □ - Trileptal □
- Depakine □ - Tegretol □
- Epanutin □ - Gardenal □
- Keppra □ - Other □

CONTINUOUS MEDICAL FOLLOW-UP:

1. Yes □
2. No □