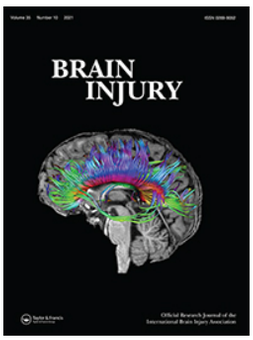

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What are the functional consequences after TBI? The SHEFBIT cohort experience

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ABSTRACT

Objectives: To investigate functional outcome after TBI and identify variables that predict outcome in a multiordinal regression model.

Background: The results of global outcome studies after Traumatic Brain Injury(TBI) differ widely due to differences in outcome measure, attrition to follow-up and selection bias. Outcome information would inform patients/families, guide service development and target high-risk individuals

Subjects/Setting: prospective cohort of 1322 admissions with TBI, assessed by face to face interviews at 1 yr.

Measures: Extended Glasgow Outcome Scale (GOSE) by structured questionnaire.

Results: At 1 year, outcome was determined in 1207(91.3%). Mean age was 46.9(SD17.3); Almost half (49.2%) had mild injury. At one year, 42.9% achieved Good Recovery but GOSE declined in 11.4% of the cohort compared to 10 weeks including 60(4.9%) deaths. In an ordinal logistic regression, increasing TBI severity, etiology (assault), more prominent CT abnormality, past psychiatric history and alcohol intoxication were independent predictors of worse GOSE. A pseudo-R^2 of 0.38 suggested that many unmeasured factors also contribute to TBI outcome. Future work needs to identify other variables that may influence outcome.

Conclusions: In a large TBI cohort, there is still considerable functional disability at 1 year. It may be possible to target high-risk groups for rehabilitation

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TBI; outcome; gose; follow-up; prognosis; cohort; icf; predictors

Introduction

Traumatic Brain Injury (TBI) remains a significant source of mortality and disability across the globe, especially in the young (1–3). It has long-lasting consequences for victims and their families(4), for society and for healthcare resources. An accurate prediction of outcome would allow better information for families and individuals thus allowing forecasting of care needs. A good understanding of prognosis after injury would inform the development of services in future as the incidence of TBI continues to increase (1,5).

Yet our knowledge of TBI outcome remains somewhat unclear; few individuals report complete symptom resolution(6) and published studies differ considerably in their findings as a result of design differences. One such key difference is that outcome itself can be measured in many ways with measures across different parameters of health (7). Some may exhibit selection bias such as exclusion of elderly or only include moderate and severe TBI, whereas most TBI is mild. The loss of subjects after TBI to follow-up is very high, as much as 70% within a few months(8). Hence, there is a need for large, prospective, high-retention follow-up studies as highlighted by many (3,5,9). This should be in a non-biased group that is truly characteristic of the TBI population(1).

In our district, an opportunity arose to create a rehabilitation pathway for follow-up of admitted TBI. This allowed a Rehabilitation Medicine team to offer advice and support for families and to organize a follow-up clinic for all admitted TBI cases. It has been shown that early rehabilitation input improves the management of TBI(10) and that coordination can improve the outcome (11,12). The new service identified all admissions, reviewed them after injury, offered support to family members and arranged any further referrals.

This pathway facilitated the follow-up of a prospective cohort with TBI that included all severities, age and injury types; the Sheffield Brain Injury after Trauma (SHEFBIT) cohort. This cohort reflects a valid picture of TBI as treated by health professionals and can help to guide clinicians and patients. It represents a "real-world" pathway and is germane to all professionals with an interest in TBI.

The primary aim of the study was to measure and document the 1 year functional outcome after TBI. The secondary aims were to try to identify if there is any key injury or demographic variable that can predict outcome in a regression model. Some demographic data from this cohort has been previously reported with no data analysis(13). But this paper presents completely new results of 1 year follow-up data and the regression analyses to investigate the best predictors of functional outcome after TBI.

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Methods

Clinical pathway/population

The organization of the TBI clinical pathway has been described elsewhere(12).The newly created Brain Injury Rehabilitation Team monitor the care of all admissions with TBI. The team assist with transfers between trauma and rehabilitation services and arranges follow-up.

Individuals admitted with TBI to a University hospital from 2011 to 15 were entered into the SHEFBIT cohort (Sheffield Brain Injury after Trauma). All participants had GCS recorded in the ED and used for TBI severity. All individuals received a head CT scan and were admitted for a minimum of one day. Those with prior TBI, age <17, resident out of region or dementia, were excluded. The diagnosis of TBI was confirmed by the American Congress of Rehabilitation Medicine criteria and position statement(14).

All individuals were followed up at 8–10 weeks in a Brain Injury clinic and again after 1 year. Those failing to attend were called for re-appointment. All patients were interviewed by the same PRM physician. Demographic and injury factors at time of injury such as gender, employment, GCS and CT scans were recorded. Psychiatric history was defined as any treatment for a diagnosed psychiatric condition at time of injury. Alcohol intoxication at the time of injury was made by taking history or from ED admission file.

Mechanism of injury was recorded as falls, assault, road traffic collisions (RTC), sporting activity and "other" mechanisms (workplace injuries or falls from a height)(15). CT scans were classed under the "overall appearance" method which labels injury as normal, mild focal, medium focal (two adjacent lobes) and diffuse injury(16). Significant medical comorbidity was measured by the Cumulative Illness Rating Scale (CIRS) and a cutoff above 10(17). The National Statistics Socio-Economic Classification (NS-SEC)(18) was used for socioeconomic class (SEC). Pre-injury employment was defined as those working (including full-time students), unemployed or retired.

The study was approved by both the University Hospital Trust and the University of Sheffield Ethics Committees (STH16208). All individuals gave consent for the study at their initial follow-up.

Glasgow outcome scale

The study outcome measure was the Glasgow Outcome Scale-Extended (GOSE) in a structured clinical interview(19). The extended version improves the discrimination between levels as well as excellent correlation with other outcomes and cognitive scores(20). Assessment by a single investigator (RS) with the structured clinical interview was used to minimize misclassification. In some cases, relatives helped with completion. As the level of vegetative state is rare, this level was merged with severe lower outcome.

Statistics

The results for demographic data are presented as frequencies with percentages. Numerical data is presented as mean and standard deviation when approximating to normal distribution or median and range otherwise. Comparison between follow-up and lost individuals was made with t-test or χ^2 test/Fisher Exact test for continuous or categorical variables as appropriate.

To assess the independent predictors of the main outcome, an ordinal logistic regression model was estimated with GOSE as the dependent outcome. All demographic and injury varables in the study were entered as continuous or categorical predictors. Post-hoc tests were applied to probe the individual variables that were significantly different but had more than 2 categories (NS-SEC, etiology, CT scan, pre-injury employment). Statistical analysis was performed using SPSS version 23.

Results

Population and injury features

Over the study period, 1934 admissions with TBI were recruited. After cases of prior TBI, dementia or non-local residence were omitted (209 individuals) as well as 319 where the diagnosis of TBI by Emergency Department could not be confirmed after history, 1406 individuals remained; follow-up appointments were arranged for 8–10 weeks and 1322 attended the first appointment. Appointments were repeated after 1 year. After one year there were 60 (4.9%) deaths and 115 (8.7%) cases were lost to follow-up. The lost group were older by 3.7 years but the only significant difference between groups was that CT scans were more likely to have mild or moderate abnormality but not severe in the lost group (Table 1). This final study population corresponds to a total of 1207 cases (including deaths) with a GOSE at one year. This represents a one year follow-up of 91.3% (Figure 1).

The cohort demographics are described in Table 1. The mean age of the cohort was 46.7 years (SD 20.0); median age was 45.6 (range 17.7–94.1 yrs). The majority of cases were male (826, 68.4%) and white ethnicity (1117, 92.5%). Women were older with higher GCS and more frequent falls but fewer RTCs (road traffic collisions). By comparison, the 115 cases who were lost to follow-up had milder CT scan abnormality and more social isolation but otherwise there were no significant differences.

There was a strong bias toward shorter lengths of stay probably due to higher frequency of mild injuries. The median admission was 2 days (range 1–163) and 86.3% had admission less than 10 days.

For etiology, falls (35.0%) and road traffic collisions (27.8%) were the most frequent cause of injury. Assaults were 17.8%. There was a high prevalence of past psychiatric history in 237 (19.6%), intoxication at injury 303 (25.1%) and medical comorbidity in 341 (28.3%) with 87 (7.2%) cases in the cohort on Warfarin or other oral anticoagulants.

For pre-injury employment, the majority were in employment or study at the time of injury (814 (67.4%)), while 172 (14.3%) were unemployed and 221 (18.3%) had retired. Higher SEC levels were less frequent when compared to the UK population from the last census

There was a high proportion of mild TBI (GCS 13–15) which is much closer to the real-life distribution of TBI than many other studies that focus on STBI (GCS < 9) or a specific

Table 1. Cohort demographics and comparison with individuals lost at 1 year.

	Followed up n = 1662	lost n = 72	$\chi^{(2)}$ or t-test, df, *p*-value
Mean Age yrs (SD)	46.7 (20.0)	50.4 (21.1)	1.92 df1320 $p = .055$
Gender			
Male N(%)	1148 (69.1%)	55(76.3)	1.738 df1 $p = .187$
Ethnicity N(%)			
White	1547 (93.1)	65 (90.3)	0.829 df1 $p = .363$
(nonwhite)	115 (6.9)	7 (9.7)	
Social Class N(%)			
Professional	114 (6.9)	3 (4.2)	13.375 df8 $p = .100$
Lower managerial	235 (14.1)	5 (6.9)	(Fisher Exact Test)
Intermediate	147 (8.8)	8 (11.1)	
Self-employed	142 (8.5)	8 (11.1)	
Lower supervisor	278 (16.7)	13 (18.1)	
Semi-routine	371 (22.3)	11 (15.3)	
Routine	220 (13.2)	18 (25)	
Never worked	80 (4.8)	4 (5.5)	
Students	75 (4.5)	2 (2.8)	
Unemployed N(%)			
Yes	683 (41.1)	28 (38.9)	1.579 df1 $p = .209$
Social Isolation			
Yes	717 (59.4)	59 (51.3)	7.59 df2 $p = .024$*
Yes	468 (38.8)	50 (43.5)	
Etiology N(%)			
Fall	423 (35.0)	46 (40.0)	3.4 df4 $p = .482$
RTC	335 (27.8)	33 (28.7)	
Assault	215 (17.8)	20 (17.4)	
Sport	77 (6.4)	3 (2.6)	
Other(work)	157 (13.0)	13 (11.3)	
On Warfarin N(%)	87 (7.2)	12 (10.4)	1.58 df1 $p = .209$
Any Comorbidity N (%)	341 (28.3)	28 (24.3)	0.795 df1 0.372
Alcohol at injury N (%)	303 (25.1)	22 (19.1)	2.02 df1 $p = .155$
Previous Psych Hx N (%)	237 (19.6)	18 (15.7)	1.07, df1 $p = .301$
Mean admission GCS	11.98 (3.12)	11.42 (3.35)	−1.82 df1320 0.088
Severity of TBI N(%)			
Severe	199 (16.5)	24 (20.9)	1.84 df2 $p = .399$
Moderate	408 (33.8)	40 (34.8)	
Mild	600 (49.7)	51 (44.3)	
CT Scan Findings N (%)			
Nil	472 (39.1)	34 (29.6)	11.5 df3 $p = .009$*
Mild	224 (18.6)	29 (25.2)	
Moderate	425 (35.2)	50 (43.5)	
Diffuse	86 (7.1)	2 (1.7)	

etiology. Injury severity as categorized by GCS, was largely mild injury; 600 (49.7%) had mild TBI, 408 (33.8%) moderate TBI and 199 (16.5%) had severe TBI.

A normal CT was noted in 38% of admissions and only 7.1% showed diffuse scan abnormalities.

GOSE

The primary outcome measure was the Extended Glasgow Outcome Scale. The changes in this measure from 10 weeks to 1 year showed considerable improvement over time as shown in Table 2. However, by one year, a Good Recovery (combining both upper and lower categories) was only achieved by 42.9% of the cohort with 11.8% still showing Severe disability. While 609 individuals had improved their GOSE over a year (50.5%), the majority only increased by one level on the scale (441, 36.5%). At the same time, 138 (11.4%) deteriorated in score. (Table 2).

In order to establish the independent predictors of GOSE, an ordinal logistic regression model was estimated. Independent variables of age, gender, ethnicity, SEC, pre-injury employment, medical comorbidity, social isolation, GCS, etiology, alcohol intoxication, psychiatric history, CT scan abnormality were also entered. The results are shown in Table 3. The model was highly significant with a Nagelkerke R^2 of 0.38 ($p < .001$)

The features that were significant for worse outcome in the model were increasing age, lower GCS, etiology (assault versus other mechanisms), positive psychiatric history, alcohol intoxication at time of injury, and worse CT scan abnormality. The odds ratios are shown in Table 3.

Discussion

We have followed up a large prospective cohort of mixed TBI admissions at a large Trauma Center. Half of these were MTBI and almost 40% had normal CT scans. It is the largest prospective single center TBI outcome study with face-to-face interviews that we know of. From an initial 1322 individuals at start 1207 (91.3%) had 1 year outcome documented representing a very high retention rate. It is well known that the loss of cases is a significant problem in TBI research. This was obviated by phoning and encouraging follow-up in those who miss their appointments. We also used a new PRM team to identify and recruit all admissions with TBI. Although any study population is subject to selection bias, we believe that this cohort is characteristic of admissions with TBI and of relevance to all health professionals working in brain injury.

We have found that a considerable level of disability remains at 1 year post-TBI; only 42.9% of individuals achieved a Good Recovery (upper and lower) which had improved from 25.1% after 8 weeks. This is surprisingly low if it is considered that most of the cohort had MTBI and is worse than most previous studies. In fact, it is comparable to levels of recovery that have previously been reported only after STBI (21,22). At the same time there are individuals with STBI who show marked improvements and several attain a Good Recovery. There was also considerable movement across levels in both directions; only 37% retained the same status as at 10 weeks and 11.4% had a deterioration of functional status which may indicate the delayed or ongoing effects of TBI which may reach their maximal effect sometime after the injury (9,13).

This highlights the difficulty in predicting outcome, based only on TBI severity. This poor outcome is disappointing and illustrates the level of disability that persists after TBI and that the condition has significant repercussions for individuals, families and for society.

The majority of previous studies have only examined moderate-severe TBI and the proportion identified with Good Recovery at one year ranges considerably from 1.3%(23) up to 74% (22,24–28). The definition of a "Good recovery" often differs. In this study, we used the structured clinical interview from the original authors of the GOSE(19).

The ordinal regression model was highly significant in predicting outcome, identifying a number of associated factors. However, the pseudo R^2 of 0.383 reveals that the model still

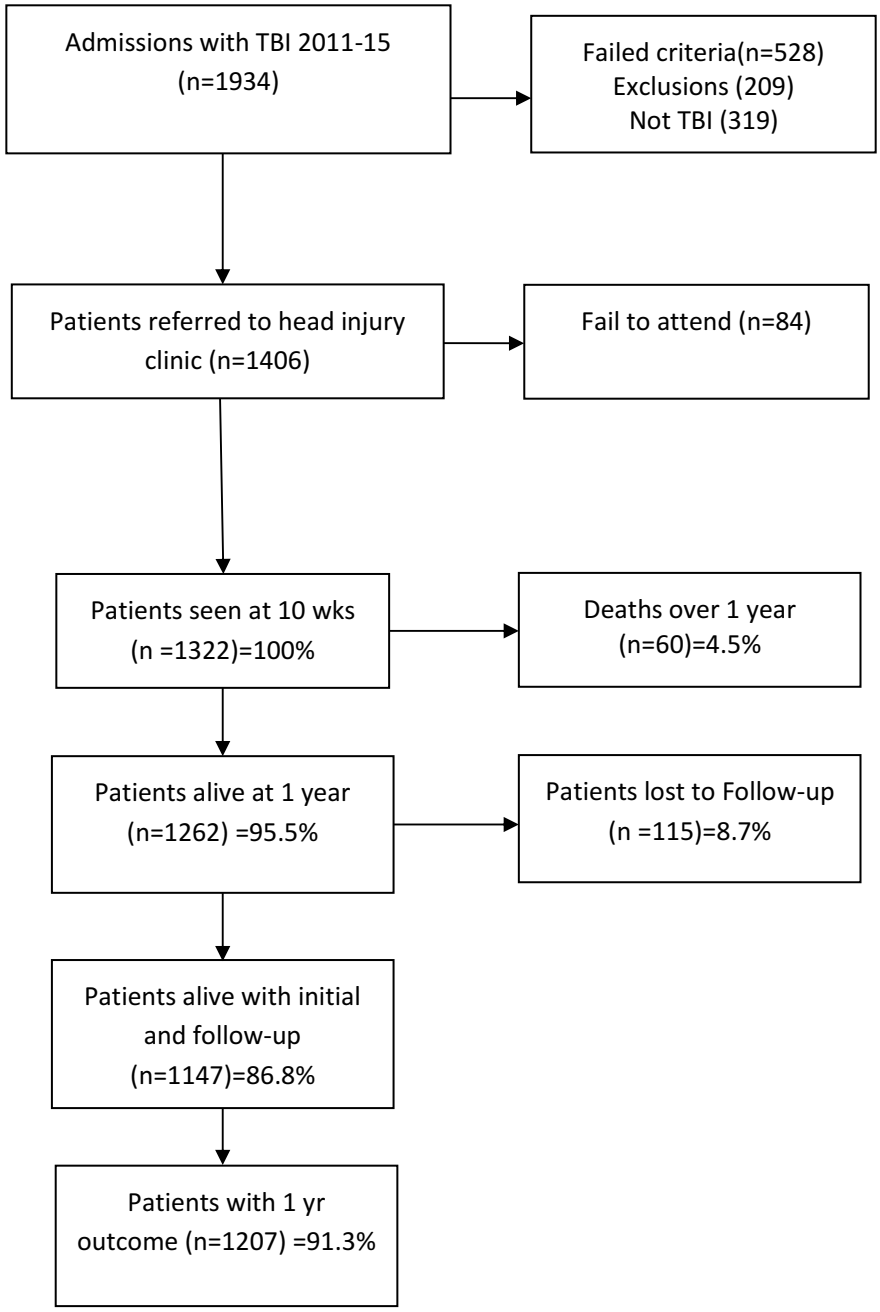

Figure 1. SHEFBIT Study patients and follow-up. Numbers and criteria are explained in the text.

Table 2. Overall GOSE at 10 weeks and 1 year and transitions between groups.

	1 year GOSE (% from 10 weeks GOSE)							
GOSE 10wks	Dead	Severe Lower	Severe Upper	Moderate Lower	Moderate Upper	Good Lower	Good Upper	Total GOSE 10wks (%)
VS	0(0)	2(100)	0(0)	0(0)	0(0)	0(0)	0(0)	2 (0.2)
Severe Lower	4(13.8)	5(17.2)	14(48.3)	6(20.7)	0(0)	0(0)	0(0)	29 (2.4)
Severe Upper	17(7.0)	3(1.2)	94(38.7)	105(43.2)	13(5.3)	10(4.1)	1(0.4)	243(20.1)
Moderate Lower	20(5.5)	1(0.3)	18(5)	126(34.7)	119(32.8)	59(16.3)	20(5.5)	363(30.1)
Moderate Upper	9(3.4)	0(0)	4(1.5)	24(9)	73(27.3)	98(36.7)	59(22.1)	267(22.1)
Good Lower	6(3.6)	0(0)	1(0.6)	3(1.8)	11(6.6)	43(25.7)	103(61.7)	167(13.8)
Good Upper	4(2.9)	0(0)	0(0)	3(2.2))	4(2.9)	6(4.4)	119(87.5)	136(11.3)
Total GOSE 1 yr (%)	60(5)	11(0.9)	131(10.9)	267(22.1)	220(18.2)	216(17.9)	302(25)	1207

leaves plenty of the variance in GOSE unexplained. In fact, this is a similar proportion to other large studies which have examined outcome from over 10,000 cases (29,30). It is therefore clear that there must be many factors that influence the variance in outcome which are not being captured or measured. The independent predictors of worse outcome that we have identified were increasing age, lower GCS or more severe injury, past psychiatric history and alcohol intoxication. With

Table 3. Ordinal regression model of 1 year GOSE. Categories described in text. OR odds ratio, *significant for $p < .05$.

				95% CI for OR	
	B	p-value	OR	Lower	Upper
Nonwhite Ethnicity	0.107	0.608	1.113	0.739	1.677
Female Gender	0.115	0.345	1.122	0.883	1.423
Age at injury	−0.011	**0.008***	0.989	0.980	0.997
Socioeconomic Class					
Professional-baseline	-	-			
Lower Manager	−0.231	0.356	0.794	0.485	1.297
Intermediate	−0.518	0.061	0.596	0.346	1.024
Small Employer	−0.902	0.002	0.406	0.231	0.712
Lower Supervisory	−0.516	0.036	0.596	0.368	0.968
Semi-routine	−0.530	0.026	0.589	0.369	0.940
Routine	−0.431	0.095	0.650	0.392	1.078
Never Worked	−1.060	0.001	0.346	0.181	0.664
Student	0.490	0.888	1.632	0.534	2.062
Pre-injury work					
Retired-baseline	-	-			
Employed	0.336	0.09	1.400	0.948	2.065
Unemployed	0.072	0.75	1.074	0.681	1.700
Social Isolation					
No- baseline	-	-			
Yes	−0.156	0.164	0.856	0.686	1.066
Nurse home	−2.291	**<0.001***	0.101	0.044	0.230
Etiology					
Assault – baseline	-	-			
Falls	0.547	**0.003***	1.728	1.212	2.462
RTC	0.455	**0.009***	1.576	1.121	2.219
Sports	0.780	**0.003***	2.181	1.292	3.680
Other	0.253	0.215	1.288	0.863	1.921
GCS	0.233	**<0.001***	1.262	1.207	1.320
Psychiatric Hx	1.056	**<0.001***	2.875	2.171	3.804
Warfarin	0.119	0.590	1.434	0.542	3.795
Comorbidity	0.237	0.104	1.267	0.952	1.685
Intoxicated	0.576	**<0.001***	1.779	1.357	2.335
CT Scan					
Diffuse-baseline	-	-			
Moderate	0.491	**0.029***	1.633	1.052	2.537
Mild	1.084	**<0.001***	2.956	1.824	4.797
NAD	0.742	**0.003***	2.100	1.280	3.442
Constant	2.284	0.069	9.814		

respect to the overall CT scan appearance, diffuse scan changes had worse outcome than normal or mildly abnormal scans but not significantly different to moderate abnormalities. With regards to etiology, assault had worse outcome than all other injury mechanisms apart from "Other" which was largely falls from height and workplace injuries. These findings may allow for targeting of certain individuals identified at high risk, for example, past psychiatric or alcohol history(31).

It is also important to recognize the variables that were not associated with outcome; these were gender, ethnicity, socioeconomic class, social support. This is not to say that there are no differences in outcome by these variables, but rather that they do not have independent predictive effects beyond those of the other positive predictors. We also recognize that many features such as cognition or physical function are also likely to influence outcome. Unfortunately in a busy clinic, there is a limit to the number of variables or patient questionnaires that can be reasonably measured.

No single risk factor has been consistently identified in the literature. Studies vary considerably in their design and population selection. Another problem is that many studies dichotomize outcome into Good/Poor. Such categorization group a wide range of possible outcomes into one group with a resultant loss of dimensional quality in an ordinal outcome.

It may be expected that TBI severity would be the likeliest risk factor for outcome and many studies find such an effect (4,22), but negative associations have also been found (6,23,32). Severe TBI is more likely to damage self-awareness and it has been suggested this may affect the ability to gauge one's limitations or impairment; as a result individuals may over-estimate their recovery and report fewer problems(33) which may account for some of the discrepancy between studies.

The association of increasing age with worse outcome, has also been noted previously (22,34,35) although some find that the effect only occurs beyond around age 40 while others find a more linear relationship. Mortality rates after TBI improved for many years but the relative inertia for any further change in recent years has been attributed to the aging of the population and the increased incidence of TBI in older individuals(1).

Previous attempts to create CT modeling for outcome works best in an acute setting for STBI and focus on the need for neurosurgical intervention (36,37). When applied across the whole TBI population, models are poor at predicting differences in outcome and a new classification system for scans is needed. The use of the "overall appearance" system allows description across the full TBI spectrum. Clearly, there will be cases where even a small lesion in a key location may result in very significant impairment. But this is the first report that we are aware of that shows a clear association of degree of CT abnormality and one year global outcome across all TBI severities.

Even those features that we have found no link with, have been found to be positive in other studies, for example, gender and ethnicity(38). Socioeconomic class or income, has also been associated with outcome in some studies(39) but not others(35) Employment at time of injury was found to be a significant predictor in a study of STBI(22) but was not noted by us.

The fact that so little consistency is apparent in the literature, illustrates the difficulty in predicting long-term outcome. Efforts to produce predictive TBI models have largely focussed on acute prognosis such as mortality with some success in the short term (29,30). However, even these models only account for around 0.35–0.4 of the variance in outcome and the majority of this can be attributed to three factors alone; age, motor score in GCS and pupillary reaction. The pseudo-variance in our study is similar to the IMPACT and CRASH models. It is likely that long-term outcome depends on a complex interplay of many factors including psychological, personality, and social factors (5,22). Many of these are difficult to measure effectively and highlight the problems in devising a model for long-term outcome. Such a model will require considerable sophistication to capture not only small changes in outcomes but also the measurement of the variables themselves.

From previous work, we know that GOSE is dynamic and that individuals can move outcome groups in both directions (13). It is therefore important to continue to follow this cohort in order to document further changes. Other studies have followed up for up to 10 years and show relatively little change in outcome over a long period (22,26,40) although seem to find better overall outcomes than we have found. This might be due to better case ascertainment in our study, especially for those who may be expected to have worse outcome. Some studies have shown an

initial recovery and then a plateauing after 2 years (25,28). The largest cohort study to date, using the TBIMS database, found that GOSE deteriorated after 5–10 years (40,41). While it is a challenge to continue a rate of follow-up beyond 1 year, we hope to report on similar long-term outcome in due course(42).

It is possible to try and predict the number of expected TBI cases over a 4 year period in the region (population 400,000). One would expect around 3500 TBI cases using reported European incidence(1) It follows that the pathway has identified more than half of all cases in the region and followed up. Again this is a notable feat. A similar TBI service reported a likely detection rate of only 3% of TBIs (43) and a multicentre study of only STBI, identified only 1/3 of likely cases(24) There is clearly considerable unrecognized or unmet need and the recognition of this is an important step in informing purchasers and health providers (4).

There are a number of key strengths of this study that should be highlighted. A key achievement has been the success of a clinical team to identify and capture all TBI admissions, prospectively followed from the date of injury onwards. The cohort has minimal exclusions and hence covers the true spectrum of admitted TBI including elderly patients. Some studies have recruited very select groups such as medicolegal cases or RTC(26). The systematic assessment and data collection and the capacity to chase up non-attenders were key strengths given the known attrition in TBI studies. A single observer to assess GOSE minimizes inter-observer bias.

There are some weaknesses to note. The results from a single trauma hospital may not be germane to all other regions despite our attempts to recruit as realistic a TBI population as possible. The GOSE does not distinguish between disability caused by TBI or other injury from trauma. It also has a limited number of levels and small changes may be unmeasured. The clinician who documents outcome was unblinded and could be biased. We did not measure quality of life nor any domain of cognition that would have added another dimension to the picture of TBI disability.

In summary, we have found that outcome after TBI is worse than many other studies have documented even in a largely mild injury group. In future, it is hoped to continue to follow up the group beyond one year and provide longer term results at 5 or even 10 years. We are also measuring a number of outcomes other than GOSE in order to broaden our understanding of the changes that occur across other domains, for example, psychosocial function or symptom levels. Further follow-up may provide more precise information about the exact trajectory of TBI disability and information and advice for individuals and families (30). Identifying those at higher risk would allow us to target rehabilitation efforts and prompt more efficient use of resources.

Disclosure Statement

The authors report no declarations of interest.

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