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IS A BRIEF RETROSPECTIVE INTERVIEW A VALID AND RELIABLE ASSESSMENT OF DURATION OF POST-TRAUMATIC AMNESIA AFTER MILD-MODERATE HEAD INJURY?

&

CLINICAL RESEARCH PORTFOLIO

VOLUME ONE

Kirsty Bell

July 2010

Submitted in part fulfilment of the requirement for the Degree of Doctor of Clinical Psychology

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And finally to Chris, thank you for everything you've done to help me through – here's to the start of a normal life again.

CHAPTER ONE

SYSTEMATIC REVIEW

Is Outcome after Head Injury best Predicted by the Glasgow Coma Scale or duration of Post-Traumatic Amnesia?

Keywords: Systematic Review; Head Injury; Glasgow Coma Scale (GCS); Post-Traumatic Amnesia (PTA); Functional Outcome

Word Count: 5917

Kirsty Bell Section of Psychological Medicine Gartnavel Royal Hospital 1055 Great Western Road Glasgow, G12 0XH Phone: 0141 211 3920 Fax: 0141 357 4899 k.bell.1@research.gla.ac.uk

Prepared in Accordance with the Guidelines for Submission to *Journal of Neurology, Neurosurgery* & *Psychiatry* (see Appendix 1.1 for contributor's notes)

ABSTRACT

Introduction Following head injury (HI) duration of Post Traumatic Amnesia (PTA) and Glasgow Coma Scale (GCS) are two early indicators of injury severity. They are also considered to be two of the best single predictors of outcome following HI. Measures most commonly used to assess disability outcome include the Glasgow Outcome Scale (GOS), the extended version of the GOS (GOS-E) and the Disability Rating Scale (DRS). This systematic review investigates whether the GCS or PTA best predicts disability outcome as defined by the GOS, the GOS-E or the DRS and whether this relationship is dependent upon the outcome measure used.

Method A systematic review of the literature was undertaken using the electronic databases, PsycInfo, All EBM reviews, EMBASE and Ovid MEDLINE, in addition to a hand search of the journal *Brain Injury*. The methodological quality of each selected study was assessed using specific rating criteria and was critiqued.

Results Thirteen studies were included. Evidence supporting the predictive ability of GCS in terms of disability outcome was mixed, but all studies using PTA as a predictor variable showed a significant relationship with disability outcome. The relationship between severity measures and disability outcome was not dependent on outcome measure.

Conclusion After considering methodological limitations of studies, PTA was found to be a better predictor of disability outcome than GCS after mild, moderate or severe HI using the GOS, the GOS-E or the DRS. The review emphasises the need for routine and valid assessment of PTA in hospitals following HI.

INTRODUCTION

Early indicators of outcome are important when planning the care and rehabilitation needs of individuals following HI. Reliable prediction of outcome is also important for the individual and their family to facilitate adaptation and planning for their future way of life. The GCS score and duration of PTA are considered to be two of the best single indicators of outcome following HI.[1]

PTA is a state of altered consciousness after HI, which is characterised by intellectual and behavioural disturbance. The duration of PTA is generally defined as the time from injury to return to continuous memory for day to day events including all periods of unconsciousness.[2] Standardised assessment tools have been developed to measure PTA duration prospectively, such as the Galveston Orientation and Amnesia Test (GOAT) [3] and the Westmead PTA Scale.[4] Prospective assessments are administered repeatedly at set time intervals to ascertain when the individual emerges from PTA and typically involve questions that focus on orientation and new learning.

In contrast to standardised prospective assessment, retrospective assessment involves interviewing the individual after they have emerged from PTA to ascertain when continuous memory for events returned. Pinpointing this time can be difficult due to a phenomenon known as "islands of memory". These isolated periods of recall can occur when the individual is less confused, making it appear as though they have emerged from PTA when in fact they have not.[2] It is imperative that this is taken into consideration and the interviewing process continues beyond the first point when memory appears to

have resumed. If an island of memory is mistakenly taken as the return of continuous memory and emergence from PTA its duration would be underestimated.

The GCS is a clinical tool that was developed to assess the depth and duration of impaired consciousness and coma following HI.[5] GCS score is determined by rating eye, verbal and motor responses. A score of fifteen indicates maximum responsiveness, including orientation. A score of three indicates minimal responsiveness, and scores of 8 or less coma. Lower GCS scores are associated with greater damage and correlate strongly with early morbidity and mortality.[6]

Specific assessment measures have been developed to assess and define outcome following HI to allow direct comparison between patients. The Glasgow Outcome Scale (GOS) focuses on how the injury has affected functioning and gives a general index of disability and recovery on a five point scale ranging from death to good recovery.[7] The GOS is simple to administer and easy to interpret making it an ideal research tool.[8] Both the GOS and its extended version (GOS-E) have good validity and reliability.[9,10,11] The GOS-E has eight outcome categories of death, vegetative, severely disabled (two levels), moderately disabled (two levels) and good recovery (two levels).[12] Outcome category is determined by exploring survival/consciousness, independence in the home, independence outside the home, work, social and leisure activities, family and friendships and return to normal life.

The Disability Rating Scale (DRS) assesses recovery and outcome after HI.[13] The DRS score is based upon the individual's level of ability in eight areas: eye opening; best verbal response; best motor response; ability to feed self; ability to toilet self; ability to groom

self; level of functioning; and employability. Scores are categorised with regards to level of disability ranging from "none" to "dead". The scale has high validity and reliability [14] and can be used as an outcome measure to evaluate final level of disability or as a means of monitoring the level of recovery during and following rehabilitation.

Although the two GOS scales and the DRS are three of the most widely used disability outcome measures, systematic reviews identifying prognostic factors for outcome following HI thus far have not focused upon studies that make use of them. One systematic review on prognostic factors for long-term functioning and productivity after HI selected studies with a variety of outcome measures such as "more independence" and "positive driving status".[15] The evidence for GCS being associated with disability and non-productivity was inconclusive and although duration of PTA was not explored in relation to disability, the evidence for longer durations of PTA being associated with nonproductivity was strong. A further systematic review focussed on prognostic factors for return to work after HI and explored outcome only in relation to return to work or not. It reported inconsistent evidence for the prognostic ability of PTA, but concluded that GCS was not a prognostic factor.[16]

Given that literature reporting standardised outcome generally makes use of the GOS scales and the DRS, the predictive ability of PTA and GCS in relation to outcome as defined by these measures would be more easily generalised than the findings of the previous reviews. This would allow a better understanding of which of these severity indicators is superior in terms of predicting disability outcome following HI. This review will therefore explore the predictive ability of GCS and PTA duration in terms of disability outcome as measured by the GOS and/or the GOS-E and/or the DRS.

Review Questions

(1) Is the GCS score or duration of PTA better at predicting disability outcome after HI?

(2) Does this (1) depend on whether the GOS or DRS was used to assess outcome?

METHODS

Literature Search strategy

The electronic search strategy is outlined below:

Keywords:

[GCS OR GLASGOW COMA SC*] or [PTA OR POST TRAUMATIC AMNESIA]

combined with

[FUNCTIONAL ADJ3 OUTCOME] and [DRS OR DISABILITY RATING SCALE OR GOS OR GOS-E

OR GLASGOW OUTCOME SC*]

combined with

[TBI OR TRAUMATIC BRAIN INJURY OR BRAIN INJURY OR CLOSED HEAD INJURY]

Databases: PsycInfo (1987-2010)

All EBM reviews

EMBASE (1980-2010)

Ovid MEDLINE (1988-2010)

Limits: January 1990 – May 2010

English language

Once studies to be included in the review were identified their reference lists and the journal *Brain Injury* (between January 1990 & April 2010) were hand-searched for further relevant studies.

Inclusion and Exclusion Criteria

Studies found via the electronic search were selected for inclusion by reviewing titles and then abstracts. Studies which appeared to fulfil the inclusion criteria and those for which this could not be ascertained from the abstract were obtained for full text review and selected according to the following inclusion criteria:

- a) All participants were adults (16 years and above)
- b) The relationship between PTA and /or full GCS score and outcome was explored
- c) The DRS and/or GOS and/or GOS-E was used to measure outcome
- d) A statistical analysis of the relationship between full GCS score and/or PTA and outcome independent of other predictor variables was reported
- e) The article was not a review paper or an unpublished dissertation

Studies were excluded if they did not meet all of the inclusion criteria.

Assessment of Methodological Quality of Studies

The methodological quality of each study was assessed using a rating scale developed for this review (Appendix 1.2) according to previously published criteria.[16-18] In order to establish inter-rater reliability with regards to methodological quality rating a sample of the articles was also assessed by an independent rater.

RESULTS

Search Strategy

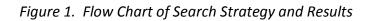
A flow chart detailing the search strategy and study selection process can be seen in Figure 1. The electronic search produced two-hundred articles. Forty-two studies were reviewed in detail and thirteen were included according to the inclusion criteria.

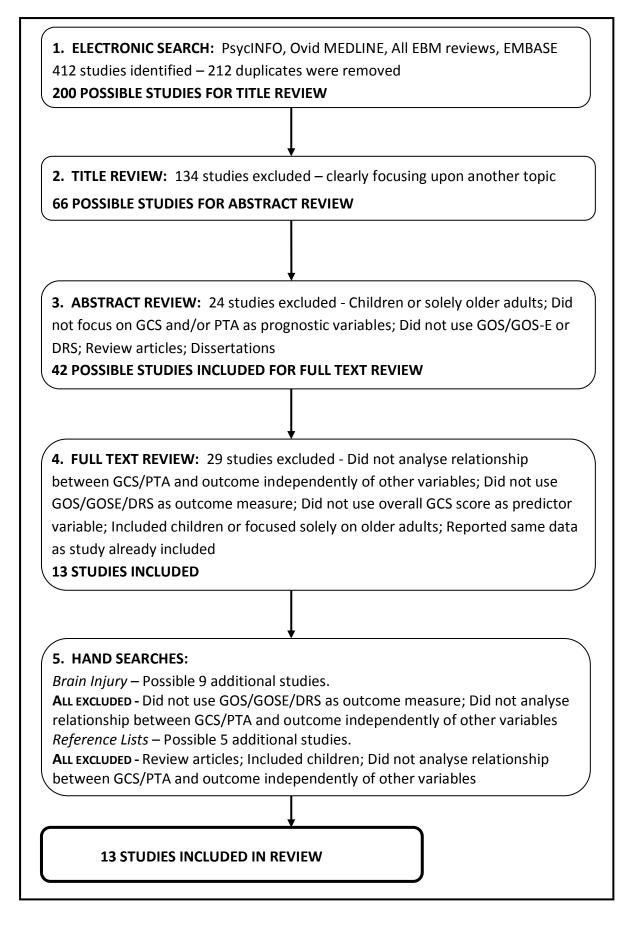
Methodological Quality Assessment

All thirteen studies were reviewed in terms of methodological quality and rated according to the quality rating criteria for this review (Appendix 1.2). Studies that included PTA (or PTA and GCS) could obtain a maximum score of 24. Studies focusing solely on GCS could obtain a maximum score of 21, as two questions in the rating scale pertain only to assessment of PTA. Each study was therefore rated by its percentage score.

A sample of the studies (n = 5) was rated independently for methodological quality by a final year Trainee Clinical Psychologist, resulting in 87% agreement with the author. Disagreements were resolved through discussion to achieve a final rating.

No study obtained a maximum rating score. Twelve of the thirteen studies obtained a rating of over 50% and seven of these were higher than 70%. The remaining study obtained a rating of 48%.





Methodological quality and percentage ratings are discussed below.

Cohen proposed using r as a measure of effect size, using the subjective standard of r = 0.1 as a weak effect, r = 0.3 as a moderate effect and r = 0.5 as a strong effect.[19] This standard will be applied for all effect sizes reported in the results section unless otherwise stated.

Findings

Key points and findings of each study are presented in Table 1 (pages 23-27).

1. Is The GCS Score Or Duration Of PTA Better At Predicting Functional Outcome After HI?

Studies Exploring GCS:

Foreman *et al.* explored the usefulness of GCS in predicting outcome in comparison to other indicators of severity for mild, moderate and severe HI.[20] A significant positive correlation (rho = 0.227, p<0.001) was found between GCS score and GOS-E score for the entire sample (n = 270), representing only a small effect size. When participants were grouped by age, the correlation between GCS and GOS-E for those aged 48 years and under (n = 210) was significant with a moderate effect size (rho = 0.300, p<0.001). The correlation between GCS and GOS-E was not significant (rho = 0.067, p = 0.611) for those aged over 48 years (n = 60). When participants were grouped according to severity of injury (mild to moderate and severe) the relationship between GCS and GOS-E for each group was non-significant (mild to moderate (n = 169): rho = 0.147, p = 0.057, severe (n = 101): rho = 0.095, p = 0.344). The methodological quality of this study was the highest of

those reviewed (95%). The only area where a maximum score was not achieved was participant selection as a convenience sample was used.

Cooke *et al.* conducted a twelve month prospective audit of the early management of HI for a sample of one hundred and twenty-five participants recruited from twelve randomly selected hospitals in Northern Ireland.[21] They examined the relationship between GCS, in addition to other severity variables, and GOS at twelve months for severe HI. Correlations between GCS and the GOS were significant (rho = 0.55, p<0.01) representing a large effect size. The study scored highly (86%) in terms of methodological quality, although the authors provide limited demographic information and do not report p values for data. The authors also fail to report effect sizes directly, although they are represented by the correlation coefficient.

Walder *et al.* explored the correlation between the Abbreviated Injury Scale (AIS) and outcome on the GOS and compared relationships between the GCS and the GOS.[22] A significant relationship between GCS and GOS (rho = 0.31, p<0.01) was found and represents a moderate effect size (n = 109). The study scored well in terms of methodological quality (76%). The authors provide limited demographic information, drop-out rates are not reported and effect size is not reported, although this can be taken as the correlation coefficient.

Wagner and colleagues explored various injury severity variables, including the GCS, in terms of their ability to predict disability and community integration following HI of all severities.[23] The DRS was used to assess outcome approximately one year post injury. Analyses showed a significant correlation between GCS and DRS scores (r = -0.386,

p<0.0001), representing a moderate effect size (n = 112). The study scored well in terms of its methodology (71%); however, it is not clear how HI was defined or which GCS score was used (initial, lowest, or highest). Outcome measures were completed approximately one year post injury (12-15 months), which meant that there was slight variance in follow-up time; however, this is minor and conducting the study with a shorter range would have been extremely challenging.

Park *et al.* aimed to identify clinical and radiological risk factors that may predict unfavourable neurological outcome in the early period after HI.[24] One hundred and fifteen participants were recruited and clinico-radiological factors, including GCS, were examined as potential risk factors of poor outcome as assessed by the GOS six months post injury. A logistic regression indicated that GCS was an independent risk factor for unfavourable outcome (p<0.005). The methodological quality rating of this study was 67%. It is not clear how HI was defined by the authors, what the exclusion criteria were and what the drop-out rate for the study was.

Zafonte *et al.* used the DRS to explore relationships between GCS and outcome at the point of discharge from rehabilitation.[25] Participant information was taken from the Multicenter National Institute on Disability and Rehabilitation Research (NIDRR) TBI Model Systems Project. Initial and lowest GCS scores correlated significantly with the DRS score (Initial GCS (n = 451): r = -0.24 p<0.0005, Lowest GCS (n = 440): r = -0.24 p<0.0005), representing weak effect sizes. The study obtained a score of 67% in terms of its methodological quality. As the outcome assessment was undertaken at discharge from rehabilitation, follow-up times were not standardised across participants, no definition is given for HI and the opt-in and drop-out rates are not stated.

Fearnside and colleagues compared pre-hospital, clinical and CT variables and outcome following severe head injury over a two year period for three hundred and fifteen patients admitted to Westmead Hospital in Sydney, Australia.[26] Outcome was grouped into categories of poor outcome (GOS 3 and 4), good outcome (GOS 1 and 2), and mortality (GOS 5). GCS significantly correlated with mortality (rho = 0.418, p<0.005) representing a moderate effect size, but not with functional outcome (good outcome or disability) on the GOS. In terms of methodological quality the study scored relatively well (62%); however, it was unclear how HI was defined, the rates of opt-in and drop-out, who undertook the outcome assessments and whether they were trained to do so.

Balestreri *et al.* explored the relationship between GCS and six month outcome in a large group of patients (n = 358) over a ten year period (1992-2001).[27] Patients were grouped according to year of admission and outcome was assessed at twelve months post HI. Data from those who were admitted within the first five years of the study period (1992-1996, n = 183) showed a significant positive correlation between GCS and GOS (rho = 0.41, p<0.00001) representing a moderate effect size. The correlation between GCS and GOS for those who were admitted in the last five years (1997-2001, n = 175) was non-significant (rho = 0.091, p = 0.226). The study was published as a short report and provides limited information regarding definitions of HI and severity of injury, opt-in and drop-out rates and who undertook the outcome assessments and whether they were trained to do so. This led to a relatively poor methodological quality rating of 48%.

Studies Exploring PTA:

Walker et al. explored the predictive ability of duration of PTA in relation to global outcome following moderate-severe HI.[28] Participants were recruited from the NIDRR TBI Model System Database (n = 1332). The GOS was used to assess outcome and the GOAT and the Orientation Log (O'LOG) were used to assess duration of PTA. The authors reported that longer PTA was predictive of poorer outcome and GCS was not predictive of outcome. Multinomial logistic regression models were fitted and confirmed that PTA was a significant predictor of GOS at one year ($\chi^2 = 158.91$, p<0.0001) and two years post injury (χ^2 = 95.37, p<0.0001). Using 95% confidence intervals, the most likely one year GOS outcome was good recovery when PTA was 18 days or less, moderate disability when PTA was 29-49 days and severe disability when PTA was 97 days or longer. The most likely two year outcome was good recovery when PTA was 26 days or less, moderate disability when PTA was 46-56 days and severe disability when PTA was 97 days or longer. In terms of methodological quality the study received a score of 71%. No details of the data collection period were given and the definition of HI was not provided. Information was not provided regarding which GCS score was used, who undertook the assessments or effect sizes.

Ellenberg *et al.* explored the ability of PTA to predict outcome following severe closed HI.[29] PTA was assessed prospectively using the GOAT. Logistic regression was used to explore the relationship between several variables, including PTA, and six month outcome (n = 259). Duration of PTA was shown to predict outcome after discharge from hospital (odds ratio = 0.98 p<0.05). The study achieved a methodological quality rating of 71%. It did not give details of the recruitment period (although it referred to another paper that did) or how severe closed HI was defined. Details regarding who undertook

the assessments in the study and their training were not given. Effect size was not reported.

Zafonte *et al.* explored the relationship between PTA duration and outcome measured by the DRS and the Functional Independence Measure (FIM) at the point of discharge from rehabilitation.[30] Duration of PTA was assessed using the GOAT. The study aimed to explore whether duration of PTA would account for a significant amount of unique variance, in addition to that accounted for by age, in predicting outcome scores. A multiple regression analysis showed that PTA was a significant predictor of outcome on the DRS ($R^2 = 0.23$, p = 0.00005), and a large effect size was reported ($f^2 = 0.37$, n = 273). The study obtained a methodological quality rating of 58%. The definition of HI was not given and it was not stated which GCS score was used. The outcome measure was completed in relation to discharge rather than time since injury, which meant that followup times were not standardised across subjects. Opt-in and drop-out rates were not reported and no detail was given regarding who undertook the assessments and their training.

Studies Comparing GCS and PTA:

Bishara *et al.* focused upon severe closed HI, as defined by GCS score, and used the GOS at six and twelve months post injury to assess outcome.[31] PTA was assessed by clinical interview whilst the participant was in hospital and following discharge (n = 89). Significant correlations between GCS and outcome at six and twelve months post injury (r = 0.45 p<0.0001 and r = 0.46 p<0.0001) were reported representing moderate effect sizes. Significant correlations were also reported for PTA and outcome at six and twelve months post injury (r = -0.5 p<0.0001 and r = -0.59 p<0.0001) representing large effect

sizes. The study scored well in terms of methodological quality (75%); however, details of who undertook the PTA assessments and their training were not provided and a validated assessment tool was not used for the PTA assessments.

Hiekkanen *et al.* used the GOS-E 12 months post injury to explore the ability of PTA and GCS to predict outcome.[32] PTA was assessed by interview using the Rivermead protocol. The number of participants who completed this study (33) was much lower than in the other studies included within this review (range: 33-1332) however a significant correlation between PTA and outcome (r = -0.458, p = 0.007) representing a moderate effect was reported. The correlation between GCS and outcome was not significant (r = 0.382, p = 0.280). In terms of methodological quality the study obtained a score of 67%. It was not clear when the period of data collection took place or how long it lasted. Opt-in and drop-out rates were not provided, it was not stated who undertook the assessments and effect size was not reported, although it can be ascertained from the data.

The evidence that GCS predicts disability outcome is mixed, with some studies reporting significant relationships with small to large effect sizes and some studies reporting nonsignificant relationships. In contrast all of the studies that included PTA as a predictor variable showed a significant relationship between duration of PTA and disability outcome.

2. Does This (1) Depend On Whether The GOS, GOS-E Or DRS Was Used To Assess Outcome?

Of the studies exploring the predictive ability of GCS six used the GOS [21,22,31,24,26,27], two used the GOS-E [20,32] and two the DRS.[23,25] Significant relationships between the GCS and the GOS were shown in all studies. One study separated participants into two groups according to date of admission resulting in the relationship between GCS and GOS being significant for the first group of participants but not for the other.[27] A weak relationship between GCS and GOS-E was found in one study [20] and a non-significant relationship in the other.[32] The relationship between GCS and DRS was shown to be significant in both studies with moderate effect sizes.

ΡΤΑ

Three studies explored the predictive ability of PTA using the GOS [28,29,31], one used the GOS-E [32] and one used the DRS.[30] The relationships between PTA and GOS, GOS-E and DRS were significant with moderate to large effects.

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Findings	<u>At 12 months:</u> Significant correlation (rho = 0.227, p<0.001) representing a weak effect.	At 12 months: Significant correlation (rho = 0.55, p<0.01) representing a strong effect.	<u>At 6 months:</u> Significant correlation (rho = 0.31, p<0.01) representing a moderate effect.
Outcome Measure	GOS-E	GOS	GOS
Predictor Variables	GCS (Initial score)	SS	SOB
Demographic Information & Duration of Follow-Up	N = 270 completed Male: 67% Female: 33% Mean Age: 36.8yrs Severity of Injuries: Mild, Moderate & Severe Follow-up: 12 months	N = 125 completed Male: Not given Female: Not given Mean Age: Not given Severity of Injuries: Severe Follow-up: 12 months	N = 109 completed Male: 86 Female: 23 Mean Age: Not given Severity of Injuries: Severe Follow-up: 6 months
Recruitment Period/Duration	1999-2004	12 months	1986-1988
Quality Rating (%)	95 %	86%	76%
Lead Author	Foreman, B. P.[20]	Cooke, R. S.[21]	Walder, A. D.[22]

Table 1. Key Points and Findings for Each Study

Lead Author	Quality Rating (%)	Recruitment Period/Duration	Demographic Information & Duration of Follow-Up	Predictor Variables	Outcome Measure	Findings
Bishara, S. N.[31]	75%	1985-1988	N = 89 completed Male: Not given Female: Not given Mean Age: Not given Severity of Injuries: Severe Follow-up: 6 & 12 months	PTA (assessed prospectively and retrospectively) GCS (initial score)	GOS	At 6 months: Significant correlation for GCS (r = 0.45, p<0.0001) representing a moderate effect. Significant correlation for PTA (r = - 0.5, p<0.0001) representing a strong effect. <u>At 12 months</u> : Significant correlations for GCS (r = 0.46, p<0.0001) representing a moderate effect. Significant correlations for PTA (r = -0.59, p<0.0001) representing a strong effect.
Ellenberg, J. H.[29]	71%	Participants recruited from database (1984- 1987)	N =259 completed Male: 82.2% Female: 17.8% Mean Age: 29yrs Severe Severe Follow-up: 6 months	PTA (Assessed by GOAT)	GOS	At 6 months: Logistic regression showed a significant relationship between PTA and outcome. Odds ratio = 0.98, p<0.05.
Wagner, A. K. [23]	71%	Participants recruited from database over one year period	N = 112 completed Male: 72.5% Female: 27.5% Mean Age: Not given Severity of Injuries: Mild, Moderate & Severe Follow-up: 12 months	ecs	DRS	<u>At 12 months:</u> Significant correlation (rho = -0.386 p<0.0001) representing a moderate effect.

Lead Author	Quality Rating (%)	Recruitment Period/Duration	Demographic Information & Duration of Follow-Up	Predictor Variables	Outcome Measure	Findings
Walker, W. C.[28]	71%	Participants recruited from national database	N = 1332 completed Male: 71.2% Female: 28.8% Mean Age: Not given Severity of Injuries: Moderate & Severe Follow-up: 12 & 24 months	PTA (assessed using GOAT or O'LOG)	GOS	<u>At 12 months</u> : Significant logistic regression ($\chi^2 = 158.91$, p<0.0001) <u>At 24 months</u> : Significant logistic regression ($\chi^2 = 95.37$, p<0.0001)
Hiekkanen, H.[32]	67%	Not given	 N = 33 completed Male: 69.7% Female: 30.3% Mean Age: Not given Severity of Injuries: Mild, moderate, severe & very severe Follow-up: 12 months 	GCS (Initial score) PTA (Assessed using Rivermead protocol)	GOS-E	At 12 months: Non-significant correlation for GCS (r = 0.382, p = 0.280). Significant correlation for PTA (r = -0.458, p = 0.007) representing a moderate effect.
Park, J- E.[24]	67%	2004-2006	N =115 completed Male: 81 Female: 34 Median Age: 47.7yrs Severity of Injuries: Mild, Moderate & Severe Follow-up: 6 months	GCS (Initial score)	GOS	<u>At 6 months:</u> GCS was shown to be an independent risk factor for unfavourable outcome (p<0.001) according to logistic regression.

Lead Author	Quality Rating (%)	Recruitment Period/Duration	Demographic Information & Duration of Follow-Up	Predictor Variables	Outcome Measure	Findings
Zafonte, R.[25]	67%	Participants taken from national database (1988- 1993)	 N = 451 (initial GCS) & 440 (lowest GCS) Male: 77% Female: 23% Mean Age: Not given Severity of Injuries: Mild, Moderate & Severe Follow-up: End of rehabilitation 	GCS (Initial and lowest score)	DRS	<u>At the end of rehab:</u> Significant correlation for initial GCS (r = -0.24, p<0.0005) and lowest GCS (r = -0.24, p<0.0005) both representing moderate effects.
Fearnside, M. R.[26]	62%	Two year period	N = 315 completed Male: 238 Female: 77 Mean Age (Survivors): 22.4yrs 22.4yrs Mean Age (Died): 37.3yrs Severity of Injuries: Severe Follow-up: 6 months	GCS (Initial score)	GOS – looked at mortality and good vs. poor outcome	At 6 months: Significant correlation between GCS & mortality (rho = 0.418, p<0.005) representing a moderate effect. GCS not a significant predictor of good vs. poor outcome.
Zafonte, R. D.[30]	58%	1988-1996	 N =273 completed Male: 83% Female: 17% Age: 81% younger than 50 Severity of Injuries: Mild, Moderate & Severe Follow-up: Discharge from 	PTA (Assessed by GOAT)	DRS	At discharge from rehab: Significant multiple regression ($\mathbb{R}^2 = 0.23$, $p = 0.00005$) with a large effect size ($f^2 = 0.37$).

Findings		<u>At 6 months:</u>	Recruitment period 1:	Significant correlation (rho = 0.41,	p<0.00001) representing a moderate effect.	Recruitment period 2:	Non-significant correlation	(rho = 0.091, p = 0.226).		
Outcome Findings	Measure	GOS								
Predictor	Variables	GCS	(Initial score)							
Demographic Information	& Duration of Follow-Up	1)N =183	2) N = 175	Male: Not given	Female: Not given	Mean Age: 34yrs	Severity of Injuries: Mild,	moderate & severe	Follow-up: 6 months	
Recruitment	Rating (%) Period/Duration	Two separate	periods:	1) 1992-1996	2) 1997-2001					
Quality	Rating (%)	48%								
Lead	Author	Balestreri, 48%	M.[27]							

DISCUSSION

GCS Score vs. Duration of PTA

All studies exploring PTA and outcome report a significant relationship, and where available, moderate to large effect sizes. Fewer studies explored PTA as a predictor variable than GCS. This may reflect the routine nature of assessing and recording GCS score in clinical practice and hence the ease by which it can be obtained for academic research.

In contrast, findings regarding the relationship between GCS and outcome are mixed and range from non-significant to significant with a large effect. This inconsistency is highlighted in one study [27], which found a significant relationship between GCS and outcome for one group of participants who were admitted to hospital during the first five years of the study period (1992-1996) but not for the second group who were admitted during the second five years of the study period (1997-2001). The authors observe that more recently developed pre-hospital treatment including intubation and sedation can obscure the initial GCS assessment and question whether this, and progress in clinical management, have affected the relationship between GCS and outcome.[33]

Overall, it would appear that PTA is a better predictor of disability in the community following HI than GCS score. In knowing the duration of PTA medical professionals have the ability to predict likely outcomes for individuals who have sustained a HI. This review has highlighted that the majority of patients with PTA lasting up to twenty-eight days are likely to make a good recovery at six months post injury.[31] Those with PTA lasting between four and eight weeks could make a good recovery or have a moderate disability,

and those with PTA lasting longer than eight weeks are likely to have a moderate or severe disability as classified by the GOS.[31]

At one year post injury it is likely that all patients with PTA lasting less than twenty nine days will make a good recovery. Those with PTA lasting between twenty-nine and fortynine days are likely to have a moderate disability and those with PTA lasting eighty days or more are likely to have a severe disability.[28] Further recovery can take place between one and two years post injury and as such outcome at two years post injury can be an improvement over outcome at one year post injury for some. At two years post injury those with PTA lasting between forty-six and fifty-six days are most likely to have a moderate disability and those with PTA lasting between the place between disability and those with PTA lasting ninety seven days or more are most likely to have a

Is This Dependent Upon Outcome Measure?

Relationships between PTA and disability outcome were found in studies using the GOS, the GOS-E and the DRS. The GCS was correlated with functional outcome as measured by the GOS in all studies. As previously discussed one study [27] reported conflicting findings with a significant relationship shown for one group of participants but not the other. GCS score had a significant relationship with outcome on the DRS in both studies reviewed [23,25], with outcome on the GOS-E in one study, [20] representing only a weak effect, and a non-significant relationship in the other GOS-E study.[32] It would appear therefore that the predictive ability of GCS and PTA duration is not dependent upon outcome measure.

Methodological Issues

Several studies did not define HI or provide inclusion and exclusion criteria and it is unclear how well the findings can be generalised given the level of information that is provided with regards to the participants and the injuries they sustained.

In many of the studies it was unclear who undertook the outcome and PTA assessments and whether they had been trained to do so questioning the reliability of the data obtained. Time of follow-up was also an issue in some studies as this was not standardised across participants. One study reported a range of time since injury that individuals were followed-up [23], however the range of three months is relatively small given the difficulties of conducting follow-up research in this area. Two [25,30] completed outcome measures at a set time following discharge but did not provide information regarding duration of stay in hospital. As such it becomes difficult when comparing the data with that of other studies, which have conducted outcome measures in relation to time of injury.

Many studies lacked detail about the number of individuals who were approached to take part in the study, the number who declined and the number who were lost to follow-up. It is unclear whether comparisons were made between those who completed the study and those who did not in order to explore whether the study group was a representative sample.

Another major limitation was the lack of justification of sample size provided. Only one study reported an effect size and although effect sizes could be determined it has been

deemed important in terms of methodological quality that authors consider sample and effect size.[17]

In reference to the methodological limitations outlined it must be noted that conducting research in this field is challenging due to the nature of the difficulties participants exhibit. The limitations must be understood in the context of the challenges of recruiting participants, obtaining reliable assessment data and ensuring that participants complete the study at follow-up.

Limitations of This Review

Drawing conclusions from this review was made difficult because of the methodological limitations outlined. As has been noted however there are significant challenges within this field of research and the conclusions made should be understood within the context of these challenges and the methodological limitations they cause.

The review excluded studies that were not published in English, unpublished data and that from dissertations. Potentially valuable information could have been discounted as a result and the review may be subject to publication bias.

Clinical Implications & Future Research

The findings of the review reinforce the importance of obtaining an estimate of PTA duration for every patient who attends hospital following a HI. It would seem pertinent to suggest that PTA assessment should form an integral part of routine clinical practice as is currently the case for the GCS assessment. An assessment of PTA duration would provide vital information that could assist medical staff to make informed clinical

decisions regarding the duration of the patient's hospital admission and their rehabilitation potential. Knowing the duration of PTA for each patient also assists staff to provide family and friends with much sought after information and reassurance regarding early and long-term outcome.[34]

The review has highlighted several important methodological limitations within HI research. It appears important that two specific limitations are addressed by future studies to allow more reliable comparison of data across studies. Firstly it should be made clear how HI is being defined within the study as the variability of diagnostic criteria used to classify HI across the literature base is vast.[35] Secondly the use of standardised PTA measures would allow conclusions to be drawn about the reliability of the estimates of PTA duration within the study as well as allowing direct comparisons with other studies. It should be acknowledged however that prospective assessment using these measures is not always possible particularly if patients do not attend hospital immediately post-injury.

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CHAPTER TWO

MAJOR RESEARCH PROJECT

Is a Brief Retrospective Interview A Valid and Reliable Assessment of Duration of Post-Traumatic Amnesia After Mild-Moderate Head Injury?

Keywords: Head Injury; Post-Traumatic Amnesia; Retrospective Assessment; Reliability; Validity.

Word Count: 5961

Kirsty Bell Department of Psychological Medicine Gartnavel Royal Hospital 1055 Great Western Road Glasgow, G12 0XH Phone: 0141 211 3920 Fax: 0141 357 4899 k.bell.1@research.gla.ac.uk

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ABSTRACT

Introduction Duration of Post-Traumatic Amnesia (PTA) following head injury (HI) can be assessed prospectively, during the amnesic period, or retrospectively, after the amnesic period has resolved. Prospective assessment of PTA can be difficult after less severe injuries because PTA duration is short. Retrospective assessment could be more practical but may be less valid and reliable. This study explores the reliability and validity of a retrospective assessment interview [1] for mild-moderate HI by examining the relationship between initial and follow-up estimates of PTA duration, and the relationship between estimates of PTA duration and outcome.

Methods Patients admitted to Glasgow Royal Infirmary following a HI were invited to take part in the study and completed the initial PTA assessment on the proposed day of discharge. Participants were contacted by telephone one to six weeks later to complete the follow-up assessment of PTA and the GOS-E.

Results Twenty-two participants completed the study. According to the GOS-E.

Conclusions A retrospective assessment interview is of great clinical relevance for patients with mild-moderate HI who often present to medical services after having emerged from PTA. This type of assessment can be used to obtain a reliable estimate of PTA duration after mild-moderate HI; however, further research into the validity of the interview is required.

INTRODUCTION

PTA is the transient state of confusion and disorientation following HI, characterised by intellectual and behavioural disturbances. The duration of PTA is classed as the time from injury to when normal continuous memory is regained, including all periods of unconsciousness, confusion and disorientation for whatever reason.[2] Alongside duration of loss of consciousness, and Glasgow Coma Scale (GCS) score, duration of PTA is a reliable indicator of HI severity with longer durations being indicative of more severe injuries.[3] PTA duration of less than one hour is classed as a mild HI, between one and twenty-four hours as a moderate HI and between one and seven days as a severe HI.[4]

PTA duration also provides an indication of likely outcome following HI. Longer durations of PTA are predictive of poorer outcome.[5-7] As such, mild injuries tend to be associated with a full or good recovery and more severe injuries tend to be associated with disability. A reliable estimate of the duration of PTA can therefore provide important information for medical staff as well as the individual and their family regarding potential recovery.

The challenges of estimating the duration of PTA were originally discussed in 1946.[3] Underestimation of PTA can occur as a result of 'lucid intervals' and 'islands of memory' during the amnesic period. Lucid intervals refer to a phenomenon whereby the individual is lucid upon interview post HI, suggesting that they have emerged from PTA, but subsequently experiences delayed confusion, generally as a result of intracranial complications such as haemorrhage.[3] Loss of memory for events during the period of PTA is not always uniform. Islands of memory can occur for special events during PTA, usually when the individual is less confused and more able to converse in an appropriate

manner.[3] In acknowledgement of these challenges standardised PTA assessment methods have been developed in an attempt to obtain reliable estimates of PTA duration.[8]

Prospective assessment of PTA duration involves repeated assessment at specific time intervals during the period of amnesia. The Galveston Orientation and Amnesia Test (GOAT) was the first published measure of this kind and consists of questions about the recall of events before and after the injury and orientation questions.[9] The GOAT is repeated every twenty-four hours until consecutive daily scores of 75% or more are obtained, which is taken as an indication that the individual has emerged from PTA. Although the GOAT provides a standardised method of assessing PTA duration it has been criticised for focusing upon assessment of orientation.[10]

Whilst in PTA the ability to retain and recall new information is impeded. As such it has been suggested that PTA assessment should explore the individual's ability to lay down new memories as well as orientation to time and place.[11-12] Measures such as the Westmead PTA Scale (WPTAS) aim to address this issue by including a basic assessment of verbal memory recall and recognition, using the examiner's face and name and picture cards as stimuli, in addition to orientation questions.[13] The WPTAS is also repeated on a daily basis and individuals must obtain a maximum score for three consecutive days before being deemed to have emerged from PTA. Although these measures do not rely upon subjective estimation of PTA duration, which suggests they might be more reliable, it can be argued that they are limited in terms of clinical utility. In order to provide an assessment of new learning, prospective measures use additional stimuli such as photographs and pictures, which could easily be misplaced in a busy hospital. They must

also be repeated regularly to ascertain when the period of PTA ends, which could prove challenging given that time available to staff is limited.[14]

In contrast, a semi-structured interview is a quick and easy assessment method that can be undertaken retrospectively as originally highlighted by Russell in 1932.[15] Retrospective interviews are carried out after the individual has emerged from PTA and ask orientation questions in addition to asking the individual to describe the sequence of events that took place immediately prior to and following their injury. Questions focus around key events known to have taken place following the injury, for example, travelling in the ambulance or arriving at the hospital. When an individual is able to describe an event in detail they must continue to do so beyond this point to confirm that continuous memory was regained as opposed to an isolated island of memory. This method of assessment relies upon the subjective judgement of the assessor to estimate PTA duration. Occasionally corroborative information regarding time-scales may be available from family, friends or hospital staff to assist in this process. It can however be difficult to provide precise estimates of PTA duration without this information, particularly for individuals with shorter durations of PTA.

Prospective and retrospective assessment methods both have advantages and disadvantages but retrospective methods tend to be viewed as less reliable, due to the subjective nature of assessment and the reliability of the injured individual's responses.[2,13,16] In the only direct comparison of the two methods McMillan *et al.* used the GOAT prospectively and a semi-structured interview retrospectively with individuals who had sustained a severe HI.[1] The study found the relationship between prospective and retrospective measures of duration of PTA to be highly significant (r =

0.87). Significant relationships were also found between retrospective estimates of PTA and outcome measures of emotional difficulties, return to work and levels of dependency. The study showed that a retrospective semi-structured interview can be used to gain as accurate and reliable an estimate of PTA duration up to six years after injury for those with severe injuries as could be obtained prospectively using a standardised measure. Whether a retrospective assessment measure could provide a valid and reliable estimate of PTA for less severe injuries is unknown.

Duration of PTA is more difficult to assess in mild and moderate HI due to its shorter length and transient nature. Many of the standardised prospective assessment measures were designed for use after severe HI and require to be repeated on a daily basis. These measures are unsuitable for those with a mild-moderate injury given that the duration of PTA for this population will not exceed twenty-four hours.

The WPTAS has been adapted for use after mild HI. The revised measure makes use of a target photograph to assess new learning and recall rather than asking the individual to remember the name and face of the assessor, and is repeated on an hourly, rather than daily, basis.[13] The revised WPTAS is shorter, making it more convenient to use clinically, but still uses pictorial stimuli for the memory component and is required to be repeated. Individuals who have sustained a mild HI could have emerged from PTA prior to being seen at a hospital. In such cases the revised WPTAS could not provide an accurate estimate of PTA duration as a maximum score would be achieved upon first administration. It seems likely that a one-off retrospective assessment measure that could be administered whenever the patient attended or was able to seen would be most appropriate for use with this population.

The reliability of patient responses during PTA assessment following mild HI has been questioned. In a previous study assessing PTA duration by patient interview retrospective estimates were not in concordance with prospective estimates for 25% of all participants.[16] The study conducted two retrospective interviews for a small sub-sample and in contrast to the earlier findings showed a lower rate of discrepancy (11%) between retrospective estimates, which were obtained once the individual had recovered from the acute effects of the HI. Although the study suggests that a patient interview could provide a reliable estimate of PTA duration when conducted retrospectively, it did not explore the validity of this measure.

The current study will add to previous work by ascertaining the reliability and validity of a retrospective semi-structured interview previously shown to be a valid and reliable measure for severe HI [1], for mild-moderate HI. The study will explore reliability by exploring the relationship between estimates of PTA duration obtained in hospital and at follow-up, and validity by examining relationships between estimates of PTA duration and outcome.

AIMS AND HYPOTHESES

Aims

- To explore the relationship between estimates of PTA duration obtained in hospital and at follow-up for mild-moderate HI to ascertain reliability.
- To explore the relationship between estimate of PTA duration and outcome defined by the GOS-E and return to work information to ascertain validity.

Hypotheses

- 1. Initial and follow-up estimates of PTA duration will be highly positively correlated.
- 2. Estimates of PTA duration will be highly negatively correlated with outcome.

METHODS

Ethics

Ethics approval for the study was granted by the West of Scotland REC 2 and R&D approval from NHS Greater Glasgow and Clyde (see Appendix 2.1).

Participants

Participants were recruited from admissions to Glasgow Royal Infirmary (GRI), a hospital in the east of the city providing district general hospital, regional, supra-regional and national acute clinical services.

Inclusion Criteria

- Aged 16 years and above.
- Sustained a HI according to the following definition: Trauma or accelerationdeceleration movement to the head, resulting in loss of consciousness.
- Assessed by medical staff and deemed suitable for discharge at the point of initial assessment.

Exclusion Criteria

- Could not speak English.
- HI did not meet the above definition.

- Not deemed suitable for discharge by medical staff.
- In police custody within the hospital.
- Likely to pose risk to the researcher.

Measures

The Post-Concussion Symptoms Checklist (PCSC), which was used at the initial assessment (see appendix 2.3), is a valid and reliable screening measure for post-concussion symptoms following mild HI.[17] The Glasgow Outcome Scale-Extended (GOSE) was used at the follow-up assessment (see appendix 2.4), to provide a standardised measure of disability outcome. The scale has good validity and reliability.[18]

Procedure

The researcher described the study to potential participants, who were provided with an information sheet and asked to complete a consent form (see Appendix 2.2). Demographic data, GCS score and information regarding alcohol use at the time of injury, as assessed by medical staff when the individual arrived at hospital, were obtained from the medical notes once consent was granted. Participants were deemed able to provide informed consent at the point when medical staff concluded that the patient was no longer in a state of confusion or disorientation and was suitable for discharge. The initial assessment took place, in most cases, relatively soon after injury when the individual had emerged from PTA, but remained in the hospital.

Once consent was gained each participant was interviewed and a structured research pro-forma, which included the semi-structured interview and the PCSC, was completed

(see Appendix 2.3). Data collection was undertaken in combination with that of another research study. As such the pro-forma included an experimental memory assessment and elements of the Modified WPTAS, which will not be explored in this study.

Four questions provide the structure around which the semi-structured interview was based (see Appendix 2.3). Further questions were asked by the researcher according to participant responses. Participants were asked to describe each event they could remember in detail, i.e. what the doctor/nurse looked like who assessed them in A&E/on the ward. The end of PTA was taken as the time when the individual was able to provide detail about an event and could continue to do so for all following events.

Each participant was contacted by telephone one to six weeks after they completed the initial interview. The follow-up interview consisted of the same semi-structured interview used for the initial assessment as well as questions relating to the participant's return to work, and the GOS-E (see Appendix 2.4).

Due to difficulties in follow-up rates participants who did not have or could not remember a telephone number were sent a brief postal questionnaire (see Appendix 2.5) in the hope of obtaining enough information to provide an estimate of PTA and to complete the GOS-E.

Researchers

Two final year Trainee Clinical Psychologists completed the initial assessment with the majority of participants. Both had experience of using semi-structured interviews for clinical assessment purposes. Each Trainee was completing an independent research

study exploring PTA assessment, therefore data collection was combined to maximise recruitment rates for both studies.

Two further researchers became involved in the study. Some initial assessments were carried out by a Consultant in Emergency Medicine at GRI who assessed PTA routinely. Some of the follow-up assessments were completed by a Senior Research Nurse within the Department of Psychological Medicine with experience in the assessment of HI.

Estimation of Required Sample Size

McMillan *et al.* obtained a highly positive correlation (r = 0.87) between prospective and retrospective estimates of PTA duration for severe head injury (n = 79) suggesting that the semi-structured interview is a reliable assessment tool for this population. The study also showed significant relationships between retrospective estimate of PTA duration and various indices of outcome suggesting that the interview is a valid measure for this population.[1] This study aims to provide preliminary information regarding the validity and reliability of this measure for those with mild HI. On the basis of McMillan *et al.* a moderate effect size of 0.4 and power of 0.8 was used in a power calculation [19] to determine the required sample size for the study (n = 34).

Data Analysis

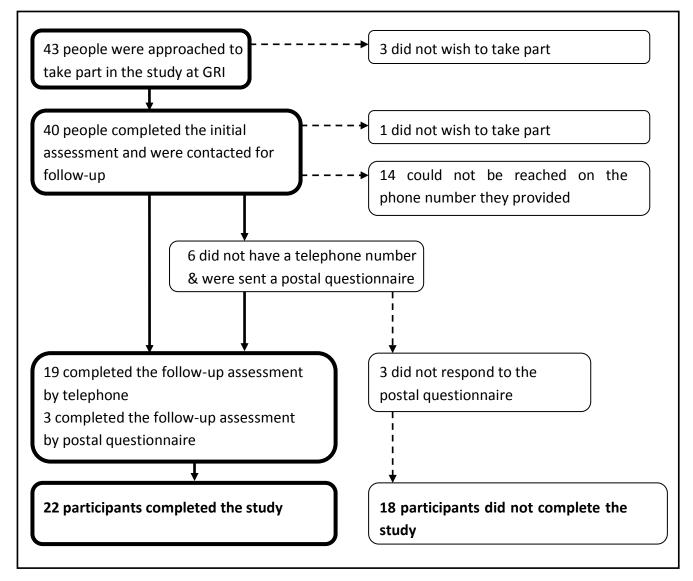
Given that estimates of PTA duration are subjectively rated, relationships between initial post-concussion symptoms (PCSC), outcome (GOSE) and duration of PTA will be explored using Spearman correlations.

RESULTS

Recruitment and Drop-Out Rates

Recruitment and drop-out rates are summarised in Figure 1. Forty participants agreed to take part in the study and completed the initial assessment during the hospital admission. Of these, nineteen completed the follow-up assessment via telephone, three completed it via postal questionnaire and eighteen were lost to follow-up.

Figure 1. Flowchart of pattern of recruitment, completion and drop-out



Demographic and Injury Information

Demographic and injury information are given in Table 1 for all participants who completed the initial assessment, including those who completed the study at follow-up and those who did not complete the study. Those who completed the study, and those who dropped-out after the initial assessment, did not differ in terms of age (t (38) = -1.213, p = 0.233), initial estimate of PTA duration (Mann Whitney U, Z = -1.050, p = 0.361) or GCS (Mann Whitney U, Z = -0.356, p = 0.789).

	All Participants Who Completed the Initial Assessment (n = 40)	Participants Who Completed the Study (n = 22)	Participants Who Only Completed the Initial Assessment (n = 18)
Mean Age	44.27 (22.113)	46.95 (22.135)	41.00 (22.268)
Age Range	17-86	18-86	17-83
Male	37 (92.5%)	20 (90.9%)	17 (94.4%)
Female	3 (7.5%)	2 (9.1%)	1 (5.6%)
Severity of Injury (GCS)			
Mild HI (13-15)			
GCS 13	-	-	-
GCS 14	11 (27.5%)	7 (31.8%)	4 (22.2%)
GCS 15	28 (70%)	14 (63.6%)	14 (77.8%)
Moderate HI (10-12)			
GCS 10	-	-	-
GCS 11	1 (2.5%)	1 (4.5%)	-
GCS 12	-	-	-
Alcohol at time of injury	35 (87.5%)	18 (81%)	17 (94.4%)
Method of Injury:			
Assault	13 (32.5%)	6 (27.3%)	7 (38.9%)
Fall	15 (37.5%)	11 (50%)	4 (22.2%)
Road Traffic Accident	2 (5%)	1 (4.5%)	1 (5.6%)
Other/Unknown	10 (25%)	4 (18.2%)	6 (33.3%)

Table 1. Demographic and Injury Information, mean and (SD) or frequency and (percent).

Of the forty participants who completed the initial assessment 92.5% were male, the mean age was 44.27, and, according to GCS, thirty-nine sustained a mild HI and one sustained a moderate HI. 87.5% of all participants were under the influence of alcohol when they sustained the injury. Only one of the forty participants was taking sedatives at the time of initial assessment and they did not complete the follow-up assessment. The most common mechanism of injury was a fall (37.5%).

The most commonly reported post-concussion symptoms at initial assessment were fatigue and headache. Table 2 details the number of participants who reported each symptom on the PCSC.

	Frequency (Percentage)		
Headache	17 (42.5%)		
Dizziness	10 (25%)		
Irritability	4 (10%)		
Memory Problems	7 (17.5%)		
Difficulty Concentrating	7 (17.5%)		
Fatigue	20 (50%)		
Visual Disturbances	5 (12.5%)		
Aggravated by Noise	7 (17.5%)		
Judgement Problems	3 (7.5%)		
Anxiety	9 (22.5%)		

Table 2. Number of Participants who Reported Each Symptom on the PCSC

Greater scores on the PCSC represent greater frequency, intensity and duration of symptoms. For each of these sub scales (duration, intensity, frequency) a score of ten is given if no complaints are reported and a score of fifty if maximum complaints are reported. For total score if no symptoms are reported a score of thirty is given and if the maximum frequency, duration and intensity of symptoms are reported a score of one hundred and fifty is given. Mean scores for each sub scale and total mean score are given

in Table 3.

Table 3. Mean Scores, Standard Deviation and Range for PCSC Sub-Scales and Total Score

	Mean	SD	Range
Frequency Sub-Scale	15.70	7.552	35 (10-45)
Intensity Sub-Scale	14.78	6.322	27 (10-37)
Duration Sub-Scale	16.48	8.443	40 (10-50)
Total	46.95	22.010	92 (30-122)

Estimates of PTA

Estimates of PTA duration have been given to the nearest whole hour (Table 4). More than half of the participants had an estimated duration of PTA of one hour at initial and follow-up assessment and around 90% within three hours.

	Initial PTA Estimate (N = 40)	Follow-up PTA Estimate (N = 22)
1 hour	23 (60.5%)	12 (54.5%)
2 hours	9 (23.7%)	7 (31.8%)
3 hours	2 (5.3%)	1 (4.5%)
4 hours	1 (2.6%)	1 (4.5%)
5 hours	-	-
6 hours	1 (2.6%)	1 (4.5%)
7 hours	1 (2.6%)	-
30 hours	1 (2.6%)	1 (4.5%)

Table 4. Duration of PTA Information

Relationship between Initial Estimate of PTA Duration and Post-Concussion Symptoms

Given that estimates of PTA are subjectively rated, relationships between PTA and other variables are explored using Spearman's rank correlation. The relationships between initial estimate of PTA duration and sub-scale scores were non-significant (Frequency: Spearman, rho = 0.093, p = 0.567; Intensity: Spearman, rho = 0.106, p = 0.514; Duration: Spearman, rho = 0.126, p = 0.438). The relationship between initial estimate of PTA duration and total score was also non-significant (Spearman, rho = 0.091, p = 0.578).

Eighteen participants reported having no symptoms or seldom having symptoms. The difference in estimates of PTA duration at initial assessment for this group and those who reported having symptoms 'often, very often or all the time' was not significant (Mann Whitney U, Z = -0.295, p = 0.798).

In the sections that follow data was analysed in two ways. Firstly data obtained from those who completed the follow-up interview via telephone and via postal questionnaire was combined for analysis. Secondly postal data was omitted and analyses repeated. Data was analysed in this way as the participants who completed the postal questionnaires provided less information to inform estimation of PTA duration.

Relationship between Initial and Follow-up Estimates of PTA Duration

Estimates of PTA were obtained at follow-up for twenty-two participants (nineteen via telephone and three via postal questionnaire). Figure 2 shows a scatter-plot of the relationship between the initial estimate and the follow-up estimate of PTA duration for telephone and postal data. Identical data points are presented alongside each other on the scatter-plot.

The correlation between initial and follow-up estimates of PTA duration was significant (Spearman, rho = 0.704, p<0.001). When the postal data was omitted the significant correlation increased (n = 19, Spearman, rho = 0.881, p<0.001), highlighting discrepancies

in the postal data, although these are relatively small in terms of actual time (see Figure 2).

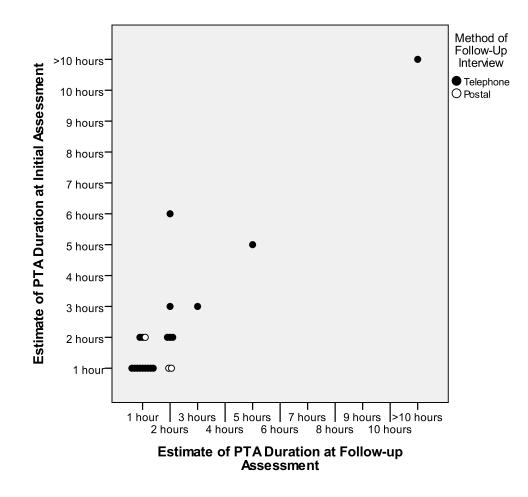


Figure 2. Association between initial and follow-up measures for PTA duration

Discrepancies in estimates of PTA duration were recorded for all three participants who completed the postal questionnaire and three out of the nineteen participants who completed the telephone interview. Four of the discrepancies represented a change in HI severity category according to PTA duration. Two changed from mild (PTA<1hr) to moderate (PTA>1hr) HI and two from moderate (PTA>1hr) to mild HI (PTA<1hr).

Relationship between PTA and GOS-E Categories

On the GOS-E 72.7% of participants were classified as good recovery and 27.3% as disabled at follow-up (see Table 5). No participants were classified as dead, in a vegetative state or lower severe disability.

Table 5. GOS-E Categories

	Frequency (Percent)		
Upper Severe Disability	1 (4.5%)		
Lower Moderate Disability	2 (9.1%)		
Upper Moderate Disability	3 (13.6%)		
Lower Good Recovery	4 (18.2%)		
Upper Good Recovery	12 (54.5%)		

The distribution of GOS-E scores according to median PTA can be seen in Table 6. The relationship between median PTA and GOS-E overall score was non-significant (Spearman, rho = 0.169, p = 0.451). The relationship remained non-significant when the postal data was omitted (Spearman, rho = 0.136, p = 0.578).

	Upper Severe Disability	Lower Moderate Disability	Upper Moderate Disability	Lower Good Recovery	Upper Good Recovery
1 hour	1	_	3	2	3
2 hours	-	1	-	-	7
3 hours	-	-	-	-	2
4 hours	-	-	-	1	-
5 hours	-	-	-	1	-
30 hours	-	1	-	-	-

PTA and Change in Dependence on the GOS-E

Of the twenty-two participants who completed the follow-up assessment, nine were working or studying prior to their injury. At follow-up five had returned to work/study fulltime, one was working reduced hours, and three had not yet returned to work. The median PTA for return to work/study was one hour (mild HI) and for partial/not return to work was two hours (moderate HI).

One participant, who was eighty-six years of age, reported being dependent on others both in and outside of the home due to physical difficulties as a result of a fall during which she sustained a mild HI (GCS = 14, PTA = 1hr). This participant obtained the lowest score on the GOS-E indicating upper severe disability.

Difficulty with regards to independence outside of the home was reported by one more participant, in that they could not travel independently. They had sustained a more severe injury according to PTA duration (30 hours) but not according to GCS (15).

Six participants reported being less involved in social and leisure activities than they had been prior to their injury (median PTA = 1hr, GCS = 15). One of these reported being unable to participate in any of their normal social and leisure activities due to anxiety about the assault that had caused the HI and the highly visible physical injuries they had sustained (median PTA = 2hrs, GCS = 15).

Three participants reported frequent psychological problems, again due to assault (median PTA = 1hr, median GCS = 15). Nine reported additional problems relating to the injury that affected them on a daily basis and stopped them from returning to normal life,

i.e. poor memory, poor concentration, headaches, dizziness and fatigue (median PTA = 1hr, median GCS = 15).

DISCUSSION

Main Effects

Reliability:

This study aimed to ascertain the reliability of the semi-structured retrospective interview by exploring the relationship between estimates of PTA duration obtained while the individual was in hospital and at follow-up between one to six weeks later. A highly significant positive correlation (rho = 0.704) between hospital and follow-up estimates of PTA duration was found, which increased when postal data were omitted (rho = 0.881). Each of these correlation coefficients represents a large effect size according to Cohen's definition.[20] The increase in the strength of the relationship when postal data were omitted highlighted the fact that there were discrepancies in estimates of PTA for all three participants who returned a postal questionnaire. Although this study only looked at data from three postal questionnaires it raises questions regarding the reliability of the measure in this format.

The correlation of 0.881, for the measure when completed verbally, is comparable to psychological assessment tools such as the widely used Wechsler Memory Scale III (WMS-III) [21] and to the GOS-E in terms of test retest reliability. The WMS-III has test-retest reliability ranging from 0.62 to 0.82 for the primary sub-tests of the scale and from 0.70 to 0.88 for the primary indexes of the scale [22] and the GOS-E has test-retest reliability of 0.85.[17] The correlation is also similar to the correlation of 0.87 found between

prospective and retrospective estimates of PTA duration for severe HI.[1] It can be concluded that as a retrospective assessment the semi-structured interview has good reliability for mild-moderate HI.

Validity:

This study also aimed to ascertain the validity of the semi-structured interview by exploring the well documented relationship between PTA duration and outcome.[23, 5-7] Outcome at one to six weeks after initial assessment measured by the overall GOS-E score was explored in relation to estimates of PTA duration; however, no significant relationship was found. The study did not obtain the required sample size to ensure that adequate power was achieved (see page 49) and as such conclusions regarding the validity of the measure cannot be made with confidence. Although a statistically significant relationship was not found for overall GOS-E score, the data suggest that specific aspects of outcome on the GOS-E (return to work, resuming social and leisure activities and psychological functioning) could be related to estimates of PTA duration providing some support for the validity of the interview.

The PCSC indicates early self-report of symptoms following HI, which are reflective of injury; however, no significant relationship between PTA and PCSC score was found. Again this may be related to sample size, however, it has been shown that scores on the PCSC may not relate to indices of injury severity such as loss of consciousness and length of stay in hospital. However, the relationship between PCSC and PTA has not been challenged.[17] It is difficult therefore to make conclusions regarding the validity of the interview according to this relationship.

Comparison with Other Studies

Previously the same semi-structured interview was shown to be a valid and reliable retrospective assessment measure for individuals with severe HI.[1] A similar semi-structured interview was found to be most reliable when completed after recovery from the acute effects of mild HI.[16] In the current study the semi-structured interview of McMillan *et al.* [1] was found to have good reliability for mild-moderate HI. Estimates of PTA duration obtained at initial assessment differed from those obtained at follow-up for 27% of the sample. However, when postal data were omitted this number fell to 16%, which is representative of the rate of discordance for the retrospective estimates of PTA duration obtained in the previous mild HI study.[16]

It is expected that PTA duration would be reliable in predicting outcome following mildmoderate HI.[24] However, this might only be clear when looking at specific aspects of outcome such as return to work rather than an overall GOS-E score as the data suggest in the current study. On such a gross measure of outcome as the GOS-E the majority of the mild HI population would be expected to make a good recovery, skewing the data set and making it difficult to interpret the findings. Less broad categories of outcome focusing on return to work, psychological functioning or return to social and leisure activities are more likely to be sensitive to differences in outcome for this population.

It has been shown in a previous study that a subgroup of participants with mild HI had poor outcome at three months post injury, which was not indicative of longer PTA duration.[25] The authors suggest that "a range of factors, other than those directly reflecting the severity of injury, appear to be associated with outcome".[25:pp568] This was supported in the current study as outcome for those who sustained a mild HI was more varied than hypothesised ranging from *upper severe disability* to *upper good recovery,* and factors such as method of injury, in particular assault, appear to have impacted upon recovery more than PTA duration. Due to the limited numbers of participants in each outcome category and for each category of injury exploration of the data in this way could not be reliably undertaken for the current study.

Strengths and Weaknesses

The majority of participants (87.5%) were under the influence of alcohol at the time of injury. This is characteristic in this clinical group, and impaired consciousness as a result of alcohol could lead to over-estimation of PTA duration. Hence, it is possible that alcohol intake might have influenced the relationship between PTA duration and outcome. It has previously been reported that "in Glasgow alcohol is an important factor contributing to the cause of head injury".[26] Given this statement the inclusion of these participants ensured that the study recruited a fully representative sample of participants. As such the conclusions drawn from the study can be generalised and applied to all Glasgow hospitals for patients attending with mild-moderate HI.

Within the study of McMillan *et al.* [1] the researcher who completed the retrospective assessments and estimates of PTA duration was blind to the prospective assessment until after the retrospective assessment was complete. This was not possible in the current study. The main author estimated PTA duration at initial and follow-up assessment for all participants taking several steps to minimise bias. Each estimate of PTA duration was made immediately following completion of the interview. After completion of the initial assessment the estimate of PTA duration was made from the information obtained and the estimate was entered into an electronic database. The follow-up estimate of PTA

duration was made immediately upon completion of the telephone interview without referring to the electronic database.

The modest sample size obtained at follow-up means that some of the findings cannot be interpreted with confidence in relation to the validity of the retrospective assessment interview, further research in this area is required. Unfortunately recruitment proved more difficult than assumed and even with four researchers working to undertake initial recruitment only forty participants were recruited in a five month period. The major challenge, however, proved to be in completing follow-up assessments. Only 55% of those recruited completed the study at follow-up, which is considerably lower than expected, for example, 73% completed the McMillan *et al.* Study.[1] Given the more favourable outcome of mild-moderate HI, individuals are more likely to resume previous activities relatively soon after the injury than they would if they had sustained a severe HI. As such contacting participants who have sustained a mild-moderate HI is likely to be more difficult as they may have returned to work or social and leisure activities and this was proven to be the case within the current study.

Practical Applications

A retrospective assessment interview has several important clinical applications. Firstly it is more convenient than prospective measures for medical staff who have limited time available to them. For mild-moderate HI PTA is relatively short and many patients will have emerged from PTA by the time they can be seen in hospital meaning that a prospective assessment cannot be undertaken. In the current study the majority of participants were deemed to have PTA duration of one hour. It is unlikely that all of these individuals would have arrived at the hospital and been assessed by medical staff

within an hour of their injury and as such prospective assessment could not have been used for 60.5% of the individuals who were recruited to this study. A retrospective assessment interview provides a reliable estimate of PTA duration for this population, which can be completed whenever the individual presents to hospital to provide an indication of injury severity, which could not in these circumstances be obtained from GCS score as this cannot be assessed retrospectively. In addition the estimate of PTA duration, which as previously highlighted could only be obtained by using the retrospective assessment interview for these individuals, would provide an estimate of likely outcome for the individual. This is of vital importance for medical staff in planning further care and potential rehabilitation needs, and for the individual and their family in order to plan for the future.

Future Studies

Given the findings of this study further research into the validity of this retrospective assessment method is suggested. Replicating the study with a larger and possibly more heterogeneous sample, in terms of PTA duration within the mild-moderate classification, is recommended. The data of the current study would also suggest that outcome on the GOS-E should be explored in terms of specific outcome categories such as return to work, return to social and leisure activities and psychological functioning for this population.

Improvement in rates of completion for follow-up assessments is of vital importance for future studies. Within the current study telephone follow-up was completed in an attempt to improve response rates by increasing convenience for participants. Unfortunately this method still resulted in a low response rate. Incorporating the followup assessment into routine hospital or GP follow-up appointments might prove helpful in improving recruitment rates; however, researchers should aim to initially recruit at least double the number of participants required at follow-up in order that this number is achieved.

Conclusion

Duration of PTA was first highlighted as an indication of the degree of damage to the brain and outcome following HI over seventy years ago. With regards to assessing PTA duration Russell suggested that the patient's memory of when he regained full consciousness would provide a "not inaccurate" indication of when they had emerged from PTA.[15:pp554] Although various methods of assessing PTA duration have been developed over the years this method of patient interview still seems most appropriate for the mild-moderate HI population who may not present to hospital immediately following injury. This study has shown a retrospective assessment interview to be reliable in this population; however, further work is required to ascertain its validity.

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CHAPTER THREE

ADVANCED CRITICAL PRACTICE I:

REFLECTIVE CRITICAL ACCOUNT ABSTRACT

Trauma, the Asylum System & Therapist Burnout

Kirsty Bell Department of Psychological Medicine Gartnavel Royal Hospital 1055 Great Western Road Glasgow G12 0XH Phone: 0141 211 3920 Fax: 0141 357 4899 k.bell.1@research.gla.ac.uk

ABSTRACT

The experience chosen to reflect upon was the most challenging experience within my clinical placement. It involved an extremely distressed client whose asylum claim had been refused and whose home was about to be removed and evoked feelings of hopelessness, frustration and exhaustion. During the reflective process I explored some of the literature around therapist burnout and therapist self-care, particularly when working in trauma services. The Model for Structured Reflection (Johns, 2009) was used to guide the reflective process.

When reviewing my reflection I explored different ways of recognising "success" within therapy. As such I hope to place less pressure on myself to facilitate impossible changes during therapeutic encounters and allow myself to facilitate client coping in the face of difficult situations that they cannot change. In relation to therapist burnout, a key trigger identified is the therapist being unable to perceive success in the treatment they provide for clients. I think that the reflective process has allowed me to become more aware of my own beliefs around therapeutic success, which in turn has made me more aware of the potential to experience therapist burnout.

CHAPTER FOUR

ADVANCED CRITICAL PRACTICE II:

REFLECTIVE CRITICAL ACCOUNT ABSTRACT

From Psychology Department to Community Mental Health Team -

Integration or Isolation?

Kirsty Bell Department of Psychological Medicine Gartnavel Royal Hospital 1055 Great Western Road Glasgow G12 0XH Phone: 0141 211 3920 Fax: 0141 357 4899 k.bell.1@research.gla.ac.uk

ABSTRACT

The New Ways of Working for Applied Psychologists document Working Psychologically in Teams (2005) makes a key recommendation that "Psychologists should seek to integrate their work within teams in a way that continues to promote their unique contribution to work with service users" (pp4. 2005). This recommendation has been echoed by the integration of Clinical Psychology Departments into Community Mental Health Teams (CMHTs) over recent years. There are many benefits of working this way, including the potential to improve service provision and the level of multi-disciplinary joint working.

This reflective account focuses upon the experience of being part of a Psychology Department in which each individual member has been integrated into a CMHT. It explores the process by which this change has taken place and the challenges the experience posed. Ultimately the account questions whether true integration is always possible and whether attempted integration can actually lead to isolation for individual team members.

The account highlights challenges that are being faced within the profession of Clinical Psychology and explores ways in which these challenges can be managed at an individual level and a service level. The reflective process has aided my own understanding of issues relating to the management and provision of Psychological services and will be of great relevance to me when I become a Clinical Psychologist.

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APPENDIX 1.1 - NOTES FOR CONTRIBUTORS JOURNAL OF NEUROLOGY, NEUROSURGERY & PSYCHIATRY

Manuscript format

All manuscripts must be submitted via Bench>Press.

All material submitted is assumed to be submitted exclusively to the journal unless the contrary is stated. Submissions may be returned to the author for amendment if presented in the incorrect format. If you are submitting a randomised controlled trial, please send with your manuscript the following:

The registration number of the trial and the name of the trial registry - in the last line of the paper's structured abstract. Trials that begin enrolment of patients after 1 July 2005 must register in a public trials registry at or before the onset of enrolment to be considered for publication. Trials that began patient enrolment on or before 1 July 2005 must register before 13 September 2005 to be considered for publication. Please see the Statement from the International Committee of Medical Journal Editors.

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Your cover letter should inform the Editor of any special considerations regarding your submission, including but not limited to:

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The title page **must** contain the following information:

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2. The name, postal address, e-mail, telephone and fax numbers of the corresponding author.

3. The full names, institutions, city and country of all co-authors.

4. Up to five keywords or phrases suitable for use in an index (it is recommended to use <u>MeSH</u> terms).

5. Word count - excluding title page, abstract, references, figures and tables.

Manuscript format

The manuscript format must be presented in the following order:

- 1. Title page
- 2. Abstract (or summary for case reports)

3. Main text (tables should be in the same format as your article and embedded into the document where the table should be cited; images must be uploaded as separate files)

- 4. Acknowledgments, Competing interests, Funding
- 5. Copyright licence statement
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Do not use the automatic formatting features of your word processor such as endnotes, footnotes, headers, footers, boxes etc. Provide appropriate headings and subheadings as in the journal. We use the following hierarchy: **BOLD CAPS, bold lower case**, Plain Text, *Italics*. Cite illustrations in numerical order (fig 1, fig 2 etc) as they are first mentioned in the text. Tables should be in the same format as your article and embedded into the document where the table should be cited. Images **must not** be embedded in the text file but submitted as individual files (view further details in File Formats.)

Filenaming convention

Where possible, please name your manuscript and image files as shown below. (Please note: the manuscript ID # appears at the top of each submission page as soon as you start your submission; author refers to the corresponding author's last name.)

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Statistics

Statistical analyses must explain the methods used. <u>Guidelines on presenting statistics.</u> <u>http://resources.bmj.com/bmj/authors - statsstatadvice.pdfGuidelines on RCTs: CONSORT,</u> <u>QUORUM, MOOSE, STARD, and Economic submissions.</u>

Style

Abbreviations and symbols must be standard and SI units used throughout except for blood pressure values which are reported in mm Hg. Whenever possible, drugs should be given their approved generic name. Where a proprietary (brand) name is used, it should begin with a capital letter. Acronyms should be used sparingly and fully explained when first used.

Figures/illustrations

Black and white images should be saved and supplied as **GIF**, **TIFF**, **EPS or JPEG** files, at a **minimum resolution of 300 dpi** and an image size of 9 cm across for single column format and 18.5 cm for double column format. **Colour** images should be saved and supplied as **GIF**, **TIFF**, **EPS or JPEG** files, to a **minimum resolution of 600 dpi** at an image size of 9 cm across for single column format and 18.5 cm for double column format. Images should be mentioned in the text and figure legends should be listed at the end of the manuscript. During submission, when you upload the figure files please label them as Figure 1, Figure 2, etc. The file label will not appear in the pdf but the order in which the figures uploaded should be sufficient to link them to the correct figure legend for identification. We can accept multi-page Powerpoint files. Alternatively, Powerpoint files can be saved as JPEG files and submitted as a standard image file. Histograms should be presented in a simple, two-dimensional format, with no background grid.

Please note: Do not submit colour figures unless you are willing to pay the cost of publishing your figures in colour. If you do not wish to pay the colour charges please submit your figures in black and white. The journal charges authors for the cost of reproducing colour images on all unsolicited articles. This charge is heavily subsidised by the journal and covers origination costs only. If an image is supplied as a **composite figure** that contains numerous parts (for example, fig 1A-D), the image will be considered as a single image, provided that all the parts are supplied within a single file that prints out at an overall size no larger that A4 (210 mm x 297 mm). The charge for **colour** processing will be **£100 + VAT** for the figure. Multi-part colour images supplied as **separate files will be charged at £100 + VAT** for each file. The charge only applies to images accepted for print publication and not online only or data supplement files. Care should be taken in planning composites because combining different images with widely varying colours can lead to contamination or loss of colour and poor quality results. When submitting your manuscript, please ensure to include a name and address where the invoice should be sent for the colour reproduction costs. If an address is not included, the invoice will be sent to the corresponding author.

Unacceptable file formats

Any file using OLE (Object Linking and Embedding) technology to display information or embed files, Bitmap (.bmp), PICT (.pict), Photoshop (.psd), Canvas (.cnv), CoreIDRAW (.cdr); Excel (.xls); and locked or encrypted PDFs are not acceptable.

Tables

Tables should be submitted in the same format as your article and embedded into the document where the table should be cited. Please note: Bench>Press **cannot** accept Excel files. If your table(s) are in Excel, copy and paste them into the manuscript file. In extreme circumstances,

Excel files can be uploaded as supplementary files; however, we advise against this as they will not be acceptable if your article is accepted for publication. Tables should be self-explanatory and the data they contain must not be duplicated in the text or figures.

References

Authors are responsible for the accuracy of references cited: these should be checked against the original documents before the paper is submitted. It is vital that the references are styled correctly so that they may be hyperlinked.

In the text

References must be numbered sequentially as they appear in the text. References cited in figures or tables (or in their legends and footnotes) should be numbered according to the place in the text where that table or figure is first cited. Reference numbers in the text must be given in square brackets immediately after punctuation (with no word spacing) - for example, .[6] not [6].Where more than one reference is cited, separate by a comma - for example, [1, 4, 39]. For sequences of consecutive numbers, give the first and last number of the sequence separated by a hyphen - for example, [22-25]. References provided in this format are translated during the production process to superscript type, which act as hyperlinks from the text to the quoted references in electronic forms of the article.

In the reference list

References must be double spaced (numbered consecutively in the order in which they are mentioned in the text) in the [slightly modified] Vancouver style. Only papers published or in press should be included in the reference list. (Personal communications or unpublished data must be cited in parentheses in the text with the name(s) of the source(s) and the year. Authors should get permission from the source to cite unpublished data.)

Punctuation of references must follow the [slightly modified] Vancouver style:

12 Surname AB, Surname CD. Article title. Journal abbreviation. Year;Vol:Start page-End page. Use one space only between words up to the year and then no spaces. The journal title should be in italic and abbreviated according to the style of Medline. If the journal is not listed in Medline then it should be written out in full. List the names and initials of all authors if there are 3 or fewer; otherwise list the first 3 and add et al.

Example references:

Journal

13 Koziol-Mclain J, Brand D, Morgan D, et al. Measuring injury risk factors: question reliability in a statewide sample. Inj Prev 2000;6:148-50.

Chapter in book

14 Nagin D. General deterrence: a review of the empirical evidence. In: Blumstein A, Cohen J, Nagin D, eds. Deterrence and incapacitation: estimating the effects of criminal sanctions on crime rates. Washington, DC: National Academy of Sciences 1978:95-139.

Book

(personal author or authors) (all book references should have specific page numbers) 15 Howland J. Social norms and drunk driving countermeasures. In Graham JD, ed. Preventing automobile injury: new findings from evaluative research. Dover, MA: Auburn House Publishing Company 1988:163-96.

Abstract/supplement

16 Roxburgh J, Cooke RA, Deverall P, et al. Haemodynamic function of the carbomedics bileaflet prosthesis [abstract]. Br Heart J 1995;73 (suppl 2):P37.

Electronic citations

Basically, websites are referenced with their URL and access date, and as much other information is given as is available. Access date is important as websites can be updated and URLs change. The "date accessed" can be later than the acceptance date of the paper, and it can be just the month accessed. See the 9th edition of the AMA Manual of Style for further examples.

Electronic journal articles

Morse SS. Factors in the emergency of infectious diseases. Emerg Infect Dis 1995 Jan-Mar;1(1). www.cdc.gov/nciod/EID/vol1no1/morse.htm (accessed 5 Jun 1998).

Use as much information as the author gives. The volume/number information in the URL will take the user to the start of the individual document; ask the author to supply or confirm. Also ask authors to supply the date they accessed the file.

Online First

Each Online First article has a unique Digital Object Identifier (DOI). This should be included in all citations.

BEFORE the article has appeared in an issue

Use the citation format:

Sabin MA, Ford AL, Holly JMP, Hunt LP, Crowne EC, Shield JPH. Characterisation of morbidity in a UK, hospital based, obesity clinic. Arch Dis Child. Published Online First: 24 October 2005. doi:10.1136/adc.2005.083485

AFTER the article has appeared in an issue

Use the citation format:

Sabin MA, Ford AL, Holly JMP, Hunt LP, Crowne EC, Shield JPH. Characterisation of morbidity in a UK, hospital based, obesity clinic. Arch Dis Child 2006; 91:126-130 doi:10.1136/adc.2005.083485 [published Online First: 24 October 2005].

Electronic Letters

Author. Title of letter. Journal name Online [eLetter] Date of publication. url eg: Krishnamoorthy KM, Dash PK. Novel approach to transseptal puncture. Heart Online [eLetter] 18 September 2001. <u>http://heart.bmj.com/cgi/eletters/86/5/e11#EL1</u>

Digital Object Identifiers (DOIs)

DOIs are a unique string created to identify a piece of intellectual property in an online environment, particularly useful for articles which have been published online before appearing in print (therefore the article has not yet been assigned the traditional volume, issue and page number reference). The DOI is a permanent identifier of all versions of an article, whether raw manuscript or edited proof, online or in print. Thus the DOI should ideally be included in the citation even if you want to cite a print version of an article.

How to cite articles before they have appeared in print

To cite an electronic article that has not yet appeared in print please use the following citation format:

1. Alwick K, Vronken M, de Mos T, et al. Cardiac risk factors: prospective cohort study. Ann Rheum Dis. Published Online First: 5 February 2004. doi:10.1136/ard.2003.001234

How to cite articles once they have appeared in print

Once the article has been printed the citation should also include the traditional year, volume and page numbers, as well as the DOI and original date of publication.

1. Vole P, Smith H, Brown N, et al. Treatments for malaria: randomised controlled trial. Ann Rheum Dis 2003;327:765-8 doi:10.1136/ard.2003.001234 [published Online First: 5 February 2004].

PLEASE NOTE: RESPONSIBILITY FOR THE ACCURACY AND COMPLETENESS OF REFERENCES RESTS ENTIRELY WITH THE AUTHORS.

Supplementary files

You may submit supplementary material which may support the submission and review of your article. This could include papers in press elsewhere, published articles, appendices, video clips, etc.

Online only material

Additional figures and tables, methodology, references, video clips, raw data, etc may be published online only to supplement the printed article. If your paper exceeds the word count you should consider if any of the article could be published online only as a "data supplement". These files will not be copyedited or typeset.

Bench>Press

All supplementary data files should be uploaded to Bench>Press using the supplementary file

section. These files are not converted to PDF but will be provided to reviewers and editors in the format in which you supply them.

APPENDIX 1.2 - METHODOLOGICAL QUALITY RATING CRITERIA

Recruitment & Participant Information Details of data collection period are given i.e. dates, number of years/months (1) No details of data collection period are given (0) A definition is given for the term used to describe participants' injuries (TBI, closed HI etc) (1) No definition is given for the term used to describe participants' injuries (0) Inclusion and exclusion criteria are stated (2) Inclusion or exclusion criteria are stated (1) Neither inclusion nor exclusion criteria are stated (0) Participant selection is by geographic cohort (3) Participant selection is by convenience sample (2) Participant selection is by some other means (1) It is not stated how participants were selected (0) Detailed demographic information of participants is given -3 + pieces of information (2) Limited demographic information of participants is given -1-2 pieces of information (1) No demographic information is given (0)

Severity of injury is defined according to GCS, duration of PTA or length of coma (2) Severity of injury is defined according to a different criteria (1)

It is not stated how severity of injury was defined (0)

It is stated which GCS score was used i.e. initial, highest, lowest (1)

It is not stated which GCS score was used (0)

Assessments – Outcome & PTA

It is stated when the outcome measure was completed in relation to time of injury (2)

It is stated when the outcome measure was completed in relation to hospital discharge (1)

It is not stated when the outcome measure was completed (0)

Follow-up times are standardised across subjects (1)

Follow-up times are not standardised across subjects (0)

Opt-in and drop-out rates are stated (2)

Opt-in or drop-out rates are stated (1)

Neither opt-in rates or drop-out rates are stated (0)

A validated measure* was used to obtain an estimate of duration of PTA (2)

Interview was used to obtain an estimate of duration of PTA (1) No detail of how PTA duration is assessed is given (0)

It is stated when the PTA assessment took place i.e. prospectively/retrospectively (1)

It is not stated when the PTA assessment took place (0)

It is stated who undertook the assessments and if they are trained in doing so (2)

It is stated who undertook the assessments (1)

It is not stated who undertook the assessments (0)

Analyses

Statistical results of the relationship between GCS/PTA and outcome are stated with p value (1)

Statistical results of the relationship between GCS/PTA and outcome are not stated (0)

Effect size is stated (1)

Effect size is not stated (0)

* Validated measures include GOAT, O'LOG & WPTAS

APPENDIX 2.1 - Letters Confirming Ethics and R&D Approval

West of Scotland REC 2 West of Scotland Research Ethics Service Western Infirmary Ground floor Tennent Institute 38 Church Street Glasgow G11 6NT e-mail: evelyn.macfadyen@ggc.scot.nhs.uk Telephone: 0141-211-1722 Facsimile: 0141-211-1847



Greater Glasgoand Clyde

26 November 2009

Miss Kirsty Bell 32 North Birbiston Road Lennoxtown East Dunbartonshire G66 7LZ

Dear Miss Bell

REC reference number:	09/S0709/79
Protocol number:	Version 2
Study Title:	Can a Brief Clinical Interview be used to Assess Duration of Post-Traumatic Amnesia Retrospectively?

The Research Ethics Committee reviewed the above application at the meeting held on 17 November 2009. Thank you for attending to discuss the study.

Ethical Opinion

The Committee asked the researcher several questions which were answered to their satisfaction, in particular:

1. The study participants will be shared with another study.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical Review of Research Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the Favourable Opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Continued...../

ivering better health

nhsggc.org.uk

26 November 2009

Letter to Miss K Bell.....continued/

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

Other conditions required by the REC

- In the protocol, section headed "Ethical Issues", last sentence, change to read "This study has been given a favourable opinion by West of Scotland Research Ethics Committee 2".
- 2. The researcher should be aware of and make allowance for the fact that the patient's recall of events when interviewed retrospectively may have been changed by other's recounts of the events that took place. It may be exceedingly difficult to assess whether the amnesia is the patients own or that effectively delivered to them by other people and the researcher will have a limited ability to assess the historical facts.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved Documents

-

The documents reviewed and approved at the meeting were:

Document	Version	Date
REC application	-	30 October 2009
Protocol	Version 2	3 July 2009
Participant Information Sheet	Version 1	23 October 2009
Participant Consent Form	Version 1	23 October 2009
Referees or other scientific critique report	-	14 July 2009
Interview Schedules/Topic Guides	Version 1	23 October 2009
Questionnaire: Validated - Modified Westmead Post Traumatic Amnesia Scale	-	23 October 2009
Supervisor's CV	-	-
Assessment Mark Sheet	-	17 June 2009
Investigator CV	-	30 October 2009

Continued...../

-2-

26 November 2009

Letter to Miss K Bell.....continued/

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of Compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After Ethical Review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/S0709/79 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

in Macka Dr S Langridge

Chair

Enclosures: List of names and professions of members who were present at the meeting "After ethical review – guidance for researchers"

Copy to: Darren Gibson, NHS Greater Glasgow and Clyde

w. Beller an Internetienen.

Coordinator/administrator: Darren Gibson/Elaine O'Donnell Telephone Number: 0141 211 6208 Fax Number: 0141 211 2811 E-Mail: <u>Darren.Gibson@ggc.scot.nhs.uk</u>

water and the second

11 January 2010

Mr Alastair Ireland Clinical Director Glasgow Royal Infirmary Jubilee Building 84 Castle Street Glasgow G4 0SF

R&D Management Approval

Greater Glasgow

R&D ManagdmGnyOffice Western Infirmary

Tennent Institute 1st Floor, 38 Church Street Glasgow, G11 6NT

Dear Mr Ireland,

Project Title: Can a Brief Clinical Interview be used to Assess Duration of Post-Traumatic Amnesia Retrospectively? Chief Investigator: Ms Kirsty Bell R&D Reference: GN09CP562 Protocol: Version 2 03/07/09

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant Management Approval for the above study.

As a condition of this approval the following information is required during the lifespan of the project:

- 1. SAES/SUSARS If the study is a **Clinical Trial** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004 (CTIMP only)
- 2. Recruitment Numbers on a quarterly basis (not required for commercial trials)
- 3. Any change of Staff working on the project named on the ethics form
- 4. Change of CI
- 5. Amendments Protocol/CRF etc
- 6. Notification of when the Trial / study has ended
- 7. Final Report
- 8. Copies of Publications & Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Yours sincerely

Dr Darren Gibson Research Co-ordinator

Cc Ms Kirsty Bell

Delivering better health www.nhsggc.org.uk



CAN A BRIEF CLINICAL INTERVIEW BE USED TO ASSESS DURATION OF POST-TRAUMATIC AMNESIA RETROSPECTIVELY?

Information Sheet

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Please ask if there is anything that is not clear or if you would like more information.

Who is conducting the research?

The research is being carried out by Kirsty Bell, Trainee Clinical Psychologist from the Department of Psychological Medicine, Gartnavel Royal Hospital.

Why is the study being carried out?

The study is being carried out as part of the requirements of the Doctorate in Clinical Psychology training course at the University of Glasgow. The study will investigate whether a short interview can be used with individuals who have had a brain injury to find out how long after the injury their memory for everyday events returned.

Why have I been invited?

You have been invited to take part in this study because you have attended the hospital after having an injury that resulted in you losing consciousness for a period of time.

Do I have to take part?

It is up to you to decide. One of the research team will describe the study and go through this information sheet, which they will then give to you. You will be asked to sign a consent form to

show that you have agreed to take part. You are free to withdraw at any time, without giving reason. This would not affect the standard of care you receive or your future treatment.

What does taking part involve?

Before you leave the hospital you will be asked several questions about what you can remember from before and after your injury and what you can remember today. Kirsty Bell will contact you by telephone within one month to ask you some of these questions again. During this telephone interview you will also be asked some questions about how you have been getting on since you left the hospital.

What happens to the information?

Your identity and personal information will be completely confidential and known only to the researchers so that you can be contacted to complete the second interview. The information obtained will remain confidential and will be stored within a locked filing cabinet. The data are held in accordance with the Data Protection Act, which means that we keep it safely and cannot reveal it to other people, without your permission.

What are the possible benefits of taking part?

It is hoped that by taking part in this research, you will be providing valuable information regarding how best medical staff can measure levels of confusion and memory loss for people who have had an injury like yours. This is important as more convenient measurement techniques will help to improve assessment of people's needs following injury.

Who has reviewed the study?

The study has been reviewed by the NHS West of Scotland Research Ethics Committee.

If you have any further questions?

We will give you a copy of the information sheet and signed consent form to keep. If you would like more information about the study and want to speak to someone else about them, please contact:

Professor Tom McMillan Department of Psychological Medicine Academic Centre, Gartnavel Royal Hospital 1055 Great Western Road, G12 0XH Tel: 0141 2113920 t.m.mcmillan@clinmed.gla.ac.uk Alastair Ireland Clinical Director, Emergency Medicine Glasgow Royal Infirmary 84 Castle Street, G4 0SF Tel: 0141 2114000 <u>Alastair.Ireland@ggc.scot.nhs.uk</u>

Researcher Contact Details:

Kirsty Bell, Trainee Clinical Psychologist Department of Psychological Medicine Academic Centre, Gartnavel Royal Hospital 1055 Great Western Road, G12 0XH Tel: 0141 2113920 <u>k.bell.1@research.gla.ac.uk</u>

What if you have a complaint about any aspect of the study?

If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint mechanism is also available to you.

Thank-you for your time and co-operation



Department of Psychological Medicine Academic Centre, Gartnavel Royal Hospital 1055 Great Western Road, G12 0XH

Subject number:

CAN A BRIEF CLINICAL INTERVIEW BE USED TO ASSESS DURATION OF POST-TRAUMATIC AMNESIA RETROSPECTIVELY?

Consent Form

Please initial the box

I confirm that I have read and understand the information sheet dated 23/10/2009
(version 1) for the above study and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

I understand that sections of my medical notes may be looked at by the research team where it is relevant to my taking part in the research. I give my permission for the research team to have access to my records.

I agree to take part in the above study.

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

1 copy to the patient, 1 copy to the researcher, 1 Original for the patients' notes

APPENDIX 2.3 – Research Pro-forma

	<u>Research Proforma</u>	GCS:
1)	.) Name: Date: _	
2)	?) Age:	
3)	3) Gender: Male 🗌 🛛 Female 🗌	
4)	Address usually residing at:	
5)	Telephone No: and/or Mo	bile No:
6)	5) Injury:	
7)	7) Date of Injury:	
8)	3) Date Admitted:	
9)) Discharge Date:	
10)	.0) Where interview taking place (i.e. A & E/Ward):	
11)	1) Taking any sedatives at time of testing? Yes 🗌	No 🗌
12)	2) Under influence of alcohol at time of injury? Yes] No 🗌
13)	.3) Under influence of alcohol at time of testing? Yes [No 🗌
14)	4) How old are you? Correct 🗌 Incorrect	:
15)	5) What is your date of birth? Correct 🗌	Incorrect
16)	.6) Show photo of face, ask patient to remember face,	identify person in photo as Kathryn and
	ask patient repeat and remember name. If the pati	ent cannot repeat the name tell them it

again.

- 17) Show each of the 3 pictures for about 5 seconds; cup, keys, bird and ensure they can repeat the names of each object.
- 18) Ask patient to repeat and remember 3 words which you will tell them; sock, mirror, umbrella. If the patient cannot repeat the words say them again.
- 19) What month are we in? Correct 🗌 Incorrect 🗌
- 20) What time of day is it? (If no answer prompt, "Is it morning, afternoon or evening?") Correct
 - Incorrect
- 21) What year are we in? Correct 🗌 Incorrect 🗌
- 22) What is the name of this place? ("Is it home, the Royal Infirmary or the Western Infirmary?")Correct https://www.correct
- 23) Ask patient the following series of questions. Please stress that you would like to know what they remember, not what others have told them. If they have difficulty remembering, please use the 'prompt' questions at the bottom of this section. If this section (23) takes longer than 5 minutes, go on to question 24 to 29 and finish completing this section afterwards.
- a) What's the first thing you remember after being injured? Details:
- b) What's the next thing you remember? Details:_____
- c) What happened next? Details: ______
- d) (Ask relevant question about today) i.e. What did you have for breakfast? Did anyone visit you today? etc Details: ______

Prompts: Do you remember; Coming to hospital? Being in casualty? Being in intensive care unit? Being on ward NSU/DHG/rehab? Being taken to another hospital? Going home from hospital? Special event (birthday/XMAS)?

24) Face. Ask "Can you id	entify which of t	these faces have you seen before?" (From choice of 6.		
Always use photo 4.)	Correct 🗌	Incorrect		
25) Name. Ask patient, "	What is this pers	on's name?"(If no answer, prompt Alex, Michelle,		
Kathryn) Correct 🗌	Incorrect]		
26) Ask "What were the 3	8 pictures I show	ved you earlier?"		
Picture 1 (cup)	Recalled 🗌	Not Recalled		
Picture 2 (keys)	Recalled 🗌	Not Recalled		
Picture 3 (bird)	Recalled 🗌	Not Recalled		
27) If patient does not rea	call all 3, ask pat	ient to identify pictures from series of 9 pictures).		
Picture 1 (cup)	Recalled	Not Recalled		
Picture 2 (keys)	Recalled 🗌	Not Recalled		
Picture 3 (bird)	Recalled 🗌	Not Recalled		
28) Do you remember;				
The 3 words I asked you to memorise earlier?				
Word 1 (sock)	Recalled 🗌	Not Recalled		
Word 2 (mirror)	Recalled 🗌	Not Recalled		
Word 3 (umbrella)	Recalled 🗌	Not Recalled		

29) If recall is not perfect ask – Can you tell me which three words I asked you to remember from this list?– read list of 9 words; picture, table, fruit, mirror, telephone, car, sock, umbrella, bicycle.

Word 1 (sock)	Recalled 🗌	Not Recalled
Word 2 (mirror)	Recalled 🗌	Not Recalled
Word 3 (umbrella)	Recalled 🗌	Not Recalled 🗌

30) Postconcussion Syndrome Checklist

Please fill out the following form by asking the patient to verbally rate each item for you based on how they feel today.

	FREQUENCY	INTENSITY	DURATION
	1 = Not at all	1 = Not at all	1 = Not at all
	2 = Seldom	2 = Vaguely present	2 = A few seconds
	3 = Often	3 = Clearly present	3 = A few minutes
	4 = Very often	4 = Interfering	4 = A few hours
	5 = All the time	5 = Crippling	5 = Constant
Headache			
Dizziness			
Irritability			
Memory Problems			
Difficulty Concentrating			
Fatigue			
Visual Disturbances			
Aggravated by Noise			
Judgment Problems			
Anxiety			

APPENDIX 2.4 – Follow-up Interview & GOS-E

A few weeks ago you agreed to take part in a research study at Glasgow Royal Infirmary that involved answering some questions at the hospital and answering a few questions over the telephone a few weeks later. Do you have time to answer a few questions just now?

Firstly I'd like to know what you remember about your injury but I would like to know everything you can remember not what other people have told you happened.

a) Can you remember what happened to you?

b) What is the first thing you remember after being injured?

c) What is the next thing you can remember?

d) What happened next?

e) What did you have for breakfast?

Prompts: Do you remember ... going to the hospital? Being in accident & emergency? Being in intensive care? Being on the ward? Being taken to another hospital? Going home from hospital? Special event i.e. (birthday/Xmas)?

I've got just a few more questions to see how you are getting on since you had your injury.

- 1. Do you have any physical difficulties as a result of your injury?
- 2. Do you require assistance to complete any day to day tasks and activities?
- 3. Do you have any difficulties since your injury with things such as your memory, how quickly you can process information and understanding information you are given?

4.	Did you work before your injury?	Yes	Go to question 5
		No	Go to question 8
5.	Have you been able to return to work?	Yes	Go to question 6
		No	Go to question 7

- 6. Are you working the same hours as you were prior to your injury?
- 7. Do you have a planned return to work date?
- 8. Are able to do everything that you used to before your injury?

Glasgow Outcome Scale - Extended

Patient's name:		Date of interview:		
Patient's name: Date of Birth:	_ Date of injury	Gender: M / F		
Age at injury: I	nterval post-injury:			
Respondent: Patient alone				
Patient + relative/ friend/ care	r Interviewer:			
CONCOURNERS				
CONSCIOUSNESS 1 Is the head injured person a	ble to obey simple	1 = No (VS)		
commands, or say any word		2 = Yes		
in any other way is no longer cons	idered to be in the vegetative state eness. Corroborate with nursing st	any word or communicate specifically e. Eye movements are not reliable aff. Confirmation of VS requires full		
INDEPENDENCE IN THE HOM				
2a Is the assistance of another some activities of daily livin	person at home essential every da	y for $1 = No$ 2 = Yes		
	ig :	2 - 168		
they need not actually look after the following activities: getting wa	nemselves. Independence includes ashed, putting on clean clothes wit nd handling minor domestic crises	ome for 24 hours if necessary, though the ability to plan for and carry out hout prompting, preparing food for s. The person should be able to carry e capable of being left alone		
2b Do they need frequent help the time?	or someone to be around at home	most of $1 = No$ (Upper SD) 2 = Yes (Lower SD)		
For a 'No' answer they should be a necessary, though they need not ac		ome for up to 8 hours during the day if		
2c Was assistance at home ess	ential before the injury?	1 = No		
	5.5	2 = Yes		
INDEPENDENCE OUTSIDE TH 3a Are they able to shop witho		1 = No (Upper SD) 2 = Yes		
This includes being able to plan w public. They need not normally sh		mselves, and behave appropriately in		
3b Were they able to shop with	nout assistance before the injury?	1 = No 2 = Yes		
4a Are they able to travel local	ly without assistance?	1 = No (Upper SD) 2 = Yes		
They may drive or use public transport to get around. Ability to use a taxi is sufficient, provided the person can phone for it themselves and instruct the driver.				
4b Were they able to travel wit	hout assistance before the injury?	1 = No 2 = Yes		

WORF	ζ		
	Are they currently able to work to their previous capacity?	1 = No 2 = Yes	
seeking the lev	were working before, then their current capacity for work should be at the g work before, then the injury should not have adversely affected their char el of work for which they are eligible. If the patient was a student before i dy should not have been adversely affected.	ances of obtaining work or	
5b	How restricted are they?a) Reduced work capacity.b) Able to work only in a sheltered workshop or non-competitive job, or currently unable to work.	1 = a (Upper MD) 2 = b (Lower MD)	
	Were they either working or seeking employment before the injury (answer 'yes') or were they doing neither (answer 'no')?	1 = No 2 = Yes	
SOCIA 6a	AL & LEISURE ACTIVITIES Are they able to resume regular social and leisure activities outside home?	1 = No 2 = Yes	
They need not have resumed all their previous leisure activities, but should not be prevented by physical or mental impairment. If they have stopped the majority of activities because of loss of interest or motivation then this is also considered a disability.			
6b	What is the extent of restriction on their social and leisure activities?a) Participate a bit less: at least half as often as before injury.b) Participate much less: less than half as often.c) Unable to participate: rarely, if ever, take part.	1 = a (Lower GR) 2 = b (Upper MD) 3 = c (Lower MD)	
бс	Did they engage in regular social and leisure activities outside home before the injury?	1 = No 2 = Yes	
EANCE			
FAMII 7a	LY & FRIENDSHIPS Have there been psychological problems which have resulted in ongoing family disruption or disruption to friendships?	1 = No 2 = Yes	
Typical post-traumatic personality changes: quick temper, irritability, anxiety, insensitivity to others, mood swings, depression, and unreasonable or childish behaviour.			
7b	What has been the extent of disruption or strain?a) Occasional - less than weeklyb) Frequent - once a week or more, but tolerable.c) Constant - daily and intolerable.	1 = a (Lower GR) 2 = b (Upper MD) 3 = c (Lower MD)	
7c	Were there problems with family or friends before the injury?	1 = No 2 = Yes	
If there were some problems before injury, but these have become markedly worse since injury then answer 'No' to Q7c.			

RET 8a	URN TO NORMAL LIFE Are there any other current problems relating to the injury which affect daily life?	1 = No (Upper GR) 2 = Yes (Lower GR)
	r typical problems reported after head injury: headaches, dizziness, tiredness, slowness, memory failures, and concentration problems.	s, sensitivity to noise or
8b	Were similar problems present before the injury?	1 = No 2 = Yes
	ere were some problems before injury, but these have become markedly work rer 'No' to Q8b.	se since injury then

Epilepsy:

Since the injury has the head injured person had any epileptic fits? No / Yes Have they been told that they are currently at risk of developing epilepsy? No / Yes What is the most important factor in outcome? Effects of head injury _____ Effects of illness or injury to another part of the body _____ A mixture of these ____

Scoring: The patient's overall rating is based on the lowest outcome category indicated on the scale. Refer to Guidelines for further information concerning administration and scoring

Dead
 Vegetative State (VS)
 Lower Severe Disability (Lower SD)
 Upper Severe Disability (Upper SD)
 Lower Moderate Disability (Lower MD)
 Upper Moderate Disability (Upper MD)
 Lower Good Recovery (Lower GR)
 Upper Good Recovery (Upper GR)

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APPENDIX 2.5 – Postal Questionnaire

Please only write what you can remember not what other people have told you about what happened or what you think might have happened. If you don't remember any of these things it is ok to say so.

- 1. What were you doing immediately before your injury?
- 2. What is the first thing you can remember after your injury?
- 3. How did you get to the hospital?
- 4. Who did you talk to in Accident and Emergency? Describe what they looked like:
- 5. How did you get to the ward?
- 6. Who did you talk to on the ward? Describe what they looked like:
- 7. Have you had any physical difficulties since you had your injury?
 (please circle your answer) YES NO
- 8. Have you had any difficulties with your concentration or your memory since you had your injury? (please circle your answer) YES NO
- Are you able to do everything you could without help before your injury? (please circle your answer) YES NO If your answer is no please give details of what you need assistance with:
- 10. If you were working before your injury have you returned to work or do you have a date when you will return to work? (please circle your answer) YES NO

THANK YOU FOR YOUR HELP

APPENDIX 2.6 – Major Research Project Proposal

ABSTRACT

Background: Duration of Post-traumatic Amnesia (PTA) is indicative of severity and outcome following brain injury. PTA must be assessed to ensure that the correct management procedure is followed. Prospective assessment of PTA can be difficult in less severe head injuries. This study will explore the relationship between prospective and retrospective measures of PTA duration.

Aims:

- To explore the relationship between prospective and retrospective estimates of duration of PTA
- To explore any differences between the prospective and retrospective estimates of duration of PTA
- To explore the relationship between estimate of duration of PTA and Glasgow Outcome Scale (GOS) score

Methods: Approximately 70 participants will be invited to complete a semi-structured interview prospectively and retrospectively. Each participant will also complete the GOS during retrospective assessment.

Applications: Prospective assessment of PTA duration for less severe brain injuries can be difficult. A brief clinical interview that can be used retrospectively would be ideal for assessing PTA duration for individuals presenting with these kinds of injury. If prospective and retrospective estimates are highly correlated and are highly correlated

with outcome measures it will provide evidence for undertaking this type of assessment whether the patient attends hospital immediately or after a delay.

INTRODUCTION

Traumatic brain injury (TBI) is associated with loss of consciousness, post-traumatic amnesia (PTA) and/or focal neurological signs (Kruijk, Twinstra & Lefers, 2001). The injury can be classified as mild, moderate or severe according to level of consciousness upon arrival at hospital, known as the Glasgow Coma Score (GCS), and duration of PTA. GCS is determined by rating an individual's level of consciousness according to their best eye response, best verbal response & best motor response. As well as providing an indication of the severity of the injury GCS and duration of PTA are thought to be the best predictors of outcome following TBI (Kruijk, Twinstra & Lefers, 2001). Duration of PTA provides an indication of recovery and functional outcome (Ahmed, Bierley, Sheikh & Date, 2000) and in mild to moderate brain injury duration of PTA as opposed to GCS upon arrival at hospital, is the best predictor of outcome (Van der Naalt *et al.* 1999).

PTA is the transient state of confusion and disorientation following a TBI. It is a measure of impaired consciousness, which is characterised by intellectual and behavioural disturbances. Duration of PTA is generally taken as the time from receiving a TBI to regaining normal continuous memory, including all periods of unconsciousness, confusion and disorientation for whatever reason (King *et al.* 1997). Longer lengths of PTA were initially recognised to predict poorer outcome by Symonds & Russell (1943, cited in Russell & Nathan 1946) thus indicating the usefulness of PTA assessment in determining prognosis and indicating the need for further research to confirm this. This finding has

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since been replicated and it is widely accepted that longer durations of PTA are predictive of poorer functional outcome (Van der Naalt *et al.* 1999).

Around 100,000 people attend hospital every year in Scotland with a head injury (Scottish Intercollegiate Guidelines Network, 2000). Those whose injury involves a loss of consciousness will be deemed to have sustained a TBI. SIGN Publication Number 46: Early Management of Patients with a Head Injury (2000) recommends that any individual who presents to A&E in a conscious state but has continuing amnesia for more than five minutes after the injury should be admitted to hospital. This highlights the importance of being able to assess duration of PTA and raises questions in terms of the most clinically effective and convenient method of doing so.

PTA can be assessed prospectively or retrospectively. Prospective measurement of PTA generally involves completing serial assessments at specific time intervals during the period of amnesia, while the individual remains in hospital. Many standardised measures have been developed to assess PTA prospectively such as the Galveston Orientation and Amnesia Test (GOAT). These assessment measures generally involve gaining information from the individual regarding their orientation to time and place as well as gaining information regarding the point at which the individual regains continuous memory. The GOAT has been criticised as the assessment of new learning and memory is important (Ponsford *et al.* 2004). In response several measures, such as the Westmead PTA Scale, include a basic assessment of verbal memory recall and recognition protocol in addition to orientation questions (Ponsford *et al.* 2004). Although prospective measures provide a

thorough assessment of PTA duration they are potentially limited in that they require to be repeated regularly, which may cause practical issues clinically (King *et al.* 1997).

Retrospective measurement usually involves conducting one or more assessments once the individual is deemed to have emerged from PTA, generally when they have left the hospital. These assessments rely upon obtaining information from the individual regarding orientation and first continuous memories following the traumatic brain injury. Retrospective assessment often takes the form of a semi-structured interview exploring various events that will have taken place since the individual sustained the injury, such as travelling in the ambulance or arriving at the hospital. As such, information is required from the hospital staff, patient records and/or family and friends to confirm whether the individual is responding correctly.

Some authors consider retrospective methods of assessment to be less reliable in assessing duration of PTA than prospective measures (Ponsford *et al.* 2004). One study has shown that retrospective assessments of duration of PTA are not in concordance with prospective assessments for 25% of participants who had sustained a mild head injury (Gronwall & Wrightson, 1980). However some of the arguments raised for the inaccuracy of retrospective assessments can also be applied to prospective assessments. 'Islands' of memory sometimes emerge for special events during PTA, often when the individual is less confused and more able to converse in an appropriate manner and so PTA can be underestimated (Russell & Nathan, 1946). Individuals can also appear to be lucid when in fact they are still in a state of considerable disorientation and as such the duration of PTA can also be underestimated in this way (Saeeduddin *et al.* 2000).

It appears that only one study has made a direct comparison of prospective and retrospective methods. McMillan, Jongen & Greenwood (1996) undertook a study that directly compared the two assessment methods in a population of individuals who sustained a severe head injury. The study measured duration of PTA prospectively using the GOAT and retrospectively using a structured interview and found no significant difference between the two. Upon further analyses the duration of PTA obtained retrospectively was shown to be highly correlated (r = 0.87) with the duration of PTA obtained obtained prospectively. It was concluded therefore that retrospective measurement of PTA is a valid assessment method for individuals who have sustained a severe head injury. King *et al.* (1997) developed a retrospective assessment protocol and assessed its inter-rater reliability across the full range of severity, however the study did not focus on the relationship between prospective and retrospective measurement of PTA.

The findings of McMillan, Jongen & Greenwood (1996) highlight the need to explore this area across the full range of severity of brain injury. If this highly positive correlation is found for less severe brain injuries it will provide evidence for the use of a retrospective interview. There are inherent difficulties in assessing PTA duration in less severe brain injuries due to the shorter period of amnesia, such as the individual having emerged from PTA by the time they arrive at A&E, which means that a retrospective assessment tool would be more beneficial clinically.

The current study will utilise a semi-structured interview in order to directly compare estimates of PTA duration obtained prospectively and retrospectively. The relationship between these estimates and outcome measures will also be explored to ascertain whether the measures are predictive of outcome and thus whether the assessment is

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providing a reasonable estimate of PTA duration. The Glasgow Outcome Scale (GOS) is one of the most widely used methods for assessing outcome following head injury (Jennett & Bond, 1975; Kaye & Andrewes, 2000) and will be used along with some additional questions to assess outcome following head injury.

Aims and Hypotheses

Aims

- To explore the relationship between prospective and retrospective estimates of PTA duration following mild, moderate and severe brain injuries
- To explore any differences between the prospective and retrospective estimates of PTA duration
- To explore the relationship between estimate of PTA duration (prospective and retrospective) and GOS score

Hypotheses

- Prospective and retrospective estimates of PTA duration obtained via interview will be highly correlated
- 2. There will be no significant difference between prospective and retrospective estimates of PTA duration obtained via interview
- Both prospective and retrospective estimates of PTA duration obtained via interview will be highly correlated with outcome measures
- 4. Longer duration of PTA will be highly correlated with poorer functional outcome

Plan of Investigation

Participants

<u>Inclusion Criteria</u>: Approximately 70 adults (aged 16 and over) who have attended hospital following a trauma or acceleration-deceleration movement to the head, which resulted in a loss of consciousness, will be invited to participate in the study.

<u>Exclusion Criteria</u>: Individuals who do not speak English will be excluded from the study as they will require the assessment to be modified thus introducing variation into the assessment method. The study is focusing upon adults therefore children under the age of 16 will be excluded from the study.

Individuals who were under the influence of alcohol when they sustained their injury will not be excluded from the study. The use of alcohol prior to obtaining a brain injury will have an impact upon measuring PTA as the period of confusion could be due to the effects of alcohol as well as the actual trauma. However duration of PTA is generally taken as the time from receiving a TBI to regaining normal continuous memory, including all periods of unconsciousness, confusion and disorientation for **whatever reason** (King *et al.* 1997). Therefore individuals who remain disorientated partly as a result of alcohol will be included and as the study will not explore between subject differences this will not affect the results.

Recruitment Procedures

Participants for the study will be recruited from Glasgow Royal Infirmary. The majority of the participants will be recruited from Ward 52, which has a maximum inpatient stay of four weeks for those who have sustained a brain injury. Participants may also be recruited from the Accident & Emergency Department at the hospital. Medical staff will provide details of patients who have sustained a brain injury and could therefore take part in the study.

Measures

Participants will complete a semi-structured interview, used in a previous study by McMillan, Jongen & Greenwood (1996), to assess duration of PTA. The assessment focuses on participants' recall of landmark events following their injury i.e. being taken to hospital, being in A&E. Participants who consent to being followed up will complete the same interview retrospectively via telephone as well as the GOS, and additional questions relating to return to employment, to assess outcome following injury.

Design

The study will be a non-experimental quantitative design. It will employ a correlational design to explore the relationship between the two primary variables, prospective estimate of duration of PTA and retrospective estimate of duration of PTA.

Research Procedures

As researcher I will contact ward staff to ascertain when potential participants are admitted and when they are likely to be discharged and will visit the hospital accordingly to conduct the prospective assessments. When visiting the hospital I will also visit the A&E department to see if any individuals who have attended with brain injuries are suitable to take part in the study.

Each participant will complete prospective assessment whilst in hospital immediately prior to discharge. Medical staff will advise when patients are likely to be discharged so that the prospective assessment can be conducted and informed consent gained prior to

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the patient leaving the hospital (see ethical considerations for further details). At this stage details of severity of head injury will also be obtained from the medical notes. If the results of the assessment suggest that the individual remains in a confused state medical staff would be informed and the individual would be re-assessed at a later stage prior to the new agreed time of discharge.

Upon completion of the assessment each individual will receive an information sheet describing the study and will be asked if they give their consent to take part and be contacted one to four weeks later to complete the assessment measures. Although the time period stipulated to obtain retrospective data may result in outcome being assessed at different stages for all participants, it will allow for potential difficulties in contacting those individuals who consented to undertaking a follow-up assessment. The participants will be contacted by telephone to complete the retrospective assessment and the GOS.

As around 70 participants are required to take part in the study I will work alongside another University of Glasgow DClinPsy trainee conducting a study exploring a different aspect of PTA assessment to recruit participants. Both studies have a distinct research question but will make use of the same semi-structured assessment measure and as such participant recruitment can be shared. In addition a Consultant working within A&E has agreed to undertake some of the prospective assessment measures. Reliability measures will be conducted in order to ensure that each assessor is undertaking the assessment and rating duration of PTA in the same way. This will involve each assessor watching a video role play of a prospective assessment and rating how long duration of PTA was so that inter-rater reliability can be ascertained.

Justification of Sample Size

McMillan, Jongen & Greenwood (1996) compared prospective and retrospective estimates of PTA and found a highly positive significant correlation (r = 0.87) for individuals who had sustained a severe head injury. It seems reasonable to assume that a similar effect size could be obtained when undertaking a similar direct comparison of prospective and retrospective estimates for those who have sustained a head injury of any severity. As a cautionary measure a more modest effect size was used when calculating sample size. By using an effect size of 0.4, and power of 0.8, a power calculation using G-Power produces a sample size of 34. In order to ensure that sufficient power is achieved I will aim to complete assessment with around fifty participants. In the aforementioned study around one third of participants who completed prospective assessment did not complete the study. To allow for this rate of attrition around seventy participants will be invited to complete prospective assessment in order that at least fifty participants complete the study.

Settings and Equipment

The study will make use of questionnaires that will be administered verbally. In order to contact participants to complete the retrospective assessments a 'pay as you go' SIM card with credit added will be required.

Data analysis

The study will provide the following data: Prospective estimate of duration of PTA; Retrospective estimate of duration of PTA; Glasgow Outcome Score & Additional outcome information relating to return to work. The correlation between prospective estimate and retrospective assessment will be explored in order to determine the strength of the relationship between the two variables. A repeated samples t-test will also be undertaken to explore differences between the two variables. The correlation between estimate of PTA, both prospective and retrospective, and the GOS (plus additional outcome information) will also be explored.

Health and Safety Issues

Researcher Safety Issues

The main health and safety issue for the researcher will be whilst conducting interviews in the hospital as individuals who can be included in the study may be in a confused state and/or under the influence of alcohol. As each participant will have been assessed by hospital staff in the first instance an assessment of risk will already have been undertaken and should any risk be highlighted the individual will not be assessed by the researcher and will be excluded from the study. The researcher will ensure that hospital staff are always available should assistance be required during the assessment procedure.

Participant Safety Issues

The main health and safety issue for the participant will be in relation to their injury. Each individual will undergo the usual admission procedures and examinations in A&E prior to undertaking the PTA assessment. Individuals recruited from the Ward will also have undertaken the standard hospital assessments and observations prior to undertaking the PTA assessment. It will be ensured that the researcher will be able to

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access medical staff during the PTA assessment should the participant's health deteriorate.

Ethical Issues

The main ethical issue concerns the process of obtaining informed consent from participants. Prospective assessment of PTA is routine clinical practice within the hospital, however the questionnaire that will be used is not used routinely. The retrospective assessment is non-routine practice. As in previous studies (Ponsford et al. 2004) participants will be given information regarding the study once they have emerged from PTA/at the point of hospital discharge and consent will be sought to take part in the study at this stage. Medical staff will have deemed it appropriate for the individual to leave medical care at this point i.e. they will have reached a level of capacity sufficient enough to manage themselves without further care. In this sense the participant should be capable of either giving informed consent to participate in the study or refusing to do so. On occasion it may become clear from the prospective assessment that the individual remains in a confused state and if this is the case medical staff will be informed and the assessment will be repeated at a later stage. If this is the case consent will have to be gained retrospectively for completing the assessment and if not gained the information will be destroyed.

As stated previously SIGN publication number 46 (2000) advocates the assessment of duration of PTA following a head injury. Participants will therefore be receiving an assessment that is deemed to be an important aspect of what is recommended as routine clinical practice. Ethics submission will be made to Glasgow Royal Infirmary.

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Financial Issues

The main financial costs of the study are as follows:

Travel costs, photocopying of assessment outlines, cost of pay as you go SIM card and call costs for follow-up interviews.

Timetable

May 2009:	Submit research proposal, systematic review outline
May – Sept 2009:	Seek ethics approval
October 2009:	Research progress meeting 1
October – Dec 2009:	Data collection
January – Apr 2010:	Data collection, research progress meeting 2
April – May 2010:	Data analyses, research progress meeting 3
June – July 2010:	Drafts submitted to supervisor
End of July 2010:	Loose bind and submit

Practical Applications

Due to the transient nature of PTA in mild to moderate brain injuries there are clear difficulties in terms of conducting a prospective assessment of PTA duration. The individual may have emerged from PTA before they reach the hospital and as such prospective assessment would not be possible. The study will confirm whether a brief semi-structured interview can be used as a retrospective assessment tool, which would be more useful clinically for this population. It will also confirm whether the assessment measure is predictive of outcome to confirm that the measure would be of benefit within a medical triage system. This would benefit staff and patients clinically in that it would serve to indicate which patients require further assessment, monitoring and treatment and which can be discharged from hospital.

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