Health status following major trauma in the West of Scotland: pilot descriptive study

在西蘇格蘭嚴重創傷後健康狀況的描述性試驗研究

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Background: Data on the long-term outcome of major trauma survivors in the United Kingdom (UK) is lacking. This pilot study aimed to investigate the health status of survivors of major trauma without significant head injury in the West of Scotland, and to compare the Short-Form 12 (SF12) questionnaire administered by telephone (TSF12) to the longer Short-Form 36 (SF36) questionnaire. *Methods:* This was a descriptive, comparative, pilot clinical study. Eligible patients had an injury severity score (ISS) >15, sustained their injuries >2 years ago, abbreviated injury score (AIS) <2 for head trauma and were treated in two Glasgow hospitals. The Short-Form 36 (SF36) health status questionnaire was completed at home, and the Short-Form 12 (SF12) questionnaire was administered by telephone (TSF12). *Results:* From 141 eligible patients (85% male, median age 35 years, median ISS 19 and median Ps 0.981), 13 patients completed the study. Despite small numbers, mean SF36 scores were significantly lower in four dimensions compared to UK means. SF36 summary scores were non-significantly below US and UK means. The TSF12 physical summary score was significantly below US and UK means. Correlations between the SF36 and TSF12, and SF12 intra-class correlations were high. One-way ANOVA showed significantly lower mental summary scores for patients with spinal injuries. *Conclusions:* This small study suggests that non-head injured survivors of major trauma have lower health status than the UK average. The TSF12 appears to be a practical alternative to the conventional SF36 and warrants larger scale evaluation. (*Hong Kong j.emerg.med.* 2007;14:29-36)

背景：英國現時缺乏嚴重創傷生還者長遠後果的數據。這試驗性研究旨在調查在西蘇格蘭嚴重受傷但沒有重大頭部創傷之生還者的健康狀況，及比較以電話執行的短表 12 問卷（TSF12）和較長的短表 36 問卷 （SF36）。**方法：**這是一個描述性比較的臨床試驗研究。在格拉斯哥兩所醫院治療而合適的病人如下：創傷嚴重性分數（ISS）大於 15，所蒙受的創傷早於兩年以上，及頭部簡化創傷分數（AIS）少於 2。短表 36 健康狀況問卷（SF36）是在家裏完成，而短表 12 問卷（SF12）是用電話執行（TSF12）。**結果：**從 141 合適的病人中（男性 85%，年齡中位數為 35 歲，ISS 中位數為 19 及生存概率中位數為 0.981），只有 13 名完成研究。儘管數目少，SF36 分數的平均值有 4 方面比英國的平均值顯著地低。SF36 總結分數比美國及英國的平均值不顯著地低，TSF12 的身體總結分數比美國及英國的平均值顯著地低。SF36 及 TSF12 的相關高，及 SF12 有高的組內相關。單向方差分析顯示脊椎受傷病人的精神總結分數顯著地低。**結論：**這小規模的研究提示非頭部受傷的嚴重創傷生還者之健康狀況比英國的平均值差。TSF12 似乎是傳統的 SF36 之另一個實用的選擇，並需要較大規模的評估。

Keywords: Health surveys, mental health, outcome assessment (healthcare), wounds and injuries

關鍵詞：健康調查、精神健康、結果評估（衛生護理）、傷口與創傷

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Introduction

Trauma remains a major public health problem.[1-3] It remains the commonest cause of death in the UK and in the US in the 1-44 year age group.[4] Road traffic accidents are predicted to become the sixth highest cause of death world-wide and the third highest cause of disability within the next 20 years.[1,5] It is likely that the most effective way to reduce the number of deaths is to improve methods of prevention.[6-8] What is unknown at present is the morbidity and disability sustained by those who survive trauma, what form it takes and how long it lasts.

Morbidity following trauma (including health-related quality of life) has not been extensively studied[9,10] in many countries, including the UK. Health related quality of life, now known as health status,[11] is a difficult concept to define and measure. It was defined by Bowling[12] as "optimum levels of mental, physical, role (e.g. work/parent/carer, etc., and social functioning, including relationships), and perceptions of health, fitness, life-satisfaction and well-being". Measurement of health status is even more difficult, with thousands of different disease-specific and generic scoring systems in existence.[13] The number of published studies for each scoring system is variable.

Major trauma is defined as an injury severity score of greater than 15.[4,14] Mortality aspects of major trauma have been extensively investigated, as death is a well-defined end point which can be easily measured.[10] Morbidity amongst survivors of major trauma is less well understood. Health status is only one aspect of overall morbidity.

The SF36 and SF12 are well-defined and validated tools that have been used as generic measures of health related quality of life for many diseases and conditions over the last ten years.[15-22] A patient group of particular interest are those who have sustained major trauma but have not sustained a significant head injury. These patients theoretically should have a good chance of making an excellent functional recovery if timely, appropriate treatment is given to them.

The objectives of this study were twofold: firstly, to perform a pilot descriptive study of health related quality of life in the survivors of major trauma initially treated in Glasgow using the SF36; and secondly, to compare the SF36 administered conventionally with the SF12 administered by telephone, to determine how well the SF12 by telephone correlated with the "gold standard" of the SF36.

Methods

Potential participants in this study were drawn from survivors of major trauma who were initially treated at the Southern General Hospital and the Victoria Infirmary in Glasgow between 1993 and May 2000. The study was performed in early 2002, and the reference point for assessing the length of time since the injuries were sustained was taken as 1 July 2002. All patients sustaining major trauma in these two centres were audited through the national Scottish Trauma Audit Group (STAG).[23,24]

Eligibility criteria for entry into this study were as follows: injury severity score >15; survivor to 90 days; no documented significant head injury (maximum abbreviated injury score for head region <2); Glasgow Coma Scale 13-15 on admission; injury sustained more than two calendar years from interview date. The STAG identification numbers were decoded locally to identify patients' names, dates of birth and dates of injury. The hospital record systems were then accessed to try to obtain details of the general practitioners, addresses and telephone numbers (where available).

A standard explanatory letter seeking consent was sent to the general practitioner (GP) of each patient in June 2002. The GP was also sent a sealed stamped envelope for onward transmission to the patient if consent was granted. Written consent was necessary from the GP prior to entry into the study. If consent

was refused, the introductory letter to the patient was returned to the investigators with the GP response form.

Patients were sent full written information and a consent form, to be returned to the investigator if they consented to participate in the study. On receipt of written consent from both the GP and the participant, the SF36 questionnaire was despatched by post to participants and around the same time, the SF12 questionnaire was administered by telephone (TSF12). There was no specific randomisation process for the order of questionnaire administration. Data on injury severity score (ISS), probability of survival (Ps) and body region of maximum abbreviated injury score (MAIS) were obtained from the Scottish Trauma Audit Group. When two body regions had the same MAIS for individual patients, this combination was used rather than one region or the other.

Questionnaire analysis

SF36 subscale scores were derived from individual questionnaires using the US algorithms published by Ware et al[17,25,26] Each subscale represents a dimension of quality of life. SF36 summary scores (norm based) were calculated for the mental (MCS36) and physical (PCS36) components of the SF36 using published algorithms.[17,25,26] The coefficients used for the analysis of this study were those of the general US population to allow consistency for comparison between groups. There is evidence that there is little difference in the PCS36 and the MCS36 scores when calculated using either the UK or US coefficients.[27] Standardised scores were generated for all responses.

SF12 summary scores were created in a similar manner to the SF36 using published algorithms.[28] Standardised summary scores for the mental summary score (MCS12) and physical summary scores (PCS12) were generated.

Statistical analysis

Descriptive statistics were derived from the raw data. Given the non-normal distribution of age, ISS and probability of survival data, the Mann-Whitney U test was used to compare medians. Correlations between the PCS36 and PCS12 and the MCS36 and MCS12 were assessed using Pearson's correlation coefficient, as the data were plausibly normal. Correlations between these variables and ISS and Ps were assessed using Pearson's correlation coefficient and Spearman's rank correlation coefficient, given the non-parametric nature of ISS and Ps.

Linear regression analyses were used to explore the dependence of PCS36 on PCS12 and MCS36 on MCS12. For comparisons with published normal values for the PCS36, PCS12, MCS36 and MCS12, the one-sample t test was used; the normal values are based on large sample sizes and the distribution of scores satisfied conditions for normality.

One-way analysis of variance was used to analyse the MAIS data with respect to PCS and MCS summary scores. Bonferroni's 95% simultaneous confidence intervals method was used to compare categories within the MAIS data. Kruskal-Wallis test was used to compare median ISS scores.

Minitab (v13.30, Minitab Inc., State College, PA) and SPSS (v9.0, Statistical Package for Social Sciences, Chicago, IL), were used for statistical analysis. Ethical approval was granted by the Research Ethics Committees of both participating hospitals. All patient data were de-identified prior to data analysis.

Results

A total of 141 patients fulfilled the entry criteria and were identified from the STAG database. Full contact details were obtained from hospital record systems for 124 patients, 105 (84.7% of these patients) were male, and 19 (15.3%) were female. The median age at the time of injury was 35 years (range 16-94 years). Median injury severity score was 19 (range 16-66) and median probability of survival was 0.981 (range 0.1377-0.9974).

Causes of injuries were as follows: road traffic accidents 29.0%, assaults 31.5%, falls less than two metres 12.9%, falls greater than two metres 20.2%, sports 0.8% and others 5.6%.

One hundred and one responses were obtained from the general practitioners, representing 81.5% of the original letters sent out. In 23 cases, no reply was received from the GP. Consent was given by the general practitioner of 71 patients to approach them to request their participation in the study. In six cases, consent was declined by the general practitioner for ongoing medical problems, such as post-traumatic stress disorder and in seven cases the patients had died since the time of discharge. In nine cases, the patients had moved away from the area and in eight cases, the patient was not known by that general practitioner.

Altogether, 19 responses were received from the 71 potential participants whose GP had given consent. Only 14 individuals consented to participate in the study but five refused to consent. Of the 14 participants, 13 completed both questionnaires. Table 1 has further details.

There were no significant differences between those who completed the questionnaires and those who did not complete the questionnaires in terms of age, ISS, sex, number of road traffic accidents, number of assaults or number of falls more than two metres. There were significantly more patients who had sustained falls less than two metres or "other" mechanisms of injury in the non-completing group. The group who completed the questionnaires were representative, therefore, for age, sex and ISS.

Mean SF36 subscale scores were all less than the published UK and US means and four categories had statistically significant differences (Table 2). These were role limitation physical (p=0.036), physical functioning (p=0.031), bodily pain (p=0.013) and social functioning (p=0.035).

Table 1. Comparison of responders and non-responders

	'Completers' n=13	'Non-completers' n=111
Age (median)	40 years	35 years
ISS (median)	20	19
Male	84.7%	84.6%
Motor vehicle crash	46.2%	27.0%
Assault	30.8%	31.5%
Fall <2 m	0	14.4%
Fall >2 m	23.1%	19.8%
Others (including sport)	0	7.2%
Time since major trauma [median months (range)]	58 (32-87)	59 (27-115)

Table 2. SF36 subscale scores

Subscale score	Mean SF36 score (95% CI)	Range	US mean	p	UK mean	p
General health	61.5 (47.4-75.6)	25-100	70.10	0.21	73.52	0.089
Role – physical	53.8 (24.4-83.3)	0-100	77.93	0.10	85.82	0.036
Vitality	53.5 (36.4-70.5)	0-100	57.00	0.66	61.13	0.350
Role – emotional	64.2 (36.3-92.0)	0-100	83.10	0.16	82.93	0.173
Physical functioning	66.5 (47.1-86.0)	5-100	82.97	0.09	88.40	0.031
Mental health	67.1 (52.8-81.4)	32-100	75.22	0.24	73.77	0.331
Bodily pain	56.6 (38.0-75.3)	12-100	70.23	0.14	81.49	0.013
Social functioning	62.5 (39.2-85.9)	0-100	83.56	0.07	88.01	0.035

p: one-sample t test between respondents' mean score and the UK/US mean
0 = poor health, 100 = excellent health.

Mean SF36 summary scores were lower than the US and UK means (Table 3), but these differences were not statistically significant. However, mean SF12 scores were also lower than published means (Table 4), although only the physical component summary score was statistically significantly lower than the US mean (p=0.028) and the UK mean (p=0.026).

The Pearson correlation coefficient for the relationship between the PCS36 and the PCS12 was 0.902 (p<0.001). Likewise, the correlation between the MCS36 and MCS12 was 0.947 (p<0.001). Linear regression analyses confirmed these very strong relationships in both cases.

One way analysis of variance (ANOVA) of the MAIS data showed that there were significant differences in mean MCS36 scores (p=0.002) and mean MCS12 scores (p=0.007). Bonferroni's simultaneous 95% confidence intervals method revealed statistically significant differences between survivors with a MAIS for spinal injuries and chest injuries; spinal injuries and chest and abdominal injuries; and spinal injuries and chest and extremity injuries. In each case, spinally injured patients had lower MCS36 scores than the other categories (Figure 1).

This pattern was repeated for MCS12 scores, with significant differences between survivors with a MAIS for spinal injuries and chest injuries; spinal injuries and chest and abdominal injuries; and spinal injuries and chest and extremity injuries. Again, spinal injury patients had lower MCS12 scores (Figure 2). There were no statistically significant differences in median ISS for the six different MAIS groups (Kruskal-Wallis test, p=0.39). Median ISS was 17 for chest (n=5), 27 for chest and abdomen combined (n=2), 34 for abdomen (n=1), 21 for spine (n=3), 33 for extremity (n=1), and 19 for chest and extremity (n=1).

Table 3. SF36 summary scores

Summary score	Mean SF36 score (95% CI)	Range	US mean	p	UK mean	p
Physical component summary	44.02 (36.66-51.39)	29.44-60.17	50.8	0.068	50.8	0.068
Mental component summary	45.36 (36.49-54.23)	18.57-61.95	50.0	0.284	52.2	0.122

One-sample t test

Table 4. SF12 summary scores

Summary score	Mean SF12 score (95% CI)	Range	US mean	p	UK mean	p
Physical component summary	41.95 (34.25-49.64)	24.50-57.37	50.8	0.028	50.9	0.026
Mental component summary	49.40 (42.07-56.73)	23.42-62.70	50.0	0.864	52.1	0.441

One-sample t test

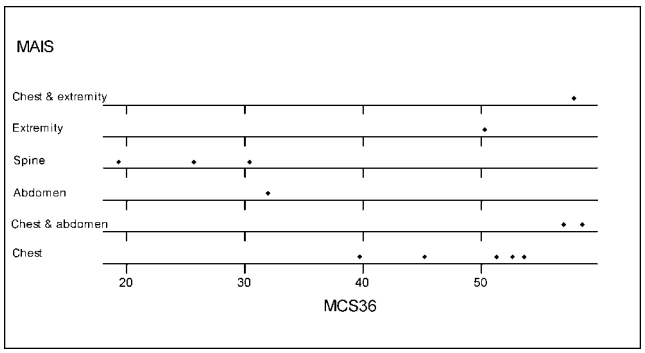

Figure 1. Dotplot of MAIS and MCS36.

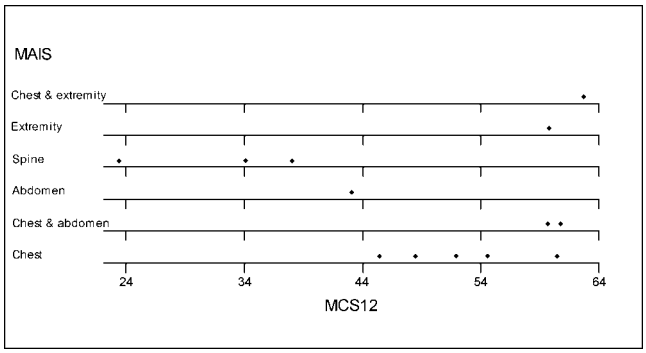

Figure 2. Dotplot of MAIS and MCS12.

Discussion

This pilot study suggests that the physical and mental health status of non-head injured survivors of major trauma in Glasgow was lower than the UK mean. While the SF36 summary scores were not significantly different from the US and UK population means, the small number of patients reduced the power of the study to detect such differences.

The study should be repeated with more participants to investigate this further. However, the SF12 summary scores showed a significant decrease in physical summary scores, compared to both the US and the UK means. These findings suggest that survivors are not returning to their pre-injury physical health status.

A high correlation was found between the SF36 and telephone SF12 summary scores. The TSF12 could be a useful tool for future larger studies of long-term health status in this field.

Despite these positive findings, the power of the study is reduced by the small numbers of participants. The ethical requirement to obtain permission from both the GP and the patient, while necessary, imposes considerable hurdles for this type of research.

In addition, the long time since the time of injury means that patients may have moved their original place of residence and may have changed their GP, and current health care computer records systems do not always record these changes which makes identification of patients' and their GP's whereabouts difficult.

The requirement to obtain the GP's consent to approach the patient inevitably introduces a degree of selection bias, as those with any significant degree of ongoing mental health problems may be excluded in good faith by their GP. The lack of difference in mental health scores may reflect this selection and inclusion bias, and it remains possible that there is significant mental health morbidity in this population which cannot be investigated with the current study design. The ethical requirement to gain the GP's consent is likely to remain, and therefore other approaches may be required, for example, longitudinal studies of trauma survivors over time from discharge from hospital, such as in some US centres.

The drawback of such an approach is the cost implications, but this may be the only way of addressing these issues. In addition, patients who have a lower health status (mentally or physically) may have been less inclined to agree to participate in the study, further increasing possible inclusion bias. However, ethical requirements demand the consent of the patient to participate in the study, and there is no way of avoiding this problem.

One potential criticism of this work is the multiple statistical comparisons that are required for the analysis. Some scientists would argue that the use of multiple comparisons demands a statistical correction to limit the possibility of a type I error, i.e. the rejection of the null hypothesis when the null hypothesis is indeed true. Such a test is the Bonferroni's correction.[29] However, there is a significant medical and statistical literature suggesting that Bonferroni's corrections are prone to decrease type I errors but at the expense of increasing type II errors significantly.[29,30]

In the current study, the effect of introducing a Bonferroni's correction on the data would render all the positive statistical comparisons negative, and therefore the entire study would be negative and there would be no value in studying this approach further. However, the counter argument to this is that the health status literature in general has not used Bonferroni's or other multiple comparison testing in recent publications and it is therefore debatable as to whether it is a necessary adjustment or not. In any case, larger scale studies are required to avoid these statistical issues by increasing statistical power to an adequate standard and to accurately describe the ongoing health status of this group of patients in the UK and elsewhere.

The fact that there was no significant relationships between ISS and health status may be a reflection of

the low numbers in the study, but this finding could also reflect the belief that health status is a much more nebulous concept that includes elements of the original injuries, the somatic and psychological response to those injuries, and the interaction of the individual and the environment in the context of the resultant disability. Thus the final post-injury health status of a patient may not be related to individual ISS.

Patients in the study were injured between 2 and 9 years before the questionnaires were completed. This may have influenced the degree of recovery that individual patients have achieved, but it should not have any effect on the comparison between the two studies. However, this could confound the absolute values for individual scores to some degree, as there is no way of controlling for this factor.

Patients with spinal injuries as their maximum area of injury have lower measures of mental health as shown by statistically significant reductions in MCS36 and MCS12 scores, but the numbers are very small and these findings need to be further explored in larger studies.

Conclusion

This small study has suggested that the SF36 questionnaire is a useful measure of health status in the trauma population. The SF12 administered by telephone appears to be a practical alternative to the conventional SF36 and it warrants further evaluation as a potential health status measurement tool for large studies of survivors of major trauma in the UK.

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