J Rehabil Med 2013; 45: 820–826

ORIGINAL REPORT

CLINICALLY SIGNIFICANT CHANGES IN THE EMOTIONAL CONDITION OF RELATIVES OF PATIENTS WITH SEVERE TRAUMATIC BRAIN INJURY DURING SUB-ACUTE REHABILITATION

Anne Norup, PhD[1], Karin Spangsberg Kristensen, MPH[1], Ingrid Poulsen, PhD[1], Christina Löfvquist Nielsen, MSc[1] and Erik Lykke Mortensen, MSc[2]

From the [1]Research Unit on BRain Injury rehabilitation, Copenhagen (RUBRIC), Department of Neurorehabilitation, Traumatic Brain Injury Unit, Copenhagen, University Hospital, Glostrup and [2]Institute of Public Health and Center for Healthy Aging, University of Copenhagen, Copenhagen, Denmark

Objective: **To investigate clinically significant change in the emotional condition of relatives of patients with severe traumatic brain injury during sub-acute rehabilitation.**

Methods: **Participants were 62 pairs of relatives and patients. Relatives completed the anxiety and depression scales from the Symptom Checklist-90-R (SCL-90-R) when the patients were admitted to sub-acute rehabilitation and at discharge. Improvement in emotional condition was investigated using the following criteria: (*i*) statistically reliable improvement; and (*ii*) clinically significant change (CSC).**

Results: **At admission, 53.2% and 58.1% of relatives had scores above cut-off values on the anxiety and depression scales, respectively. On the anxiety scale 69.7% of these experienced a reliable improvement according to the Reliable Change Index (RCI) and 45.5% also obtained CSC, as their end-point was below the cut-off value. On the depression scale the corresponding figures were 44.4% and 41.7%, respectively. When comparing relatives with and without CSC, we found that CSC in symptoms of anxiety was associated with significantly better functional improvement during rehabilitation and a shorter period of post-traumatic amnesia in the patients.**

Conclusion: **Of the relatives who reported scores above cut-off values on the anxiety and depression scales at patient's admission, approximately 40% experienced CSC in anxiety and depression during the patient's rehabilitation. Relatives of patients experiencing improvement during inpatient rehabilitation are more likely to experience CSC in anxiety.**

Key words: emotional distress; anxiety; depression; relatives; sub-acute rehabilitation; traumatic brain injury; clinically significant change; reliable change index; functional improvement; SCL-90-R.

J Rehabil Med 2013; 45: 820–826

Correspondence address: Anne Norup, Department of Neurorehabilitation, Traumatic Brain Injury Unit, Copenhagen University Hospital, Glostrup, Denmark. E-mail: anne.norup@regionh.dk

Accepted April 25, 2013

INTRODUCTION

A number of studies has provided evidence that relatives of patients with brain injury experience significant emotional distress (e.g. 1–3), and high frequencies of anxiety and depression have been reported in the years following a family member acquiring a brain injury (4, 5). Studies have indicated that long-term deficits in the patient, such as changes in personality, behaviour and social cognition, are among the most distressing changes for the family (6–8). Mixed results have been found regarding associations between the patient's level of consciousness and function and the emotional condition of the relatives (2, 9). Cross-sectional studies conducted in the early phases of rehabilitation have indicated an association between the patient's level of consciousness and function and the emotional condition of the closest relative (10–13). These mixed results might be due to the fact that different predictors are important in different phases of rehabilitation. So far, no studies have investigated the possible associations between patient's recovery and changes in the emotional condition of the closest relative. To investigate causal inferences requires a longitudinal design, and only a few longitudinal studies have been conducted (13–16), with even fewer studies in the early phases of rehabilitation (15, 17). These longitudinal studies have reported a decrease in distress over the years following brain injury, as would be expected as the situation stabilizes and the family adapts. However, it is difficult to assess whether the reported decrease is clinically meaningful. Despite families experiencing a significant decrease in distress, they may still be living with severe distress caused by the continuing consequences of brain injury. Thus, there is a need to investigate the magnitude of the change and to evaluate whether the end-point is below the cut-off for pathology established in reference populations.

In 1984, the term clinically significant change (CSC) was introduced by Jacobson et al. (18). CSC was defined as the extent to which a subject moves outside the range of the dysfunctional population or within the range of the functional population. Some years later, Jacobson & Truax (19) elaborated by publishing a paper introducing ways of operationalizing the term. In this paper, the authors proposed

the term Reliable Change Index (RCI) as a means of determining whether the magnitude of change is statistically reliable. The introduction of this term led to the two-fold criterion for CSC used in this paper.

Aims

The current study aimed to investigate change in the emotional condition of relatives of patients with severe traumatic brain injury (TBI) during inpatient rehabilitation using the following criteria: (*i*) statistically reliable improvement; and (*ii*) CSC. Moreover, group differences were investigated between relatives who experienced change and those who did not.

METHODS

Participants

The study sample consisted of relatives of patients with severe TBI admitted to intensive specialized sub-acute rehabilitation at a TBI unit. A relative was defined as a child, parent, spouse, boyfriend, girlfriend or sibling. Relatives who did not speak Danish, and relatives with a psychiatric diagnosis or a progressive brain disease were excluded from the study. If more than one relative was present the family decided which relative should complete the questionnaire. Relatives of patients fulfilling the following criteria were included:

- Diagnosis of TBI.
- Aged 16 years or older.
- Glasgow Coma Scale (GCS) (20) score during the first 24 h after injury ≤ 8.

Patients were excluded if they met any of the following criteria:

- Violence-related cause of TBI (with the exception of war-related violence).
- Serious conditions causing mental disability prior to the TBI, such as developmental handicap (e.g. Down's syndrome), residual disability after previous TBI, confirmed dementia, or serious chronic mental illness (schizophrenia, psychosis or confirmed bipolar disorder).

Measures

Demographics. Data concerning gender, age and employment status of the patient and the relative were collected at admission. Moreover, cohabitant status and relationships were registered.

Relatives' emotional well-being. The emotional well-being of the relatives was investigated at patients' admission and discharge and assessed with measures of anxiety and depression. Symptoms of anxiety and depression were evaluated with the relevant scales of the Symptom Checklist (SCL), a self-report checklist designed to reflect symptom patterns and levels of distress (21). Each item is scored on a scale of 0 ("not at all") to 4 ("extremely"), indicating the degree of distress, and the respondents are asked to answer according to their condition over the previous 7 days. The anxiety and depression scale scores were evaluated using the gender-specific norms for a Danish population sample provided by Olsen et al. (22). The Danish population study revealed high alpha coefficients of the two scales used in this study, depression and anxiety: 0.91 and 0.86, respectively (22).

Neuropsychological support. The amount of contact that relatives of patients admitted to the unit had with a neuropsychologist was recorded. Both individual sessions and participation in group sessions were registered during the patient's hospitalization. The contact time was registered in units of 15 min. Scheduled contacts with the relative, unplanned or informal contacts, and phone contacts regarding patient's treatment were registered. The number of sessions with the neuropsychologist was also registered.

Patient's condition. As a standard procedure, relevant data were collected regarding the patient's condition. Severity of injury was assessed using GCS (20) and Injury Severity Score (ISS) (23).

GCS scores range from 3 to 15. Patients with scores of less than 9 are considered to be in a coma, and patients with scores of 15 have spontaneous eye opening, are able to follow commands and are fully oriented. According to criteria for injury severity, patients with GCS scores of 8 or less are classified as having severe brain injuries. GCS scores were rated by the treating physician at admission. The treating physician also calculated the ISS, which consists of an anatomical scoring system that provides an overall score for patients with multiple traumatic injuries. The ISS ranges from 0 to 75. Each injury is assigned an Abbreviated Injury Scale (AIS) score and is allocated to 1 of 6 body regions: head, face, chest, abdomen, extremities and skin. Only the highest AIS score in each region of the body is used. The scores of the 3 most severely injured regions are added together to produce the ISS score.

At admission and discharge, the patient's level of consciousness was assessed by a neuropsychologist using the Rancho Los Amigos Levels of Cognitive Functioning Scale (RLA) (24). Scores on this scale range from Level 1, which describes a comatose condition with no observable response, to Level 8, which is a condition with purposeful and appropriate responses.

The scale measuring Early Functional Abilities (EFA) (25) is an assessment tool used in the early neurological rehabilitation stage, which describes clinically observable change in the early functional abilities of the patient. The EFA Scale contains 20 items and assesses early basic abilities related to 4 functional areas: vegetative, face and oral, sensory-motor, and sensory cognitive functions. Each item is rated on a 5-point scale, from "not obviously observable" to "no essential functional limitation". The total score ranges from 20 to a maximum of 100, where higher scores indicate better functional ability.

The Functional Independence Measure (FIM) (26) is an 18-item rating scale assessing activities of daily living (ADL): self-care, bowel and bladder management, mobility, communication, cognition, and psychosocial adjustment. Each item is rated on a 7-point scale, from "total assistance" to "complete independence". A total FIM score ranges from 18 to 126, with higher scores indicating greater independence. The FIM Scale has been shown to be valid and reliable for measuring functional outcome after TBI (27).

Both the FIM and the EFA were assessed within 72 h of admission and discharge by the nurses, physiotherapists and occupational therapists.

Procedure

A total of 77 pairs of patients and relatives were included in the study during the enrollment period from 1 October 2007 to 31 December 2011. The relatives were contacted when the patient was admitted and were given oral and written information about the study. If the relatives gave consent to participate in the study, they were enrolled.

As the aim was to investigate changes from admission to discharge based on the difference between the 2 assessments, only complete data were used. Eight relatives were excluded because of missing data (2 did not return the admission questionnaire, and 6 did not return the discharge questionnaire). Four relatives of patients were excluded because the patient died during hospitalization, and one relative chose to withdraw consent to participate and was therefore excluded. Two patients were transferred to a psychiatric ward, and thus their relatives were excluded, as we expected that the situation of these relatives was not similar to those of patients discharged to further rehabilitation. In total, 15 pairs of relatives and patients were excluded, and data are reported for the 62 remaining pairs.

No significant differences were found between excluded patients and relatives and the included sample with respect to the patient's age, GCS score and level of consciousness, or the age and gender of the relatives.

The study was approved by the Committees on Biomedical Research Ethics of the Capital Region of Denmark and the Danish Data Protection Agency.

Table I. *Demographics*

Characteristics	Patient ($n=62$)	Relative ($n=62$)
Age, years, mean (SD)	35.10 (18.68)	50.21 (11.37)
Range, years	16–82	27–78
Gender, *n* (%)		
Male	50 (80.6)	11 (17.7)
Female	12 (19.4)	51 (82.3)
Employment status, *n* (%)		
Full-time work/studying	52 (83.9)	
Unemployed/pension	10 (16.1)	
Cohabitants, *n* (%)		
Yes		41 (66.1)
No		21 (33.9)
Relationship, *n* (%)		
Spouse/cohabitant		19 (30.6)
Parent		36 (58.1)
Children		3 (4.8)
Others		4 (6.4)

SD: standard deviation.

Statistical analysis

Data are described with means (standard deviation (SD) and range, and categorical data with frequencies and percentages. Mean raw scores were calculated on each of the two outcome measures and compared with the Danish reference population (22), and the number of cases above cut-off was counted.

Analyses of change were conducted in a series of steps: firstly, the RCI was used to assess whether the individual change was statistically significant. The RCI is defined as the change in scores divided by the standard error of the difference for the test being used (19). The standard error of difference was calculated based on the standard deviation and the reliability coefficient (Cronbach's alpha) given in the Danish SCL-manual (28). The cut-off for statistical significance on the RCI is 1.96, which equates to the 95% confidence interval (CI).

Secondly, the number of participants obtaining CSC, defined as subjects improving significantly reliably and obtaining a raw score below cut-off at patient's discharge, was investigated. Evaluation of CSC requires participants to be above cut-off for caseness (e.g. in the dysfunctional range) at admission, and consequently all relatives below the cut-off were excluded from these analyses. Thirdly, the sample of relatives reported as cases initially were categorized according to the RCI, and, finally, the number of relatives experiencing a CSC and relatives not experiencing such a change were counted.

Statistical differences between groups were calculated using Wilcoxon signed-rank tests when comparing ordinal data, and McNemar's tests when proportions of cases were investigated. Effect sizes within groups were expressed as the difference between means at admission and discharge, divided by the SD at admission (29).

Group differences were investigated using χ^2 tests and independent samples *t*-tests.

For significance test, alpha was set at 0.05. All statistical analyses were conducted with SPSS version 19.0.

RESULTS

Description of the sample

The sample of relatives consisted of 82.3% females, who were primarily parents (58.1%) or spouses (30.6%) of the patients. The mean age of the sample was 50.21 years (SD 10.37; range 27–78 years). Most of the relatives were living with the patient at time of injury (66.1%).

The sample of patients was primarily male (80.6%) and had a mean age of 35.10 years (SD 18.68; range 16–82 years). The sample of patients was transferred to sub-acute rehabilitation 19.02 days after injury (SD 10.02 days), and the relatives completed the admission questionnaire 6.31 days after admission (SD 6.69 days). Patients had a mean length of stay of approximately 92.29 (SD 50.83) days, and the relatives completed the discharge questionnaire 10.98 (SD 19.67) days after discharge. Consequently, the mean follow-up time between admission and discharge questionnaires was 96.96 days (Table I).

The clinical status of the patients at admission and discharge is shown in Table II.

During rehabilitation the relatives received the standard intervention provided by the neuropsychologists working in the unit. On average, the relatives were provided with 15 units (SD 10; range 0–46 units) of 15 min duration during the patient's hospitalization, corresponding to a total of approximately 4 h. The amount of time was averagely spent in approximately 5 sessions.

Condition of relatives at admission and discharge

Raw scores on the anxiety and depression scales are shown in Table III. One sample *t*-test showed that the sample had significantly higher scores on both the depression and the anxiety scales at both admission and discharge, compared with Danish norms (28). When comparing scores at admission and discharge, change effect sizes for the total sample were 0.64

Table II. *Clinical status at admission and discharge*

	Admission			Discharge			Difference		
Variable	Median	IQR	Range	Median	IQR	Range	Median	IQR	Range
ISS ($n=62$)	29	25–38	16–59	–	–		–	–	
GCS ($n=62$)	11	8–14	5–15	–	–		–	–	
RLA ($n=62$)	4	2.75–5	2–7	8	6–8	3–8	3**	2–4	0–6
EFA ($n=62$)	39	29.75–72.5	21–98	99	76.50–100	43–100	42**	24–56.50	2–75
FIM ($n=62$)	18	18–25	18–115	104	44.75–117.50	18–125	68.50**	13.75–90.25	0–104

*$p<0.05$, **$p<0.01$.

Difference refers to the difference between patient's admission and discharge scores, and the statistical significance of this difference was calculated using Wilcoxon signed-rank test.

ISS: Injury Severity Score; GCS: Glasgow Coma Scale; RLA: Rancho Los Amigos; EFA: Early Functional Abilities; FIM: Functional Independence Measure; IQR: interquartile range.

Table III. *Emotional condition of relatives at admission and discharge*

	Anxiety					Depression				
	Mean (SD)	Range	D	*t*	*p*-value	Mean (SD)	Range	D	*t*	*p*-value
Admission ($n=62$)	1.32 (0.72)	0–3.36	0.88	9.61	<0.001	1.68 (0.67)	0.15–3.15	1.09	12.76	<0.001
Discharge ($n=62$)	0.86 (0.69)	0–3.27	0.42	4.85	<0.001	1.33 (0.83)	0–3.31	0.74	7.04	<0.001
Effect size	0.64					0.52				

p-values: 1-sample *t*-test.
D: difference to Danish norms; SD: standard deviation.

and 0.52 for anxiety and depression, respectively, indicating a moderate to large effect size (Table III).

The number of cases above cut-off levels on the 2 scales were counted, and it was found that 53.2% scored above cut-off on the anxiety scale at admission and 29.0% scored above at discharge (cut-off = 1.15 for females, and 0.94 for males). On the depression scale, 58.1% scored above cut-off at admission and 40.3% at discharge (cut-off = 1.60 for females, and 1.29 for males) (Table IV). The differences between the number of cases at admission and discharge were significant for both anxiety ($p=0.003$) and depression ($p=0.019$).

No significant group differences were found when comparing cases vs. no-cases on anxiety or depression with respect to the relative's gender, age, relationship to the patient or the patient's age, GCS, ISS, EFA, FIM or RLA scores at admission.

Changes in the condition of relatives during patients' rehabilitation

Total sample. The RCI was calculated for the total sample and, based on these calculations, the relatives were divided into 3 groups; deteriorating, no reliable change, and reliably improved (see Table IV). On the anxiety scale, 50.0% experienced a statistically reliable improvement, as did 32.3% on the depression scale.

No significant group differences between sub-samples with and without RCI on anxiety or depression were found with respect to the relative's gender, age, relationship to the patient, amount of neuropsychological support or the patient's age, GCS score, ISS score, duration of post traumatic amnesia (PTA) or progress on the EFA, FIM or RLA during admission.

Table IV. *Changes in emotional condition of relatives during patient's rehabilitation*

	Anxiety ($n=62$)		Depression ($n=62$)	
	% (*n*)	95% CI	% (*n*)	95% CI
Number of cases				
Admission	53.2 (33)	41.0–65.1	58.1 (36)	45.7–69.5
Discharge	29.0 (18)	19.2–41.4	40.3% (25)	29.0–52.8
Significance of change	0.003		0.019	
Change status (RCI)				
Deteriorated	8.1 (5)	3.1–17.9	8.1 (5)	3.1–17.9
No reliable change	41.9 (26)	30.5–54.3	59.7 (37)	47.2–71.0
Reliably improved	50.0 (31)	37.9–62.1	32.3 (20)	21.9–44.7

Cases were defined as a raw score above the cut-off: 1.15 for females and 0.94 for males on the anxiety scale, and 1.60 for females and 1.29 for males on the depression scale. Significance of change was calculated using McNemar's test.
RCI: Reliable Change Index, CI: confidence interval.

Analysis of cases. The classification of CSC necessitates initial case status (e.g. at patient's admission) and, consequently, all no-cases were excluded from the rest of the analyses. When investigating the remaining proportion of the relatives (cases; anxiety: $n=33$, depression: $n=36$) (Table V), we found that 69.7% experienced a reliable improvement according to the RCI, and 45.5% also obtained CSC, as their end-point was below cut-off on the anxiety scale. On the depression scale, 44.4% experienced a statistically significant improvement, and 41.7% also obtained CSC.

After the exclusion of relatives below the cut-off, effect sizes increased compared with the total sample. The effect sizes for the case sample were 1.21 and 1.02 for anxiety and depression, respectively, indicating a large change effect size.

When comparing relatives who experienced CSC with those who did not, in relation to anxiety we found that CSC was associated with significantly shorter duration of PTA ($t=2.964$, $p=0.007$) and significantly more improvement on the FIM during rehabilitation ($t=2.324$, $p=0.027$) in the patients. Patients of relatives experiencing CSC in relation to anxiety had a mean PTA duration of 45 (SD 31) days, whereas patients of relatives not experiencing CSC had a duration of 114 (SD 94) days. This pattern was also seen in relation to functional improvement, where patients of relatives experiencing CSC had a median improvement on the FIM of 87 points (interquartile range (IQR) 78–92) during rehabilitation, and patients of relatives not experiencing CSC had a median improvement on the FIM of 62 points (IQR 78–92).

No significant differences were observed between relatives with and without CCS in relation to depression.

DISCUSSION

Condition of relatives at admission and discharge

The results of this study revealed that the sample had significantly more symptoms of anxiety and depression at both patients' admission and discharge compared with a reference population. In the total sample, 53.2% and 58.1% scored above cut-off on the anxiety and depression scales, respectively. These numbers are comparable with our previous results (10, 30). In spite of the obvious limitations when comparing results of studies with methodological differences, these results do support the few studies conducted in the early phases of rehabilitation showing increased levels of both depression and

Table V. *Change status in the case "group" (after excluding no-cases at admission)*

	Anxiety ($n=33$)		Depression ($n=36$)	
	Mean (SD)	95% CI	Mean (SD)	95% CI
Admission	1.83 (0.57)	1.63–2.01	2.12 (0.45)	1.97–2.27
Discharge	1.14 (0.71)	0.9–1.38	1.66 (0.83)	1.39–1.93
	% (*n*)	95% CI	% (*n*)	95% CI
Change status (RCI)				
Deteriorated	6.1 (2)	0.7–20.6	11.2 (4)	3.8–25.9
No reliable change	24.2 (8)	12.6–41.2	44.4 (16)	29.4–60.5
Reliably improved	69.7 (23)	52.5–82.8	44.4 (16)	29.4–60.5
Clinically significant change (CSC)	45.5 (15)	29.8–62.0	41.7 (15)	27.1–57.8
Effect size	1.21		1.02	

A participant is classified as experiencing clinically significant change when the magnitude of change should be statistically significant and symptoms are reduced to an end-score (discharge) below the cut-off for caseness. RCI: Reliable Change Index; CI: confidence interval: SD: standard deviation.

anxiety. Oddy et al. (17) reported that 39% of the relatives were above the cut-off score for clinical depression 1 month after injury, in comparison with the present study, in which more than half of the relatives scored above the cut-off in this sample approximately 3 weeks after injury. However, the patients in Oddy et al.'s sample had less severe injuries than the patients in our sample.

Novack et al. (15) found that 9% of patients were clinically depressed and 33% of caregivers were clinically anxious at admission (46 days post-injury). The levels reported in this study were low compared with those in our study and the study of Oddy et al. (17). However, the caseness criteria used were higher (Beck Depression Inventory > 18, State-Trait Anxiety Inventory > 90th percentile) than recommended (31).

Changes in the condition of relatives during patients' rehabilitation

Total sample. Using the RCI, we found that, of the total sample, 50.0% experienced a statistically reliable improvement on the anxiety scale, and 32.3% experienced a statistically reliable improvement on the depression scale. A relatively large proportion of these relatives reported no measurable degree of change (anxiety 41.9% and depression 59.7%).

Despite the relatively large percentages experiencing no reliable change, effect sizes indicated moderate-to-large effects. This emphasizes how large effect sizes do not reflect improvement for all relatives, as more than half of the sample did not report any reliable change. These results emphasize the need for a clinically meaningful definition of change.

Analysis of cases. When we excluded the no-cases at admission from the further analyses and once again calculated the RCI, we found that only 24.2% and 44.4% reported no reliable change on anxiety and depression scales, respectively. This indicates that the majority of relatives experiencing pathological symptoms of anxiety and depression did report a reliable improvement. Moreover, in the "case" group 45.5% reported CSC on anxiety and 41.7% on depression. In the sub-sample with case status, change effect sizes for both anxiety and depression were large.

To the authors' knowledge, no other studies in the field of brain injury have used the concept CSC to investigate changes in the wellbeing of relatives. Most relatives do experience a decrease in symptoms of distress, anxiety and depression during the patients' rehabilitation, which is to be expected as the patient recovers and the situation stabilizes (3, 13, 15, 17, 32, 33). However, whether this decrease is statistically reliable and clinically important has not been investigated. A significant decrease in score level may not be clinically significant if the end-point is still above the cut-off for pathology. Thus, the evaluation of change in symptomatology should include both the magnitude and reliability of the improvement, as well as the end-point score of relatives.

Investigating group differences

We found that patients with relatives who experienced a CSC in relation to anxiety experienced a larger functional improvement during in-patient rehabilitation and a shorter period of post-traumatic amnesia. This emphasizes the associations between patient's recovery and the well-being of the relative. To the authors' knowledge, no other studies have investigated associations between the patients' functional improvement and emotional improvements in relatives. Previous studies have used a cross-sectional design revealing associations between indices of severity of injury (e.g. GCS (12, 13)), level of function (e.g. Disability Rating Scale (EFA) (2, 9, 10, 34)) and the emotional condition of family members. The results of these cross-sectional studies have been mixed, as authors have also reported no associations between functional level (e.g. FIM (9)) and the condition of relatives. As mentioned in the Introduction, the innate problem of cross-sectional studies is that they do not provide information about changes over time, e.g. improvement in patients' status in relation to the emotional condition of relatives. The present study is the first to report such an association in the early phases of rehabilitation, and this underlines how the wellbeing of relatives is connected to the physical condition of patients. Some authors have pointed out that this association might be reciprocal, indicating that the emotional condition of relatives might influence the final outcome after the patient's rehabilitation (35). However, this issue needs further investigation.

Thus, the improvement in the emotional condition of the relatives was expected, but the reported association between relatives with CSC and patient's recovery is interesting, and to the authors' knowledge this has not been demonstrated before. However, no associations were found between patient's recovery and the change in relatives' depression scores. Moreover, no associations were found between the amount of neuropsychological intervention and the improvement in relatives' condition. This might suggests that the recovery observed is primarily spontaneous, reflecting that the relatives gradually adapt to the new life situation with a close family member who is seriously ill. The relatives are likely to be in

a crisis during the most acute phase of the patient's illness, and their emotional state improves as they gradually learn to cope with the situation and adapt to the long-term perspective.

Limitations

In the current study changes in emotional distress were investigated, but no assessments of social support were carried out. Social support is known to have an impact on emotional well-being (22). Moreover, both coping style and personality affect how relatives deal with the situation facing a close relative with a severe brain injury. For example, the broad personality dimension of neuroticism is known to be related not only to health-related quality of life (HRQoL), anxiety and depression, but also to coping strategies (36, 37). Thus, the inclusion of a personality inventory would have strengthened the study.

Another limitation is the registration of the neuropsychological intervention, which was recorded as duration in minutes as well as number of sessions. This is not an adequate way of measuring a psychological intervention, as duration does not necessarily equate to quality. However, this method was used for pragmatic reasons, as the data were collected as part of another study (30). A different research design and methods are required to evaluate the true effect of the neuropsychological intervention administered and associations with changes in the emotional condition of the relative. Randomized studies could include relative's ratings of the benefits from various elements in the intervention. This procedure has been used by other family intervention researchers (38). Moreover, it appears that the timing of the intervention is critical. This is discussed further in another paper in this special issue (39).

Moreover, we did not register the support administered by other professionals, e.g. nurses, physicians, therapists, or the support that relatives received from their families, which is known to be important.

Clinical implications

When investigating change in relatives' wellbeing, previous studies have neglected to evaluate whether the reported change is clinically meaningful. Reporting this dimension of research reduces the gap between clinicians and researchers. This enables and assists the researchers and clinicians in translating the results into clinical practice (40).

There has not been sufficient focus on the importance of the condition of the relatives during the early phases of rehabilitation in rehabilitation research. Since symptoms of anxiety and depression influence the collaboration between staff and families as family members, it is important that clinicians are aware of the distress that families experience, when a patient is admitted to rehabilitation (41). Furthermore, the symptoms of distress experienced by relatives may have important long-term consequences for the family and the patient with respect to employment, quality of life, and prevention of marital disruption.

Moreover, results have indicated that the association between the condition of the family and the patient is reciprocal; meaning that the distress that the family experiences also influences the condition of the patient (35). This has emphasized the need and importance of early detection of symptoms of distress and the necessity for emotional support, which may, to some extent, prevent the more long-term symptoms of depression.

This study has also emphasized the fact that relatives of patients who do not make progress with respect to functional level, have higher risk of experiencing anxiety and depression. This emphasizes the need for specific support for families of patients without functional progress during rehabilitation. These families may also need substantial support after the patient's discharge, which might be provided by more systematic follow-up of patients and families.

Future research

Future studies should assess the changes over time in the emotional condition of relatives of patients with severe brain injury using a reliable threshold for change and examining whether the reported change is statistically reliable and clinically important.

There is a lack of research describing the early impact of brain injury on family members, thus future studies should focus on the early phases of rehabilitation. Exploring associations between the functional improvement in patients and the relatives' wellbeing will enable professionals to identify relatives and families who are at risk of developing or maintaining high levels of anxiety and depression throughout the early phases of rehabilitation. This is important for the triangle in rehabilitation: patients, relatives and professionals. Healthcare professionals and health organizations need to establish support systems that can adequately meet the needs of the families. Support systems should be based on clinical experience, while they still lack evidence-based supported interventions in the early phases of rehabilitation. Health organizations and rehabilitation services should have a structured approach towards supporting the family during and after the patient's rehabilitation. The support system can include professionals working in the rehabilitation settings or provide relatives with links to other public or voluntary organizations.

Conclusion

Of the relatives reporting scores above the cut-offs on the anxiety and depression scales at patient's admission, the majority experienced reliable improvement according to the RCI, and approximately half of the relatives also obtained CSC, as their end-point was below the cut-off score on the anxiety scale. On the depression scale, just under half of the relatives experienced a statistically significant improvement, and approximately 40% also obtained CSC. The study also found that relatives of patients who had a shorter duration of PTA and who experienced functional improvement, were more likely to experience CSC in symptoms of anxiety. This emphasizes the need for increased awareness about families of patients who are not progressing or who are progressing slowly during rehabilitation.

ACKNOWLEDGEMENTS

The authors would like to thank participants in the study, and additionally acknowledge the data collection conducted by the staff at the Department of Neurorehabilitation, Traumatic Brain Injury Unit, Copenhagen University Hospital, Glostrup. The authors would also like to thank Dr John Whyte and Dr Tessa Hart, Moss Rehabilitation Institute, Philadelphia, USA, for kind permission to use data on neuropsychological support collected in a collaborative study.

REFERENCES

1. Brooks N, Campsie L, Symington C, Beattie A, McKinlay W. The 5 year outcome of severe blunt head-injury – a relative's view. J Neurol Neurosurg Psychiatry 1986; 49: 764–770.
2. Kreutzer JS, Rapport LJ, Marwitz JH, Harrison-Felix C, Hart T, Glenn M, et al. Caregivers' well-being after traumatic brain injury: a multicenter prospective investigation. Arch Phys Med Rehabil 2009; 90: 939–946.
3. Livingston MG, Brooks DN, Bond MR. Patient outcome in the year following severe head–injury and relatives psychiatric and social functioning. J Neurol Neurosurg Psychiatry 1985; 48: 876–881.
4. Machamer J, Temkin N, Dikmen S. Significant other burden and factors related to it in traumatic brain injury. J Clin Exp Neuropsychol 2002; 24: 420–433.
5. Rivera P, Elliott TR, Berry JW, Grant JS, Oswald K. Predictors of caregiver depression among community-residing families living with traumatic brain injury. Neurorehabilitation 2007; 22: 3–8.
6. Ergh TC, Rapport LJ, Coleman RD, Hanks RA. Predictors of caregiver and family functioning following traumatic brain injury: social support moderates caregiver distress. J Head Trauma Rehabil 2002; 17: 155–174.
7. Groom KN, Shaw TG, O'Connor ME, Howard NI, Pickens A. Neurobehavioral symptoms and family functioning in traumatically brain-injured adults. Arch Clin Neuropsychol 1998; 13: 695–711.
8. Ponsford J, Olver J, Ponsford M, Nelms R. Long-term adjustment of families following traumatic brain injury where comprehensive rehabilitation has been provided. Brain Inj 2003; 17: 453–468.
9. Douglas JM, Spellacy FJ. Correlates of depression in adults with severe traumatic brain injury and their carers. Brain Inj 2000; 14: 71–88.
10. Norup A, Siert L, Mortensen E.L. Emotional distress and quality of life in relatives of patients with severe brain injury: the first month after injury. Brain Inj 2010; 24: 81–88.
11. Norup A, Welling KL, Qvist J, Siert L, Mortensen EL. Depression, anxiety and quality-of-life among relatives of patients with severe brain injury: the acute phase. Brain Inj 2012; 26: 1192–2000.
12. Pielmaier L, Walder B, Rebetez MM, Maercker A. Post-traumatic stress symptoms in relatives in the first weeks after severe traumatic brain injury. Brain Inj 2011; 25: 259–265.
13. Turner B, Fleming J, Parry J, Vromans M, Cornwell P, Gordon C, et al. Caregivers of adults with traumatic brain injury: the emotional impact of transition from hospital to home. Brain Impairment 2010; 11: 281–292.
14. Marsh NV, Kersel DA, Havill JA, Sleigh JW. Caregiver burden during the year following severe traumatic brain injury. J Clin Exp Neuropsychol 2002; 24: 434–447.
15. Novack TA, Bergquist TF, Bennett G, Gouvier WD. Primary caregiver distress following severe head injury. J Head Trauma Rehabil 1991; 6: 69–77.
16. Oddy M. 7 years after – a follow-up-study of severe head-injury in young adults. J Clin Exp Neuropsychol 1985; 7: 165.
17. Oddy M, Humphrey M, Uttley D. Stresses upon relatives of head-injured patients. Br J Psychiatry 1978; 133: 507–513.
18. Jacobson NS, Follette WC, Revenstorf D. Psychotherapy outcome research: methods for reporting variability and evaluating clinical significant change. Behavior Therapy 1984; 17: 308–311.
19. Jacobson NS, Truax P. Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. J Consult Clin Psychol 1991; 59: 12–19.
20. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. Lancet 1974; 2: 81–44.
21. Derogatis LR. SCL-90-R: Symptom Checklist-90-R. Administration, scoring and procedures manual. 3rd edn. Minneapolis: National Computer Systems; 1994.
22. Olsen LR, Mortensen EL, Bech P. Mental distress in the Danish general population. Acta Psychiatr Scand 2006; 113: 477–484.
23. Baker SP, Oneill B, Haddon W, Long WB. Injury severity score – method for describing patients with multiple injuries and evaluating emergency care. J Trauma-Inj Infect Crit Care 1974; 14: 187–196.
24. Hagen C, Malkmus D, Durham P. Levels of cognitive function. Downey, CA: Rancho Los Amigos Hospital Communication Disorders Service; 1972.
25. Heck G, Schmidt T, Steiger-Bachler G. Early functional abilities (EFA) – eine Skala zur Evaluation von Behandlungsverlaufen in der neurologischen Fruhrehabiltation. Neurol Rehabil 2000; 6: 125–133.
26. Keith RA, Granger CV, Hamilton BB, Sherwin FS. The functional independence measure: a new tool for rehabilitation. Adv Clin Rehabil 1987; 1: 6–18.
27. Corrigan JD, Smith-Knapp K, Granger CV. Outcomes in the first 5 years after traumatic brain injury. Arch Phys Med Rehabil 1998; 79: 298–305.
28. Bech P, Olsen LR, Poulsen A, Mortensen EL, Munk V. [SCL-90-R Manual.] Virum: Dansk Psykologisk Forlag; 2006 (in Danish).
29. Cohen J. Quantitative methods in psychology: a power primer. Psychol Bull 1992; 112: 155–159.
30. Norup A, Kristensen KS, Siert L, Poulsen I, Mortensen EL. Neuropsychological support to relatives of patients with severe traumatic brain injury in the sub-acute phase. Neuropsychol Rehabil 2011; 21: 306–321.
31. Beck AT, Steer RA. Beck Depression Inventory – manual. San Antonio: Psychological Corp.; 1987.
32. Marsh NV, Kersel DA, Havill JH, Sleigh JW. Caregiver burden at 6 months following severe traumatic brain injury. Brain Inj 1998; 12: 225–238.
33. Marsh NV, Kersel DA, Havill JH, Sleigh JW. Caregiver burden at 1 year following severe traumatic brain injury. Brain Inj 1998; 12: 1045–1059.
34. Livingston LA, Kennedy RE, Marwitz JH, Arango-Lasprilla JC, Rapport LJ, Bushnik T, et al. Predictors of family caregivers' life satisfaction after traumatic brain injury at one and two years post-injury: a longitudinal multi-center investigation. NeuroRehabil 2010; 27: 73–81.
35. Lehan T, Arango-Lasprilla JC, de los Reyes CJ, Quijano MC. The ties that bind: the relationship between caregiver burden and the neuropsychological functioning of TBI survivors. NeuroRehabilitation 2012; 30: 87–95.
36. Gunthert KC, Cohen LH, Armeli S. The role of neuroticism in daily stress and coping. J Pers Soc Psychol 1999; 77: 1087–1100.
37. McCrae RR, Costa PT. Personality, coping, and coping effectiveness in an adult sample. J Personality 1986; 54: 385–405.
38. Kreutzer JS, Stejskal TM, Godwin EE, Powell VD, Arango-Lasprilla JC. A mixed methods evaluation of the Brain Injury Family Intervention. NeuroRehabil 2010; 27: 19–29.
39. Norup A, Siert L, Lykke Mortenensen E. Neuropsychological intervention in the acute phase: A pilot study of emotional well-being of relatives of patients with severe brain injury. J Rehabil Med 2013; 45: 827–834
40. Evans C, Margison F, Barkham M. The contribution of reliable and clinically significant change methods to evidence-based mental health. Evidence-Based Mental Health 1998; 1: 70–72.
41. Kross EK, Curtis JR. Burden of psychological symptoms and illness in family of critically ill patients: what is the relevance for critical care clinicians? Crit Care Med 2008; 36: 1955–1956.