Patterns of change and stability in caregiver burden and life satisfaction from 1 to 2 years after severe traumatic brain injury: A Norwegian longitudinal study

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Abstract

Objectives: To assess burden and life satisfaction in caregivers of patients with severe traumatic brain injury (sTBI) at 1 and 2 years post-injury, to examine if change in burden can be predicted by caregiver and patient demographics, patient’s functional status, caregiver’s social network or caregiver’s level of burden at 1 year.

Design: Prospective national multicenter study. Self-report from caregivers, patient data collected from a national cohort study on patients with sTBI.

Participants: 80 caregivers.

Main outcome measure: The Caregiver Burden Scale (CBS), life satisfaction.

Results: The total caregiver burden increased significantly between years 1 and 2 post-injury (p=0.04). Life Satisfaction was significantly lower at 2 years follow-up (p=0.03) than at 1 year. Thirty percent of the caregivers reported an increased burden, 55% were stable, and 15% had a decrease in burden between the two follow-up times. Logistic regression analyses revealed that experiencing loneliness was an independent predictor of increased burden from 1 to 2 years post-injury (OR=4.35, p<0.05).

Conclusions: The results demonstrate a need for long-term follow-up of patients and caregivers that particularly focuses on professional support to relieve caregiver burden and risk of loneliness or social isolation. This group may benefit from additional follow-up interventions tailored to their needs.

Keywords: caregiver burden, life satisfaction, traumatic brain injury, social network
INTRODUCTION

Severe traumatic brain injury (TBI) is a major public health challenge, as it is one of the most common causes of death and disability in young adults (Sundstrom, Sollid, & Wester, 2005). TBI is considered a “silent epidemic” because society seems to be unaware of the magnitude and socioeconomic consequences of the injury (Roozenbeek, Maas, & Menon, 2013). Family members serve a critical function as an extension of the health care system, but they lack formal training and support to care for persons with severe TBI (Ramkumar & Elliott, 2010). Caregiver burden has been defined as the social, psychological, physical, economic or emotional strain that caregivers may experience (George & Gwyther, 1986). This burden may also accumulate when providing care to an individual over a long period of time (Kasuya, Polgar-Bailey, & Takeuchi, 2000). The concept of life satisfaction has been described as a conscious cognitive judgment that compares one’s personal life circumstances with a set of self-imposed standards of needs or wants (Diener, Oishi, & Lucas, 2003; Fugl-Meyer, Melin, & Fugl-Meyer, 2002). In the present study, life satisfaction was considered the caregiver’s view of satisfaction with his or her life.

In the past decades, a substantial amount of literature on the impact of severe TBI on family members has pointed to a high level of caregiver burden, diminished life satisfaction, unmet family needs, adaptation to new roles, anxiety, depression, social isolation, emotional difficulties and challenges with family functioning (Bayen et al., 2012; Braine, 2011; Doser & Norup, 2016; Douglas & Spellacy, 1996; Gillen, Tennen, Affleck, & Steinpreis, 1998; Godwin & Kreutzer, 2013; Kolakowsky-Hayner, Miner, & Kreutzer, 2001; L. A. Livingston et al., 2010; Manskow et al., 2014; McKinlay, Brooks, Bond, Martinage, & Marshall, 1981; Norup, Siert, & Lykke Mortensen, 2010; Norup, Welling, Qvist, Siert, & Mortensen, 2012; Oddy, Humphrey, & Uttley, 1978). When a close relative experience lower burden, less anxiety and a good health, this is shown to have a positive impact on the person with severe
TBI (O'Neill & Carter, 1998). The close relation between the health and wellbeing of the injured and the relatives makes it important to identify interventions to improve the situation for both the patient and the relative/caregiver (Verhaeghe, Defloor, & Grypdonck, 2005).

Within the concept of caregiver burden or strain, several longitudinal studies have been reported, with inconsistent findings: A study from New Zealand on caregiver burden in 52 caregivers of patients with severe TBI 6 and 12 months post-injury found no change in burden over time (Marsh, Kersel, Havill, & Sleigh, 2002), whereas Brooks et al. found greater strain in caregivers 5 years post injury than at 1 year (Brooks, Campsie, Symington, Beattie, & McKinlay, 1986). The French PariS-TBI study measured caregiver burden 1 and 4 years post injury and reported a decrease in burden from 1 to 4 years after the injury (Bayen et al., 2014; Bayen et al., 2012). Livingston and colleagues investigated 57 caregivers of patients with severe TBI 3, 6 and 12 months post injury and found a high level of perceived burden at all follow-up times, with a slight increase in burden at 6 and 12 months. Sander et al. found a decrease in perceived burden during the first year post injury, investigating 69 caregivers at 3 different follow up times during the first year post injury (M. G. Livingston, Brooks, & Bond, 1985; Sander, High, Hannay, & Sherer, 1997). Nearly all prospective studies following the same sample have been conducted during the first year post-injury.

Regarding predictors of burden, there is strong evidence that burden is correlated with patient’s neurobehavioral problems (Bayen et al., 2014; Bayen et al., 2012; Kreutzer, Gervasio, & Camplair, 1994). Other studies have found that a patient’s level of functioning is connected to the caregiver’s reported burden or strain (Boycott, Yeoman, & Vesey, 2013; Brooks et al., 1986; Kreutzer et al., 2009; Manskow et al., 2014). Social network is a broad concept that may include all social resources available to an individual; interpersonal ties, health resources and professional support. The concept can also be defined more narrow as the individuals’ social network (A. G. Anke et al., 1997; Gottlieb & Bergen, 2010). A poor
social network have previously been shown to predict caregiver burden by Manskow et al., reporting that caregivers with a high burden 1 year post-injury were more lonely and met with friends and family less frequently (Manskow et al., 2014). Knight and colleagues found no relationship between caregiver burden and lack of a social network (Knight, Devereux, & Godfrey, 1998), while other studies indicated that a lack of social network in terms of perceived social support were related to a higher caregiver burden (Hanks, Rapport, & Vangel, 2007; Kreutzer et al., 2009).

Few studies have reported on life satisfaction measured at several time points in family members of patients with TBI. Kolakowsky-Hayner found diminished life satisfaction in family members to patients with TBI several years post injury compared to the reported level pre injury (Kolakowsky-Hayner et al., 2001). A large longitudinal study from the USA reported on life satisfaction in family caregivers of patients with TBI 1 and 2 years post-injury and found no changes in life satisfaction scores between years 1 and 2 (L. A. Livingston et al., 2010). These findings are supported by a cross-sectional study by Kreutzer et al. that showed no difference in life satisfaction compared to normative data 1, 2 or 5 years post injury (Kreutzer et al., 2009). A simultaneous study of caregiver burden and life satisfaction in caregivers of patients with stroke, found that the caregivers reporting lower life satisfaction also reported significantly more caregiver burden.(Bergstrom, Eriksson, von Koch, & Tham, 2011)

To our knowledge, the present study is the first to analyze simultaneous changes in caregiver burden and life satisfaction over time in a population of family members of patients with severe TBI. In addition, a unique aspect of our study is the regression analysis of the predictors of change in burden from 1 to 2 years post-injury. Based on the above literature review of caregiver burden and life satisfaction over time in family members of patients with severe TBI, we hypothesized that (1) the level of burden would be stable from 1 to 2 years
post-injury, (2) the level of burden would be associated with caregivers’ satisfaction with life, and (3) that an eventual change in burden would be predicted by the functional impact of severe TBI and caregivers’ social networks.

METHODS

Design

The study was a prospective, population-based, multicenter cohort study covering all regions of Norway. We included adult family members or acquaintance of patients (≥ 16 years old) with severe TBI injured between January 2009 and December 2011. All patients were admitted to one of the four trauma referral centers in Norway. The inclusion criteria for the participants in the present study were as follows:

- Closest family member or acquaintance of a patient included in the national multicenter study on severe TBI (i.e., unsedated Glasgow Coma Scale (GCS) score of 8 or less during the first 24 hours post-injury) (Andelic et al., 2012).
- Participant was listed as the patient’s closest family member or acquaintance either by the patient and/or in the patient’s medical journal.
- Age ≥ 18 years.

Data collection

The regional project coordinator at each trauma center identified a close family member or acquaintance. Written informed consent was required from both the person with severe TBI and all participating family members. The family member consented on behalf of the patient if he/she was unable to give consent due to cognitive impairment. Family members were then
contacted by telephone and informed about the study by the coordinator at the University Hospital of North Norway (responsible for the database). The questionnaires and informed consent form were sent by mail, and data were collected at 12 and 24 months post-injury. All participants had the opportunity to withdraw from the study at any time. The study was approved by the Committee for Medical Research Ethics for Southeast Norway number 2009/702. Data on patients were collected through the national multicenter patient study (Andelic et al., 2012).

Participants

In the present study we choose to name the closest family member or acquaintance as “family member”. As seen in Figure 1, a total of 171 family members were identified and contacted for possible participation in the present study. At 1 year, 119 family members completed the questionnaire, and 80 participated at both 1 and 2 years post-injury, giving a response rate of 70% and 47%, respectively (Figure 1).

The characteristics of the family members not participating were not available. Patient characteristics did not differ between those participating and non-participating, except the proportion of male patients was higher among the participating group. Descriptive data for the family members and the patient-related variables are presented in Table 1. There were no statistically significant differences between participants at 1 year and participants at both 1 and 2 years post-injury. Around 75% of family members were female, and nearly half were
married/cohabitant to the patient. We included only family members who responded at both 1
and 2 years (n=80) for the further analysis.

Family member measures at 1 and 2 year follow-up

A structured self-report questionnaire was used to obtain all information from the family
members. The Caregiver Burden Scale (CBS) was used to assess the family members burden.
The questionnaire is a generic 22-item scale developed to measure different dimensions of a
caregiver’s subjective burden (Elmståhl, Malmberg, & Annerstedt, 1996). It has previously
been used to assess burden in caregivers of patients with stroke and dementia as well as in
caregivers of patients with severe TBI (Andren & Elmstahl, 2005; Dahlrup, Nordell, Andren,
& Elmståhl, 2011; Manskow et al., 2014). The CBS contains 5 subscales, representing each
dimension of the scale: general strain (8 items), isolation (3 items), disappointment (5 items),
emotional involvement (3 items) and environment (3 items). The construct validity and
internal consistency of the scale have been described previously, yielding Cronbach’s alpha
coefficients of 0.70 to 0.87 for all subscales except for environment (0.53) (Elmståhl et al.,
1996). Elmståhl et al. (1996) also reported good test-retest reliability, with kappa values
ranging from 0.89-1.00 for all subscales except environment (0.69) (Elmståhl et al., 1996).
The items are scored from 1 to 4 (1; not at all; 2, seldom; 3; sometimes, 4; often), and the total
score for the whole scale ranges from 22-88. A high score indicates a high burden. Because
the subscales consist of a different number of questions, an index score was calculated by
using the sum score of each subscale divided by the total number of items. An index score of
1.0-1.99 indicated a low burden, 2.0-2.99 a moderate burden, and 3.0-3.99 a high burden (Bergstrom et al., 2011; Elmståhl et al., 1996).

Life satisfaction was measured with one global item: “Overall, how satisfied are you with your life right now?” The item was rated on a 5-point ordinal scale: 1 (very dissatisfied), 2 (dissatisfied), 3 (neither satisfied nor dissatisfied), 4 (satisfied) or 5 (very satisfied). This item has been used and has shown validity previously for caregivers after traumatic brain injury (Kolakowsky-Hayner et al., 2001). Based on previous results, two questions related to the family member’s personal social network were included in the analysis (Manskow et al., 2014). One questions tapped the social network quantity: “How often do you meet friends and relatives with whom you do not live, for example, visits each other’s home, go out together, talk on the phone?” (once a week, less than once a week but at least once a month, and less than once a month). The other question assessed an aspect of the quality of their social network that taps social support: “Do you ever feel lonely?” (never or rarely, sometimes, often) (A. G. Anke et al., 1997).

**Patient outcome measures at baseline and 1 year follow-up**

Acute injury severity was assessed by the most commonly used and previously validated scale: the abbreviated injury severity scale (AIS) (AAAM.org;, 2008). The AIS head score was used in the present study to indicate the severity of the brain injury; a higher severity score indicated a progressively more severe injury. The Glasgow Coma Scale (GCS) was used to assess the patient’s level of consciousness in the acute phase of the TBI, and the lowest GCS score within the first 24 hours was registered (Teasdale & Jennett, 1974). The Glasgow Outcome Scale Extended (GOSE) was scored with the structured interview and used to evaluate the patient’s functional level at the 1 year follow-up (Wilson, Pettigrew, & Teasdale, 2014).
The GOSE categorizes patient status into one of eight categories: dead (1), vegetative state (2), lower severe disability (3), upper severe disability (4), low to moderate disability (5), upper to moderate disability (6), low to good recovery (7), and upper good recovery (8).

**Statistical analysis**

The Statistical Package for Social Sciences (SPSS) for Windows version 23.0 was used for statistical analyses. The descriptive data are presented as the mean and standard deviation or as proportions of subjects. Cross-tabulations with $\chi^2$-tests were performed for nominal data. Assumptions of a normal distribution were visually inspected and tested with a skewness test statistic. Non-parametric statistical analysis was applied when the data were not normally distributed. The subscales Emotional Involvement and Environment of the CBS were skewed in a positive direction. Independent sample t-tests were used to compare the means between two or more groups. Paired sample t-tests or Wilcoxon Signed rank tests were used as the parametric and non-parametric tests, respectively, to compare the CBS score at the 1 and 2 year follow-up. If there were 1 (or 2) missing data point(s) on the CBS, the data were replaced with the caregiver’s mean value on each subscale. Participants who had more than 2 missing data points on the CBS scale were excluded.

We investigated how many participants in each group had a stable, improved or worsened CBS sum score between 1 and 2 years. At first, a distribution-based method was used to calculate the standard error of measurement (SEM, based on Cronbach’s alpha and the observed variance statistic), which indicated the smallest raw score change that reflected a true change and not measurement error. A difference of at least one SEM has been used to designate the minimal clinically important difference (Copay, Subach, Glassman, Polly, & Schuler, 2007). However, we chose a stricter definition and required 2 SEM, which in practice represented one-half the SD of the CBS total score, also used to indicate the minimal
clinically important difference (Norman, Sloan, & Wyrwich, 2003). The total CBS score at 1 and 2 years were inspected for each participant and differences of at least 2 SEM noted.

A chi-square test was performed to investigate the longitudinal change in caregiver burden between 1 and 2 years, dichotomizing the participants into two groups at 1 year post-injury: (1) low burden and (2) moderate to high burden. A binary logistic regression analysis with backward stepwise regression was then conducted to assess predictors of worsened caregiver burden from 1 to 2 years post-injury. Co-linearity was checked and only variables with correlation coefficients <0.7 were entered together in the regression analyses. The CBS dependent variable was coded as 0-stable/improved or 1-worsened.

Independent variables entered were for patients: age, gender, education, and GOSE; for caregivers: gender, relation to patient, education, time spent with patient, and frequency of meeting friends/family and loneliness measured at 1 year post-injury. First univariate analyses were conducted to analyse the association between each independent and the dependent variable. Then all variables were entered into the multivariate logistic regression analysis with the Enter method and backward removal of insignificant variables. The results are presented as adjusted odds ratios (ORs). Model fit was investigated by applying the Hosmer and Lemeshow test, and the amount of explained variance in the outcome was investigated using Nagelkerke’s R². The level of significance was set at p< 0.05.

RESULTS

At 1 year post-injury 12.5 % of caregiver experienced a high caregiver burden, 37.5 % a moderate and 50 % a low burden. The mean total CBS sum score (Table 2) showed a statistically significant increase in burden at 2 years compared with 1 year post-injury (paired t-test, p<0.05), and thereby rejecting our hypotheses of no change in CBS score between these
time-points. Supplementary analyses to identify subscales with significant changes showed increases in the CBS subscales disappointment, emotional involvement and environment increased significantly (Table 2). A proportion of 30% of the caregivers reported an increased burden, 55% a stable burden and 15% a decrease in burden from 1 to 2 years post-injury.

Insert Table 2 here

Life satisfaction scores decreased significantly with a mean score of 3.7 (SD 0.85) at 1 year to a mean score of 3.5 (SD 0.96) at 2 years post-injury (p<0.05, Wilcoxon signed rank test). As indicated in Figure 2, the proportion of caregivers scoring “very satisfied” decreased from 20% to 13% with a comparable increase in individuals dissatisfied with life as a whole.

Insert Figure 2 here

Testing our hypotheses nr. 2, the correlations between the total CBS scores and the Life satisfaction scores were strongly negative at both 1 and 2 years post-injury (Spearman's correlation =-.79 and -.79, respectively, p<0.001 for both).

Longitudinal individual changes in Caregiver Burden scores
The CBS sum score at 1 year post-injury had a Cronbach’s alpha of 0.96. The formula for the standard error of measurement (SEM) led to 1 SEM equating a change of 0.15 points. Hence a change of 0.30 points or more (2 SEM) defined a minimal clinically important difference between 1 and 2 years post-injury. Using 2 SEM individual changes in total CBS scores from 1 to 2 years post-injury are shown in Table 3 trichotomised into better, same and worse. The longitudinal changes in CBS score were statistically significant for both those reporting a low degree of burden at the 1-year follow-up, and those reporting an initially moderate/high degree of burden (p< 0.05). A larger degree of change was observed in the moderate/high burden group according to the reported p-values. By inspecting the cell numbers describing the change, 53% (10 of 19) and 82% (14 of 17) of those changing did so in a negative direction in the low and moderate/high burden groups, respectively (Table 3).

Insert Table 3 here

**Predictors of an increased caregiver burden from 1 to 2 years post-injury**

The analyses of predictors of worsened CBS from 1 to 2 years post-injury is shown in Table 4. In the univariate analyses p-values <0.1 were observed for a low GOSE score (2-5), caregiver male gender and caregiver feeling lonely often. Since the association between worsened total CBS score and low GOSE score was marginally significant (p=0.067), it was not reported further. The final model retained gender (p=0.11) and loneliness (p=0.04), explaining 12% (Nagelkerke R²) of the variance in increase in burden and correctly classifying 72.5% of the cases. The Hosmer and Lemeshow test indicated a good model fit (chi-squared: .54, df=1 and p= .46). As seen in Table 4, feeling of loneliness at 1 year post-
injury was the only statistically significant predictor of an increase in caregiver burden from 1 to 2 years post-injury in this model.

Insert Table 4 here

DISCUSSION

The present study found a significant increase in caregiver burden and a decrease in life satisfaction at 2 years compared to 1 year post-injury, rejecting our hypotheses of no change in CBS score between these time-points. The level of caregiver burden remained stable in approximately half of the caregivers. We found as predicted a significant strong correlation between burden and life satisfaction. A significant predictor of an increase in caregiver burden was the feeling of loneliness at 1 year post-injury, which partly confirmed our third hypothesis regarding social network as a predictor of an increase in burden.

Caregiver burden

Although in general the changes in burden in the present study were rather small and around half of the participants reported stable values from 1 to 2 years post-injury, the finding that 30% of the participants had clinically significant increases in burden should be relevant for health care services. In addition, caregiver burden increased more frequently among caregivers with a moderate-high burden at 1 year post-injury than in caregivers who had a low burden at 1 year post-injury. In a study by Marsh et al., no significant change in caregiver burden was found between 6 and 12 months post-injury (Marsh et al., 2002). The PariS-TBI study found a decrease in burden at 4 years compared with 1 year (Bayen et al., 2014; Bayen et al., 2012). However, Bayen and colleagues did not compare the same population at these
two time points; they reported the degree of burden in two different studies at 1 and 4 years
post-injury. Both the different populations and the longer time span post-injury could explain
the discrepancy in results compared with the present study. The difference in tools used to
assess burden may have also influenced the results. In our study, the results were robust, as
the burden increased significantly both in mean CBS scores and when measured as numbers
with minimal clinically important different changes. A recent study from Denmark (2016)
assessed caregiver burden with the CBS 3-6 years after a severe TBI and found almost similar
burden scores within each subscale of the CBS as the present study, although the Danish
study only assessed the burden at one time point (Doser & Norup, 2016).

There may be several possible explanations for the findings of increased burden over
time in the present study. At 1 year post-injury, the caregivers may still hope for an
improvement in the patient’s conditions and may not be fully aware of the long-term
consequences of the injury. At 2 years post-injury, the caregiver may also be receiving less
help from the community healthcare system than after 1 year. According to Lezak (Lezak,
1986), family members of a person with TBI go through 6 stages of reactions; from pleasure
of the patient returning home and optimism for the future, to anxiety when energy and
optimism decreases after 9-24 months post-injury and further. This last stage is often followed
by anxiety, depression, mourning and emotional disengagement. Psychological interventions
in addition to professional support in care may help families negotiate these stages and helps
them to understand the nature and long-term effects of the injury (Lezak, 1986).

Correlation between caregiver burden and life satisfaction

We found a strong correlation between caregiver burden and life satisfaction, indicating a
relationship in which a low burden was associated with a high satisfaction with life and vice
versa. The strong association between burden and life satisfaction was not unexpected. The findings are in accordance with a Swedish cross-sectional study that investigated caregiver burden and life satisfaction in caregivers of patients with stroke using the CBS and Li-Sat 11 and found that the caregivers who were not satisfied with life had a higher burden (Bergstrom et al., 2011). The present study is the first to investigate caregiver burden and life satisfaction simultaneously after severe TBI. To our knowledge, only two Swedish studies have previously investigated the relationship between caregiver burden and life satisfaction; Andren and Elmståhl reported that caregivers of patients with dementia could experience a moderate burden and great satisfaction at the same time (Andren & Elmstahl, 2005), while the Bergström and colleagues found that caregivers of patients with stroke reporting lower life satisfaction also reported significantly higher caregiver burden (Bergstrom et al., 2011). Both studies used the same CBS as in the present study, although they used the Caregiver Assessment of Satisfaction Index and the Life Sat11 respectively to measure life satisfaction.

Attention to the increasing burden and decrease in life satisfaction of caregivers needs to be addressed in community health care (family doctors, district nurses, teachers, etc.) as well as in specialized health care services. For patients, multidisciplinary rehabilitation programs that have integrated or separate programs for family members should always be considered (Becker, Kirmess, Tornas, & Lovstad, 2014). The use of programs for family members focusing on education and coping strategies and providing information about available services and social rights are indicated (Ramkumar & Elliott, 2010), and have in previous studies shown to reduce the burden in family members of patients with TBI (Holland & Shigaki, 1998; Perlesz & O'Loughlan, 1998).

Life satisfaction
The results in the present study are in reasonable accordance with a study by Livingston and colleagues who reported small but non-significant decreases in life satisfaction in caregivers of patients with TBI between 1 and 2 years post-injury, although they used the more extensive Satisfaction With Life Scale (L. A. Livingston et al., 2010). A limitation in the present study was the single item, but a previous study has confirmed validity (Kolakowsky-Hayner et al., 2001), and in addition the high negative correlation to the CBS supports the validity of the measure. Further, our findings indicate that the one-item question showed a good sensitivity to change. Kolakowsky-Hayner et al. used the same life satisfaction item as in the present study to compare an assessment after at least 4 years post injury with reported pre-injury satisfaction in 57 caregivers of patients with TBI (Kolakowsky-Hayner et al., 2001). They found a long term decrease in life satisfaction; 87 % of the caregivers reported to be satisfied and very satisfied with life pre-injury, diminishing to 59 % satisfied/very satisfied at time of assessment several years post injury, a somewhat higher proportion satisfied family members than in our study at 2 years post-injury.

Predictors of an increase in caregiver burden

Feeling lonely was a significant independent predictor of an increase in burden from 1 to 2 years post-injury. Loneliness has been regarded as a psychological aspect of social isolation and has been referred to as perceived subjective isolation (Cacioppo, Cacioppo, & Boomsma, 2014). Loneliness has previously been assessed by Anke and colleagues, who described loneliness as an aspect of low perceived social support and an important indicator of social network quality (A. G. Anke et al., 1997). Manskow et al. recently found that loneliness was independent associated with a higher caregiver burden 1 year after severe TBI (Manskow et al., 2014). However, loneliness and social isolation must be viewed as two separate concepts,
as feeling lonely does not necessarily mean that the person is socially isolated (Nicholson, 2012). Few studies have aimed to study caregivers’ loneliness in the TBI population. Oddy et al. reported loneliness as being the most difficult aspect of social adjustment in caregivers of TBI survivors (Oddy, Coughlan, Tyerman, & Jenkins, 1985). In a qualitative study on caregivers of patients with acquired brain injury, Braine found loneliness to be a key theme contributing to their overwhelming sense of loss and burden (Braine, 2011).

In the present study, we revealed that men experienced an increase in burden over time more often than women, although this was not statistical significant. In a clinical review on caregiver burden gender was not mentioned as a risk factor for increase in burden over time, and this issue should be explored in future studies (Adelman, Tmanova, Delgado, Dion, & Lachs, 2014). The patient’s level of functioning at 1 year post-injury was not a significant independent predictor of an increased burden from 1 to 2 years in the present study, indicating that an increase in burden over time was not influenced by the patients’ functional status.

However, there was a tendency to a positive association between low GOSE score at 1 year and increase in burden in the univariate analyze (p=0.067), indicating a risk for a statistical Type 2-error. The results may also suggest that other factors such as no or little support from health and/or social services, family and friends are more important factors contributing to increases in burden (Hanks et al., 2007; Manskow et al., 2014).

Consideration of methodology and design

No established values to indicate a minimal clinically important change in CBS score at the individual level have previously been reported. To investigate change and stability in CBS, we decided to use a difference of 0.30 points between the two time points as the minimum clinically important change. This corresponds to 10% of the range of the scale (1.0-4.0), a percentage previously reported to indicate a minimal clinically important change in other
measures (Fayers, Langston, Robertson, & group, 2007). In general, the definition of the minimal clinically important difference is debated in the literature, and no consensus has yet been reached (Copay et al., 2007). Although one standard error of measurement (SEM) has been reported to indicate a minimal clinically important difference (Norman et al., 2003), the chosen value of 0.3 was twice the SEM and close to the alternative distribution-based method using half the SD as the measurement of a minimal clinically important change (Copay et al., 2007).

The Life satisfaction item used in the present study was uni-dimensional and only assessed overall satisfaction with life, whereas there are other multidimensional scales measuring satisfaction with life, for example the Life Satisfaction Index A (Neugarten, Havighurst, & Tobin, 1961), and the Life satisfaction checklist (Fugl-Meyer et al., 2002). The use of a one-item overall assessment of life satisfaction is transferrable to the use of a single overall assessment of patients’ health status and quality of life which has previously been highlighted as an extremely useful indicator of a patients well-being (Fayers & Sprangers, 2002). The one-item questionnaire was chosen in accordance with previous studies, and responsiveness and validity were supported in the present study (A. Anke et al., 2014; Fujita & Diener, 2005; Kolakowsky-Hayner et al., 2001).

Strengths and limitations of the study

A clear strength is the study’s design as a national prospective multicenter study. In addition, the use of established and validated instruments and the assessment at two points in time are strengths. The literature recommends prospective, longitudinal studies that use similar follow-up times post-injury and the same level of TBI severity to assess burden over time (Ramkumar & Elliott, 2010; Thompson, 2009). The participation rate for those who answered
at both follow-up times was 47%. Though lack of information regarding the non-consenting family members, the patients in non-participating families did not differ significantly from patients in participating families. However, we cannot exclude the possibility of selection bias: Those who did not participate may have been family members with a higher or lower burden than the participants. Although the number of participating family members were higher than in most previous longitudinal studies, the relatively small number of participants led to low statistical power.

A limitation could be the one-item question of loneliness tapping social support, but the association between social support and burden is supported by several studies, also with more extensive measures (Hanks et al., 2007; Kreutzer et al., 2009). Another limitation is the lack of available neuropsychological data that would provide more information about the patients cognitive functioning. We are also aware that other factors not measured in this study are known to be important for family members burden and life satisfaction such as the relatives coping style, resilience and mental health status (Ponsford & Schonberger, 2010; Simpson & Jones, 2013). Whether these factors influence change in burden or life satisfaction is not investigated in the present study. We acknowledge that our results may not be generalizable to (all) other countries or cultures caused by national differences in systems for support after discharge and traditions for family involvement. (Norup et al., 2015). Age of family member was not measured in this study. However, as significant association between age of family member and caregiver burden are not found in previous studies, we do not think this weakens the results.

CONCLUSION
An increase in caregiver burden, a decrease in life satisfaction and a strong association between caregiver burden and life satisfaction over time, has significant clinical implications. Family members play a fundamental role in the long-term care and rehabilitation of patients with severe TBI. The consequences of caregiving must be recognized and met with targeted actions if caregivers are expected to effectively fulfill this role, participate in the society and maintain their quality of life. The results demonstrate a need for future long-term follow-up of patients and caregivers that particularly focuses on professional support to relieve caregiver burden and risk of loneliness or social isolation. The ability to identify family members with a moderate to high burden is crucial in order to develop relevant interventions.

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