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Original article

A comprehensive picture of 4-year outcome of severe brain injuries. Results from the Paris-TBI study



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ABSTRACT

Objectives: Survivors of severe traumatic brain injury have a great variety of impairments and participation restrictions. Detailed descriptions of their long-term outcome are critical. We aimed to assess brain injury outcome for subjects with traumatic brain injury in terms of the International classification of functioning, disability and health.

Materials and methods: Four-year follow-up of an inception cohort of adults with severe traumatic brain injury by using face-to-face interviews with patients and proxies.

Results: Among 245 survivors at 4 years, 147 were evaluated (80% male, mean age: 32.5 ± 14.2 years at injury); 46 (32%) presented severe disability, 58 (40%) moderate disability, and 40 (28%) good recovery. Most frequent somatic problems were fatigue, headaches, other pain, and balance. One quarter of subjects had motor impairments. Rates of cognitive complaints ranged from 25 to 68%, the most frequent being memory, irritability, slowness and concentration. With the Hospital Anxiety and Depression Scale, 43% had anxiety and 25% depression. Overall, 79% were independent in daily living activities and 40 to 50% needed help for outdoor or organizational activities on the BICRO-39. Most had regular contacts with relatives or close friends but few contacts with colleagues or new acquaintances. Subjects spent little time in productive activities such as working, studying, looking after children or voluntary work. Quality of life on the QOLIBRI scale was associated with disability level ($P < 0.0001$).

Conclusion: Management of late brain injury needs to focus on cognitive difficulties, particularly social skills, to enhance patient participation in life.

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1. Introduction

Traumatic brain injury (TBI) is an important public health issue, with an overall incidence of 262 hospitalizations/100,000 inhabitants per year in a recent European synthesis [1], with high frequency among young adults. Severe TBI, although representing

about 10% of TBI cases, is responsible for the worse consequences, with 39% early mortality rates and 60% unfavourable outcomes [2].

A great number of studies have provided data on the outcomes and prognostic factors of severe TBI, but most focused on 6-month or 1-year outcomes [3]. Longitudinal studies with information on late TBI outcome are less frequent [4]. The particularities of the natural history of severe TBI require long-term outcome data. The greater part of recovery takes place within the first year in terms of motor impairments [5], but changes in cognition or levels of participation are frequently observed at later stages [6,7]. The late outcome of patients must be described.

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TBI outcome is generally understood as mortality or global disability when considered at early stages [8]. However, a specificity of this condition is its multifiform nature, with a great variety of long-term consequences [9]. Typical impairments include neurological deficits such as motor, sensory, and cerebellar impairments; muscle tone abnormalities and orthopaedic problems; and various cognitive impairments [10]. Few cohorts have provided detailed descriptions of late impairments after severe TBI [9], and relative frequencies of each of these are not well known.

As patients strive to resume their pre-injury functioning, late outcome is also involved in consequences of impairments in everyday life. According to the World Health Organization framework of the International Classification of Functioning, Disability and Health (ICF), such consequences include:

- limitations in activities that the person can execute;
- restrictions in participation, which refers to involvement of the person in real life situations [11].

Therefore, a comprehensive assessment of TBI outcome should cover a wide range of dimensions, taking into account such activities and participations.

Epidemiological and late outcome data for severe TBI in France comes from several studies. The cohort with TBI of various severity in the Aquitaine region has been followed starting in 1996 [12] and up to 9 years post-injury [13]. The ESPARR longitudinal cohort has been addressing 1- to 5-year outcomes after traffic-related injuries, including TBI, since 2004 [14]. However, the epidemiology is in constant evolution, with a gradual shift from mostly traffic-related injuries in predominantly young males to mostly fall-related injuries in older people in developed countries [2]. Pre-hospital and early care of injuries has also greatly evolved in the past years. Information on post-TBI outcome requires continuous updating. The purpose of the Paris-TBI cohort, which started in 2005–2007, was to renew epidemiological knowledge on TBI and its outcome.

The objective of the present study was to describe the 4-year outcome of this cohort in terms of detailed impairments, activities, participation and quality of life.

2. Patients and methods

2.1. Design of the Paris-TBI study (severe traumatic brain injury in the Parisian area)

The Paris-TBI study was a large prospective inception cohort study undertaken in 2005 in the Île-de-France region (Paris metropolitan area, 12 000 km², 11.6 million inhabitants). Consecutive patients were included by mobile emergency services and firemen brigades of the region over a 22-month period. Criteria for inclusion were patients ≥ 15 years old with severe TBI (lowest Glasgow Coma Scale [GCS] score [15] before hospital admission ≤ 8 , in the absence of other causes of coma). A total of 504 patients were included. Main causes of injury were road traffic accident (52%) and falls (34%).

A 1-year outcome assessment, performed by telephone, included measures of overall disability, executive functions and employment [16]. The present report addressed results from the second outcome evaluation conducted 4 years post-injury [17–19]. Patients and their relatives were contacted by telephone and mail, and a face-to-face interview with a trained neuropsychologist was scheduled. When a direct interview was not possible, patients or their relatives were contacted by telephone to obtain minimal outcome data.

2.2. Patient assessment

The 4-year assessment was designed following the ICF framework of impairments, activities and participations, and used disease-specific validated instruments whenever possible. Overall disability was assessed by the Glasgow Outcome Scale Extended (GOSE) [20], French version [21]. This widely used scale is based on a structured interview and provides an ordinal classification of disability into 8 categories ranging from death to upper good recovery.

Clinical evaluation and standardized questions assessed the presence of neurological, motor, sensorial, orthopaedic and low urinary tract impairments. Self-reported neuropsychological impairments were provided by questions from the Brain Injury Complaint Questionnaire [22], a clinician-derived instrument to assess most common cognitive or behavioural changes, with yes/no answers. A short cognitive and behavioural evaluation involved the Neurobehavioural Rating Scale-Revised (NRS-R) [23]. The NRS-R is a 29-item instrument addressing different domains of cognition and behaviour frequently impaired after a TBI, based on a semi-structured interview. For each item, scores range from 1 (absence of dysfunction) to 4 (severe dysfunction); the total score ranges from 29 to 116. The test has been found sensitive to the effect of TBI [24]. Mood impairments were measured by the Hospital Anxiety and Depression Scale (HADS) [25], which has two subscores, for anxiety and depression, both ranging from 0 to 21 (highest anxiety or depression).

Independence in activities of daily living was measured by the Barthel Index [26] (score ranging from 0 to 100 [full independence], with 5-point increments). To assess real participation in instrumental, social and productive activities, proxy answers to the Brain Injury Community Rehabilitation Outcome-39 scale (BICRO-39) were obtained [27]. This tool, derived from the ICF concepts, has been validated in populations of brain-injured people [27] and translated into French. It includes 8 dimensions (mobility, self-organization, socializing, parent/siblings contact, partner/child contact, productive employment, psychological, personal care), of which the first 6 are presented in this study because psychological difficulties are addressed by the HADS and aspects of personal care by the Barthel Index.

The Quality of life after brain injury scale (QOLIBRI) is a TBI-specific patient-reported measure of quality of life [28] validated in a large multinational TBI population [29]. It includes 37 items measuring 6 dimensions. Four dimensions address the level of satisfaction with cognition (e.g., memory, orientation, decision making), self (e.g., self-image, accomplishments, motivation), daily life and autonomy (in instrumental activities) and social relationships. Two dimensions measure the degree of botheredness with emotions (e.g., feeling of loneliness, anxiety, aggression) and physical problems. It was proposed as a written self-reporting questionnaire; participants were instructed to complete the form at home with a proxy help when necessary and to return it by postal mail.

When only minimal telephone evaluations were possible, these included at least the GOSE assessment, for which face-to-face and telephone assessment are well correlated [30]. General information such as employment status and living place was also obtained.

2.3. Statistical analyses

Data are reported with mean \pm SD for quantitative variables and number and percentages for categorical variables. Data were sometimes incomplete, because some participants received shorter telephone interviews and some did not provide answers to all questionnaires. In case of missing data, percentages were based on the number of subjects who answered the given questionnaire.

2.4. Ethical concerns

In accordance with French legislation, patients and their relatives were informed about the initial inclusion in the database, and informed consent of participants or their legal representatives was obtained before late assessments. Approvals from Commissions that enforce research database legislation in France were obtained at each study stage. Approvals from the local Ethical Committee (*Comité de protection des personnes*, CPP XI) were obtained before outcome assessments. The study was posted to ClinicalTrials.gov (no. NCT01437683).

3. Results

3.1. Population characteristics

Among 245 survivors, 147 underwent the 4-year assessment (complete interview or minimal telephone assessment); 62 were lost-to-follow-up, and 36 refused to participate. Mean delay from injury to evaluation was 50.9 ± 6.4 months. Most participants were home-dwellers; 5 were in long-term care facilities. As previously reported [31], non participants and participants did not differ in age, gender, and TBI severity, but non participants more frequently had a history of pre-injury alcohol abuse or unemployment. Among the 147 subjects included, 117 (80%) were male, and mean age at injury was 32.5 ± 14.2 years (range: 15–81). Mean initial GCS score was 5.9 ± 2.0 , and mean time to follow was 13.0 ± 12.3 days.

3.2. Global outcome and impairments

On the GOSE scale ($n = 145$), 15 subjects (10%) had lower-level severe disability, 31 (21%) upper-level severe disability, 33 (22%) lower-level moderate disability, 25 (17%) upper-level moderate disability, 33 (22%) lower-level good recovery, and 10 (7%) upper-level good recovery. One person had a tracheostomy, and one had a gastrostomy.

Rates of somatic and neurological impairments are in Fig. 1; 128 subjects (83.7%) presented at least one of the impairments. Most frequent problems were fatigue, headaches, other pain, and balance difficulties. Nearly one-quarter of the subjects presented

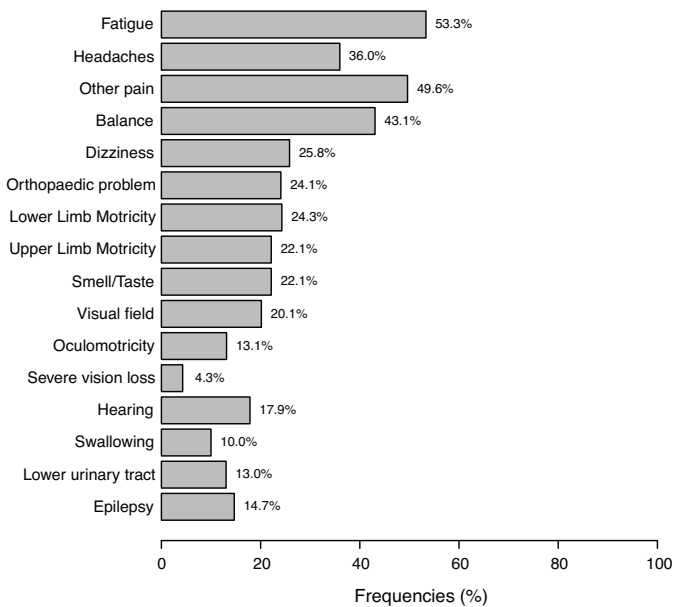


Fig. 1. Rates of somatic and neurological disturbances for subjects with traumatic brain injury ($n = 140$). Severe vision loss corresponds to major or complete unilateral or bilateral visual acuity loss.

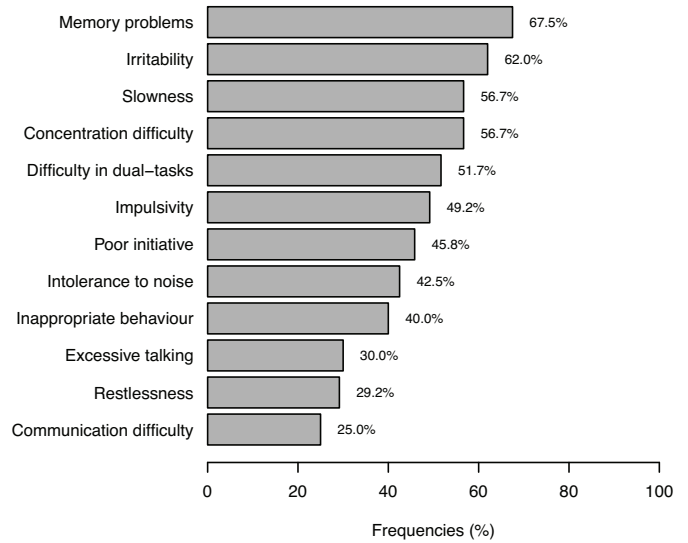


Fig. 2. Rates of cognitive complaints ($n = 120$).

upper-limb or lower-limb motor problems. Most frequent cognitive complaints were memory problems and irritability (Fig. 2). Rates of cognitive complaints ranged from 25% to 68%. Mean HADS scores were 7.2 ± 4.5 for anxiety and 5.2 ± 4.5 for depression ($n = 118$). Using the previously defined 8-point cut-off score for these subscales [32], 51 subjects (43%) had an anxiety disorder and 29 (25%) had depression.

Assessment of the NRS-R was performed for 96 subjects (Table 1). Subjects who completed the NRS-R assessment did not differ from those not completing the assessment in terms of age, brain injury severity, GOSE score or HADS score but were more independent in terms of the Barthel Index (mean difference = 6.4, $P < 0.01$). Mean total NRS-R score was 37.6 ± 7.3 , and 95% of

Table 1 Rates of disturbances in the Neurobehavioural rating scale-revised (NRS-R) ($n = 96$).

Domains of the NRS-R	Positive finding ^a
Anxiety	62 (64.6%)
Irritability	62 (63.9%)
Memory difficulties	56 (58.3%)
Attention difficulties	46 (47.9%)
Mental fatigability	43 (44.8%)
Depressive mood	42 (43.8%)
Decreased initiative or motivation	38 (40.0%)
Guilt	30 (31.2%)
Difficulty in mental flexibility	23 (24.2%)
Difficulties in oral comprehension	21 (21.9%)
Conceptual disorganisation	20 (21.1%)
Blunted affect	20 (21.1%)
Emotional withdrawal	20 (20.8%)
Motor slowing	19 (19.8%)
Self appraisal difficulties	18 (18.9%)
Difficulties in oral expression	18 (18.8%)
Difficulty in planning	18 (18.9%)
Disorientation	15 (15.8%)
Suspiciousness	14 (14.6%)
Reduced alertness	11 (11.5%)
Hyperactivity/agitation	9 (9.4%)
Difficulties in articulation	9 (9.4%)
Disinhibition	8 (8.3%)
Lability of mood	8 (8.3%)
Exaggerated somatic concern	6 (6.3%)
Unusual thought content	4 (4.2%)
Excitement	4 (4.2%)
Hostility	2 (2.1%)
Hallucinations	2 (2.1%)

^a Positive findings include mild, moderate and severe dysfunction.

subjects showed disturbances in at least one item of the scale. Anxiety and irritability were the most frequent impairments (two-thirds of subjects), followed by memory problems. More than 40% of subjects showed decreased initiative, attention difficulties, mental fatigability and depressive mood.

3.3. Activities, participation and quality of life

On the Barthel Index ($n = 138$), 110 subjects (79%) had the maximum score, 13 (9%) scores of 90 or 95, and 16 (12%) scores 20 to 75. Limitations in the instrumental activities of the BICRO-39 subscales of mobility and self-organization, as acknowledged by subjects' proxies, are specified in Fig. 3. About 40% of subjects needed partial or complete help for any of the mobility items, but > 50% needed help for any of the self-organization items, and only one third of subjects could write official letters independently. Although 95 subjects (69%) declared that they used to drive pre-injury, and 65 (47%) were driving post-injury. The car had been specifically adapted for injury consequences for 3 subjects. Only 29% of subjects who had resumed driving had validated their licence at the Regional Driving Licence Commission, although it is legally required after a brain injury in France.

Pre-injury, 51 subjects (36%) declared having a spouse or partner and 91 (64%) were single, divorced or widowed. Post-injury, the proportions of marital situations were similar (36% with a partner and 64% single). For many subjects, the marital status had changed after the injury: 16 had married or were in a couple relationship, and 16 had become single or divorced. Frequencies of relationships with friends, colleagues or family members are in Fig. 3, with the Socializing and Contacts subscale of the BICRO-39. Regular contacts were especially present with siblings, other relatives and closest friends, although with various frequencies. In total, 51 subjects (36%) declared having a professional activity. Apart from professional activity, most participants spent very little time in productive activities such as studying, looking after children or voluntary work (Fig. 3, Productive employment subscale of the BICRO-39).

As shown in Fig. 4, the mean quality of life scores seemed poorer with lower disability levels for nearly all subscales of the QOLIBRI, especially for satisfaction with physical problems and daily life, whereas satisfaction with emotions and cognition appeared more preserved in patients with severe disability. The mean QOLIBRI total score was 84.0 ± 2.0 for subjects with "good recovery", 66.5 ± 2.2 with "moderate disability" and 55.9 ± 3.5 with "severe

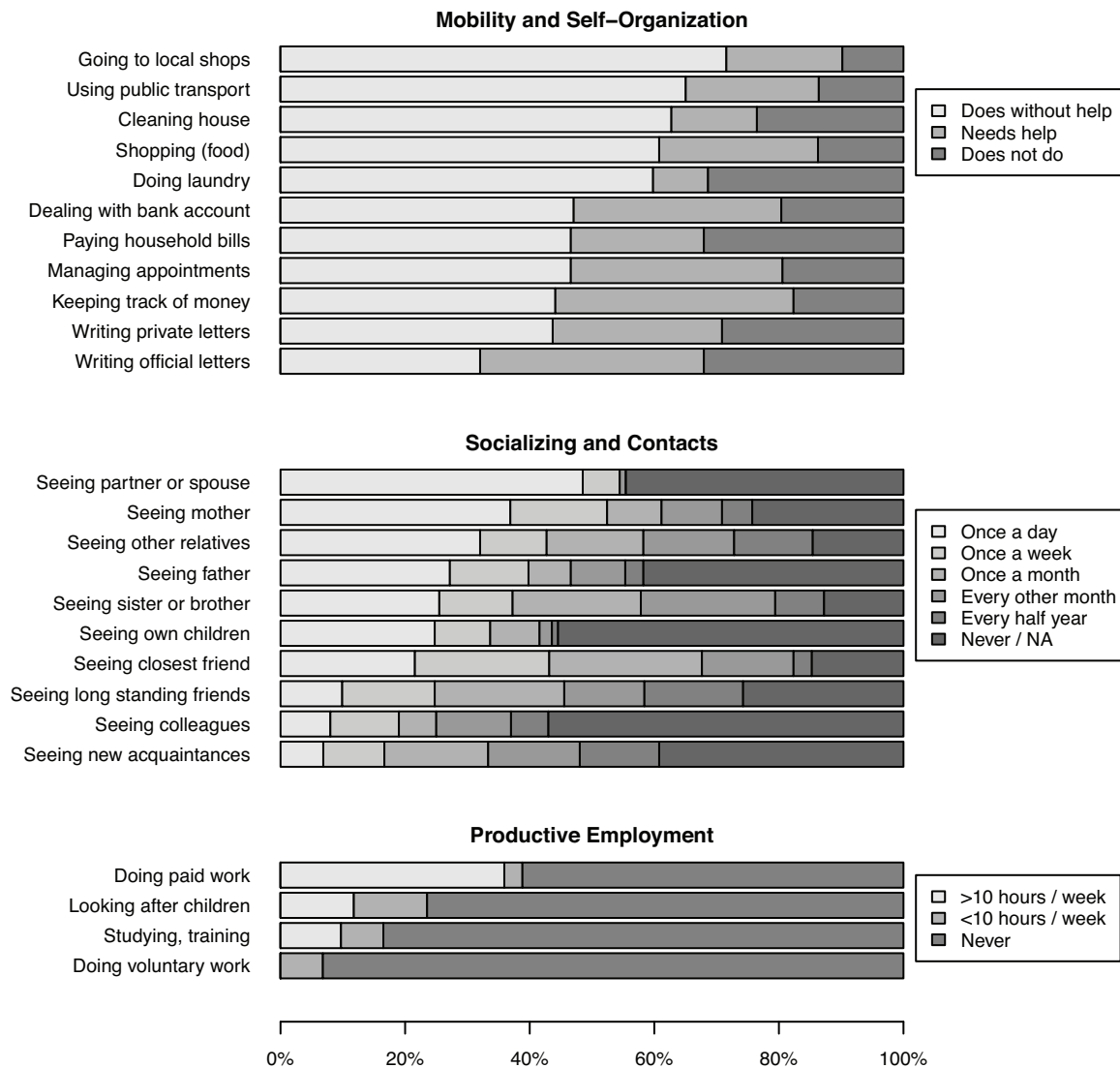


Fig. 3. Answers to items of the BICRO-39 participation scale, assessed by subjects' proxies ($n = 102$). To facilitate reading of the graph, the class "needs help" includes "needs prompt help", "some help", "a lot of help", "constant help." The class "< 10 hours/week" includes "5 to 10 hours a week", "1 to 4 hours a week" and "< 1 hour a week". The class "> 10 hours/week" includes "11 to 20 hours a week" and "> 20 hours a week".

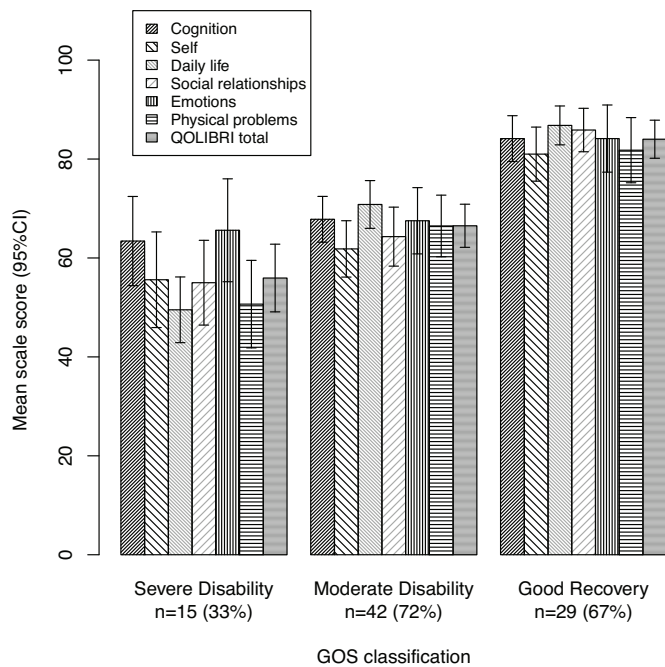


Fig. 4. Mean scores of subscales and total scale of the QOLIBRI quality of life by the 3 groups of the Glasgow Outcome Scale ($n = 85$). Because the scale was a self-reporting questionnaire to return by postal mail, only 15 of 46 subjects in the “Severe Disability” group completed the scale (i.e., 33%); in the 2 other outcome groups, participation rates were higher (72% and 70%). 95% CI (95% confidence interval) defined by mean \pm 1.96 \times standard error of mean.

disability” ($P < 0.0001$ on Anova). The last question in the QOLIBRI scale assessed the global degree of botheredness after the TBI independent of other questions. In total, 12 subjects (14%) were very bothered, 19 (22%) rather bothered, 19 (22%) moderately bothered, 24 (28%) a little bothered, and 12 (14%) not at all bothered.

4. Discussion

These results from a large homogeneous cohort with TBI confirmed that disability remained important even some time after these severe brain injuries. Only 7% of the sample achieved a return to quasi-normal life, the criterion for upper-level good recovery. Hence, permanent sequelae affected most patients, albeit at various levels. The detailed description of impairments, activities and participation provided the opportunity to comment on common post-TBI problems in different domains of the ICF.

The classical notion that people with TBI show better recovery of motor than cognitive functions is illustrated in Figs. 1 and 2. However, non-cognitive impairments were not rare. These motor, balance and sensory deficiencies can overburden people with TBI and increase difficulties for them to compensate cognitive impairments. The predominance of dizziness and balance difficulties, headaches, pain, fatigue was consistent with literature findings of severe TBI. Ponsford et al., in a longitudinal follow-up at 2, 5, and 10 years post-TBI, found remarkably similar frequencies and few changes in these symptoms at 10 years [9].

These results also highlight the heterogeneity of TBI sequelae. None of the impairments studied were present in more than two-thirds of the subjects, but almost all presented at least one of them (95% for cognitive impairments on the NRS-R, 84% for somatic or neurological impairments). The diversity of clinical situations illustrated here demands a specific individualization of TBI care, which explains the challenge in planning adequate health care for

TBI, although care pathways are starting to be established [33]. Moreover, heterogeneity of TBI implies challenges in TBI clinical and observational research, for which current trends lean to recruiting high numbers of subjects into large multinational studies [34].

Neuropsychological deficiencies described by subjects and by the evaluator both revealed a predominance of memory problems, attention deficiencies, irritability and anxiety. The cognitive assessment tools used in this study lack reference values in healthy populations, so attributing all these difficulties to injury consequences is difficult. However, studies from most cohorts also found that memory, attention, irritability and cognitive fatigue were the most common problems late post-TBI [9,35–37]. Therefore, the use of rehabilitation techniques to address brain-injury-related memory or attention deficiencies is essential for these patients, as are techniques to help them cope with irritability and anxiety. Rates of significant anxiety and depression defined by the HADS, although comparable to previous results [38], were remarkably high. Recent findings regarding patients’ opinions on post-TBI health care needs consistently showed that their priority needs were “improving cognition” and “managing stress” [39,40].

Following the ICF framework, results from this study also confirmed the previously known fact that individuals usually regain the ability to perform simple daily living activities, measured by the Barthel Index, even after a severe TBI. The answers to the BICRO-39 scale questions by proxies further specified the activities that subjects performed in reality. There was an interesting autonomy gradient highlighted by the BICRO-39 findings. Recovery was better in mobility activities, then self-organization, then social contact and finally job market inclusion. This finding might be related to the growing cognitive input required by these activities. Deficiencies in social skills also factor into these results, with the highest difficulties in establishing new relationships, participating in volunteer activities or taking care of children. TBI research shows a growing interest in the domain of social cognition and social skills, and recent studies have shown correlations between some measures of social cognition and functional outcome [41].

The fact that in-home activities were performed better than social or professional involvement might also point to higher “environmental barriers” as defined in the ICF in the outdoor social or professional setting for people with TBI. In the indoor setting, proxies provide high amounts of informal help, stimulations or supervision [17], which could in the long term improve participation of people with brain injury and represent “facilitating” environmental factors.

Findings of quality of life were consistent with previous studies involving the QOLIBRI or other scales and finding correlations with disability level [13,28,42]. Other reports have found that for some patients with very severe disability, life satisfaction could be surprisingly high [42,43], which might relate to a lower awareness of difficulties by highly impaired people. Fig. 4 also suggested that in high recovery groups, scores in different domains of quality of life were similar, while high contrasts existed for patients with severe disability between daily life and physical dimensions on the one hand and cognition and emotions on the other. Differential profiles of satisfaction with life between severely disabled and non-disabled subjects have been previously described [42].

Our study contains several limitations. First, because of the time required for assessments and variable involvement of subjects and proxies, some evaluations were not performed for the whole sample. Although information on overall disability was obtained for all subjects, the number of subjects for the other scales varied from 96 for the NRS-R to 140 for descriptions of impairments. Therefore, some caution is needed in directly comparing frequencies for the different scales. Second, loss-to-follow-up rate was 42%, which is high although common in brain-injury cohorts

[8]. Our sample seemed representative of the original cohort in terms of age, gender and injury severity. However, an important proportion of subjects with severe TBI were not accounted for, as is unfortunately often the case in TBI outcome research. The worse pre-injury social status [31] and the difficulties in contacting these subjects at 4 years suggest that their societal participation was poorer than that of the study sample. We did not test the representativeness of the initial cohort with severe TBI occurring in the area. Some patients may have been transported by private ambulances and therefore did not participate in the recruitment. The initial recruitment appeared homogeneous in terms of geographical distribution and injury times. However, in comparison to international literature data, the situation of the Paris-TBI cohort seemed particularly severe, with high severity markers and mortality rates. Therefore, the present findings might reflect the outcome of patients with very severe TBI.

In conclusion, this comprehensive description of late outcomes after severe TBI stresses several requirements of TBI care, such as the need to individualize care and to tailor rehabilitation to specific cognitive disorders. Because the main goal at this stage is to enhance participation, social skills and environmental factors should be priority targets for interventions.

Disclosure of interest

The authors declare that they have no competing interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.rehab.2015.10.009>.

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