

Case Series Illustrating the Use of Consistent Rehabilitation Outcome Measures in Traumatic Brain Injury

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Abstract

Despite the prevalence of persons with traumatic brain injury (TBI), there is limited research evidence on rehabilitation outcomes for this population or therapy efficacy, making it difficult to document overall program outcomes. This may in part be due to the heterogeneity of the condition presentation, therapist and center treatment variability, and the expert recommendations for multidisciplinary care which complicates research design. A different approach may be to accept the heterogeneity of the population and gather consistent outcome data. A set of consistent measures used across the population may allow individual clinicians, managers and researchers to track therapy efficacy and over time improve management of this unique client population. This case series reports on the first three clients seen in one outpatient rehabilitation clinic where a consistent set of simple but clinically relevant physical rehabilitation outcome measures were added to therapy at evaluation and after every ten subsequent sessions. Measures selected were chosen to document key movement impairments and quality of life issues after TBI, yet be simple enough for use in routine clinical practice. Despite the considerable variation in client presentation (time since injury, age, clinical presentation) these measures were able to track improvement for each client. It is proposed that clinicians develop a standard battery of easily administered, functionally relevant outcome measures that can be used to study the effects of individualized therapies on this diverse population.

Keywords: Brain injury; Case series; Outcome measures

Introduction

Traumatic brain injuries (TBI) are among the most common neurologic disorders encountered in the health care system, with an estimated 1.7 million occurring annually in the US [1,2]. The cost to society is also enormous with very high direct and indirect medical costs [2]. Since it is acknowledged that one of the largest groups of people with disabilities worldwide is that of TBI survivors [3], evidence-based rehabilitation guidelines are badly needed.

Unfortunately, the deficits seen post elsewhere TBI are unlike those demonstrated in many other neurologic conditions in that there is not a condition specific pattern of impairment [4-6]. In addition, research in rehabilitation post TBI is less advanced than that for other neurologic conditions [4] and randomized clinical trials in physical rehabilitation are uncommon [5]. The heterogeneity of TBI presentation may be one explanation for this as it makes formation of homogeneous groups for trials difficult. Published trials frequently study interventions in isolation and trial requirements for a relatively homogeneous sample limit generalization [6]. There are published guidelines for TBI management, but they acknowledge the difficulties of finding research evidence specific to TBI and the necessity of relying on evidence extrapolated from other conditions and consensus opinion [e.g. see 7-9]. Another problem, particularly noted in studies of physical rehabilitation is the multiplicity of outcome measures used and the wide variation of management techniques used by different centers and therapists [4]. There are calls for more TBI specific research, and for use of a common set of outcome measures [4,5,10,11].

The difficulties mentioned above limit the ability of individual clinicians, managers and researchers to track therapy outcomes and develop guidelines for managing this unique population. One approach may be to use a simple, set of consistent readily applied outcome measures with all clients with TBI. While this would not limit individualized management it is it has the potential to allow comparative outcome evaluation across the population. This case series was designed to examine the feasibility of using this approach with a

heterogeneous group of clients with TBI in typical clinical practice. It reports on the first three individuals put through the selected set of outcome assessments.

Materials and Methods

Following approval by the Institutional Review Board (IRB) of Central Michigan University, three clients referred for rehabilitation services to Hope Network Rehabilitation Services, Mt Pleasant and Michigan were identified by clinic staff. Clients were required to have a history of TBI of sufficient severity to require physical therapy services for coordination and movement impairments. All participants completed informed consent. A short battery of clinical tests (described below) was administered at initiation of therapy and all but one test repeated after every 10 treatments until discharge. While some of these assessments would have been used in the usual clinic evaluations, and all are accepted measures in rehabilitation, the complete set would not typically have been done or repeated at such fixed treatment intervals. Tests were administered by the treating physical therapist (CH). Therapy was not restricted with the physical therapist being free to adapt treatments for individual client presentation. There were some commonalities in the approach used based on his treatment philosophy but was individualized to meet the needs of each client. After data collection was complete, clinic staff "cleaned" outcome measures to

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remove all 18 Health Insurance Portability and Accountability Act (HIPAA) identifiers before sharing results with other researchers.

Participant Descriptions

The three clients in this report represent three very different TBI presentations, in terms of age, injury history and clinical presentation. Our selection criteria was developed in part to illustrate the use of standardized outcome measures with a heterogeneous set of clients, each of whom received individualized treatment derived from a common set of treatment philosophies.

Participant 1

At the time of evaluation Participant 1 was 48 years old and just less than two months postinjury. He sustained his TBI as the driver of a motorcycle which hit a car that pulled into his lane. He was thrown from the motorcycle sustaining multiple trauma with the following injuries: closed head injury (he was wearing a helmet); fractures of the left clavicle, multiple ribs, right femur, right distal radius, and right ulna; degloving of right lower extremity; right pulmonary contusion; grade IV splenic laceration and grade II liver laceration. Acute surgical procedures included splenectomy, femoral operation, reduction and internal fixation (ORIF), exploratory laparotomy, and tracheostomy. His previous medical history was unremarkable and included high cholesterol, repair of an inguinal hernia repair, and an appendectomy.

At out-patient evaluation his initial problem list was general debility, gait abnormality, muscle weakness, right frozen shoulder, pain (mainly in the area of the right hip), and ataxia. He was living in a setting with 16 hours per day of supervision and attendant care at the start of therapy, and this progressed to independent living by his discharge almost eight months later. At the start of therapy he was ambulating with a standard cane. At discharge he did not use an ambulatory assistive device.

Treatment consisted of ultrasound (right shoulder soft tissue); manual therapy consisting of joint mobilizations to the right hip and left shoulder using Kaltenborn grades 1, 2, and 3; and a variety of therapeutic exercises. Exercises and handling techniques used a combination of PNF, NDT, functional retraining and activity simulations. Aerobic exercise and balance training were also used. Specifics of these included static and dynamic balance training on the Bosu® (Ashland, Ohio), ambulation on uneven surfaces and over obstacle courses, ambulation combined with head motion, and use of recumbent bicycle, Nustep® (NuStep Inc., Ann Arbor MI), and treadmill. He also completed sessions using the Nintendo Wii Fit® (Nintendo of America Inc., Redmond, Washington) program. From initiation of outpatient therapy to discharge he completed 59 sessions over a period of seven months. The length of treatment was affected by the complicating comorbidities.

Participant 2

At the time of referral and evaluation Participant 2 was 23 years old and 16 years post the injury which was sustained at the age of 7. It occurred when he was a pedestrian hit by a car causing a closed head injury which left him with a left hemiparesis. He also sustained a right femoral fracture. Further details of the initial injury and treatment were not available, but he had persistent speech dysarthria, left hemiparesis and ataxia with associated falls. There was no other significant previous medical history.

He was referred for this episode of therapy due to gait impairment and generalized ataxia, difficulties with static and dynamic balance,

and muscle weakness. The only noted comorbidity was a diagnosis of depression. The only assistive device used was an old supra-malleolar orthosis (SMO) on the left, which had been used for many years. It was considered inappropriate for his current needs and one physical therapy intervention was to have this replaced with a carbon fiber ankle foot orthosis (AFO), which was then used throughout the course of therapy.

His evaluation generated a physical therapy problem list of balance impairment including difficulty with single leg and tandem stance, gait abnormalities, dysmetria and dysdiadochokinesia during coordination tasks, difficulty with functional strength including compensatory strategies used with squatting, and decreased ankle dorsiflexion on the left. More detailed evaluation of the left leg found hypomobility of the left rear foot and mid foot. Great toe extension was limited bilaterally.

Due to safety concerns and behavioral impulsivity, CD did not live alone but continued to reside with his parents, although he was able to be left unsupervised for variable amounts of time in his home setting.

Physical therapy was initially given three times a week, with this gradually reduced to twice a week and then once a week until discharge. Therapeutic philosophies used in treatment were a combination of PNF, NDT and functional retraining/simulation activities. Each session included a warm up and aerobic exercise on a recumbent bicycle, Nustep®, or treadmill. He performed static and dynamic therapeutic exercise, balance training including use of the theBosu®, gait training on multiple surfaces, and community ambulation. He also used components of the Nintendo Wii Fit® program, participated in a fitness gym exercise program and attended yoga classes with recreational therapy. He was discharged after attending for a total of 40 sessions over four months.

Participant 3

At the time of evaluation Participant 3 was 64 years old and 13 weeks post MVA. His injury was sustained when he experienced a “black-out” while driving, left the road, and hit a telephone pole. No cause for the initial loss of consciousness was identified. Other trauma, besides the closed head injury, included a right femoral fracture, respiratory failure resulting in ventilator dependence, and MRSA pneumonia. The femoral fracture was treated with ORIF.

Previous medical history was significant for alcohol abuse, congestive heart failure and atrial fibrillation. He had a history of lung cancer treated with lower lobe resection. In his remote history there was a left ulnar neuropathy from a sports injury sustained in his early 20's. At the time of the accident he smoked one pack of cigarettes a day. Since the accident he has not smoked or consumed alcohol.

The physical therapy problem list generated from the evaluation included generalized ataxia, extreme debility and muscle weakness, impaired gait and balance. Therapy was expected to be complicated by mild cognitive deficits (confusion, forgetfulness inaccuracies with history etc.).

At the time of writing, he is still receiving therapy at a frequency of three times a week, and has completed over 30 treatments. At treatment initiation he used a two-wheeled walker for ambulation, progressed from that to a standard cane, and is now not using any assistive device for ambulation.

Therapy sessions were designed using a combination of PNF, NDT and functional retraining/simulation activities, individualized to his requirements. Each session includes a warm-up and aerobic

exercise session. This is followed by Kaltenborn mobilizations to the right hip (grades 1, 2, and 3), therapeutic exercise including balance and gait training and community mobility. He currently lives with his spouse who provides supervision as needed, and also has support and supervision from multiple family members who live in the area and assist frequently. It is anticipated that comorbidities will increase the duration of therapy.

Clinical evaluations

Evaluations selected were all validated measures commonly used in physical rehabilitation. They included the Berg Balance Scale (BBS) [12], the Functional Gait Assessment (FGA) [13], the Functional Reach (FR) [14], and the Brief Ataxia Rating Scale (BARS) [15]. In the BBS ≤ 45 points indicates high fall risk as does ≤ 22 points on the FGA. In the BARS, higher scores indicate greater ataxia severity, with a possible maximum score of 30. In the FR, means and standard deviations for healthy men in our participant age groups would be 16.7 ± 1.9 inches for men between 20 and 40, and 14.9 ± 2.2 inches for men between 41 and 69 [14]. All the above measures were done at initiation of treatment and every 10 treatments until discharge or until the client had reached the measure ceiling twice. One other measure, the Quality of Life after Brain Injury (QOLIBRI) instrument [16] was administered at admission and on discharge. This relatively new condition specific health related quality of life (HRQoL) measure consists of six scales that examine different dimensions of HRQoL impacted by TBI. Scales can be scored separately or as a total score on a 0 to 100 scale with higher scores representing better quality of life [16].

Selection of the tests was made by the researchers based on a combination of factors. The BBS, FGA and FR are often used in rehabilitation, have established clinical validity and were considered to be both the most frequently used in “typical” treatment and most likely to yield meaningful data for use in designing clinical treatment programs. The BARS was selected to impairments frequently seen with TBI that the other tests did not evaluate and the QOLIBRI was considered important for gathering information on overall client quality of life and changes seen over the course of a complete treatment.

Results

Scores of the repeated assessments used are included in Table 1. Participants had mild-to-moderate mobility impairments. Their score

	Evaluation ^a	Retest 1	Retest 2	Retest 3	Retest 4	Retest 5
Participant 1						
FR(in)	11.0	11.5	11.5	11.0	12.6	12.2 ^b
BBS	52	56	56	*	*	*
BARS	6	1	0	0	0	*
FGA	15	26	27	29	30	30
Participant 2						
FR(in)	13.0	12.5	13.0	11.25	13.3 ^b	
BBS	51	56	56	*	*	
BARS	7	4	5	3	2	
FGA	20	23	23	26	28	
Participant 3						
FR(in)	5.5	6.6	6.7			
BBS	37	51	52			
BARS	3	2	2			
FGA	18	21	20			

^aTests were administered as admission and after every 10 therapy sessions;
^bDischarge evaluation, may be fewer than 10 treatments from previous testing
^{*}Indicates participant not retested as had reached test ceiling twice

Table 1: Participants' Outcome Scores.

changes can be interpreted in light of what is known of the minimal detectable changes (MDC) and norms for these scales. Although there were changes in the BARS scale we were unable to locate relevant MDC for this relatively new scale. It was used as it captures an important and common impairment post TBI and it is hoped that MDC will soon be established.

On the BBS initial scores ranged from 37 to 52, with only Participant 3 being classified at high risk of falling. All three increased their score with participants 1 and 2 reaching the ceiling of the BBS during their treatment. All participants improved at least 4 points. Research on the BBS in different populations has reported MDC ranges from 2.5 points in persons with chronic stroke [17] to 5 points for individuals with initial scores between 35-44 points [18]. The largest MDC reported for people post TBI was 3.83 points [19]. This suggests that the changes seen in our clients were clinically meaningful.

The FGA initial evaluations findings differed from the BBS results in that it placed all participants at increased fall risk with initial scores below 22. Again improvement occurred during therapy with two of the three participants no longer classified as having increased risk of falls, and one of them reaching the ceiling of 30 in this scale. The changes seen in Participants 1 and 2 would be considered clinically significant in other populations where MDC has been studied. For example Lin et al. [20] studying stroke found that the MDC for that groups was 4.2 (clinically 5) points. At the time of writing Participant 3 remains classified as having an increased risk of falls with only a 3 point improvement. He continues to receive therapy.

The FR was below population norms for all three participants at the start and remained so at the end of the study, which was also the discharge point for two of the participants. Changes in the FR did not reach the MDC identified by Katz-Leurer et al. [21] for individuals with sub-acute stroke.

The QOLIBRI score are not included in the table due to its different administration schedule and because of having entry and discharge information on only two participants. Participant 1 had a score of 71 on entry which improved to 90 on discharge, while Participant 2 improved his score from 47 to 80.

Discussion and Conclusion

In recent years there has been an increased interest in developing guidelines for TBI, acknowledging the high level of disability often associated with even mild TBI and the increasing focus on identification of injuries [1,2]. Given the inherent heterogeneity of TBI there is a lack of published evidence and clinical trials, with many rehabilitation recommendations based on extrapolations from other populations [7,9,22]. There have been calls for use of common datasets and outcome measures as one step in improving the management of this important condition [10,11]. This project illustrates how an easily administered set of physical rehabilitation measures can be added to routine clinical practice, standardizing times of administration, applying them to a heterogeneous set of clients, and allowing the individualized multidisciplinary care. This is the form of management most suggested for individuals with persistent problems post TBI [4,5,7,8,22].

Our approach is consistent with recent suggestions that researchers change the way they study therapy for TBI to accommodate the variability and need for multidisciplinary management [6]. Instead of restricting enrolment criteria and thereby limiting generalizability there are suggestions that we embrace the heterogeneity, that organizations use comparative effectiveness research (CER) and that interventions

are tested in settings similar to typical practice setting with outcome measure that are meaningful to patients [6,23]. Our trial of the use of a consistent set of measures for a diverse population of individuals with TBI in one clinical setting is a small attempt to document outcomes in a meaningful way and illustrates the practicality of such an approach in a clinical setting.

Despite the differences in our participant presentation (age, complicating comorbidities, impairments, time since injury, and individualized management details) a simple set of short, easily applied outcome measures was able to document progress over the course of therapy. Measures were deliberately chosen for ease of use and their ability to be quickly done during the course of typical clinical practice. The selection was also based on clinician input regarding which measures were most likely to assist in designing treatment programs. The inclusion of a HRQoL was considered important for documenting this key concept even though this is not typically used in routine physical rehabilitation practice. The BARS was felt to include aspects of movement impairments that the other physical scales did not. Overall choice for this trial was made by researchers and clinicians in an attempt to create a set of measures small and fast enough for use in a clinic yet broad enough to cover key dimensions in this population. We acknowledge that this is a limitation of our approach, but a more comprehensive test battery would be impractical for therapists in routine clinical practice. Should other therapists adopt a similar approach to TBI evaluation and management it may be possible to reach a broader consensus of the best set of measure to use for tracking outcomes efficiently in the population of TBI survivors.

In conclusion, our experience suggests that despite the heterogeneity of TBI, it is possible for clinicians to use a simple set of measures with at least the majority of patients with TBI to accumulate meaningful data on outcomes and treatment effectiveness. Should a similar approach be widely adopted it should lead to the collection of data which ultimately can be used as one part of a CER approach to evaluation of TBI management. We encourage other clinicians to adopt a similar approach and seek to open a dialog on selecting the optimum battery of evaluations for this purpose.

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