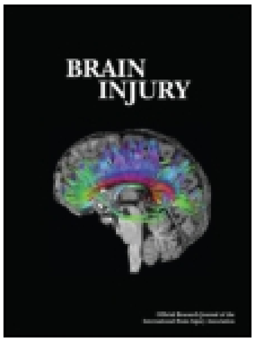

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Evaluation of the effectiveness of two clinical training procedures to elicit yes/no responses from patients with a severe acquired brain injury: a randomized single-subject design

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Evaluation of the effectiveness of two clinical training procedures to elicit yes/no responses from patients with a severe acquired brain injury: a randomized single-subject design

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Primary objective: Thirteen (10 males) participants with severe acquired brain injuries (ABI) were randomly assigned to two treatments, A or B (ABAB, BABA) in a crossover study to determine which treatment approach elicited more consistent and reliable yes/no responses.
Research design: Treatment A consisted of an enriched stimulus environment, collaborative multidisciplinary interventions and additional yes/no response training, while Treatment B consisted of the standard hospital environment and interventions.
Main outcomes: An ANOVA showed no order effect (AB vs BA; $p = 0.60$), but a trend (A vs B; $p = 0.07$) towards statistical significance for increased responsiveness with treatment A. Inter-rater reliability ($n = 10$) ranged from fair-to-good, intra class correlation (ICC) 0.51; 95% confidence interval (CI) (0.29–0.93). *Post-hoc* analyses showed statistically significant increased responsiveness for four participants with treatment A ($p < 0.001$).
Conclusion: Evidence is provided that enhanced communication strategies can improve responsiveness in a sub-group of participants with severe acquired brain injuries.

Introduction

Clinicians have great difficulty assessing patients with severe acquired brain injuries because of their reduced responsiveness, slow rate of change and complex medical needs. As many as 37–50% of patients with severe acquired brain

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injuries may be misdiagnosed as being in a persistent vegetative state when they are, in fact, minimally responsive [1-3]. These patients, living at home or in a chronic care facility, are often referred for medical intervention because of severe orthopaedic, nutritional, respiratory or behavioural concerns. However, without a consistent yes/no response, it is not only difficult to differentiate between those who are in a vegetative state from those who are minimally responsive [3–7], but also to adequately determine their complex medical and behavioural issues.

For patients with severe brain injuries, traditional strategies have focused on increasing arousal and attention with various stimuli and using yes/no answers to identify specific stimuli as part of the hierarchical assessment of cognitive functioning [8–11]. However, sensory stimulation as an effective treatment modality is controversial. The heterogeneity of this ABI population, combined with a lack of functional target behaviours, can cause considerable differences in responsiveness and make demonstration of treatment effects difficult to detect [8, 9]. Nevertheless, sensory stimulation and yes/no responses to specific questions have formed the basis of assessment tools such as the Sensory Modality Assessment Rehabilitation Technique (SMART), the Sensory Stimulation Assessment Measure (SSAM) and the Western Neuro Sensory Stimulation Profile (WNSSP). These measures were designed to assist clinicians in evaluating the cognitive status of patients with severe acquired brain injuries [11–19].

A comprehensive literature review revealed a paucity of research that examined ways to improve functional communication in patients who are minimally responsive and/or in a vegetative state. Recent studies utilized communication techniques that involved the (a) evaluations of team members who spent considerable time with the patients (e.g. nurses, physiotherapists, occupational therapists) to choose the best response method; (b) training of that response action with questions about familiar objects; and (c) the administration of structured questions to evaluate the patients' cognitive status [20–23]. However, the patient population was not well described, making it difficult to determine the participants' level of impairment. Therefore, it is not known whether such methods are transferable to other patients with severe acquired brain injuries, especially those who score less than Level V on the Rancho Level of Cognitive Functioning Scale (LCFS).

The objectives of this study were to (1) develop clinical training procedures that optimally elicit consistent and reliable yes/no responses from patients with severe acquired brain injuries and (2) compare two different rehabilitation approaches to evoking correct responses to yes/no questions from those patients. The experimental condition, treatment A, incorporated (i) a collaborative and consistent interdisciplinary team response; (ii) structured response training with familiar visual and auditory stimuli; (iii) autobiographical and general yes/no questions asked in a functional context; and (iv) an enriched physical environment. Treatment B, involved (i) individualized treatment by a speech and language pathologist (SLP); (ii) sensory stimulation for arousal using non-personal stimuli; (iii) general yes/no questions; and (iv) a typical hospital room environment. This latter condition formed a more traditional therapy approach to rehabilitation with these patients.

Table 1. WHO classification of non-traumatic and traumatic brain injuries

ICD - 9 codes	Number of subjects
348—anoxia	3
430—subarchnoid haemorrhage	4
431—intracerebral haemorrhage	1
487—encephalitis	1
812—815—motor vehicle accident	4

Method

Subjects

There were 13 subjects (10 males) admitted into the study between 1999–2001. Eligible subjects included those who sustained an acquired brain injury and remained (1) at Level IV or less on the LCFS; (2) were uncommunicative or unable to provide a consistent and accurate yes/no response 80% of the time; and (3) had families willing to supply personal mementos and biographical information. Nine of the subjects were admitted into the Chedoke Slow-to-Recover Acquired Brain Injury Programme, Hamilton Health Sciences, Hamilton, Ontario. Two subjects were chronic care residents in the William Osler Hospital, Brampton, Ontario, while two others resided in a specialized ABI facility (Anagram) in Niagara-on-the-Lake. The mean time post injury of subjects was 33 months (SD = 10, range 8–105 months). This significant variability in the range of chronicity is typical of patients with slow recovering severe acquired brain injuries. The mean age of the subjects was 41.3 years (SD = 1.5, range 17–66 years).

Impairment was categorized using the World Health Organization's (WHO) International Classification of Diseases [24]. Four subjects suffered traumatic brain injury following a motor vehicle traffic accident, while the remaining nine subjects suffered a non-traumatic type of brain injury (table 1).

Assessments

Western Neuro Sensory Stimulation Profile (WNSSP)
The Western Neuro Sensory Stimulation Profile (WNSSP) consists of 33 items divided into six sub-scales that give a total score that ranges from 0–113 [12–14]. The sub-scales and the number of items per sub-scale are as follows: arousal and attention (4), auditory response (8), expressive communication (3), visual response (12), tactile response (5), and olfactory response (1). Reliability and normative data are provided for the WNSSP. It was designed not only to assess patients at levels II, III, IV and the early stages of level V on the LCFS, but also to monitor behavioural changes in patients who remain at Rancho levels II and III for long periods of time.

Rancho Level of Cognitive Functioning Scale (LCFS)
The Rancho Level of Cognitive Functioning Scale (LCFS) categorizes the levels of behavioural function in brain-injured patients into eight levels [25]. Various states of decreased responsiveness are classified as levels from I–III. Level IV characterizes patients as confused and agitated.

Clinical Outcome Variable Scale (COVS)

The Clinical Outcome Variable Scale (COVS) is a modification of the physical mobility items from the Patient Evaluation Conference System [26]. It has an 11-item mobility sub-scale that includes rolling, lying to sitting balance, transfers, ambulation and wheelchair mobility. There are two items for arm function. The maximum score is 77. Intra-rater reliability was high, 85–96%, weighted κ 0.79–0.98. Inter-rater reliability had an ICC of 0.97, 95% CI 0.63–0.99.

Western Aphasia Battery (WAB)

The Western Aphasic Battery (WAB) [27] sub-test of yes/no questions consists of 20 concrete and abstract yes/no questions. Verbal and gestural responses are included in the total score. Intra-rater reliability for the auditory comprehension composite score (e.g. yes/no questions, auditory word recognition and sequential command sub-tests) was high for the normative sample of aphasic subjects. Inter-rater reliability was also high for the auditory comprehension sub-tests for the normative sample of aphasic subjects. Correlation coefficients ranged from 0.985–0.993, $p < 0.001$ [28]. The average inter-correlation across eight judges was 0.998, $p < 0.001$ [28]. No data for intra- and inter-reliability for the yes/no questions sub-test in isolation is available.

Procedure

This study applied a crossover single subject design [29–31]. Each subject was randomly assigned to an ABAB or BABA treatment sequence. The duration of each treatment sequence was 8 weeks, with 2-week intervals for each condition. Signed informed consent for each subject was obtained from the individual with legal authority for personal care. Baseline evaluation of yes/no responses was collected during the first 2 weeks of admission into the study. Cognitive function was assessed at admission using the LCFS and the Glasgow Coma Scale (GCS) [32]. The WNSSP was administered during the baseline period and at the end of the study. A SLP, who did not work on the ABI programme, was blinded to the conditions of the study by having the study participants brought to her office; she administered the yes/no question sub-scale of the WAB at the end of each treatment phase (weeks 2, 4, 6, 8) and at 6 months following discharge from the study. Five personally relevant questions were added to the 20 concrete and abstract yes/no questions of the WAB and randomly ordered for each test administration. The COVS was administered at admission to assess gross motor physical activity. The multidisciplinary team, consisting of nurses and nursing assistants, physician, psychologist, physical therapist, occupational therapist, recreational therapist and speech and language pathologist, determined the optimal method of indicating a yes/no response (table 2).

For treatment A, family members completed a detailed questionnaire outlining their relative's personal interests and previous activities. The SLP, after gathering information from other team members as to which body movement might have potential for yes/no responses, developed a communication script that had explicit instructions outlining the response mode and procedures to elicit a yes/no response. Nurses, nursing assistants, occupational therapist, physiotherapists and families were trained by a Communication Disorder Assistant (CDA) to follow these scripted procedures to increase arousal/attention and to elicit yes/no responses. A minimum

Table 2. Optimal response methods for answering yes/no questions (n = *13*)

Subject	Optimal response 'yes'	Optimal response 'no'
1	eye blinks	eye blinks
2	head nod	head shakes
3	pointing to cards	pointing to cards
4	head nod	head shake
5	head nod	head shake
6	eye movements	eye movements
7	eye movements	eye movements
8	head nod	head shake
9	absence of response	smile/facial expression
10	chewing	eye blinks
11	chewing	smile/facial expression
12	finger squeeze	eye blinks
13	head nod	head shake

of 85% inter-rater agreement was established for each subject's yes/no responses. Data sheets were placed daily in the subject's room. Staff and family were trained in data recording. An ongoing series of inservices for staff and families were conducted during the 8 weeks of the study to encourage data collection and to ensure compliance with the scripted protocols.

In addition to regular speech therapy, the client received a 30 minute yes/no response training three times a week with the CDA. The CDA trained the subject using relevant personal information (e.g. Are you married? Show me 'yes') and factual statements (e.g. Do candles hum? Show me 'no'). A cueing hierarchy, that consisted of (1) a spontaneous response, (2) verbal prompting, (3) gestural prompting, (4) physical prompting or (5) hand-over-hand assistance, was used in training the yes/no responses (table 3).

Enhanced stimulus material consisted of familiar personal items such as the participant's favourite objects and family photos and taped voice recordings of family members. Mozart sonatas were played for $\sim$ 4 hours per day [33, 34]. The enriched physical environment consisted of the regular hospital room decorated with curtains, plants and personal mementos that were made visible to the client by using a mobile suspended over the bed.

For the traditional condition, treatment B, the subject participated in speech therapy that did not differ between treatment conditions. The SLP informed the team of the optimal method of communication. Team members asked yes/no questions in the context of regular therapy interactions. The stimulus material consisted of items typically brought by the family to decorate the subject's room. Visual stimuli consisted of family photos, greeting cards and magazine pictures tacked to a bulletin board or the wall behind the bed. During sensory stimulation sessions held three times a week, auditory stimuli consisted of voices and sounds; visual stimuli were non-personal; gustatory and olfactory stimuli were either noxious or pleasant; and tactile stimuli consisted of touch with various textures. The environment was a hospital room, consisting of a dresser and a bed with a special blanket or comforter. Patients had their own music. Staff and families were trained in data collection.

For both treatment conditions, the number and type of responses to various questions asked during the course of the day were collected. The questions were

Table 3. Hierarchical levels of cueing in response training

Prompts	Instruction guidelines
Spontaneous response	Participant gives yes or no response quickly and spontaneously to the question, Are you cold? • Questioner does not need to give additional cueing
Verbal	Participant requires verbal encouragement • Questioner repeats question: e.g. Are you cold? and requests the participant to produce a 'yes or no' response (e.g. nod your head for yes, close your eyes for no)
Gestural	Participant requires a visual cue in addition to verbal encouragement • Questioner repeats question (e.g. Are you cold?) and demonstrates the physical action to the subject while requesting participant to produce a 'yes or no' response (e.g. nod your head for yes, close your eyes for no). Examiner repeats the question and waits for a response
Physical	Participant requires a physical (touch) cue in addition to the gestural and verbal prompting • Questioner repeats question (e.g. Are you cold?) and lightly gives physical contact to the body part required to generate a response while requesting participant to produce a 'yes or no' response (e.g. nod your head for yes, close your eyes for no). Examiner repeats the question and waits for a response
Hand-over-hand	Participant requires physical guidance to produce a response • Questioner repeats question (e.g. Are you cold?) and physically assists the total movement while requesting participant to produce a 'yes or no' response (e.g. nod your head for yes, close your eyes for no). After the physical cue, the examiner again repeats the question and waits for a response

categorized into the following domains: personal care, treatment, meals, comfort and pain, movement and position, environment, family and friends, social and factual information. There were four possible treatment responses: (i) yes, (ii) no, (iii) don't know (the participant provided a response but it could not be determined as a 'yes' or 'no' response) or (iv) no response. The number of questions per session varied with a minimum of 12 questions per session.

Family members completed a satisfaction questionnaire utilizing a 15-point Likert scale. The survey focused on how family members perceived either positive or negative changes in the way their family member responded, in whether the quality of their communication was better or worse and their overall satisfaction with participation in the study.

The tapes of 10 participants responding to yes/no questions were shown to rehabilitation staff that consisted of nurses, nursing assistants, physiotherapists and physiotherapy assistants, with 50% of the group having no previous knowledge of the patients. The SLP and CDA together established the 'gold standard' for the videotapes of the participants.

Results

At admission, seven participants were randomized to treatment A and six to B. Admission assessment scores and demographics were collected at admission (table 4). Mean admission scores on the assessment measures were as follows: GCS 4.8

Table 4. Admission Demographics (n = *13*)

Subject	Age	LCFS	GCS	WNSSP	COVS
1	50	III	NA*	39	15
2	17	III	4	14	10
3	23	IV	4	68	17
4	32	IV	5	NA	NA
5	37	IV	4	33	13
6	26	II	3	16	13
7	60	III	NA	55	13
8	60	II	6	61	13
9	32	II	3	35	13
10	38	II	5	23	13
11	34	II	NA	18	10
12	62	III	6	14	10
13	66	III	8	52	28

* Not available.

(SD = 1.5), WNSSP 35.7 (SD = 19.1), WAB 22.5 (SD = 18.6), and COVS 14.0 (SD = 4.9).

An ANOVA was used to test for order effects and treatment differences. χ^2 analyses were used to test for treatment response differences between conditions in individual participants. The proportion of responses (x) was transformed using an arcsine (square root (x)) transformation function to adjust for the varied number of questions asked in various therapy sessions [35]. A weighted analysis of variance was used to test for a statistically significance difference ($p < 0.05$) between the proportion of responses of treatments A or B. The SAS System for Windows, Release 8.1 was used for all statistical analyses.

An ANOVA showed no order effect (AB vs BA; $F = 0.29$; $p = 0.60$), but a treatment trend (A vs B; $F = 3.84$; $p = 0.07$) towards statistical significance for treatment A over B (mean proportion; 0.69 (SD = 0.04) vs 0.64 (SD = 0.06)). Inter-rater reliability, judged by rehabilitation staff from videotapes of 10 subjects, ranged from fair to good, ICC 0.51; 95% CI 0.29–0.93.

Individual χ^2 analyses showed that there was increased responsiveness for four participants with treatment A (proportion range; A, 0.32–0.78 vs B, 0.12–0.68) that was statistically significant ($p < 0.001$). Those patients with acquired brain injuries who showed significant improvement in yes/no responses with treatment A had higher admission WNSSP scores (Wilcoxon, 2 sample exact test, $p < 0.05$, mean treatment A 55.7 (SD = 12.4) vs mean treatment B 27.3 (SD = 11.6)). There was no significant difference between participant scores on the WAB at admission and 6 months later (Wilcoxon, 2-sample exact test, $p > 0.05$, mean treatment B 13.5 (SD = 10.6) vs mean treatment A 21.8 (SD = 19.9)).

There were two statistically significant group effects when examining the proportion of responses for the question type (personal care ($F = 5.35$, $p = 0.04$); social ($F = 6.62$, $p = 0.02$)). After correction for multiple testing, the results for the proportion of responses were not significant. When analysing the data by question, there were more 'yes' responses for environmental questions in the enriched condition, Treatment A ($F = 7.69$; $p = 0.01$), but this finding did not remain significant after adjusting for multiple comparisons.

From the family satisfaction questionnaire ($n = 8$), a large majority of families (87.5%) indicated that their family members' participation in the study improved the clarity and distinctiveness of their 'yes or no' responses. Furthermore, 62.7% felt that they were now better able to communicate with their family members.

Discussion

Despite the importance of finding methods to enhance the communication skills of patients with severe acquired brain injuries, few studies have addressed this issue. The results provide evidence that some patients with severe head injuries improve in their ability to communicate yes/no responses when provided with consistent training and environmental enrichment (treatment A). Ladtkow ([36], p. 64) reported 'the introduction of such basic augmentative assistive communication aids such as very simple yes/no techniques can provide a patient with a highly structured way to respond to his or her environment, using over-learned skills'. Although it is not known which component in the enhanced clinical training procedure had the greatest impact for this group, one agrees with Piguet *et al.* [22] that consistent methods that include education of staff and families to establish protocols and full team participation are critical factors. Also, current motor learning theory supports the underlying principles of treatment A with its repetitive stimulation, random practice, feedback and the use of meaningful, familiar stimuli [36–39]. There is some evidence that classical music may play a role in enhancing verbal communication as well [33, 34]. When interdisciplinary team members and families used a consistent communication strategy, a shift was seen in the response level in some patients where such a change in a relatively short period of time does not usually occur. One study has shown that, when critical care nurses worked with unresponsive patients who gradually showed some comprehension, their interaction and communication with these patients increased [41]. More interaction between rehabilitation nurses and nursing assistants was informally observed to take place once a yes/no response was more discernible. Although there was no difference in answering randomized, standardized yes/no questions on the WAB at admission and 6 months later, there was a statistical and clinical difference in responses to personal care questions. Staff reported that important issues of comfort, seating, positioning and pain were often resolved with a discernable yes/no response from the patient.

From the family satisfaction questionnaire, it was evident that the scripted protocols for eliciting a maximal response to yes/no questions were beneficial. Families felt that the training conditions improved the way their family member showed a yes/no response, an important aspect of improving the quality of life for both the patients and their families. More than half of the families felt that they were better able to communicate with their severely impaired family member. Efforts to include these patients with severe acquired brain injuries in day-to-day interactions have had rewarding results.

The inter-rater reliability in discerning responses was fair-to-good, despite known difficulties of assessing inter-rater reliability from videotapes [42–44]. These results indicate that other clinicians were able to interpret the patients' answers and confirmed the absence of investigator bias.

The group showing increased responsiveness to the enhanced treatment condition (treatment A) did not differ significantly from the other clients with respect to age, sex, time post-injury, Rancho level or initial WAB. However, the admission WNSSP scores were statistically higher for those patients who improved with treatment A as compared to those that showed no significant change. It would appear that the WNSSP may identify those minimally responsive, slow-to-recover patients with increased potential to improve.

The single-subject methodology is useful in this population where the resulting impairments and functional deficits are so varied. One of the limitations of the study was the short duration of the treatment sequences; this was a function of the limited length of stay in the specialized slow-to-recover rehabilitation unit. Optimally, a 16-week treatment sequence may have allowed enough treatment opportunity for the participants who scored lower on the baseline WNSSP scores. This study also experienced difficulties similar to Piguet *et al.* [22] in data collection. Often on the weekends there were part-time off-site agency workers who had restricted knowledge of the communication protocols and recorded fewer responses. For this reason, one was not able to control the total number of questions asked in each condition. As this design is heavily dependent on accurate data collection, some of the findings lost significance when statistical methodology was applied to counterbalance the variance in the number of questions asked.

Future research needs to identify the component(s) of treatment A, the enriched clinical training procedure, which had the greatest impact on increased responsiveness and whether increased responsiveness promotes caregiver interaction with individuals with severe brain injuries. Tracking the fluctuating level of alertness in these patients with severe acquired brain injuries could enable more effective clinical training of yes/no responses. As well, different approaches to collecting data need to be explored in light of today's limited health care resources.

Conclusion

The ability of patients with severe head injuries to consistently communicate a reliable yes/no response impacts significantly on their care and, most importantly, on their ability to gain quality of life. It would appear from this study that a subgroup of patients with severe head injuries were capable of developing a highly consistent yes/no response in an efficient manner when provided with enhanced communication strategies. Furthermore, responsiveness was also observed with contextually relevant questions.

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