

A Randomized Controlled Trial to Assess the Efficacy of Auditory Stimulation on Selected Parameters of Comatose Patients with Traumatic Brain Injury

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Abstract

Problem Considered Prevention of sensory deprivation and early sensory stimulation are essential to enhance optimal recovery in patients with traumatic brain injury (TBI). This was an RCT to assess the efficacy of auditory stimulation on various physiologic parameters and level of consciousness in comatose patients of TBI.

Methods A total of 80 comatose patients with TBI were enrolled and 40 were assigned using computer-generated random table in each intervention and control group. In intervention group, auditory stimulation was provided by a family member talking to the patient for 10 minutes, twice daily for 2 weeks. Physiologic parameters such as heart rate, respiratory rate, blood pressure, SpO₂, and level of consciousness were recorded before, during and after each intervention. Parameters in the control group were recorded on days 1, 7, and 14.

Results Baseline characteristics in both the groups were comparable. On day 7, GCS was significantly higher (7.26 ± 2.39) in intervention group as compared with (5.54 ± 1.75) control group. On day 14, GCS was again significantly higher (8.17 ± 2.06) in intervention group as compared with (6.34 ± 2.36) control group. There was significant increase in PR and SpO₂ during and after intervention.

Conclusion Auditory stimulation by family members appears to be effective in improving level of consciousness in comatose patients with TBI.

Keywords

- ▶ traumatic brain injury
- ▶ coma
- ▶ auditory stimulation
- ▶ communication
- ▶ consciousness

Traumatic brain injury (TBI) is a leading cause of morbidity, mortality, disability, and socioeconomic losses worldwide.¹ It is estimated that nearly 1.5 to 2 million persons are injured and 1.6 lakhs die every year in India.² The prognosis of patients is determined by multiple factors.³

TBI-induced altered state of consciousness results in a state of sensory deprivation. Early sensory stimulation could help in a speedy recovery.^{4,5} Communication to the unconscious patient is required to meet their psychologic

or emotional need. Studies have reported that auditory stimulation leads to changes in physiologic or neurophysiologic parameters and speedy recovery.^{4,5} However, responses of the patient with disorder of consciousness with auditory stimulation have always been a subject of controversy. Sufficient evidences are unavailable to determine whether environmental stimulation has a role in recovery of comatose patients with TBI. Auditory stimulation to comatose patients can be provided by their

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loved ones and health care professionals. The present study was undertaken with the objectives of assessing the efficacy of auditory stimulation using familiar voice on various physiologic parameters and level of consciousness in comatose patients with TBI.

Methods

Design

In this randomized controlled trial (RCT) total enumeration sampling technique was used to select 80 patients who were aged between 15 and 65 years, admitted in neurosurgery wards within 72 hours of TBI with an admission of Glasgow Coma Scale (GCS) 4 to 8. Patients with admission GCS 3 were excluded due to high mortality. It was confirmed verbally from the significant relative of the patient who consented for the study that patient had normal hearing ability before sustaining injury. Using computer-generated random number table, 40 patients were randomly allocated to each intervention and control group.

Data were collected through observation, records, and biophysical measures. Demographic and clinical information of the patient was furnished using an assessment sheet and the outcome was assessed using GCS, a gold standard to assess the level of consciousness. GCS that is based on the motor, eye, and verbal response is a reliable and objective way of recording the conscious state of a person for initial as well as subsequent assessment. Total score of GCS ranges from 3 to 15.⁶ Physiologic parameters such as heart rate (HR), respiratory rate (RR), blood pressure (BP), and peripheral capillary oxygen saturation (Spo₂) along with GCS were monitored at admission followed by before, during, and after intervention, two times a day for 14 days. Same parameters of control group were monitored at admission, 7th and 14th days.

The protocol for the auditory stimulation was developed by the researcher and the content validity of the same was obtained from various experts in the field of psychology, nursing, and neurosurgery.

Intervention

A protocol for auditory stimulation was developed based on the importance of providing the comatose TBI patient with psychologic, spiritual, and social support as well as assurance on recovery. An individualized script for each patient was prepared with the help of significant family member keeping a common frame line. The written script of 8 to 10 minutes duration included present condition of illness, patient-related events, and information about family members, colleagues, home, workplace, etc. The significant relative was explained to approach the client by calling the name of the patient, to introduce themselves and talk to the patient based on the prewritten script in such a way that it brings hope and a feeling of worthiness in the patients. Repetitive use of patient's name was emphasized while speaking. An assurance is given to the patient that he/ she is not alone and there are many people around to help. Termination of the talk was done by providing information

regarding the next visit by the family member. Protocol was translated in Hindi and Punjabi and was validated by experts. This intervention was provided twice a day for 2 weeks.

Data Collection

The present study was approved by the institute ethics committee and written permission was taken from the concerned in charges. All the patients admitted with TBI in the neurosurgery ward were assessed and all comatose patients with TBI who met the inclusion criteria were included. Sociodemographic profile of the patient was collected from the close relative and data related to clinical profile were obtained from case file. Information sheet was given and written informed consent was obtained from close relative of each patient. The relatives of patients who were supposed to provide auditory stimulation were trained to do so and minimal modification of content was allowed according to each patient's background. Written content along with protocol was also provided to each relative. Each patient's relative in the intervention group sat near the patient and spoke to him/her in an audible manner. Privacy was provided.

Physiologic parameters and GCS score were monitored as planned. Routine care was provided to both the groups that aimed at maintaining adequate cerebral perfusion, preventing infection, and maintaining normal ICP.

Analysis

This study was aimed at assessing the effectiveness of auditory stimulation on physiologic and neurologic parameter of comatose patients with head injury. Data were entered in the Microsoft Excel spreadsheet (2007) and exported to Statistical Package for Social Sciences (SPSS version 16.0 Inc.) for analysis. Paired *t*-test, independent *t*-test, chi-square test, multivariate analysis, and ANOVA (analysis of variance) were applied to determine level of significance that was kept at 0.05.

Results

Mean ages of the patients in control and intervention groups were 41.32 ± 12.83 and 34.95 ± 13.98 years, respectively, and most of them, that is, 82.5% in control group and 85% in intervention group, were male. Based on clinical variable, both groups were found to be homogenous in nature, 75% each in control and intervention groups sustained TBI due to road traffic accident (RTA); 92.5% in control and 82.5% in intervention group had supratentorial lesion (**Fig. 1**, **Table 1**). As shown in **Table 2**, baseline level of consciousness was comparable as GCS was 5.10 ± 1.37 in control and 5.12 ± 1.20 in experimental group, and among physiologic parameter, respiration rate and Spo₂ were significantly high in intervention group, but others were comparable.

At day 7, GCS in intervention group was significantly higher, that is, 7.26 ± 2.39 as compared with 5.54 ± 1.75 in control group ($p = 0.001$). When each component of GCS

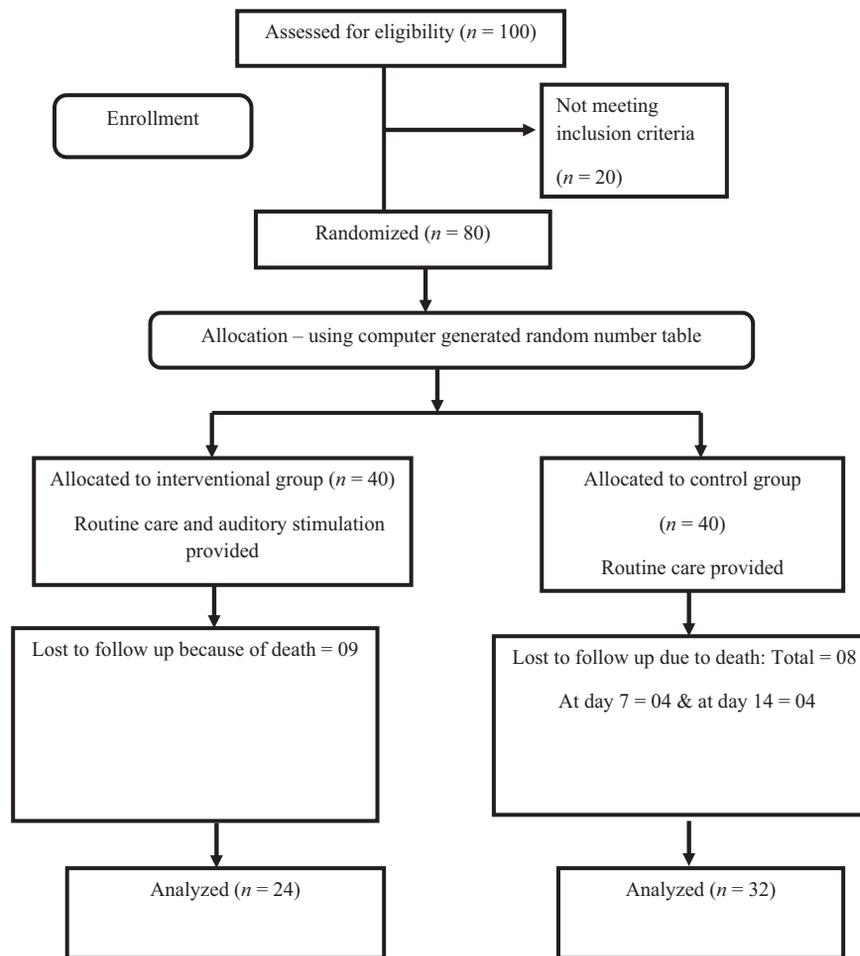


Fig. 1 Consort diagram.

was compared, motor response score was significantly higher, that is, 4.90 ± 1.01 as compared with 3.97 ± 1.32 in control group ($p = 0.002$). There was no significant difference in eye and verbal response scores of both the groups (►Table 3).

At day 14, total GCS in intervention group was significantly higher, that is, 8.17 ± 2.06 as compared with 6.34 ± 2.36 in control group ($p = 0.004$). The motor response score in intervention group was significantly higher, that is, 4.92 ± 1.06 as compared with 4.09 ± 1.49 in control group ($p = 0.025$). Eye opening score was also significantly high, that is, 3.25 ± 1.15 in intervention group as compared with 2.16 ± 1.17 in control group (►Table 3).

As depicted in ►Table 3, SpO_2 in intervention group was significantly higher, that is, 97.85 ± 3.53 on seventh day as compared with 93.91 ± 4.65 in control group ($p = 0.002$), but other physiologic parameters did not show any statistical significant difference. There was no statistical significant difference in physiologic parameters of control and experiment groups. (►Table 3)

Physiologic parameters were compared before, during, and after intervention, and a total of 575 observations were analyzed to evaluate the effect of auditory stimulation. Pulse rate (PR) was significantly increased from 99.26 ± 17.05 to

102.51 ± 16.32 during intervention, and it was significantly reduced to 101.53 ± 16.92 within 5 minutes of providing intervention but was significantly higher compared with preintervention. SpO_2 was significantly increased from 96.84 ± 4.30 to 97.43 ± 3.93 during intervention and remained 97.42 ± 4.28 after intervention (►Table 4).

Discussion

The pathophysiology of TBI is complex interplay of several factors influencing its recovery.⁷⁻⁹ Many interventions are required to stimulate arousal mechanism of comatose patients. Brain stimulation at an early phase of recovery can prevent plasticity changes. One such intervention is coma stimulation that helps in stimulating the arousal mechanisms.¹⁰ Exposure to frequent and various sensory stimulation may enhance both dendritic growth and improve synaptic connectivity between the injured nervous systems.¹¹ Types of stimulation include auditory, tactile, visual, olfactory, taste, and proprioception/movement. Stimulation is usually provided by the staff caring for these patients or their family members. The effectiveness of auditory stimulation on brain activity^{5,12-16} and patient recovery^{4,17} are well reported. Auditory

Table 1 Baseline clinical-demographic characteristics

Variables	Control group	Intervention group	p Value
Age (y)	41.32 ± 12.84	34.95 ± 13.98	0.04
Male	33(82.5%)	34(85%)	0.76
Education			0.94
Illiterate and primary	13 (32.5%)	12 (30%)	
Secondary and senior secondary	22 (55%)	22 (55%)	
Graduate and above	05 (12.5%)	06 (15%)	
Occupation			0.89
Professional/skilled	16 (40%)	18 (45%)	
Unskilled	05 (12.5%)	05 (12.5%)	
Unemployed	19 (47.5%)	17 (42.5%)	
Marital status			0.005
Married	03 (7.5%)	13 (32.5%)	
Unmarried	37 (92.5%)	27 (67.5%)	
Monthly PCI (Rs)	2349.12 ± 1361.84	2327.92 ± 1617.15	0.55
Habitat			0.81
Rural	26 (65%)	27 (67.5%)	
Urban	14 (35%)	13 (32.5%)	
Lifestyle pattern			0.66
Sedentary	03 (7.5%)	03 (7.5%)	
Moderate	29 (72.5%)	32 (80%)	
Severe	08 (20%)	05 (12.5%)	
Alcoholic	13 (32.5%)	12 (30%)	0.80
Drug addiction	01 (2.5%)	01 (2.5%)	1.00
Mode of injury			0.59
RTA	30 (75%)	30 (75%)	
Falls	09 (22.5%)	10 (25%)	
Assault	01 (2.5%)	0 (0%)	
Location of injury			0.18
Supratentorial	37 (92.5%)	33 (82.5%)	
Infratentorial	03 (7.5%)	7 (17.5%)	
Duration since injury (h)			
0–24	10 (25%)	08 (20%)	0.66
25–48	22 (55%)	26 (65%)	
> 48	08 (20%)	06 (15%)	

Abbreviations: PCI, per capita income; RTA, road traffic accident.

stimulation may affect the RAS and increase arousal and attention to the incoming stimuli. It also may stimulate the higher threshold of neurons in reticular activating system (RAS) and enhance the growth of dendrites.^{5,18,19}

Intervention was started within 72 hour of injury as coma stimulation should be provided as soon as the patient is hemodynamically stable as the evidences emphasize that early and repetitive sensory stimulation enhances the relearning in damaged brain.^{5,15,16} Though a number of studies have reported positive outcome even when the

auditory stimulation was started after 72 hour of injury,^{20–22} various types of auditory stimulations have been reported in previous studies such as music,^{13,23} recorded MP3 sound, and recorded familiar voice of family member or friend.^{4,5,14,24,25} In present study, close family members directly talked to the comatose patients by addressing the patient by name²⁶ based on the individualized script that was prepared for the patient. Enhancement of brain activity to the familiar voice is well reported,^{4,5} and it is superior to unfamiliar voice¹⁴ and other types of auditory stimulation.¹³

Table 2 Baseline physiologic and neurologic parameters

Parameters	Control group Mean \pm SD	Intervention group Mean \pm SD	p Value
Eye response	1.08 \pm 0.16	1.02 \pm 0.27	0.31
Verbal response	1.00	1.00	
Motor response	3.98 \pm 1.20	4.12 \pm 1.20	0.58
GCS	5.10 \pm 1.37	5.12 \pm 1.20	0.93
PR (beats/min)	93.58 \pm 20.14	94.60 \pm 18.44	0.81
RR (breaths/min)	23.26 \pm 4.10	20.31 \pm 7.18	0.03
SpO ₂ (%)	94.52 \pm 5.07	97.60 \pm 3.66	0.003
SBP (mm Hg)	127.70 \pm 13.04	129.82 \pm 17.04	0.53
DBP (mm Hg)	79.58 \pm 7.76	77.58 \pm 10.77	0.34

Abbreviations: DBP, diastolic blood pressure; GCS, Glasgow Coma Scale; PR, pulse rate; RR, respiratory rate; SBP, systolic blood pressure; SpO₂, peripheral capillary oxygen saturation; SD, standard deviation.

Even though cortical activity of the brain is enhanced, there are no untoward effects of auditory stimulation reported such as changes in intracranial pressure or hemodynamic parameters.²⁴ Voice of family members has emotional significance too.²⁷

The script of the talk was prepared based on the important principles and protocols of providing auditory stimulation.^{5,18} It was individualized for each patient while keeping a common frame line. The script included news from home, family members, and patient-related events. It

also ensured that the patient has a feeling of hope and worth and that everything best is going on for his or her recovery. Therefore, one close relative of each patient who had at least more than 1 year contact with the patient during the previous 1 year was selected, trained on the script, and was allowed to visit the patient in order to provide auditory stimulation using all precaution of infection prevention. Applying the principle that repetition of stimuli enhances the relearning,^{5,18} auditory stimulation was provided for 8 to 10 minutes, twice daily for 14 days. Similar duration was

Table 3 Level of consciousness and physiologic parameters at 7 and 14 days

Outcome variables	Control group Mean \pm SD	Intervention group Mean \pm SD	p Value	
Day 7	Eye response	1.57 \pm 0.85	2.52 \pm 1.26	0.31
	Verbal response	1.00	1.13 \pm 0.56	0.18
	Motor response	3.97 \pm 1.32	4.90 \pm 1.01	0.002
	GCS	5.54 \pm 1.75	7.26 \pm 2.39	0.001
	PR (beats/min)	99.54 \pm 17.62	97.15 \pm 16.58	0.62
	RR (breaths/min)	25.23 \pm 5.78	25.45 \pm 7.87	0.90
	SpO ₂ (%)	93.91 \pm 4.65	97.85 \pm 3.53	0.002
	SBP (mm Hg)	129.17 \pm 13.94	133.65 \pm 12.25	0.24
	DBP (mm Hg)	81.09 \pm 12.23	82.60 \pm 9.92	0.64
Day 14	Eye response	2.16 \pm 1.17	3.25 \pm 1.15	0.001
	Verbal response	1.00	1.00	1.00
	Motor response	4.09 \pm 1.49	4.92 \pm 1.06	0.025
	GCS	6.34 \pm 2.36	8.17 \pm 2.06	0.004
	PR (per minute)	104.84 \pm 15.89	99.00 \pm 15.46	0.20
	RR (per minute)	24.94 \pm 4.43	26.85 \pm 4.74	0.15
	SpO ₂ (%)	94.06 \pm 4.23	94.35 \pm 3.59	0.80
	SBP (mm Hg)	129.09 \pm 15.50	128.45 \pm 8.46	0.87
	DBP (mm Hg)	76.19 \pm 10.075	77.95 \pm 6.004	0.48

Abbreviations: DBP, diastolic blood pressure; GCS, Glasgow Coma Scale; PR, pulse rate; RR, respiratory rate; SBP, systolic blood pressure; SpO₂, peripheral capillary oxygen saturation; SD, standard deviation.

Table 4 Comparison of physiologic parameters before, during, and after intervention

Parameters	Before intervention Mean \pm SD	During intervention Mean \pm SD	After intervention Mean \pm SD	p Value
PR (beats/min)	99.26 \pm 17.05	102.51 \pm 16.32	101.53 \pm 16.92	< 0.001
RR (breaths/min)	23.27 \pm 6.61	23.20 \pm 6.47	23.22 \pm 6.48	0.863
SpO ₂ (%)	96.84 \pm 4.30	97.43 \pm 3.93	97.42 \pm 4.28	< 0.001
SBP (mm Hg)	130.53 \pm 14.15	130.18 \pm 13.67	130.70 \pm 13.63	0.215
DBP(mm Hg)	79.24 \pm 9.43	79.10 \pm 9.16	79.43 \pm 9.28	0.521

Abbreviations: DBP, diastolic blood pressure; PR, pulse rate; RR, respiratory rate; SBP, systolic blood pressure; SpO₂, peripheral capillary oxygen saturation; SD, standard deviation.

used in previous studies of auditory stimulation in comatose patients with TBI.^{4,13,25} To avoid over- and understimulation, duration was kept limited. To assess the effect of auditory stimulation, patients in intervention group were monitored daily on level of consciousness and hemodynamic parameters before, during, and after the family member talking to the patient. GCS⁶ is a standardized scale to assess the level of consciousness and has been used by many researchers^{4,17} to assess the effect of auditory stimulation on level of consciousness.

The present study results show that providing repetitive auditory stimulation by allowing the close family member to talk to the patient enhances recovery in patients with TBI as GCS score was significantly higher in intervention group at the end of first and second weeks. However, GCS remained unchanged immediately after intervention. Significant improvement in the LOC after 6 days of family visiting program had been reported.¹⁷ Gorji et al in 2014 reported significantly shorter duration to attain full consciousness in comatose patients with TBI who had been provided with auditory stimulation using familiar voice.⁴ Davis and Gimenez in 2003 reported a significantly better GCS at discharge in patients who underwent structured auditory sensory stimulation.²⁰

In the present study, there was a significant increase in PR as well as SpO₂ during and immediately after intervention though RR and BP remained unchanged. Similar to these findings, Jones et al in 1994 has reported increase in PR on auditory stimulation¹³ and Puggina and Silva in 2011 reported that voice messages are effective in increasing PR and SpO₂ of comatose patients with TBI.²³ Marzieh et al in 2012 found in similar sample that light music stimulation increases SpO₂ and reduces PR, RR, BP, and body temperature.²⁸ Therefore, auditory stimulation using familial voice could be safely executed as it helps improve the SpO₂ and does not produce any detrimental effects on the patient's physiologic parameters.²⁴ With these evidences of improvement in SpO₂, further studies can be done to identify the effect of auditory stimulation on cerebral oxygenation. The betterment in the level of consciousness could be caused by the improvement in cerebral perfusion.²⁹

Loved ones of comatose patients play an important role in recovery of these patients. Even the best efforts taken by the members of medical team are futile if not complimented

with the caring and loving attitude and hope, which come from their family members and friends. Families of patients with head injury must adjust to the fact that the recovery process is a slow "labor of love."

Providing auditory stimulation using the similar protocol is simple and inexpensive method as the patients' relatives were directly talking to the patients. In the present study auditory stimulation is provided as early as possible within 72 hours of injury. This particular intervention also helps the family members identify the caregiving agency within them³⁰ and improves their confidence in providing care to their loved ones. Nurses and other health care personnel can also be a part of this intervention by talking to the patients and by providing psychologic as well as emotional support while providing care. Long-term effect of auditory stimulation also can be assessed using Glasgow Outcome Scale (GOS). Auditory stimulation by allowing the family members to talk to the patient can also be used in other intra- or extracranial pathologies leading to coma and can also be done at hospital or home setting.

Conclusion

One hallmark of severe TBI is loss of consciousness. Facts from the science have contributed that recovery following TBI starts soon after the traumatic incident. It was found in the present study that providing early auditory stimulation by significant relatives talking to the comatose patient with TBI is effective in improving level of consciousness. Therefore, family members should be involved in care of comatose patients with TBI and encouraged to talk so as to meet patients' psychologic, spiritual, and social needs, and hence promoting recovery.

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