

Effectiveness of Coma Stimulation Therapy on Sensory Function of Unconscious Patients in Selected Hospitals, Kollam, Kerala.

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ABSTRACT

Coma and vegetative state follows traumatic brain injury in about one out of eight patients, and in patients with non-traumatic injury the prognosis is worse. Patients with traumatic brain injury who is in prologue unconsciousness but gain consciousness when eyes are open and moved is call as unrelenting vegetative state in which stimulus induced arousal is seen due to responsiveness of sleep awake cycle. Apart from coma and vegetative state another state in which a patient of TBI can be classified as minimal conscious state. The use of sensory stimulation for coma and vegetative state has gained popularity during the 1980's but beliefs and opinions about its effectiveness vary substantially among health professionals. Minimal conscious state is the condition in which a patient is recovering from the vegetative state and there is minimal preservation of consciousness to self or environment. Assessment of level of consciousness is the good analyst of the prognosis after traumatic brain injury. Glasgow coma scale is widely used as the predictor of consciousness due to high validity and reliably. Other than GCS, Rancho los amigos scale (RLA) and disability rating scale can also be used as the outcome predictor of consciousness.

KEYWORDS:--Coma, Stimulation, Sensory, Unconscious, Conscious, Disability, Sensory Stimulation, Traumatic Brain Injury, Consciousness Level, Cognitive Function.

Objectives of study

To assess the effectiveness of sensory stimulation therapy on sensory function of unconscious patients.

Methodology:--

- ∞ Randomised or controlled trials that compared sensory stimulation therapy with standard rehabilitation in patients in coma.
- ∞ Data collection and analysis.

INTRODUCTION

About half of people in a deep unconsciousness because of traumatic brain injury will wake within a year of the accident. Speeding recovery to allow people to wake sooner is a priority for them and their family. One type of treatment uses sensory stimulation to try to keep the person's brain working normally. Sensory stimulation methods vary greatly, from one or two hourly sessions of a day, through to shorter sessions every hour for 12 to 14 hours a day. The review found there is no strong evidence to determine whether sensory stimulation benefits people in comas. According to the Traumatic Coma Data Bank, 54per cent of the vegetative

survivors from severe head trauma regain consciousness within one year post- injury and 42 per cent improve to a higher Glasgow Outcome Scale within six months. The remaining individuals die or remain in a vegetative state for months or years. The outcome for individuals in coma or vegetative state with non- traumatic brain injury is worse than that for those with traumatic brain injury. In one trial, of 100 patients, 25 recovered consciousness within five months, 35 had died by six months after onset, and 40 remained unconscious for the remainder of their lives. Only seven individuals were alive after 75 months of follow- up. The intensity of sensory stimulation treatment proposed by different authors has varied considerably. Ranging from one or two cycles of stimulation daily, of approximately one hour each , to one session of multimodal stimulation and one session of unimodal stimulation a day for 10 minutes each , to hourly stimulatory cycles, lasting approximately 15- 20 minutes, for 12- 14 hours per day, six days a week . Yet another approach has been proposed by Wood, who in 1991, performed a critical analysis of the concept of sensory stimulation. He outlined that "clinical experience has shown that patients exposed to an undifferentiated bombardment of sensory information lose the ability to process information due to the background noise (habituation)". Wood introduced the 'Sensory Regulation' approach, based on the concept of regulating the way in which stimulations are delivered. Owing to the severe impact on the life of many individuals, both those with a brain injury and their relatives, it is urgent to know whether these treatments are more effective than a standard rehabilitation therapy in promoting recovery from coma and vegetative state. Moreover, as randomised control trials do not seem to be easily accepted in the rehabilitation community we will discuss potential problem in designing and conducting RCTs in this area.

HYPOTHESES

- ⌘ IMS and Sensory Regulation therapy are more effective than standard rehabilitation treatment in arousing patients from coma.
- ⌘ IMS and Sensory Regulation therapy are more effective than standard rehabilitation treatment in reducing time to recovery from coma.

In addition, its being discussed the methodological quality of relevant studies to identify their major drawbacks and suggest appropriate directions for future research.

Types of studies

1. All Randomised Controlled Trials (RCT)
2. Intense Multisensory Stimulation (IMS) therapy,
3. Not- Intensive Stimulation therapy or Sensory Regulation therapy .

Types of participants

Patients diagnosed as brain injured with traumatic and non- traumatic etiology (i.e. anoxic), of any age and gender were selected from two private hospitals, Kollam, Kerala. Patients are defined in different ways in original studies. For the purpose of this review I accepted two definitions.

- ⊗ a) Coma: unarousable with absence of sleep/wake cycles on electroencephalogram and loss of the ability of environmental interaction. Major neurobehavioral criteria: the patient's eyes do not open either spontaneously or to external stimulation, the patient does not follow any commands.
- ⊗ b) Vegetative State: loss of the ability to interact with the environment despite the capacity for spontaneous or stimulus- induced arousal, sleep/wake cycles may be present on EEG and subcortical reflexes are partially or fully preserved. Major neurobehavioral criteria: the patient's eyes open spontaneously or after stimulation; the patient does not follow any commands.
- ⊗ the Cochrane Injuries Group's specialized register
- ⊗ the Cochrane Controlled Trial register
- ⊗ MEDLINE
- ⊗ EMBASE
- ⊗ CINAHL
- ⊗ PSYCHLIT

Assessment of risk of bias in included studies

To identify relevant studies abstracts were screened by one reviewer (FL). Studies for inclusion were then independently selected by three reviewers (FL, ADT, MT) and disagreement resolved by consensus. For studies that met the inclusion criteria data was independently extracted by three reviewers using a pre- specified data extraction sheet. Information extracted included types of patients and interventions, outcomes measured and timing of assessments, method of randomisation, and selection criteria for patients, number of patients lost to follow- up and blinding of outcome assessors. I relied on what was reported in the paper and did not seek additional information from the authors.

Since there is evidence that the quality of allocation concealment particularly affects the results of studies , two reviewers scored this quality on the scale used by Schulz as shown below, assigning C to poorest quality and A to best quality:

- ⊗ A=trials deemed to have taken adequate measures to conceal allocation (i.e. central randomization; numbered or coded bottles or containers; drugs prepared by the pharmacy; serially numbered, opaque, sealed envelopes; or other description that contained elements convincing of concealment).
- ⊗ B=trials in which the authors either did not report an allocation concealment approach at all or reported an approach that did not fall into one of the other categories.

⊗ C=trials in which concealment was inadequate (such as alternation or reference to case record numbers or to dates of birth).The searching identified 26 potential studies. Of these, two studies met the inclusion criteria.

The following level of evidence was use for the review. (Table 1)

Level 1	Systemic reviews, meta-analysis, RCTs
Level 2	Non RCT ,case control trials
Level 3	Pre-test-post test design, cross sectional studies case series
Level 4	Single subject design
Level 5	Case reports ,narrative literature reviews

Along with the level of evidence PEDro scale was used to assess the quality of the randomised control trials. (partitioned; 2003).

Stephen

This was a randomised controlled trial including 14 male coma patients with GCS equal to or less than eight who suffered acute brain injury due to a road traffic accident and were admitted within 24 hours to an Intensive Care Unit. Patients were randomly assigned into two groups. Seven patients (mean age 27.7, mean GCS 4.8) were allocated to the active intervention group who underwent therapeutic sessions where all five senses (olfactory, visual, auditory, gustatory, tactile) were vigorously stimulated. The sessions lasted 20 minutes a day throughout the patients stay in ICU. The other seven patients (mean age 31.4, mean GCS 4.8) in the control group, received usual care without any specified sensory stimulation programme. The outcome measures, which were assessed daily, were GCS, state of ventilation, spontaneous eye movements, oculocephalic response and oculovestibular response. Skin conductance, heart rate were assessed 20 minutes before and after treatment.

Jhonson

This was a controlled clinical trial (CCT) with 16 head injured patients at least two weeks after the trauma. There were 10 male and 6 female participants, (mean age 28 years) with GCS ranging from three to 14 and length of coma ranging from six hours to three months. The study compared a multisensory stimulation programme with usual rehabilitation. The two groups (active intervention and usual rehabilitation), with 9 patients each, were matched for age, sex, type of injury, GCS and length of time from injury each selected from two different health care facilities. Within the two groups, patients were further classified into three subgroups on the basis of GCS score: Severe (GCS 3- 6), Moderate (7- 10) and Mild (11- 14). The experimental treatment consisted of a section of stimulation of five modalities: olfactory, visual, auditory, gustatory, tactile that lasted 30 minutes, twice a day, six days per week until the patients were aroused from coma. Maximum duration of treatment was three months. The outcome measure assessed was 'Level of Cognitive Functioning' (LCF) at two weeks and three months after injury.

Patients and Methods

This was a randomized clinical trial performed in two private hospitals including 60 head injured comatose patients with an initial Glasgow coma score (GCS) of less than 8. Patients were randomly assigned to receive sensory stimulation by a qualified nurse (nurse group; n = 15), by the family (family group; n = 15), or usual care (control group; n = 30). The sensory stimulation program involving the nurses and patients' families was conducted, twice daily, in the morning and evening for 7 days. The level of consciousness, level of cognitive function, and basic cognitive sensory recovery of the patients were evaluated and monitored using the GCS, Rancho Los Amigos (RLA), and Western Neuro-Sensory stimulation profile (WNSSP). Data were analyzed by chi square, Kruskal-Wallis, and repeated-measures tests using SPSS.

COMA

Coma is mainly the result of trauma related to road traffic accidents. While patients frequently recover from comas, those with severe traumatic brain injury (TBI) will experience an alteration in their level of consciousness and cognitive function for a period of time. An increased length of these alterations (coma) is associated with worse outcomes; as such, most of those who survive are unable to live a normal life due to impaired cognitive function. Prolonged hospitalization, social isolation, and complete bed rest in these patients will result in reduced sensory perception secondary to reduced sensory input. The involvement of families in patient care has been considered in other areas of care; however, family involvement in intensive care units (ICUs) is limited to open visitation policies that provide a supportive and more familiar environment for patients and improve the relationship between nurses and families. It has been shown that family visits in ICUs are effective in offering programmed and structured approaches to providing nursing care to patients.

Study residents

This was a double blind clinical center affiliated with Shiraz University of Medical Sciences during a 10-month period from January to Octo.2015. It was estimated that a sample size of at least 16 individuals per group was needed to detect an effect size of 1, as determined in another study with an alpha risk of 0.05 and power of 0.80. We decided to include 20 subjects per group to compensate for non-evaluable patients. We included 60 adult comatose patients suffering from severe TBI. Eligible patients were approached on their fourth day of admission if they were in a state of a coma during the first three days of admission, had a GCS score of 3 - 8, a Rancho Los Amigos (RLA) scale of I - II, and stable hemodynamics. Patients who were older than 65 years of age, opium and drug addicts, receiving sedatives, suffering from blindness, deafness and delusional disorders, and seizures were further excluded from the study.

Randomization and Intervention

The demographic information including age, sex, marital status, education, type of injury, injuries along with the head injury, cause of hospitalization, and vital signs upon admission consisting of temperature, heart rate, respiratory rate, and blood pressure were recorded in a data-gathering form. All the eligible patients were randomly assigned to one of three study groups. Those assigned to the family group received the sensory stimulation program from family members (n = 15), while those in the nurse group received the same program from a nurse (n = 15). Those assigned to the control group received usual care (n = 30). For the two intervention groups of the study, the second author assisted the family members to list all the stimulators familiar to the patient to be used in the program and the specific stimulus for each sense was chosen in accordance with the patient's priorities, his or her favorites, and acquainting the patient's family with the stimulus. The family members were also encouraged to bring perfumes, objects, and tapes at any time to vary the selection of stimuli. In the family group, a training session was first held with patients' families and they were asked to introduce someone who was emotionally closest to the patients among their family and friends and was capable and willing to do the sensory stimulation program. The sensory stimulation program was conducted in both groups twice a day, in the morning and in the afternoon shift, each lasting for half an hour. The program was conducted for 7 days for each patient. The sensory stimulation protocol was developed based on previous studies and was given to the head nurse of the ICU and a neurosurgeon. The protocol was then revised based on their recommendations; the details of the program are provided in the following session:---

Author	No of patients/ inclusion	Study design	treatment	result	Level of evidence /pedro
Stephen	356/ GCS: < 8	Systematic review	Multimodal sensory stimulation	Improvement in LOC	Level 1
Jhonson	GC S: <8	Systematic review	Auditory and tactile stimulation by family	Significant improvement in GCS within 24 hours	Level 1
Shiraz University	54/ GCS: < 8	Randomised control trial	EG- Auditory stimulation 15min/day For 7 days CG-	Significant improvement in intervention group after 3rd	PEDro: 8 Level 1

			only headphones are applied no music tap was played	day	
Mandee15	80/ RASS 2-4 GCS: < 8	Quasi experimental study	EG- music therapy(Beach walk music) 60- 80 beats/min 15 min/day for 7 days CG – silent headphones for 15 min	Significant improvement in GCS on 6 th and 7th day till then no improvement	Level 2
Urbenjaphol 16	332/ GCS: <8 RASS:2-4	Systematic review	Sensory stimulation	High quality trial are needed to establish protocol	Level 1
Salmani et al. 18	30 GCS:<8	RCT A-MSS B-MSS Cconventional For 2 weeks	A-5 times/d 20 min B-2 times/d 50 min C-2 times/d PROM ex. 10 rep	Significant improvement in GCS & WNSSP A&B High fr. short duration is more effective	PEDro 7/11 Level 1

*GCS- Glasgow coma scale,EG-experimental group, CG- Control group,RASS-Richmond Agitation-Sedation Scale, RMNSRight median nerve stimulation, MMS- Multimodal stimulation, NBP- Normal blood pressure, WNSSP- Western neuro sensory stimulation profile, UG- Usual treatment group, SMART- Sensory modality assessment and rehabilitation technique, PROMPassive range of motion

Sensory Stimulation Therapy

The sensory stimulation program consisted of the following:

1. Awakening for 5 Minutes :

First, a nurse or a close relative to the patient introduced himself/herself to the patient and spoke to the patient. During this process, a nurse or a close relative of the patient opened the patient's eyes or called him/her while moving his/her body at the same time or moistened the patient's face with a wet gauze.

2. Auditory Stimulation for 5 Minutes

At this stage, the patients' favorite music or taped recordings of the voice of the patient's family members and acquaintances who were speaking directly to patient or just talking to each other were played for the patient.

3. Visual Stimulation for 5 Minutes

Patient held one of the objects, a family photograph, a family film, a mirror, colored paper, and a 40-watt light bulb colored in blue, and green, before the patient's eyes. If the patient's eyes were closed, they were kept open with one hand.

4. Tactile Stimulation for 5 Minutes

For tactile stimulation, a close relative to the patient touched his/her shoulder outside the patient's visual field with a soft brush and a comb, and a hair brush/comb or a soft brush was applied to various body parts. The patient's lips, around the top and bottom, were touched with the tip of a pen or spoon.

5. Olfactory Stimulation for 5 Minutes

This was done using aromatic stimuli with a fragrance to which the patient had been accustomed. These included the patient's favorite aromas, such as perfumes, spices and herbs.

6. Gustatory stimulation for 5 Minutes

This was done using touching tongue with cotton swab dipped in orange or lemon peels, and garlic.

To monitor the possible adverse effects of the stimulation program, patients' pulse rate, mean arterial blood pressure, and respiratory rate were assessed before and after the sensory stimulation period to cease the intervention if a problem arise.

CONCLUSION

The application of sensory stimulation by families led to significant increases in the consciousness, level of cognitive function, and basic cognitive sensory recovery of comatose patients with severe injuries. Recent evidences support that sensory stimulation techniques in coma has potential effect in the recovery of comatose patients. From the review sensory stimulation 2 sessions per day for at least 15 min of each stimulation could give more significant improvement in level of consciousness. Although Family centered early multimodal stimulation gives better outcomes in level of consciousness in comatose patient

after traumatic brain injury but further high-quality studies are required to justify the ideal dosage, frequency and most effective method of application for each stimulation.

LIMITATION

Different intervention methods are used in every studies

Heterogeneous measurement tools were used in studies.

FUTURE RECOMMENDATION

Further studies are needed to know the effectiveness of the intervention protocol for the stimulation and with the use of homogenous measurement tools (GCS, CRS).

More exploration of dosage and most efficient delivery method is recommended in future studies.

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