

Effectiveness of Structured Communication by Family Member on Clinical Parameters among Unconscious Patients Admitted in Intensive Care Unit: A Randomized Controlled Trial

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Abstract

Background: Patients who stay in ICU suffer cognitive, emotional and behavioural impairments that remain in a long duration of coma state. Unconscious patients experience sensory deprivation because their ability to respond internal as well external stimuli threshold of the reticular activating system gets disturbed. One of the easy ways to prevent sensory deprivation of unconscious patients is to use the auditory stimulation.

Aim: To evaluate the effectiveness of structured communication by family member on clinical parameters among unconscious patients admitted in ICU.

Method: A prospective, randomized controlled trial of 60 unconscious patients aged 18 years and older, with more than 24 hour on mechanical ventilation were recruited. Structured communication was recorded by closest family member in his/her voice in a separate room and was played on headphones for 10 minutes, two times daily for four days for subjects in the experimental group. The data collection tools were assessed at pre and post intervention. The main outcome were Level of consciousness and physiological parameter.

Results: There was statistically significant difference ($p = 0.003$) on the level of consciousness on the fourth day of intervention between experimental and control group. There was no statistically significant difference found in physiological parameters, duration of ICU stay ($p = 0.33$) and mechanical ventilation ($p = 0.32$) between experimental and control group.

Conclusion: The study concluded that nurse could use the structured communication as a protocol in Intensive care unit along with treatment and nursing care to improve the patients level of consciousness.

Clinical Implication: Structured communication found effective on the level of consciousness so nurse should use structured communication as a protocol in ICU which help in recording the family member's voice.

Nurses should encourage and motivate caregivers to communicate with the patients admitted in ICU.

Keywords: Auditory Stimulation; Family Member; Level of Consciousness; Mechanical Ventilation; Physiological Parameters; Structured Communication; Unconscious Patients

Introduction

Critical care is the multidisciplinary approach to the management of seriously ill medical and surgical patients [1]. The major illnesses which lead to common intensive care unit admissions are hypoxia, shock, acid-base imbalance, respiratory insufficiency, Cerebral vascular accident, drug toxins, brain tumours, trauma and other surgical cases [2].

In the past two decades, there has been an enormous growth in intensive care medicine in India. About 46.4% of patients had equal to or more than 1 organ failure. Nearly, 37% of patients received mechanical ventilation and 22% patients had on Vasopressor. Approximately 12.2% of patients had developed an infection in the Intensive care unit. Nearly, 28.3% of patients had developed severe sepsis during their ICU stay after admission. Almost 60.7% of patients received antibiotics without infection in an Intensive care unit. About 546 deaths and 183 terminal discharge from Intensive care unit (along with left against without medical advice). ICU mortality rate was (18.1%). Moderate severity of illness like severe sepsis, shock, organ failure or patients on inotropes and receiving mechanical ventilation with artificial airways relatively those patients have high mortality in ICU [3]. Coma is one of the outcomes of severe illness.

Effective and useful communication is one of the cornerstones of professional nursing practice and the art of caring comprehensively for patients [4]. Undoubtedly, in hospital nurses are only the health care professional group which has the extensive contact with the patients, affirming their communication requirements are fully met has been prevailing as one of the most paramount skills of nursing [5]. Communication used by the nurse help to offer directions, reassurance, provide psychological support, counselling, interpret, receive information and carry out different duties. Without communication, nurses can neither develop interpersonal relationship nor assess, plan, implement and evaluate care effectively [6]. However, Communication with critically ill patients in the Intensive care unit brings out specific challenges like patients on ET/Tracheostomy tube and various drug i.e. sedation. Sensory deprivation is one of the complications of a long duration of stay in the Intensive care unit. Providing an organized auditory stimulus is play a crucial role for people who are affected severely by sensory deprivation. In the context of nursing, unconscious patients totally depend on nursing care.

Othman., *et al.* had done a study and he recommended to explore the effect of structured communication on clinical outcome [6]. Hence the current study is aimed to evaluate the effectiveness of structured communication by family member's voice on clinical parameters of unconscious patients in AIIMS. The present study hypothesised that structured communication effect on the level of consciousness, physiological parameters and duration of ICU stay and mechanical ventilation.

Materials and Methods

Study design and setting

The present study was designed as a prospective, randomised controlled trail and conducted in All India Institute of Medical Science, New Delhi Hospital. The study was conducted among the unconscious patients who were admitted in Intensive care unit. The study include for the sample were fulfilled inclusion and exclusion criteria.

Sample size

Considering the study "Effect of structured communication on clinical outcomes among unconscious patients" by Othman., *et al.* [7] reported that mean FOUR score was (11.83 ± 2.09) . Assuming that the present study subject's standard deviation were 2 to find the significant difference of structured communication by family member in control and experimental group. So, for critical value 1.96, power 90% at 5% level of significance, we require to the study approximately 22 study subject in each arm. Considering an attrition rate of ap-

proximately 30% we require 30 - 32 study subjects in each, so total sample size required is 60. In this study, 60 patients were assessed for eligibility for the study from July to November 2019. Patients who were admitted in ICU were screened for eligibility based on the inclusion and exclusion criteria and recruited in to the study.

Randomization and allocation

Random assignment was done by using computer generated random number table into experimental and control group with the help of Statistician from Biostatistics department. Sequentially, Numbered, Opaque, Sealed Envelopes (SNOSE) were prepared by researcher's colleagues. Envelopes were opened by the researcher only after the family members provided written informed consent to participate in the study and then subjects were allocated in the experimental and control group as shown in consort.

Eligibility criteria and study sample

The eligible patient include patients aged between 18 to 60 years, Patients who had level of consciousness score in between 4 - 10 based on (FOUR score Scale), Patients who were on mechanical ventilation for more than 24 hour, Hemodynamic stable after admission of 24 hours, patient's sedation level score in between 1 - 4 according to MAAS (Motor activity assessment scale). Family member's willing to participate and closest to the patients and able to understand and can speak in Hindi/English language. The exclusion criteria for the study include patients with Brain Injury, Patients who had history of impaired hearing, Patients with history of excessive consumption of alcohol and narcotic substance, diagnosed with injury of auditory pathway, Patients on induced coma by neuromuscular blockade drug and who has Quadriplegia.

Intervention

Structured communication recorded in closest family member's voice.

Structured communication content format has been developed by researcher and its validity was done by three Nursing experts and two medical experts. An individualized script for each patient was prepared with the help of significant family member keeping in a common frame line. Repetitive use of patient's name was emphasized while speaking. The written script included three categories which are given below:

1. Category I: (1 - 2 mints): Orientation about environment to the patient by family member.
2. Category II: (2 - 3 mints): Family member's wishes for the patients come back to home.
3. Category III: (3 - 4 mints): Family member's concerned about patient's recovery.

Total duration of recorded structured communication by family member was 8 - 10 minutes and it was done in separate room situated near the ICU. During the recording written and oral instruction was provided by the researcher.

Outcome measurement and study instrument

Socio-demographic and clinical profile sheet

A structured tool was prepared with items on socio-demographic datasheet and relevant clinical profile.

Full outline unresponsive score scale (FOUR)

The Full outline Unresponsiveness score (FOUR) is a standardized and well established scale. It is used to assess the level of consciousness of the patients in ICU. It has 4 component Motor response, eye response and Brainstem reflexes and respiration pattern. Each component has maximum score of 4 and minimum score of 0. So, total the maximum score is 16 and minimum score is 4. The reliability and validity of FOUR score scales is (Cronbach α 0.87 and a Kappa coefficient of 0.99) done by Iyer, *et al.*

Clinical sheet for parameters

It is a sheet for recording various selected parameters. It includes level of consciousness, heart rate, respiratory rate, oxygen saturation, systolic blood pressure, diastolic blood pressure, mean arterial pressure and level of consciousness. Level of consciousness was assessed by FOUR score scale and physiological parameters were recorded by cardiac monitor.

Motor activity assessment scale

Motor activity Assessment scale is standardized scale. It is used to assess the level of sedation of Patients who are on mechanical ventilation. It is a 7 point scale in which maximum score is 6 and minimum score is 0. The reliability and validity of tool is established by researcher Devlin JW, *et al.* ($\kappa = 0.83$ [95% confidence interval, 0.72 to 0.94] in the study.

Data collection

The baseline data were collected by using the socio-demographic sheet, clinical parameters sheet before and after administered of intervention till 4 days. All the data collection tools were applied by the researcher.

Procedure for data collection

Patients admitted in ICU who met the inclusion criteria were enrolled in the study. For subjects who were found eligible, Participant Information sheet were given to family member and explaining the purpose of the study. They were also required to sign a participant Informed consent form and thereby enrolled into the study. The subjects were allocated to experimental and control group by using Sequentially, Numbered, Opaque, Sealed, Envelope (SNOSE). Baseline information regarding socio-demographic and clinical profile sheet was collected from patient's file. Structured communication was recorded by closest family member's voice in a separate room. In Experimental group and control group a baseline level of consciousness was assessed by FOUR score scale and physiological parameters were recorded by cardiac monitor. The subjects in the experimental group were provided with recorded structured communication by family member via headphones for 10 minutes and in control group not provided with structured communication by family member. After 10 minutes, level of consciousness and physiological parameters were reassessed. Intervention was carried out twice a day for 4 days.

Statistical analysis

The collected data was first coded and then summarized in master data sheet. Data analysis was done using SPSS (version.15.1) both descriptive and inferential statistics were used. Frequencies, percentage, mean, standard deviation were calculated using descriptive statistics. Chi-square, fisher exact test were used in categorical variable. Independent t-test was used for comparing means of two groups.

Ethical consideration

Ethical clearance for conducting the study was obtained from the Ethics committee of All India Institute of Medical Sciences, New Delhi. After getting permission from the ethics committee start to take eligible patient and informed family member to explain the purpose and implications of the study for patients. Participant Informed consent Form (PICF) was taken from the family member prior to enrolment. Confidentiality and privacy of the information in recorded structured communication was maintained.

Result

Comparison of socio demographic between experimental and control group

Table 1 shows that the mean age of subjects in experimental group was 42.8 ± 12.2 years. The mean age of subjects in control group was 41.4 ± 10.75 years. Majority of subjects in both the groups were male (60% in experimental group and 64% in control group). In both

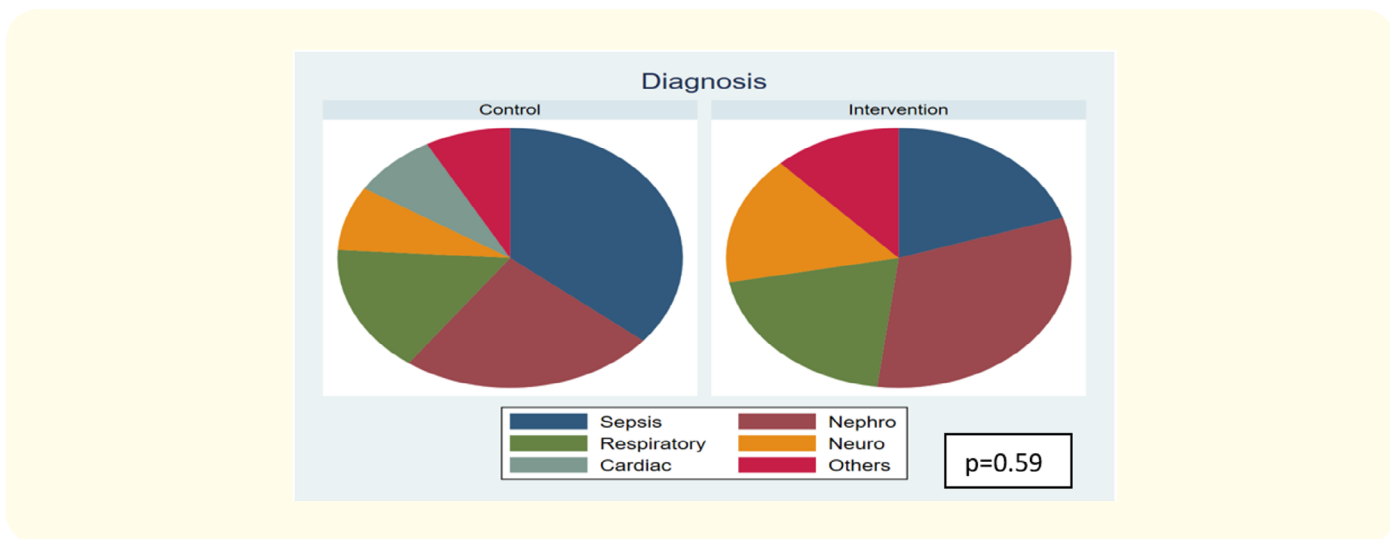
the groups, majority were married (76% in experimental group and 92% in control group). Majority of subject’s education level were up to primary (28% in experimental group and 44% in control group). On comparison, there was no statistically significant difference ($p > 0.05$) between the experimental and control group with regard to socio-demographic profile.

S. No	Variables	Experimental (n1 = 25) f (%)	Control (n2 = 25) f (%)	P value	
1.	Age (Years) mean ± SD	42.8 ± 12.2	41.4 ± 10.75	0.65 ^a	
2.	Sex	Male	15 (60)	0.77 ^b	
		Female	10 (40)		09 (36)
3.	Marital Status	Married	19 (76)	0.24 ^c	
		Unmarried	06 (24)		02 (8)
4.	Education	Illiterate	7 (28)	0.08 ^c	
		Primary	7 (28)		11 (44)
		Secondary	3 (12)		0 (0)
		Graduate	4 (16)		8 (32)
		Post Graduate	0 (0)		3 (12)

Table 1: Comparison of sociodemographic between experimental and control group. n = 50.

^aIndependent t test, ^bChi-square, ^cFisher exact test.

Figure 1 shows the comparison of clinical profile between experimental and control groups. In experimental group, 20% subjects were diagnosis of sepsis and in control group 36% subjects were diagnosis of sepsis. In experimental group, 32% subjects were related to kidney diseases and in control group 24% subject were related to kidney disease. In control groups, heart related disease, neuro disorder and other like autoimmune disease each of the subjects were 8% while in experimental group, 16% subjects were Neuro related disorder and 12% subject were considered as a category others. Respiratory problem in control and experimental group was 16% and 20% respectively. On comparison, there was no statistically significant difference ($p > 0.05$) between experimental and control group with regard to clinical profile.



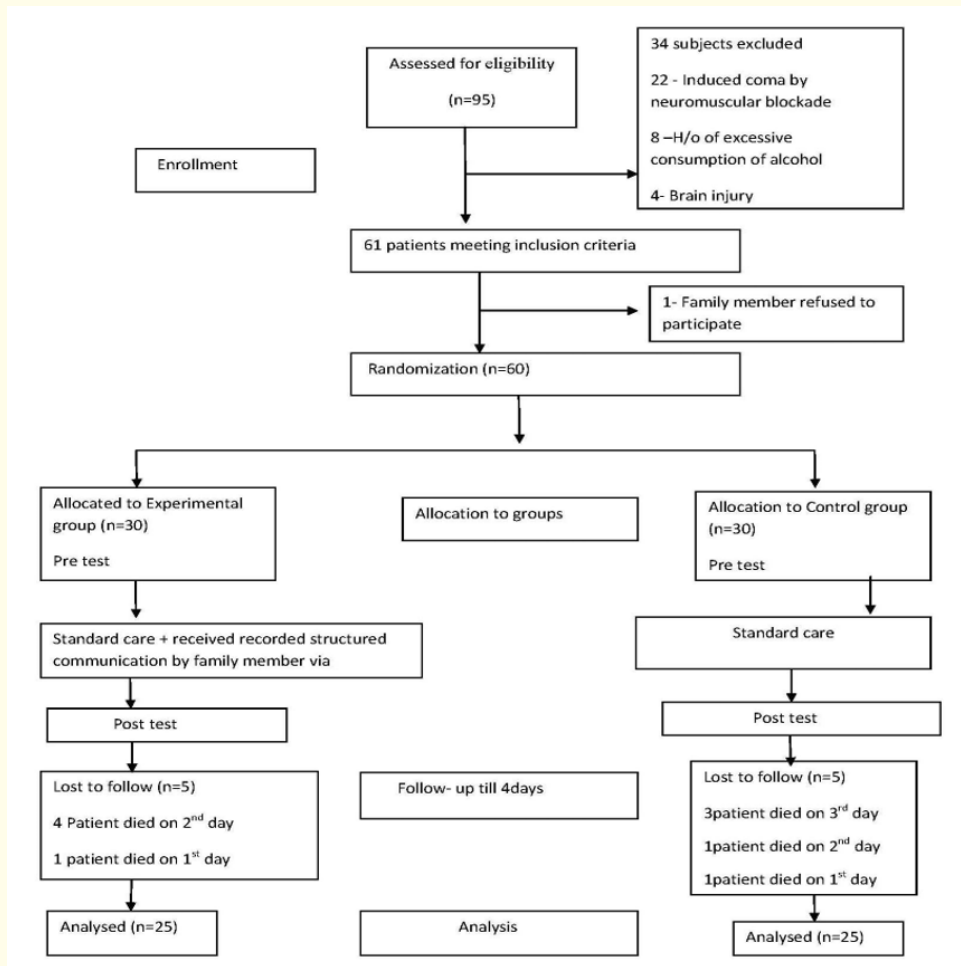


Figure 1: Comparison of clinical profile n = 50.

Table 2 shows the comparison of level of consciousness in experimental and control group. On the first day, the mean score of level of consciousness in experimental and control group were 5.56 ± 1.32 , 6.28 ± 1.69 respectively which was not statistically significant. Hence, it concludes that the experimental and control group were comparable in terms of level of consciousness on first day of the study. On the fourth day, the mean score of level of consciousness in experimental group was 8.60 ± 2.14 while in control group the mean score of level of consciousness was 6.36 ± 1.93 . Between group comparison by independent t- test revealed a statistically significant difference in the level of consciousness of experimental group as compared to the control group ($p = 0.003$).

Table 3 as shown the comparison of physiological parameters in experimental and control group. There were no statistically significant found in any physiological parameters pre and post intervention till 4 days as shown.

Discussion

In the present study, level of consciousness in the experimental group as well as control group was not found to be statistically significant on 1st day whereas there was significant difference in the level of consciousness between both groups on 4th day which was

statistically significant at ($p = 0.003$). The finding of this study is in consistence with the results of the study done by Farzad R., *et al.* [8] who reported that level of consciousness among comatose patients increased on the seventh day of the study and the difference in level of consciousness in the intervention and control group was statistically significant ($p = 0.001$). Another study which was in agreement with the present study was done by Salmani F Mohammadi., *et al.* [9] who reported that there was significant improvement in level of consciousness in intervention group and no significant changes in the control group and placebo group. The finding of the present study is in agreement with the study done by Parveen Y., *et al.* [10] who reported use of familiar voice improved in level of consciousness on 7th day among traumatic patients.

Tavanger H., *et al.* [11] who reported auditory stimulation by family member has significant improve in level of consciousness on the 10th day. Other study done by Heidari Gorji., *et al.* [2] study had reported the means of GCS's scores on the 10th day indicated a significant difference ($p = 0.0001$), in the intervention group. Hosseinzadeh., *et al.* [12] who reported the ten-day study period in both intervention and control groups led to significantly increase in the levels of GCS scores ($p < 0.001$). Megha., *et al.* [13] reported that there was significant difference in mean of GCS scores between intervention group that received multimodal coma stimulation in after 2 weeks and control group. Urbenjaphol., *et al.* [14] in their study found that two weeks after the programs of sensory stimulation on traumatic brain injury patients, the mean of GCS's scores were significantly more than those in the control group ($p < 0.05$). Bassampoor., *et al.* [15] by comparing the mean level of consciousness scores on the 1st day before the intervention with the mean scores of consciousness level on the 14th day after the intervention showed that in the intervention group there was a significant difference ($p < 0.001$). Karma and Rawat., *et al.* [16] in their study reached to this conclusion that the means of GCS's scores on the 14th day in both control and intervention groups were significantly difference and this mean in the intervention group was more than control group. The number of days in present study was less as compared to above study. Hence, this signifies that the auditory stimulation is effective in improving the level of consciousness of patient irrespective of the duration of stimulation.

In a study done by Puggina A., *et al.* [17] who reported that the familiar message by headphone was showed more effective as a stimulus to improve in level of consciousness compared to any music. Similar study done by Abbasi M., *et al.* [18] reported family members involved in patient's communication revealed highly stimulating effects on the level of consciousness. The researcher in the present study had also used voice of family members and found it to be effective in improving the level of consciousness among unconscious patients. The present study is agreement with this study expected the duration and frequency of intervention along with number of days. Present study concluded the mean difference of intervention and control group on the fourth days.

In the present study, subjects in the experimental group have no changes (variation > 10%) in physiological parameters (i.e. Heart rate, respiratory rate, oxygen saturation, systolic blood pressure, diastolic blood pressure and mean arterial pressure) after receiving structured communication by family member. The p value was found to be insignificant in all the Physiological parameters between the groups. The finding of present study is agreement with the study done by Khojeh., *et al.* [19] conducted study to determine the effect of familiar voice on physiological indices who reported that there was no statistically significant in physiological parameters.

Parveen Y., *et al.* [10] who indicated in the study that effect of auditory stimulation by family member statistically significant in the mean of physiological parameters on 14th days. Puggina A., *et al.* [17] who reported the significant difference in mean of oxygen saturation on day 1 and day 3, Diastolic blood pressure on day 2 after providing stimulation of familiar voice three session a day for consecutively three days.

Limitation of the Study

There were found some limitation in the present study that researcher were the only one who administered intervention as well as data collected from both the group that it could be potential performance bias. The intervention administered till 4 days twice a day due to potential constraints of time. Therefore, long term effect of intervention unknown. The present study conducted to only in single centre of unconscious patients so, result could not generalise to all the unconscious patients.

Conclusion

The structured communication by family member was found to be effective in improving the level of consciousness.

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No funding was received for conducting the research.

Conflict of Interest

There is no conflict of interest among.

Clinical Trial Registration Number

REF/2019/01/023623.

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