



The Effect of the Organized Auditory Stimulation with a Familiar Voice on Pain Intensity and Physiological Indices of Comatose Patients Admitted to the Intensive Care Unit

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ABSTRACT

Pain in the admitted comatose patients is an unpleasant experience, which directly affects the treatment results. One of the newest pain relief techniques is coma stimulation, particularly the auditory stimulation. Therefore, the objective of the present study was to investigate the effect of the organized auditory stimulation with a familiar voice on pain intensity and physiological indices of comatose patients admitted to the intensive care unit (ICU). The objective of present study was investigating the effect of organized auditory stimulation with a familiar voice on pain intensity and physiological indices of comatose patients admitted to the Intensive Care Unit. This study is a randomized clinical trial, conducted on 40 intubated patients who met inclusion criteria and admitted to ICU. The patients were selected based on convenience sampling and randomly placed into two groups (n=20). In the experimental group, the auditory stimulation was done with the patient's favorite person for three consecutive days, each day for 15 minutes; the control group received no auditory stimulation. The intended physiologic indices and pain were measured and recorded at similar intervals. The behavioral pain scale was used to determine the pain intensity. Data were analyzed using the statistical tests via SPSS 22 at the significance level lower than 0.05. Two groups were not different in demographic and clinical variables ($P>0.05$). In the experimental group, pain intensity showed significant reduction after the intervention ($P=0.019$) while it did not show statistically significant difference in the control group. Furthermore, the physiological indices did not show a statistically significant change in two groups during research and two groups did not show any difference ($P>0.05$). Auditory stimulation with familiar voice reduces the pain intensity of the patients admitted in ICU, but it does not significantly affect the physiological indices. Conducting modern and low-cost methods effective in reducing the pain of patients admitted in ICU is one of the priorities of the research and evidence-based treatment.

Key words: Intensive Care Unit (ICU), Pain, Coma, Auditory Stimulation, Physiological Indices

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INTRODUCTION

Brain injuries are one of the main causes of coma and other consciousness disorders and are the most important cause of death and hospitalization among accidents and incidents [1]. Traumatic

head injuries are the leading cause of death and disability [2]. Trauma has the second place of mortality in Iran; it is among the first-ranked countries in terms of incidents and accidents [3] such that the injuries caused by road accidents result in seventy deaths per day [4]. Most of the people with traumatic brain injuries are in the range of 15-24 years old and, with a secondary increase, in the 60-70-year-old age group [5].

Coma is the result of the extreme head injuries and the increased coma duration decreases the reversibility probability of which [6]; hence, the immediate clinical rehabilitation in these patients is very important [7]. The comatose patients in ICU units will not have a natural level of brain activity because of the nature of the disease and as a result of the reduced sensory inputs and irregular and meaningless sensory stimulations; finally, they face sensory deprivation [8] which may impair the process of recovery of the neural lesion [9]. Sensory stimulation for comatose patients is regarded as the necessary nursing cares in ICU; however, with regard to the care of the completely dependent patients, the nurses often lack sufficient time and energy for creating necessary sensory stimulations [10].

The patients admitted to ICU experience pain as an important stressful factor for various reasons such as acute diseases, surgery, trauma, aggressive procedures, and therapeutic and nursing interventions [11]. In ICU unit, pain is one of the most prevalent and important problems of the patients [12] and it has been considered as the fifth vital sign by the American Pain Society [13].

Pain has unfavorable impacts including the increased neuroendocrine system activity and sympathetic tone with tachycardia, the increased need of heart myocardial to oxygen, the suppressed immune system, increased blood coagulation, increased catabolism, movement limitations, pulmonary problems, and finally delay in hospital discharge [14]. Furthermore, the existence of chronic pain in these patients and remembrance of the inpatient pain in the next years can independently result in Post-Traumatic Stress Disorder (PTSD) [15]. New studies have shown that the unconscious patients are able to remind the painful experience and even its intensity [16]. Regarding the 33-percent prevalence of pain at rest time and the 56-percent prevalence of which at the times of doing therapeutic methods [17] in the patients admitted to the intensive care unit, the existence of the causes such as inability to communicate as a result of decreased consciousness level, and getting sedative medications and mechanical ventilation, it is difficult to evaluate the pain and the inefficient management and control of which compared to the conscious patients and it is one of the challenges in nursing cares [18]. According to the American Pain Society, when patients are not able to report their pain, a pain recognition

instrument can be used so as to recognize the existence of pain [19]. It has been indicated in many studies that the Behavioral Pain Scale (BPS) can be a reliable instrument for measuring pain in patients with no verbal power in ICU [20]. In addition to different medication methods, nowadays, different nursing practices such as mental imagery, gradually progressive relaxation, and the use of music have been taken into consideration so as to reduce pain [21]. In the recent years, the coma stimulation method has been proposed to improve the results of coma in which the multi-dimensional stimulation of the sensory system is used purposively [6]. Beginning these sensory stimulations at the first 72 hours after concussion plays a very important role in saving the patient, improving the quality of life, and the long-term prognosis of the disease [22].

These stimulations may include hearing, eyesight, olfaction, taste, and touch stimulations [22] that can be done in two forms of one dimensional, i.e. the stimulation of one sense, and multi-dimensional, i.e. the stimulation of several senses of the patient [23].

The stimulation of the hearing sense is one of the one-dimensional stimulations. The hearing sense is the last sense that disappears in comatose patient and there is no barrier to use it [9]. Moreover, the sensational stimulations (particularly hearing stimulations) can be applied to relieve pain and reduce some states such as anxiety and relaxation [24]. Comatose patients respond to familiar voices or the voice of the family members with a more probability compared to the voice of a stranger [25]. As such, the presence of the patient's family beside him can be an appropriate source for creating familiar sensory stimulations and provide the participatory opportunity of whom for caring the favorable person [10, 26]. Unfortunately, meeting the patient has been limited and even banned nowadays because of the traditional belief that the presence of the family beside the patient interferes with care providing and may increase the infectious complications and the patients' mental and physical stress [27, 28]. Furthermore, nurses are also concerned that the presence of the family beside the patient may lead to hemodynamic disorders in the patients [29]. However, contrary to these beliefs, the available evidence rejects these beliefs and stresses the useful effects of the presence of the family in ICU [30-35]. Visiting is one of the ten important needs

of the patients admitted to ICU [36]; in addition to that it is a humane duty, it is a religious duty along with spiritual rewards [37].

Because the sensory stimulation and sensory regulation are unproven treatments for decreasing coma duration or improving the performance of the patients with abnormal levels of consciousness, they are still the most extensive rehabilitation treatment under study for the patients [38]. As a result, the objective of the present study was to determine the effect of the organized auditory stimulation from the side of the patient's family on pain and physiological indices of comatose patients admitted to the intensive care unit (ICU).

MATERIALS AND METHODS

This study is a randomized double-blind clinical trial which was conducted on 40 patients who had the inclusion criteria and were admitted to ICU units from February to August, 2017. The inclusion criteria included an 18-50-year-old age, head trauma with a consciousness level between 5 to 8 (according to Glasgow Coma Scale), the existence of pain with at least the score of 5 (according to Behavioral Pain Scale (BPS)), the existence of an artificial airway (tracheal tube or tracheostomy), maximally 48 hours of coma duration at the beginning of the study, no hearing impairment, neuromuscular and sensory-motor disorders by referring to the patient's document and asking the patient's family, and lack of fracture or paralysis of all organs. The exclusion criteria also included brain death, death or discharge of the patient from ICU, increased level of consciousness and verbal communication ability of the patient during study (extubation of the patient), increased dose of sedative drugs and anesthesia during the study, abnormal and severe hemodynamic symptoms during intervention, and the incident of any unwanted conditions that conflict with the health of the patient and the intervention.

After the approval of the project, the agreement of the Ethics Council of Gonabad University of Medical Sciences, and presenting a written letter to hospital manager, the samples of the study were selected based on purposive availability sampling (after obtaining informed consent of his father or legal guardian); they were randomly placed into two groups using quadrilateral permutable blocks method. In the experimental

group, the families were interviewed, the favorite person of the patient was identified, and the oral and written instruction for recording the message with a common and understandable accent to the patient's was presented to him. Then, before the beginning of the intervention and at the first 72 hours of the patient hospitalization, the voice message was recorded by the voice recorder device in the presence of the researcher and in the visiting room of ICU (before visiting hour). The duration of the voice message was between 10 to 15 minutes for all participants. The content and schedule of the message were carried out in a way that the favorite person of the patient first introduced himself for 1 minute and informed the patient of time and place, briefly explained to the patient what happened to him for 1 minute, and narrated the common and promising sweet memories for 4-6 minutes. Finally, he told the patients some optimistic and encouraging statements about recovery, his coming back to the family, and the plans they will have for the future for 4-6 minutes. After preparing the voice message and controlling the content of the message by the researcher, the hearing stimulation was done for the experimental group for three consecutive days, one time each day, via mp3 player and headphone. Regarding the crowded ICU and doing examinations by the doctors, the hearing stimulation was carried out in the afternoon and before the visiting hour; any manipulation and touch of the patient were avoided during the intervention. BPS instrument was used to assess pain 5 minutes before beginning hearing stimulation and 5 minutes after hearing stimulation in every session. The physiological indices including blood pressure, pulse, temperature and oxygen saturation of the arterial blood 2 minutes before hearing stimulation, 5 minutes after beginning (during intervention), and 2 minutes after intervention (hearing stimulation) were measured and recorded so that the effect of intervention on physiological signs would be specified and the intervention be interrupted in the case of hemodynamic instability (based on the exclusion criteria). It is worth noting that the evaluation of and recording pain and physiological indices were done by a research assistant who was unaware of the intervention.

In the control group, the physiological indices and pain were measured and recorded without hearing stimulation (only headphone was applied), according to the above schema and

similar intervals to the patients in the experimental group.

This study was approved by the Ethics Council of Gonabad University of Medical Sciences with the ethics code of IR.GMU.REC.1395.120 and recorded in the Iranian Registry of Clinical Trials (IRCT) with the code of IRCT2017072035196N1.

RESULTS

The results of the present study indicated that the average age of the research units in the intervention group and control group was respectively 38.95±7.70 and 37.00±8.87. Other demographic variables are shown in Table 1.

Table1: The frequency distribution of the research units in terms of the quantitative and qualitative demographic variables in the two intervention and control groups

Variables	Control group No. (%)	Experimental group No. (%)	Sig.
Gender	Male 15(75%)	5(25%)	P=1
	Female 15(75%)	5(25%)	
Marital status	Single 9(45%)	5(25%)	P=0.3
	Married 11(55%)	15(75%)	
Duration of hospitalization	1 to 24 hours 5(25%)	4(20%)	P=1
	24 to 48 hours 15(75%)	16(80%)	
Educational level	Below diploma 2(10%)	1(5%)	P=0.8
	Diploma 8(40%)	8(40%)	
	Academic education 10(50%)	11(55%)	
Underlying diseases	Cardiorespiratory 4(20%)	4(20%)	P=0.2
	Neuromuscular 4(20%)	9(45%)	
	Without previous disease 12(60%)	7(35%)	
History of addiction	No 17(85%)	15(75%)	P=0.6
	Yes 3(15%)	5(25%)	
The score of the level of consciousness based on Glasgow Coma Scale (SD±Mean)			
Score of the level of consciousness	First day 7.25±0.71	7.35±0.81	P=0.56
	Second day 7.50±0.68	7.60±0.50	P=0.80
	Third day 7.65±0.58	7.80±0.41	P=0.42

Regarding the findings related to the objectives of the study, the variables of pain and physiological indices were investigated. With regard to the variable of pain, the result of the Mann-Whitney U test indicated that the pain of the research units in the two groups was not different in the first to third days of research before intervention, but it was significantly different in the experimental group after intervention such that pain has decreased by the intervention. The average difference of pain before and after intervention in the two groups indicated that pain intensity in the

experimental group was significantly decreased compared to the control group (Table2).

Table 2: The comparison of the average difference of the pain of the research units in the two control and experimental groups, before and after intervention, in the first to third days of research

Day	Control group	Experimental group	The result of the Mann - Whitney U test
	SD±Mean	SD±Mean	
First day	0.05±0.22	0.75±0.63	Z=4.3 P<0.001
Second day	0.05±0.22	0.30±0.47	Z=2.74 P=0.06
Third day	0.00±0.00	0.85±0.67	Z=4.51 P<0.001

To do a more precise investigation, the average difference of the research units in the two groups was investigated by the precise Friedman test during the research (Table 3). The results of this test indicated that pain did not have a significant difference in the control group during the research, but it was significant in the experimental group such that the pain in the experimental group decreased during research (P=0.019).

Table 3: The comparison of the average difference of the pain of the research units in the two groups during three days of research

Time Group	First day	Second day	Third day	Result of Friedman test
	SD±Mean	SD±Mean	SD±Mean	
Control	0.05±0.22	0.05±0.22	0.0±0.0	X ² =1 P=0.607
Experimental	0.75±0.63	0.30±0.47	0.85±0.67	X ² =7.96 P=0.019

Furthermore, the results of the study indicated that the physiological indices did not have a significant difference in the two groups. The results of the Mann-Whitney U test indicated that the body temperature of the research units in the two groups was not significantly different in the three days of the research (P>0.05). Moreover, according to the results of the independent t-test, the systolic blood pressure, diastolic blood pressure, oxygen saturation of the arterial blood, and the heart rates (pulse) of the research units in the two groups (before, during, and after intervention) did not have a statistically significant difference in all three days of the research (P>0.05). To investigate more completely and interpret more precisely the results, the statistical Friedman test was used to compare the changes of these physiological indices (the difference between before and after intervention) in the two groups during the research period.

According to the results of this test, the physiological indices in the two groups did not have a statistically significant difference during three days ($P>0.05$).

DISCUSSION

Various studies have been done regarding the effect of sensory stimulations such as hearing stimulations in the patients. Ferguson mentioned in his study that individual characteristics and educational level can affect the individual's response to hearing stimulation [39]. In this study, the difference of the individuals' demographic characteristics and some other intervening variables were controlled by group homogeneity and random sampling with permutable blocks method. Furthermore, all units of this research did not have a statistically significant difference in terms of the major effective variables in the results of the research such as age, gender, job, marital status, educational level, history of addiction, and the duration of hospitalization.

The result of the present study confirms that hearing stimulation with familiar voice decreases the pain of the hospitalized patients and this finding is in line with the results of the other similar studies. Ajri Khameslou *et al.* conducted a study on the effect of hearing stimulations on physiological criteria of the pain of the unconscious patients admitted to ICU and concluded that these stimulations have decreased the patients' pain [40]. Moreover, the results of the study done by Mahmoudi *et al.* indicated that the increased visiting times of the patients admitted to ICU decreases the average pain of the patients admitted to these units [41]; this finding may relate to the effect of hearing the familiar voices. Yaqubinia *et al.* conducted a study on determining the effect of music as a familiar hearing stimulus on the pain intensity of the patients with reduced level of consciousness in ICU and measured pain intensity in three consecutive days after the implementation of the intervention, using the Behavioral Pain Scale (BPS). The results of the study indicated that using instrumental music can decrease the pain of the patients with decreased level of consciousness [42]. It seems that regardless of the kind of the voice played, hearing stimulation decreases the pain intensity of the patients in the intervention group through mechanisms such as secretion of endorphins and interference in the pain processing path [43]. Smolen *et al.* justified the changes taken place in

the pain intensity, anxiety, and the physiological indices of the patients undergoing surgery due to listening to music by considering Roy adaptation model. They mentioned that music helps patients physiologically adapt to therapeutic conditions [44]. Petersson and Almerud also believe that music affects the brain, stimulates alpha brain waves, and results in the secretion of endorphins and relaxation, and reduces pain and anxiety [45]. The results of all these studies are in line with the results of the present study and indicate the positive effect of hearing stimulation with a familiar voice on the pain intensity.

Furthermore, according to the results of the present study, there was no statistically significant difference between physiological indices including blood pressure, body temperature, and oxygen saturation of the arterial blood before and after intervention in this study. Boukje *et al.* conducted a study on determining the effect of music on physiological response and relaxation scores of the relieved patients under mechanical ventilation and concluded that the hearing stimulations with familiar voice had no effect on physiological indices of the comatose patients and had no negative effect on the clinical status of these patients [46]. The results of the study conducted by Nilsson *et al.* indicated that music has no significant effect on average arterial blood pressure, number of pulses, number of breaths, and the oxygen saturation percentage of the patients undergoing cardiac surgery [47]. Zwerneman, Navid Hamidi, and Eshvandi also conducted a similar study and showed that hearing stimulations do not significantly affect physiological indices [48-50]. Some other studies also achieved similar results [51-54] and their findings are in line with the results of the present study.

Furthermore, the results of the present study are not consistent with the results of some of the studies. In general, the reasons for different results of the most of the studies are different number of days, the nature of the voice played, and the duration of the intervention. Puggina *et al.* conducted a research on 60 comatose patients in three consecutive days and carried out the hearing stimulation with the recorded voice message of one of the immediate relatives of the patient, three times every day in the intervention group, and showed that there is a significant difference between vital signs of the two control and intervention groups [55]. It seems that the

number of the daily sessions and the increased duration of hearing stimulation compared to the present study are the reasons for this difference. Han et al. conducted a study and indicated that music resulted in decreased blood pressure, number of pulses and breaths in the experimental group [56]; this difference may have also originated from the nature and duration of the hearing stimulation for the intervention group. Johnny et al. also concluded that the regular supportive visiting of the family caregivers can balance the physiological indices of the patients with spinal cord injury [57]. The aforementioned study was done on non-ventilated patients and the number of sessions, duration, and the manner of the intervention of which are completely different with the present study.

Regarding the comparison of the duration and the number of the times of doing auditory stimulation in different studies, for example, the study of Nilsson et al. in which the intervention was done for two days and its results are in line with the present study, with the studies of Puggina et al., it can be concluded that short-term interventions would not result in considerable changes in physiological indices. It is needed to increase the number of days and the number of the hearing stimulation periods in the days of the study so as to achieve a better response of the hemodynamic status of the patients.

Moreover, regarding the comparison of the duration of other studies, for example, the study conducted by Chung, that of Maleki, and that of Heidari that were done during 14 days of patients' hospitalization, with the present study which was conducted in the three first days of head trauma, it may be said that the patients in the present study were in a more critical condition than the patients in other studies, with regard to the interval between the damage to the end of the study; the existence of further tensions including the process of damage and disease and the physiological responses of the body may have led to an insignificant difference between the two groups.

CONCLUSION

With regard to the results of this study, comparing it with similar studies, and the necessity of applying modern, low-cost, and uncomplicated methods for decreasing the pain of the patients admitted to ICU, it seems that hearing stimulation with familiar voice, as an effective, uncomplicated,

and lesser-known method can reduce the pain of the hospitalized patients, increase the satisfaction of the family members, and create the feeling of usefulness in the treatment procedure of the favorable person. However, one can comment more definitely in this regard after conducting further research.

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What Is Known About This Topic

- Coma is one of the most challenging problems of the intensive care process, and its management not only includes the patient but also the patient family and his relatives.
- Pain and sensory deprivation is one of the main problems of coma patients
- Pain management is important aspects in managing critically ill patients.
- Conducting new methods with low complications is the priority of research and nursing cares.

What This Paper Adds

- Stimulation with familiar voice has been recognized as an effective, uncomplicated and less known method, reducing the pain of patients admitted in the intensive care unit and more satisfaction of the family members by creating a feeling of usefulness in the treatment of considered person.

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