



ISSN No: 2319-5886

International Journal of Medical Research & Health Sciences, 2016, 5, 9S:288-295

Effect of music therapy and reflexology on pain in unconscious patients: A randomized clinical trial

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ABSTRACT

The current study was conducted to compare the effect of music and foot reflexology on pain intensity in patients with loss of consciousness. Pain is the common phenomenon among the patients in Intensive Care Unit and can be due to invasive procedures, mechanical ventilation and physical situation of ICU. The clinical trial study was used. 90 eligible patients were selected conveniently and then were randomly allocated into three music therapy, reflexology and control groups of 30 persons in intensive care unit in one educational hospital in 2015. Intervention was carried out through playing instrumental music of Arnd Stein in 3 sessions of 30 minutes via headphone. In reflexology group, intervention was done for 30 minutes once a day for three consecutive days. Control group only received the routine care about pain relief. Measuring the pain was done through Behavioral Pain Scale (BPS), 5 minutes before and immediately after the interventions. In control group, measurement was done with the same interval and frequency. Data were analyzed using ANOVA, paired T-test, chi-square by SPSS 15. After the intervention in both interventions groups, the mean score of pain was significantly reduced ($p < 0.0001$). This reduction was significant between the intervention and control groups ($p < 0.0001$). Also, in the first and second days of intervention, this difference was significantly different between the music therapy and reflexology groups ($p < 0.0001$). The application of complementary methods such as music and reflexology can reduce the intensity of pain in patients with loss of consciousness. Thus, these methods can be used as simple and practical methods in pain relief in ICU. The complementary methods such as music and reflexology as practical, affordable, and simple methods are recommended to decrease the pain and increase the patient comfort.

Keywords: music- reflexology- pain- loss of consciousness

INTRODUCTION

Pain is the common phenomenon among the patients in Intensive Care Unit and is more prevalent than the other symptoms. Pain as a natural threat needs to pay attention [1]. Due to its importance, American Pain Society considers it as the fifth vital sign [2].

Negative clinical effects in association within effective monitoring and management of pain are including deep vein thrombosis, pulmonary embolism, pneumonia, delayed wound healing, insomnia and demoralization. These consequences can lead to medical and economic problems such as increase the length of stay in hospital, re-

hospitalization; and lack of patient satisfaction with medical care. Inadequate management of pain can also causes physical and psychological stress, which may have negative effects on patients [3].

Like other patients in general wards, critically ill patients in ICU experience pain. Although the assessment and management of pain is among the priorities in intensive care units, but the prevalence of pain in ICU patients is above 50 percent [4]. The prevalence of pain in patients requiring mechanical ventilation admitted to the ICU has been reported 33 percent at rest. However, the prevalence of pain at the time of medical procedures has also been reported up to 56 percent [5].

Studies about patients who discharged from intensive care unit showed that the 82 percent of them reported pain following endotracheal tube and 77 percent of them expressed moderate to severe pain for a long time after discharge from the ICU [4].

Control and management of pain especially in patients with loss of consciousness need for attention of nurses, but it is neglected in most cases [6]. The timely and correct diagnosis of pain, the NSAIDs, opioids, nerve blocks at spinal cord level can be used to reduce of pain [1,7].

On the other, due to side effects of opioids and other drugs, the using of non-pharmacological methods that has fewer side effects than the drugs should be considered. One of these methods is the complementary medicine. A variety of methods that can be used are aromatherapy, acupuncture, music therapy, biofeedback techniques, massage therapy, relaxation techniques and reflexology [8].

Music is an important, available, low-cost and effective tool in complementary medicine [9]. The music is appropriate and can lead to stress reduction when it has a steady rhythm, low frequency and calming melody. It must be at a constant level in terms of sound and tone to have a positive impact on the listener [10] and must be in the range of 60-80 beats per minute [11].

Some studies were conducted about the effect of music on pain or other problems in patients. In one of them, results showed a significant difference in pain in intervention group [12], but in some of them which were conducted on the ventilated patients, results showed that there was no significant difference between the pain score of patients before and after the music in intervention group [13]. These results are challenging and controversial and there is a need for further investigation.

In addition to music, other methods of complementary medicine may be used in pain control. They may have different effect on pain relief. One of these methods is reflexology [14]. The mechanical stimulation during the massage can affect on the central nervous system and blocking the ascending neural pathways to brain [A&C fibers] and acts as a relief method. It causes the secretion of beta-endorphin and enkephalin from midbrain. Consequently, the pain is inhibited [15].

In study by Quinn [2008] in order to determine the effect of reflexology on pain intensity in patients with low back pain, results showed that the reduction of pain in intervention group was occurred [16]. Unlike this study, in a study by Gunnarsdottir et al [2007] which was conducted in order to determine the effect of foot reflexology on anxiety in patients undergoing CABG in Iceland, results demonstrated that there was no significant reduction in anxiety and systolic blood pressure in intervention group [17].

Therefore, with regard to the controversial findings of reviewed studies, conducting further research for the examining of efficacy of these methods is essential.

According to the low cost and low side effects of complementary medicine in compare with pharmacological methods, their application by nurses and the importance of physical and psychological effects of pain even after the discharge from critical care units, the performing of study in this field is essential. Also, yet there is challenge in complete pain relief in patients in ICU.

On the other, few studies have been done about the pain in patients with loss of consciousness, also due to the underutilization of complementary medicine in intensive care units [18]; the current study was conducted to compare the effect of music therapy and reflexology on pain intensity in patients with loss of consciousness in ICU.

MATERIALS AND METHODS

The current study was conducted to compare the effect of music therapy and foot reflexology on pain intensity in patients with non-traumatic loss of consciousness in intensive care unit in 2015. This was a randomized, three groups, pretest-posttest clinical trial study.

The population was the non-traumatic adult patients on mechanical ventilation with loss of consciousness in ICU in one hospital. Inclusion criteria were including: GCS score 5-8, the absence of hearing loss, receiving IV sedation (Fentanyl) 25-50 µg according to protocol, the first hospitalization in ICU, lack of addiction to drugs, alcohol and cigarettes, having healthy feet.

Patients were excluded from study if they had exclusion criteria consisted of fixation invasive catheters except IV catheters and endotracheal tube during the study, consciousness and extubation during the study, change the type and dose of sedation or its discontinuation.

According to calculated sample size based on Motahedian study (19) 30 patients in each group were enrolled. 90 eligible patients were selected conveniently and then were randomly allocated through permuted blocks into three music therapy, reflexology and control groups of 30 persons. Arranging the blocks were randomly and through using random numbers table and the patient entered into three groups based on the blocks. One of the researchers generated the random allocation sequence who did not participate in data gathering.

Data collection tools including the demographic information form including 3 questions, disease information form about the underlying disease; and Behavioral Pain Scale (BPS).

BPS was used for measuring the pain intensity in patients with loss of consciousness and unable to communicate. This scale consists of 3 major parts including facial expressions, compliance with ventilation and upper limbs, each part is scored from 1 to 4. The minimum of total score is 3 and the maximum is 12. The higher the score achieved in each area reflected higher levels of discomfort and pain. Reliability and validity of this scale has been confirmed in several study (20; 21; 22; 23).

Reliability of scale was also confirmed in our study by inter-rater reliability and a correlation coefficient of 0.86 was reported. Patients who were studied for confirming the reliability of scale were excluded from the study sample.

The present Study was conducted after obtaining permission, on 24.05.2015, the license number ir.zaums.rec.1394.52 Ethics Committee of the University. Sampling and data collection were lasted from 05.06.2015 till 18.12.2015.

After explaining the process and purpose of the study for patients' relative and completing of consent form, the researcher collected data. The researcher collected data on evening shift in order to lack of interference the intervention with usual activity in ICU. After patient selection based on inclusion criteria, they were randomly allocated into three groups as music therapy, foot reflexology and the control group. One of the researchers assigned the patients to interventions and control groups who did not participate in intervention and related measurement.

Demographic information and disease information form was completed for all of the patients. Pain intensity was measured and recorded twice a day by BPS in all three groups.

In music therapy group, intervention was carried out through playing instrumental music of Arnd Stein (Strandspaziergang Beach Walk from the album Top Hits zum Entspannen Vol 01) in 3 sessions of 30 minutes via headphone during the three consecutive days between 4 pm to 6 pm.

Features of the music include the following: A piece of music that is not sad or exciting, has the smooth rhythm and melody and absorbs the feelings and concerns in the context of itself (24). To perform the intervention, a Sony headphone, and a Sony MP3 player was used. Measuring the pain was done through BPS, 5 minutes before and immediately after the music therapy. It should be noted that the person who was assessed the pain was blinded to group assignment and patients.

In the second experimental group, foot reflexology was done. It should be noted there researcher passed the workshop on reflexology and received certificates. In this group, the patient was in the supine position by raising the head of the bed in 30 degrees. The researcher's hands were warmed before the intervention and any metal object like a ring came out.

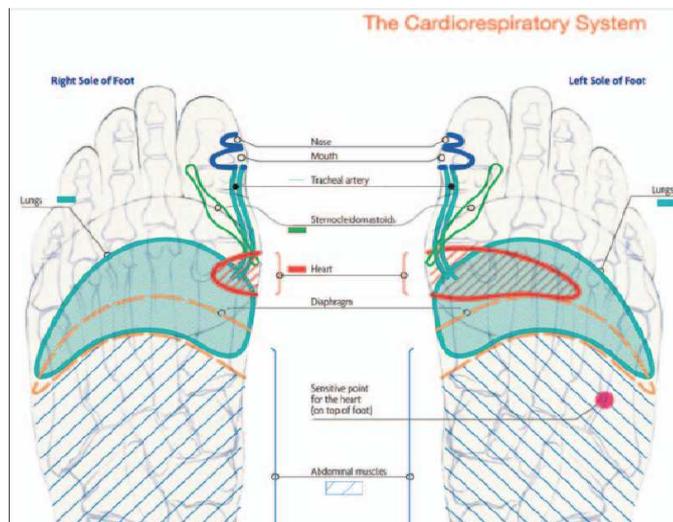


Figure 1: Foot massage in location that is related to lungs

The researcher sat on a chair next to the patient's leg. Also, she used from the lubricant jelly for the foot massage. Then the massage was given in area of the patient's toes in the location that is related to lungs (according to figure 1) for 15 minutes for each foot. This location was chosen because the pain related to lung and intubation was considered. According to this, for relieving pain, this location was chosen. Measuring the pain was done through BPS, 5 minutes before and immediately after the foot reflexology. This intervention was done once a day for three consecutive days and between the 4 pm to 6 pm.

In the control group no intervention was performed and the patient was lying on the bed and just pain intensity were measured and recorded. Patients in this group received routine care of the ward concerning the pain relief similar to other patients. Measurement was done the same as intervention groups.

Statistical analysis

Data were analyzed in SPSS 15 and using paired T-test, chi-square and ANOVA. ANOVA test was used to compare quantities variables (pain score) between the three groups. Chi-square test was used to compare categorical variables (demographic data) between the three groups. All comparisons were two-tailed and p-values <0.05 were considered significant.

Ethical Considerations

The current study was approved in 2015 by the Research Ethical Committee. Also, the study has been registered with the code number IRCT2015051722300N1.

All patients' relatives were provided with standardized information about the procedure. Informed consent was sought from patients' relatives and they were guaranteed about the refuse of participation of their patients in the study. All codes of ethics in human research were respected.

RESULTS

Patients' characteristics:

In current study, 30 patients in music therapy group, 30 patients in reflexology group and 30 patients in control group were studied. There was no significant difference in age between the music therapy group (50.97 ± 9.69 , range 30-64 years), reflexology group (51.23 ± 9.22 , range 28-6 years), and control group (50.37 ± 7.9 , range 30-64 years; $P = 0.91$).

In music therapy group, 53.3 percent of patients were men and in reflexology group 53.3 percent were women, while in control group, the number of men and woman was the same and the chi-square test showed no significant differences between the three groups in terms of gender ($p=0.87$).

Also, there was no significant difference between the three groups in terms of marital status ($p=0.48$). Results showed that the most common underlying disease in music therapy group was pulmonary disease (26.7 percent), in

reflexology was neurology disease (35 percent) and heart disease in control group (23.3 percent). Chi-square test showed no significant difference between the groups ($p=0.93$).

Experimental results

Results are presented according to three days of intervention. Data analysis of the first day of intervention demonstrated that the mean and standard deviation of pain before the intervention was 7.2 ± 1.03 , 6.87 ± 1 and 6 ± 1.28 respectively in music, reflexology and control and 4.57 ± 0.97 , 4.83 ± 0.91 and 5.97 ± 1.18 respectively after the intervention. The mean change in pain score was significantly difference between the groups ($p<0.0001$).

Also ANOVA test showed that there was significant difference between before and after the intervention in terms of pain score in the first day. Consequently, Tukey's test showed that the mean change in pain score in the first day was significantly difference between music therapy and control groups ($p<0.0001$), between reflexology and control ($p<0.0001$) and between the music therapy and reflexology groups ($p=0.003$) (Table 1).

Data analysis of the second day of intervention demonstrated that the mean and standard deviation of pain before the intervention was 5.83 ± 1.14 , 5.5 ± 1.07 and 6.33 ± 1.09 respectively in music, reflexology and control groups and 3.73 ± 0.86 , 4.1 ± 0.8 and 6.337 ± 1.06 respectively after the intervention. The mean change in pain score was significantly different between the groups ($p<0.0001$).

Also ANOVA test showed that there was significant difference after the intervention in terms of pain score in the second day which was indicative of the effectiveness of the intervention.

Consequently, Tukey's test showed that the mean change in pain score in the second day was significantly difference between music therapy and control groups ($p<0.0001$), between reflexology and control ($p<0.0001$) and between the music therapy and reflexology groups ($p=0.001$) (Table 2)

Data analysis of the third day of intervention demonstrated that the mean and standard deviation of pain before the intervention was 4.87 ± 0.9 , 4.63 ± 0.96 and 6.2 ± 1.99 respectively in music, reflexology and control and 3.17 ± 0.37 , 3.27 ± 0.58 and 6.2 ± 0.99 respectively after the intervention. The mean change in pain score was significantly different between the groups ($p=0.003$).

Also ANOVA test showed that there was significant difference after the intervention in terms of pain score in the third day which is indicative of the effectiveness of the interventions.

Consequently, Tukey's test showed that the mean change in pain score in the third day was significantly different between music therapy and control groups ($p<0.0001$) and between the reflexology and control ($p<0.0001$), but the mean change was not significant different between the music therapy and reflexology groups ($p=0.125$).

DISCUSSION

The findings of current study showed that the application of complementary methods such as music and reflexology can have positive effect on pain relief in patients with loss of consciousness. The mean change score of pain was significant different in two intervention and control groups in three consecutive days. This means that the pain control was better in two intervention groups.

The mean pain score was significantly different in three groups after the intervention. This difference was between the two intervention groups with control group. Also the mean change score between the music and reflexology groups was significantly different in the first and the second days of intervention. In other words, the pain relief in music group was greater than the reflexology group and the intervention was more effectiveness in music therapy group.

A few studies have found regarding the compare the effect of music and reflexology. In study by Abolhasani (2008) in order to compare the effect of music and back massage on chest pain, results demonstrated that the both interventions caused a significant reduction in pain during the two days of intervention. Pain relief was more than in the music group in compare with back massage that is corroborated the finding of current study (25).

In study by Taghinejad et al (2010) titled "Comparison between massage and music therapies to relieve the severity of labor pain" results showed that the mothers in the massage therapy group had a lower level of pain compared with those in the music therapy group. A significant difference was observed between the two groups in terms of pain

severity after intervention. These results were different from our study. In current study the severity of pain was reduced more in the music group. The reason of this difference may be due to location and type of massage and type of patients. In this study, massage points were the lower area of the abdomen, shoulders, back and pressed pubic area, but in current study foot reflexology in area related to lung was done.

In another study by baby titled “effectiveness of music therapy vs. foot reflexology on pain among postoperative patients in selected hospitals at Mangalore”, foot reflexology was more effective than the music therapy that is inconsistent with our findings (26). Perhaps the reason for this difference is due to the different type of patients. In our study patients did not have incision that may have a different response to pain treatment.

The results of Ajri’s study (2012) showed that the using of music can cause the reduction in pain in unconscious patients that is similar to current study. The type of music in Ajri’s study was different from the music in our study. In his research, the patient-preferred music was used, but in current study the same music was used for all of the patients in music therapy group.

It seems that regardless of the type of music, the nature of this method with some mechanisms such as increased secretion of endorphins and interfere with pain processing pathways were leading to pain reduction (27; 28) in the intervention group. The study of Ajri (2012) is similar to our study in terms of type of patients; in his study the patients with GCS 5-10 were enrolled. Also in current research the non-traumatic patients were studied that were different from traumatic patients in terms of reactions to painful stimuli that is similar to Ajri’s study.

In study of Akombo (2006) to determine the effect of music on pain and anxiety of patients undergoing bone marrow transplant, according to Visual Analogue Scale, the pain severity was reduced after the intervention that is similar to our study. (10). Ikonomidou et al (2004) reported that the application of music can reduce the pain intensity after the surgery (29) The results of these studies are consistent with current study, although there are differences in the type of patients, type of music and assessment tool.

Also in study by Vaajoki et al (2012) to determine the effect of music on pain severity after the abdominal surgery, results demonstrated that the pain severity was reduced in the first and second days of intervention (30) that is corroborated the findings of current study.

In some cases, conflicting results have been reported. For example in study by Bessel et al (2006), there was no significant reduction in pain after the music therapy in patients under mechanical ventilation that is inconsistent with our study. This could be due to the small sample size and difference in instrument in Bessel study. In this study the graphic rating scales was used, it seems that this tool don’t have sufficient sensitivity to assessment the pain (31). Also in study by Mohammadaliha et al (2013) to determine the effect of foot reflexology on pain relief in surgical site in abdomen and chest surgery, results showed that there was no significant difference in pain intensity before and immediately after the intervention, but there was significant reduction in pain score in 10 and 24 minutes after the intervention between the intervention and control groups (32). In current study, the pain severity was reduced immediately after the intervention. Perhaps the reason for this difference is due to the different type of patients. In Mohammadaliha study the patients undergoing surgery were enrolled, but in current research non-traumatic patients were studied whom were undergoing the same invasive procedure such as intubation and IV catheter and didn’t receive additional invasive procedure.

In another study by Babajani et al (2014) to determine the effect of foot reflexology massage on the level of pain during chest tube removal after open heart surgery, foot massage in the reflexology point related to the heart and chest in anterior one-third of the left metatarsus was effective in reducing ascending pain due to chest tube removal in compare with the placebo-treated and control groups (33) that is consistent with our findings.

The results of the present study in some cases support the findings of other studies on the effect of music and reflexology on pain. The pain severity in patients with loss of consciousness decreased with application of complementary methods.

This study has a number of limitations. Because of the nature of the study and intervention, there was no possibility for blindness. Also, effect of music on pain was assessed in patients with different disease spectrum such as respiratory problems, renal, cardiac, gastro-intestinal and neurology disorders. Although the two groups were similar in terms of the underlying disease and the confounding variables were controlled, but the different pain intensity in various disease due to various nature of underlying disease was out of the researcher’s control.

Table 1: Comparison of mean and SD of pain score before and after intervention in the experimental and control groups in the first day

Group	Time	Before	After	Changes	Paired T-test
		Mean & SD	Mean & SD	Mean & SD	
Music Therapy		7.2± 1.03	4.57 ±0.97	2.63 ±0.76	<0.0001
Reflexology		6.87 ±1.00	4.83 ±0.91	2.03 ±0.8	<0.0001
Control		6.00±1.28	5.97±1.18	0.03±0.41	0.66
ANOVA Test		<0.0001	<0.0001	<0.0001	

Table 2: Comparison of mean and SD of pain score before and after intervention in the experimental and control groups in the second day

Group	Time	Before	After	Changes	Paired T-test
		Mean & SD	Mean & SD	Mean & SD	
Music Therapy		5.83± 1.14	3.73 ±0.86	2.1 ±0.84	<0.0001
Reflexology		5.5 ±1.07	4.1 ±0.8	1.4 ±0.81	<0.0001
Control		6.33±1.09	6.33±1.06	0.00±0.37	1.00
ANOVA Test		0.16	<0.0001	<0.0001	

CONCLUSION

In conclusion, our findings suggest that application of complementary methods such as music and foot reflexology can reduce pain in patients with loss of consciousness. These methods are practical, affordable, and simple to decrease the pain and increase the patient comfort. The findings reinforce the role of non-pharmacological methods to manage the pain in ill critically patients in ICU. Using these methods in ICU can help to better management of pain in unconscious patient.

What is known about this topic?

- Pain is a major experience in patients hospitalized in ICU.
- Complementary medicine may be used in pain control in some patients.
- The management of pain is insufficient in patients in ICU.

What this paper adds?

- Music and foot reflexology can reduce pain in patients with loss of consciousness.
- Classical Music has the greater effect than reflexology on pain relief in patients with loss of consciousness.
- The classical music has a good effect of pain reduction in patients with loss of consciousness.

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