Fascia Science and Clinical Applications

The effect of foot massage on the level of consciousness and delirium of intensive care patients: A randomized single-blind controlled trial

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ABSTRACT

Introduction: Depressed level of consciousness and delirium are associated with multiple complications in cognitive, perceptual and sensory functions in the patients of the intensive care units. The present study aimed to determine the effect of foot massage by a nurse and patient's family on the level of consciousness and delirium in patients admitted to the intensive care units (ICU).

Methods: This was a randomized parallel single-blind controlled trial. Seventy-five ICU were assigned in three groups (massage by a nurse, massage by patient's family and control group) by stratified block randomization method. Both feet were massaged with Swedish massage (10 min) once a day for six days by a nurse or patient's family. Delirium and level of consciousness was measured before, and post-intervention.

Results: The mean level of consciousness in all the three groups increased significantly one-week post-intervention. However, there was no significant difference in the level of consciousness among the three groups during the study. The frequency of delirium in the massage group by the family was 20% before the intervention, which decreased to 12% after intervention. In the massage group by a nurse and control group, 16% of the samples had delirium before the intervention. After the intervention, the prevalence of delirium was 8% in the massage group by a nurse, and it decreased to 12% in the control group, none of which was statistically significant.

Conclusion: The use of Swedish foot massage did not change the level of consciousness and delirium of patients admitted to the ICU.

1. Introduction

Depressed level of consciousness (LOC) is a condition that decreases the ability to wake up and respond to visual, auditory, and tactile stimuli (Karma and Rawat, 2006). Increased time of changes in the level of consciousness is associated with worse outcomes such as delirium (Kashluba et al., 2008; Sinha et al., 2013). Delirium is one of the most common complications of hospitalization in the intensive care units (ICU) and affects 20—80% of patients admitted

to these units (Allen and Alexander, 2012; Heidari et al., 2014). Delirium is an acute change in the level of consciousness that is associated with a lack of attention, cognitive-perceptual impairment (Bell, 2011), and reduced orientation to the environment (Hshieh et al., 2018). The causes of delirium include genetic factors (Massimo et al., 2017), oxidative stress, network dis-connectivity (Sanders, 2013), post-traumatic-stress-disorder (PTSD) (Grover et al., 2019), functional & cognitive decline (Liang et al., 2014). In the ICU, hypertension, stroke, dementia, the severity of acute illness, substance abuse and drug abuse, low physical resistance, and long-term use of sedation are among the cause of developing delirium (Patel et al., 2014). Patients with delirium are prone to catheter withdrawal, bed sore, pneumonia (Heidari et al., 2014). Therefore, patients with delirium are at risk of increasing the duration of mechanical ventilation, increasing the length of hospitalization, increasing mortality and neuropsychiatric disorders

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for a long time after discharge (Pandharipande et al., 2013). Patients diagnosed with delirium at the time of admission have a mortality rate of 25%–70%, and 15% of patients die within one month, 25% within six months (Jannati et al., 2013), and 35%–40% within a year (Hshieh et al., 2018). In the ICU, the risk of overall mortality increases 200%–400% (Hshieh et al., 2018).

However, the recognition of delirium seems crucial, studies show that 32–66% of cases remain un-recognized by the physicians & nurses (Hshieh et al., 2018). There are many tools and approaches to recognize delirium and measure its severity. According to Jones et al.'s systematic review, six high-quality instruments with a broad range of clinical applications are the Confusion Assessment Method, Confusional State Examination, Delirium-O-Meter, Delirium Observation Scale, Delirium Rating Scale, and Memorial Delirium Assessment Scale (Jones et al., 2019).

Along with treatment of the underlying cause, pharmacological and non-pharmacological methods are used to treat delirium. As pharmacological treatment, drugs such as haloperidol and non-typical antipsychotics like olanzapine are used (Allen and Alexander, 2012).Research has shown that benzodiazepines and narcotics, which are commonly used in treating delirium in ICU, make it worse (Truman and Ely, 2003). For non-pharmacological treatment, factors like participating a family member, improving sensory reception by providing patients' with their own glasses and hearing aids, keep the patients' mobility, and using complementary and alternative therapies (Hshieh et al., 2015, 2018; Levy et al., 2017). The complementary and alternative therapies are increasingly considered for symptom management in such patients such as massage therapy. Massage stimulates nerve fibers, tactile receptors, and skin pressure, which sends nerve impulses to the brain (Chanif et al., 2013). Massage reduces the patient's blood pressure and heart rate and makes the patient feel comfortable and relaxed (Buttagat et al., 2011). Following the relaxation of the muscles, the production of endorphin is increased and it improves sleep quality, relieves pain, and muscle cramps, increases a pleasant feeling and reduces the need for sedation (Vaillant et al., 2009). The results of Azimiyan et al. study showed that the LOC in the intervention group after the massage was significantly different from that of the control group (Azimiyan et al., 2015). Makinian et al. (2015) performed a study on the effects of hand, and foot massage on delirium in older women admitted to CCU. The results showed that hand and face massage reduced delirium intensity in the intervention group compared to the control (Makinian et al., 2015).

Regarding the importance of the level of consciousness and the diagnosis and control of delirium in intensive care units, and given the destructive effects of sedative drugs and narcotics on the level of consciousness and exacerbation of delirium, it is necessary to control these complications using non-pharmacological strategies specifically. It seems that non-pharmacological and simple methods of complementary medicine, such as massage, can be used as a simple, inexpensive, and easy to use intervention in intensive care units to control some of the complications of admission in the ICU by nurses such as delirium. Therefore, the present study aimed to investigate the effect of foot massage by a nurse and patient's family on the LOC and delirium in patients admitted to the intensive care units.

2. Materials and methods

2.1. Study design and setting

This study was a randomized, parallel, single-blind controlled clinical trial conducted in ICUs of Shahid Bahonar Hospital in Kerman in 2017. Shahid Bahonar Hospital has three trauma intensive care units, a total of 46 beds, and it is a trauma ICU center in the

southeast of Iran.

2.2. Sample size and sampling

The samples were selected using convenience sampling. Then, they were allocated into three groups (two intervention groups and one control group) by stratified block randomization method (the three groups were matched according to sex and addiction variables). Inclusion and exclusion criteria are reported in Fig. 1. In addition, patients who were sedated after surgery and expected to be transferred to ward were not included in the samples. Previous studies were used to estimate sample size (Adib-Hajbaghery et al., 2012). The confidence coefficient was calculated to be 95%, the confidence interval was 1.96, and the type II error was calculated to be 10% (1.63). The sample size was adjusted based on the number of study groups. Therefore, the sample size required for this study was 21 subjects in each group, which was considered to be 75 samples (25 samples per group) with a probability of dropout. The first author, generated the random allocation sequence, enrolled participants, and assigned participants to the groups.

2.3. Measurements

Data collection tools in this study included underlying information questionnaire (age, sex, marital status, employment status, history of intensive care unit admission, addiction, other underlying diseases), the Full Outline of UnResponsiveness (FOUR) scale, the Glasgow Coma Scale (GCS), and the Confusion Assessment Method for the ICU (CAM-ICU) questionnaire. The GCS and FOUR were used to assess the LOC. The GCS Scale was described in 1974 by Graham Teasdale and Bryan Jennett for assessing the level of consciousness of patients with an acute brain injury. This scale consists of 3 areas of patient's responses (motor, verbal, and eye responses). Its possible values range from 3 to 15 (Teasdale and Jennett, 1974). The FOUR scaleconsists of 4 components with four items. Its score is from zero to 16, in each component, zero shows no function, and a score of 4 shows normal function. This scale was developed by Eelco Wijdicks in 2005. The CAM-ICU was designed by Ely et al., in 2002 at Vanderbilt University. The questionnaire has four steps. If the patient does not have an altered level of consciousness, that is, the Richmond Agitation-Sedation Scale (RASS) score is higher than −3, delirium will be checked (Heidari et al., 2014). The first step is to investigate the acute change or fluctuations in the patient's mental state. The second step is to assess the lack of concentration. The third stage is to assess the altered level of consciousness with the RASS scale. The fourth stage is to study non-organized thinking, which consists of four oral questions and two simple instructions. Finally, the interpretation of this tool is that if the first and second stages did not exist, the delirium would be negative and there is no need to consider the subsequent stages. If the first and second stages were both positive, the positive state of either third or fourth stages would be enough for the positive delirium (Heidari et al., 2014). Wei et al. (2008), in a systematic review showed that the CAM-ICU sensitivity was 94%, and its specificity was 89% (Wei et al., 2008). This questionnaire has been translated into ten languages such as Persian and is commonly used to evaluate delirium in the intensive care unit, especially intubated patients (Heidari et al., 2014; Wei et al., 2008). The results of Luetz et al. study showed that CAM-ICU had a sensitivity of 81% and specificity of 96% and it is more accurate than other tools for assessment of delirium (Luetz et al., 2010).

2.4. Data collection and intervention

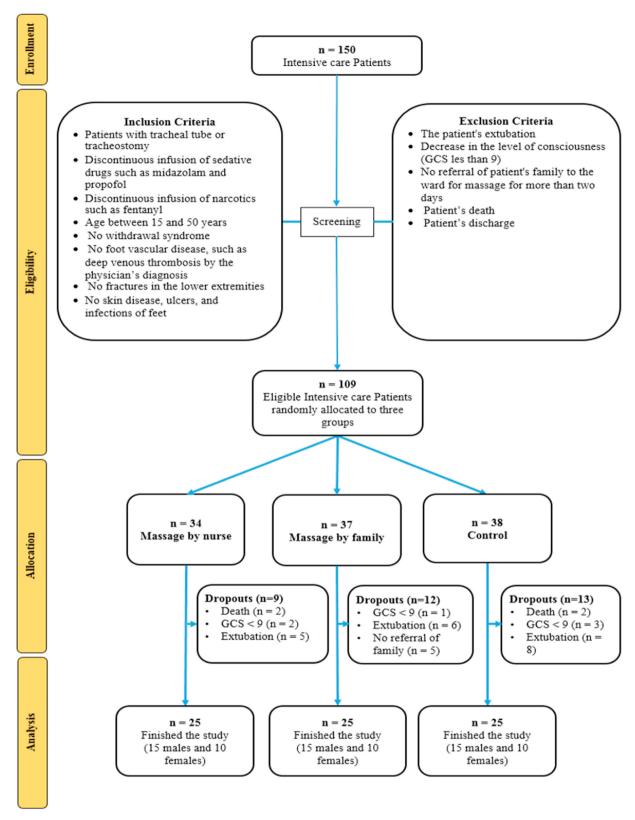After receiving the code of ethics, and the code of clinical trial

Fig. 1. The flow chart of the study.

registration, the researcher attended the Shahid Bahonar Hospital in Kerman, Iran. The written consent was obtained from the patient's guardian after coordination with the head of the hospital and the authorities of the intensive care units, as well as after

explaining the goals and method of study. The LOC and Delirium were measured in three groups before the massage. Before or during the intervention, a nurse or family member communicated with the patient, and after their introduction, the patient's feet

were massaged with Swedish massage. Then 30 min after the sixth day massage and one week after the massage, the LOC and delirium were assessed in three groups, again. The LOC and delirium were measured by the researcher's assistant who had sufficient training and did not know about the allocation of samples in each group. Therefore, it was a single-blind study. The researcher was trained under the supervision of a physiotherapist and initiated the intervention after her confirmation. In the intervention groups, in addition to routine care, the patient's feet (from knee to bottom) were massaged by the nurse or family of the patient with a Swedish massage once a day for 10 min (5 min for each foot) for six consecutive days. The procedure was as follows: first, the patient was placed in a supine position and a pillow was placed under the feet so that they were bent slightly from the knee and the head was placed at an angle of 30–45°. The cover of the massage area was removed from about 10 cm above the patient's knee, and the other parts of the body were covered. Then the researcher was placed at the bottom of the patient's feet and, after examining the feet for the presence of massage barriers, began to massage them. Massage in this study was a Swedish one that included stroking, effleurage, vibrations or kneading. Baby oil was used to make the area slippery and easy to massage (about 1–2 cc for each foot), and it had no other therapeutic value. The massage was performed at 15–17 p.m. when the workload of the intensive care units was lower. Upon completion of the massage, the patient's feet were cleaned using a cloth to remove the remaining oil on the patient's body. Since in traditional Iranian medicine, massage is one of the principles of maintaining health and has a special place in prevention and treatment, and people are generally familiar with its concept, participants had a good cooperation (Bahrami taghanaki et al., 2016).

The control group did not receive any intervention except routine care. Also, in the massage group by the patient's family, a member of the patient's family, who was mostly on his bedside, was trained under the supervision of the researcher and, initiated the intervention after her confirmation. In the massage group by the family, massage was performed by a maximum of two family members.

2.5. Data analysis

Data were analyzed by SPSS 18. Descriptive statistics (frequency, percentage, mean and standard deviation) were used to describe patients' demographic characteristics and disease information. Chi-Square test, Fisher's exact test, Kruskal-Wallis test, and ANOVA were used to examine the similarity of the three groups regarding the underlying variables. Repeated measures ANOVA was used to compare the mean LOC before, 30 min after the sixth day massage and one week after intervention within and among the three groups. Friedman test was used to compare the frequency of delirium within the three groups. Fisher's Exact test was used to compare the delirium among the three groups. A significant level of 0.05 was considered.

3. Results

The mean age of the samples of the massage group by the family was 41.12, the mean age of the samples of the massage group by a nurse was 39.40, and the mean age of the control group was 42.87 (P > 0.05). The majority of samples in both groups was male, married with a high-school degree (P > 0.05) (Tables 1–3).

Pre-intervention, in the massage group by family, 20% of the samples had delirium, and this amount reduced to 12% one-week post-intervention, but it was not statistically significant. Pre-intervention in the massage group by a nurse and control group, 16 percent of the samples had delirium. Post-intervention, in the

massage group by a nurse, the prevalence of delirium reduced to 8% and in the control group it decreased to 12%, none of which was statistically significant. The prevalence of delirium before the intervention, immediately, and one week after intervention were not significantly different among the three groups (Table 4).

The LOC in the group of massage by the family increased from 10.25 before the study to 10.63 one week after the intervention, which was statistically significant. In the massage group by a nurse, the mean LOC increased from 10.00 before the study to 10.56 one week after the intervention, which was statistically significant. Also in the control group, the mean LOC increased from 9.92 before the study to 10.56 one week after intervention, which was statistically significant. There was no statistically significant difference among the three groups in the LOC (Table 5). In addition, during the intervention and one week after the intervention no patients were suffered due to massage and we did not have any side effect. In addition, the causes of dead for two participants of the massage by a nurse group were subdural and epidural hemorrhage.

4. Discussion

The results of this study showed the LOC in all the samples in all the three groups increased significantly after two weeks from the beginning of the study, but there was no significant difference among the three groups of massage by the family, massage by a nurse and control in the level of consciousness during the study. Also, the prevalence of delirium was between 16% and 20% in all three groups at the beginning of the study, and decreased by 8%–12% one week after intervention. There was no significant difference among the three groups of massage by a nurse, massage by family and control group in a decreased level of delirium.

Similar to the results of the present study, the results of Ehsai et al. showed that compared with the control group, sensory stimulation including tactile stimulation (back massage), auditory, visual and thermal stimulations once per hour and for 10 min had no effect on the level of consciousness of patients (Ehsai et al., 2004). In contrast, the results of some studies were not consistent with that of the present study. The results of some studies showed that foot massage and sensory and auditory stimulation by a nurse (Azimiyan et al., 2015; Hosseinzadeh et al., 2012) and sensory and auditory stimulation by family members (Heydari Gorji et al., 2013; Goudarzi et al., 2010) have led to the increased LOC in patients with traumatic brain injury in ICUs. The difference between the results of the current study and that of the mentioned studies may be due to early sensory stimulation. For example, in some studies, the initiation of sensory stimulation was carried out from the very beginning of the admission, but in the present study, the intervention was not started from the very beginning of the patient's admission, and since the maximum brain reconstruction occurs during the first week after the stroke, no significant change was observed in the LOC in the current study. Also, a longer period of sensory stimulation of patients may be a reason for the different results of the studies with that of the current study.

Similar to the results of the present study, Mitchel et al. examined the effect of a familial involvement to reduce delirium in patients admitted to the ICU. Based on the results, there was no significant difference between the intervention and control groups in the prevalence of delirium. The prevalence of delirium at the end of the study was 50% in the baseline group, 56% in the control group, and 59% in the intervention group (Mitchell et al., 2017). In contrast, the results of some studies did not support that of the present study. For example, in Makinian et al. study, hand and face massage significantly reduced delirium in older women admitted to CCU (Makinian et al., 2015). The differences in the study population, the mean age of the samples, the absence of mechanical

Table 1
Comparison of demographic variables in three groups of massage by the family, massage by a nurse and control.

Group Variable	Massage group by family		Massage group by a nurse		Control group		Statistical test	P value
	Mean	SD	Mean	SD	Mean	SD		
Age	41.12	9.29	39.40	10.79	42.80	6.65	H = 0.88	0.42
	Frequency	Percent	Frequency	Percent	Frequency	Percent		
Sex								
Male	15	60.0	15	60.0	15	60.0	–	–
Female	10	40.0	10	40.0	10	40.0		
Marital status								
Single	8	32.0	6	24.0	4	16.0	1.75**	0.42
Married	17	68.0	19	76.0	21	84.0		
Job								
Employed	14	56.0	12	48.0	13	52.0	0.32**	0.96
Unemployed	11	44.0	13	52.0	12	48.0		
Education level								
Uneducated	6	24.0	3	12.0	8	32.0	7.88*	0.24
High school	8	32.0	14	56.0	10	40.0		
Diploma	7	28.0	6	24.0	7	28.0		
University degrees	4	16.0	2	8.0	0	0.0		

* Fisher's exact test, ** Chi-square test, H = Kruskal-Wallis test.

Table 2
Comparison of medical history in three groups of massage by the family, massage by a nurse and control.

Group Variable	the massage group by family		The massage group by a nurse		control		Statistical test	P value
	Frequency	percent	Frequency	percent	Frequency	percent		
History of admission in ICU								
Yes	2	8.0	4	16.0	2	8.0	1.08*	0.72
No	23	92.0	21	84.0	23	92.0		
History of other diseases								
Yes	11	44.0	12	48.0	12	48.0	0.11**	>0.99
No	14	56.0	13	52.0	13	52.0		
Current history of addiction								
Yes	11	44.0	11	44.0	11	44.0	–	–
No	14	56.0	14	56.0	14	56.0		
History of smoking								
Yes	9	36.0	7	28.0	9	36.0	0.48**	0.86
No	16	64.0	18	72.0	16	64.0		
History of seizure								
Yes	0	0.0	3	12.0	0	0.0	4.26*	0.10
No	25	100.0	22	88.0	25	100.0		
Hypertension								
Yes	10	40.0	10	40.0	9	36.0	0.11*	0.94
No	15	60.0	15	60.0	16	64.0		
History of taking hypertension medications								
Yes	10	40.0	9	36.0	9	36.0	0.11**	0.99
No	15	60.0	16	64.0	16	64.0		
History of surgery during current hospitalization								
Yes	21	84.0	20	80.0	20	80.0	0.26*	0.99
No	4	16.0	5	20.0	5	20.0		
Type of disease								
Lesions without bleeding	6	24.0	9	36.0	9	36.0	1.10**	0.70
Lesions with bleeding	19	0.76	16	0.64	16	0.64		

* Fisher's exact test, ** Chi-square test.

Table 3
Comparison of the distribution of Glasgow coma scale score, duration of hospitalization in ICU and respiratory status in three groups of massage by the family, massage by a nurse and control before intervention.

Group Variable	Massage group by family		Massage group by a nurse		Control group		Kruskal-Wallis test	P value
	Mean	SD	Mean	SD	Mean	SD		
Glasgow coma scale	9.28	0.54	9.08	0.28	9.12	0.33	2.87	0.24
Length of hospitalization in ICU	5.96	4.82	5.68	5.38	7.76	5.85	5.86	0.06
The amount of spontaneous breathing	2.64	1.52	2.20	1.53	2.48	1.64	1.41	0.49
the amount of assisted spontaneous breathing	12.08	1.96	16.88	21.95	16.20	20.00	1.06	0.59
the percentage of inspired oxygen	50.00	0.00	50.80	4.00	50.00	0.00	2.00	0.37
Positive End Expiratory Pressure	5.64	1.22	5.52	1.08	5.52	1.08	0.22	0.90

Table 4
The Prevalance of delirium in three groups of massage by the family, massage by a nurse and control at different times.

Time group		Delirium before intervention		Immediately after intervention		One week after intervention		Friedman test' P value
		Frequency	Percent	Frequency	Percent	Frequency	Percent	
Massage group by family	No	20	80.0	23	92.0	22	88.0	0.37
	yes	5	20.0	2	8.0	3	12.0	
Massage group by nurse	No	21	84.0	24	96.0	23	92.0	0.31
	Yes	4	16.0	1	4.0	2	8.0	
Control	No	21	84.0	22	88.0	22	88.0	0.87
	Yes	4	16.0	3	12.0	3	12.0	
Fisher Exact test		0.27		1.12		0.41		
P value		>0.99		0.87		>0.99		

Table 5
Comparison of the level of consciousness in the three groups of massage by the family, massage by a nurse and control at different times.

Group Level of consciousness	massage group by family		massage group by a nurse		Control group		Repeated measures ANOVA	P value
	Mean	SD	Mean	SD	Mean	SD		
Before intervention	10.25	0.74	10.00	0.000	9.92	0.64	1.38	0.26
Immediately after intervention	10.50	0.72	10.20	0.41	10.24	0.52		
One week after intervention	10.63	0.82	10.56	0.58	10.50	0.58		
Statistical test	7.21*		16.18*		13.84**			
P value	0.002		0.001		0.001			

*Sphericity, **Greenhouse-Geisser.

ventilation, delirium evaluation tools, research setting, and delirium evaluation in different times may be the reasons for different results in the studies. Also, in the study of Makinian et al., all the samples had delirium at the beginning of the study, while in the present study, the incidence of delirium was studied. The mean age of the samples in the Makinian study was 60 years or older, while the mean age of the subjects of the present study was 40 years old. Therefore, the population with various ages may response to massage differently.

One of the limitations of this study was to create an intervention in the study due to taking sedation, which reduced the limitation by postponing the measurement of LOC and Delirium in these conditions. Another limitation of this research was that patients were less aware of the delirium assessment tool, which was reduced by repeating items of the questionnaire. Also, the lack of cooperation of some families which was reduced by training the family and reducing their concerns, and some families, despite being trained about the safety of the study did not accept to do the intervention. Also, some families were not present at a proper time, and this limitation was reduced by contact with families. In the case of their absence, massage would have been done by another person after training. At last, as this study has conducted in one center, the generalizability of the results to other centers should be with caution.

5. Conclusion

The results of current study showed that the LOC in all the samples in all three groups increased significantly post-intervention, but increasing the LOC in the intervention groups did not differ from that in the control group. Also, the prevalence of delirium was between 16% and 20% at the beginning of the study and decreased by 8%–12% post-intervention in the three groups. Delirium reduction in the intervention groups did not differ from that in the control group. Therefore, given the contradictory results on the effect of Swedish massage of the foot on the LOC and delirium in patients admitted to ICU, it is suggested that more

extensive studies be conducted with a larger sample size in different study settings and research communities.

Disclosure statment

None to be decaled.

CRediT authorship contribution statement

Masoumeh Momeni: Methodology, Software, Data curation, Writing – original draft. **Mansour Arab:** Conceptualization, Methodology, Supervision, Writing – review & editing. **Mahlagha Dehghan:** Conceptualization, Methodology, Software, Visualization, Investigation, Validation, Writing – review & editing. **Mehdi Ahmadinejad:** Visualization, Investigation, Supervision.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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