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Research Paper: Effects of Foot Reflexology and Tactile Stimulation on Consciousness and Physiological Indicators of Traumatic Patients

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ABSTRACT

Background: Brain injuries are a major cause of mortality and disability. Sensory stimulation can reduce the complications of brain injuries in the patients.

Objectives: To compare the effect of foot reflexology with tactile stimulation of the hand on level of consciousness and physiological indicators in traumatic brain injury (TBI) patients

Materials & Methods: 60 TBI patients hospitalized in the ICU of selected hospitals in Qazvin, Iran assigned to three intervention groups and one control group using block randomization. The patients were matched using the glasgow coma scale (GCS) (score of 8) and the Richmond agitation and sedation scale (RASS) (scores -2 to +2). The first intervention group received tactile stimulation of the hand from the wrist downwards, the second intervention group received foot reflexology, and the third both tactile stimulation and foot reflexology, while the controls received routine care. The Data collected were analyzed in SPSS V. 21. $P<0.05$ was set as the level of statistical significance.

Results: The Mean±SD level of consciousness was the highest in the foot reflexology group(9.38±3.3) compared to that in the group of tactile stimulation of the hand (9.03±2.18), the group receiving both treatments (7.96±1.8) and the control group (6.92±3.3) ($P<0.001$). The findings also revealed reductions in the heart rate, respiratory rate and systolic blood pressure and increases in peripheral capillary oxygen saturation (O_2 sat) and level of consciousness in the TBI of the foot reflexology group.

Conclusion: Foot reflexology can decrease the heart rate, respiratory rate and systolic blood pressure, and increase O_2 sat in TBI patients and increase the level of consciousness.

Keywords: Consciousness; Intensive care units; Brain injuries

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Highlights

- Foot reflexology increases level of consciousness and improves physiological indicators in TBI patients in ICU
- Foot reflexology improves peripheral capillary oxygen saturation (O_2 sat) in TBI patients in ICU

Introduction

With an incidence of 67-317 per 100000, TBI is considered the most common cause of mortality in the first three decades of life that threatens the health of communities [1]. Brain injuries are the most destructive type of accident-associated injuries that remain a major cause of disability and mortality, especially in the young, despite the growing advances in medical information and sciences [2].

TBI can therefore cause huge costs associated with intensive and long-term care of the patients [3]. In Iran, accidents are the second leading cause of mortality after cardiovascular diseases in different ages, and the first cause in below fourty years of age in both genders [4]. The Center for Disease Control and Prevention defined TBIs as brain injuries caused by bump and penetrating blows, disrupting normal brain functioning and being classified as mild to severe. Brain injuries are caused by trauma associated with external factors, including blows to the head, traffic accidents and blows due to sports or military activities [5]. Brain injuries caused by head traumas include epidural hemorrhage (EDH), subdural hematoma (SDH), intracranial hemorrhage (ICH), sub-arachnoid hemorrhage (SAH), diffuse axonal injury (DAI) and cerebral contusion. [1].

Hospitalization in the ICU is associated with complications such as anxiety, pain, and causes hemodynamic instabilities, i.e. increases in blood pressure, heart rate and respiratory rate, poor level of consciousness and reduced GCS scores [6]. Sensory stimulation is a fundamental human need [7]. In fact, appropriate sensory stimulation is a nursing intervention that can increase in level of consciousness. Massage is a touch therapy that involves the stimulation of neurons and skin layers containing cutaneous receptors, which transmit neural impulses to the brain [8, 9].

Massage generally causes reflexive and mechanical effects. The cutaneous reflexive effects are caused by stimulating peripheral receptors that transmit signals to the brain through the spinal cord, causing a pleasing sensation and comfort. The mechanical effects include those assisting in the return of blood flow and lymph [7]. Starting sensory stimulation within the first 72 hours of TBI has been shown to be crucial for saving the patients' life, enhancing their quality of life and the long-term prognosis of the disease [10].

Massage affects hormones such as dopamine, serotonin, epinephrine (adrenaline), norepinephrine (noradrenaline), oxytocin and cortisol. Mechanical stimulation during massage act as an analgesic by affecting the central nervous system and blocking ascending neural pathways to the brain (A and C fibers), and cause the secretion of central analgesics from the midbrain, including beta-endorphin and encephalin [11]. The present research was performed to investigate the effects of foot reflexology and tactile stimulation of the hand on level of consciousness and physiological indicators in patients hospitalized with TBI in the ICU of selected hospitals in Qazvin, Iran.

Materials and Methods

The present randomized controlled clinical trial was conducted in 2018 on 60 patients with TBI hospitalized in the ICU of Shahid Rajaee and Razi Hospital in Qazvin Province, Iran.

According to a study conducted by Azimian et al. in 2015, the Mean±SD post-intervention level of consciousness was estimated at 10.6±2.41 in the intervention group and 6.94±3.03 in the control group [8]. The sample size was therefore estimated using the following formula with a type I error level of (α=0.05) and a type II error level of (β=0.95).

$$n=\frac{(z_{1-\frac{\alpha}{2}}+z_{1-\beta})2(\sigma_1^2+\sigma_2^2)}{(\mu_1-\mu_2)^2}$$

σ_1^2: Variance of the intervention group

σ_2^2: Variance of the control group

μ^1: Mean of the intervention group

μ^2: Mean of the control group

$\alpha=\beta=0.05$

$$n=\frac{(1.96+1.64)^2(3.3+2.41)^2}{(10.6-6.94)^2}=14$$

The sample size was therefore calculated as 14 per group, with a total sample size of 56. Applying a 10% dropout rate, the total sample size was selected as 60 (n=15 in each group).

The eligible subjects were divided into three intervention groups and one control group using block randomization with 4 block (A, B, C, D) and a table of random numbers. The patients were matched using the GCS (score of 8) and the RASS (scores -2 to 2). After receiving the approval of the Ethics Committee of Qazvin University of Medical Sciences, Qazvin, Iran, the eligible patients were selected and assigned to three experimental groups and one control group. The inclusion criteria comprised: 1. The absence of fractures, wounds, infections and skin diseases from the ankle to toes in the feet and from the wrist to fingers in the hands; 2. Normal motor abilities and hearing, sight and touch health before TBI and coma; 3. No history of diabetes, cardiovascular diseases, coma, sensory and neurological disorders and symptoms of fat embolism; 4. The lack of addiction to narcotics and other substances; 5. An age of 15-65 years; 6. The absence of swelling in the eyes and eyelids; 7. And absence of brain death.

The exclusion criteria consisted of: 1. The accompaniments' unwillingness for the patients to continue participation in the study; 2. Transferring the subjects to centers outside the city of Qazvin; 3. A severe and sudden drop in level of consciousness, i.e. a GCS score of over 3, in all the four groups. Data were collected using demographic questionnaires, clinical status forms, vital signs and physiological indicators forms, the GCS and the RASS. Eligible subjects were selected after briefing their accompaniments on the study objectives and their completion of informed consent forms. In addition to routine care, the first intervention group received the tactile stimulation of the hands from the wrist downwards for 5 minutes twice a day.

In this group, the nurse's fingers were gently wrapped around the patient's wrist without applying any pressure, and the entire hand surface was touched from the wrist downwards. The second intervention group received the five-minute reflexology of both feet twice a day using the stroke method (ankle, heel and sole). After washing and drying both hands, the nurses massaged the right foot and then the left without wearing gloves and applying lubricants. In this group, superficial massage was slowly and regularly performed from the ankle and heel towards the toes using the pressure of the entire palm followed by deep massage from the toes towards the ankle and heel.

In the first step, the sole of the foot was held with one hand and light pressure was applied using the thumb or other fingers along the grooves between the tendons connecting the ankle to toes. In the second step, while keeping the foot with one hand, the entire sole and heel were massaged up to the bump under the toes with the fingers of the other hand. In the third step, the toes were individually pulled back and forth. In the fourth step, the thumb and other fingers of the massager were slid on the toes of each foot to the lateral part of the feet. Moreover, every step lasted for about one minute. The third intervention group received the sensory stimulation of the hands and foot massage. The fourth group as the control group (no intervention) received the routine care provided in all healthcare centers. In all groups, level of consciousness and vital signs were evaluated and recorded.

All the intervention were performed for two weeks at 11:00 AM and 03:00 PM before the visiting hours and the patients' position change, and continued until discharge or transfer to the general ward. Level of consciousness was examined and recorded one day before the intervention and daily afterwards using the GCS, and pain scores using the RASS. The data collected were analyzed in SPSS V. 21 using statistical tests such as the Chi-squared, the independent t-test and the paired t test with a significance level of below (0.05).

Results

The findings suggested that 42(70%) participants were male and 18(30%) female. The cause of hospitalization was motor vehicle accidents in 45(75%) patients, falling in 12(20%) and fights in 3(5%). The study population were 15-65 years old and had a mean age of 39.8±18.9 years. The frequency distribution of the subjects in terms of using sedatives showed no statistically-significant differences between the four groups of TBI patients (P>0.05). The maximum frequency was associated with midazolam.

The frequency distribution of the study subjects by the type of TBI in four groups of TBI patients does not show a statistically-significant difference (P>0.05) (Table 1). One-way ANOVA suggested statistically significant differences between the four therapeutic groups in terms of the mean level of consciousness on all the study days (P<0.0001) (Table 2).

Table 1. The frequency distribution of the study subjects by the type of TBI in four groups of TBI patients (P>0.05)

DX Group	Concussion	SAH	Dura Hemorrhage EDH-SDH	DAI	Chi-Squared Test
Tactile stimulation of the hand	1	2	3	1	
Foot massage	1	1	6	0	
Foot massage and tactile stimulation of the hand	1	1	2	1	F-exact=6.4 P=0.9
Control group	2	1	5	3	
Total	5	5	16	5	

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EDH: Epidural hemorrhage; SDH: Subdural hematoma; ICH: Intracranial hemorrhage; SAH: Sub-arachnoid hemorrhage; DAI: Diffuse axonal injury

In the first intervention group (group A), receiving the tactile stimulation of the hands, the mean level of consciousness was 7.86±1.9 on the first day, 10.5±2.6 on the fifth day. The results suggested a significant ascending trend in the mean GCS scores in this group over the five-day period (P<0.001). In the second intervention group (group B), receiving foot massage, the mean level of consciousness was 8.2±4.6 on the first day, 10.7±3.1 on the fifth day. The results also suggested a significant ascending trend in the mean GCS scores in this group over the five-day period (P<0.001). In the third intervention group (group C), receiving the tactile stimulation of the hands and foot massage, the mean level of consciousness was 6.6±1.4 on the first day and 9.6±2.2 on the fifth day. The results also suggested a significant ascending trend in the mean GCS scores in this group over the five-day period (P<0.001). In the fourth group (control group), receiving no interventions, the mean level of consciousness suggesting no improvements (change) in level of consciousness in the control group (P>0.001).

Moreover, the effect of time (within-group) and group (between-group) were investigated using repeated-measures ANOVA. The results showed significant differences between the patients in the mean GCS score over the seven-day period. Time therefore exerted a significant effect on their mean GCS score (P<0.001). The results of repeated-measures ANOVA also showed a descending trend and significant differences between all the intervention groups in terms of the mean heart rate over the seven-day period (P<0.001). The highest reduction in the mean heart rate was observed in the tactile stimulation of the hand group, this reduction was almost the same in the group of foot reflexology and in the foot and hand massage group.

Comparing the trend of the mean scores of diastolic blood pressure in the four groups before and after the intervention showed a decrease in this value in the patients receiving foot reflexology and in those receiving both types of massage, although no significant reductions were observed in the group receiving hand tactile stimulation. Comparing the trend of the mean body temperature before and after the intervention showed a daily decrease in this value in all the groups and significant differences over the seven-day period (P<0.001). In ad-

Table 2. Daily Mean±SD level of consciousness in groups of TBI patients

Group	Days					P
	Mean±SD					
	First	Second	Third	Fourth	Fifth	
Tactile stimulation of the hand	7.86±1.9	8.2±2.1	8.9±2.3	9.7±2	10.5±2.6	<0.001
Foot massage	8.2±4.6	8.6±3.2	9.4±2.7	10±2.9	10.7±3.1	<0.001
Foot massage and tactile stimulation of the hand	6.6±1.4	7.2±1.2	7.7±1.9	8.7±2.3	9.6±2.2	<0.001
Control group	6.7±3.3	7.1±1.3	6.8±1.2	6.8±1.2	7.2±1.6	>0.05

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dition, the highest reduction in the mean scores of systolic blood pressure was observed in the hand stimulation (group A) and the hand stimulation and foot massage group (group C) compared to in the other two groups. The mean blood pressure showed a generally-decreasing trend over time in these two groups after the intervention, although no special trends were observed in this mean in the other two groups.

The maximum reduction in the body temperature was observed in the foot massage group, which can be explained by reductions in anxiety and risk of sensory deprivation and fear and pain and an improvement in the sense of security, which caused the patients' peace of mind and reduced their respiratory rate, heart rate and body temperature. A descending trend was also observed in the mean body temperature of the controls. Investigating the mean O_2 sat after compared to before the intervention showed that the maximum effect was exerted on the foot massage group ($P<0.0001$). An increasing trend in this value was observed in all the groups up to the sixth day. In the foot massage group, this trend continued up to the seventh day and beyond. The mean O_2 sat score generally increased by up to 2% in all the groups, and this score increased from 90-96% before the intervention to 92-98 after the intervention. Variations in the control group were not, however, noticeable, and they were even decreasing in this group. A significant descending post-intervention trend was observed in the mean respiratory rate in all the three groups, with the maximum reduction being associated with the group of hand tactile stimulation and foot massage and the group of hand tactile stimulation.

Discussion

Based on the present results, a significant ascending trend was observed in mean level of consciousness in the three intervention groups on all the study days. This mean level did not change in the controls who received no interventions.

Abdi et al. (2013) examined the effect of foot massage on level of consciousness in 40 comatose patients hospitalized with TBI in the ICU, and found a daily five-minute stroke massage of both feet for 14 days to cause significant differences between after and before the intervention in the mean level of consciousness in the intervention groups, which is consistent with the present results [12].

A study by Hosseinzadeh et al. (2013) on the effect of ten-day organized auditory stimulation in comatose TBI patients admitted to the ICU showed improved levels of consciousness in these patients following the twice-a-day stimulation by a nurse [13], which is consistent with the present study. These authors used auditory stimulation as the intervention, whereas the present study found tactile stimulation of the hand and foot massage to increase level of consciousness.

A study by Mohamadpour et al. (2012) on the effect of foot reflexology on physiological indicators in 68 stroke patients showed that this intervention can be used as a safe, effective and economical nursing intervention for reducing the heart rate [14].A study by Fakhr-Movahedi et al. (2015) entitled "The effect of touch on the vital signs of agitated patients undergoing mechanical ventilation: An interventional study" showed significant reductions in systolic blood pressure, heart rate and respiratory rate [15], which is consistent with the present study. These authors found the presence on the bedside of the patients coupled with the touch of their wrist to significantly decrease systolic blood pressure, heart rate and respiratory rate compared to not touching the wrist. No significant differences were, however, observed between the two groups in terms of diastolic blood pressure and body temperature [15].

The present study found a significant difference and a decreasing trend in the mean heart rate over the seven-day period in all the groups. Moreover, the highest reduction in the mean heart rate was observed in the hand tactile stimulation group, while this reduction was almost the same in the other two intervention groups. A study by Hajihosseini et al. (2017) examined the effect of massage on vital signs of comatose patients in the ICU, and demonstrated the effectiveness of massage in the patients' systolic and diastolic blood pressure, which is inconsistent with the present research [7]. These authors applied massage for three days, whereas the present study applied foot massage, sensory stimulation of the hands and their combination for five days.

Moattari et al. (2016) investigated the effect of sensory stimulation by nurses and the family on cognitive functioning levels and basic sensory cognition in 60 comatose patients with severe TBI, and found five-minute sensory stimulation to improve level of consciousness. They also found the seven-day sensory coupled with auditory stimulation to have increased consciousness levels [16].

A study by Mandeep et al. (2012) entitled "Effectiveness of early intervention of coma arousal therapy in traumatic brain injury patients" and conducted in India on thirty TBI patients admitted to the ICU with a maximum GCS score of 8 found arousal therapy to improve comatose patients with TBI, which is in line with the present study. The intervention group underwent two-week stimulation of four senses, i.e. kinesthetics, sight, hearing and touch, twice a day, and five-second tactile stimulation was conducted on each limb twice a day once every 3 seconds [17]. The limitations of Man-

deep et al's study include the shortness of intervention, i.e. below three minutes a day, compared to other studies on the subject. The stimulation lasted five minutes for each limb in our study.

A study by Zolfaghari et al. (2012) conducted on 69 patients in three groups of 23 showed that therapeutic touch significantly decreased the heart rate, respiratory rate and blood pressure during catheterization in the intervention group. The first (intervention) group underwent 10-15 minutes of therapeutic touch one hour before catheterization. The second (placebo) group received 10-15 minutes of simulated touch. The third (control) group received no interventions. This study investigated the effects of therapeutic touch on anxiety, vital signs and dysrhythmia in women undergoing cardiac catheterization, whereas the present study examined the effects of tactile stimulation of the hand and foot reflexology on level of consciousness and physiological indicators in patients hospitalized with TBI in the ICU [3]. The results of the cited study are consistent with the present findings.

In contrast to the present research, a study by Zare et al. (2010) investigated the effect of hand touch tactile stimulation on vital signs in patients before undergoing coronary bypass surgery, and found sensory stimulation had not affect on systolic and diastolic blood pressure [18]. A relatively descending pattern was observed in the present study in the mean diastolic blood pressure in the group of foot reflexology and group of hand touch tactile stimulation + foot massage, although no significant reduction was observed in this mean score in the group of tactile stimulation of the hand. The study by Zare et al. focused on patients with cardiac diseases, while the present study investigated patients with TBI in the ICU [18].

Comparing the trend of the mean body temperature before and after the intervention showed a daily decrease in this value in all the intervention groups and significant differences over the seven-day period. The maximum reduction in the body temperature was observed in the group B of foot massage. Fakhr-Movahedi et al. (2015) in theit study found out that the mean of heart rate significantly decreased to 4 beat per minute [15].

A study by Hosseini et al. (2017) examined the effect of massage on vital signs of comatose patients in the ICU, and showed significant differences in the mean heart rate, which is consistent with the present study [7]. Zare et al. (2010) in their study found the mean heart rate to have reduced to 7 beat per minute in the intervention group, and tactile stimulation to be proved effective [18], which is consistent with the present study. Given that massage has been shown to increase the general blood flow in the body and oxygenation [16] and the increase in level of consciousness in the subjects appears to be associated with foot massage and tactile stimulation of the hand.

Conclusion

As an effective stimulant, massage can increase level of consciousness, improve patient health status, accelerate discharge from the ICU and reduce hospital costs in patients hospitalized with TBI in the ICU. An increase in daily mean levels of consciousness over a seven-day period, a decreasing trend in the mean body temperature, reductions in the mean heart rate and an increasing trend in the mean O_2 sat of the patients in the intervention group shown in the present study suggest the positive effects of foot massage on level of consciousness and physiological indicators in TBI patients in the ICU. This can encourage the use of massage as a complementary medicine and a type of sensory stimulation, which is currently being less emphasized owing to time constraints, workforce shortage, using top technologies and the increasing complexity of the required care.

Ethical Considerations

Compliance with ethical guidelines

The study protocol was approved by the Ethics Committee of Qazvin University of Medical Sciences (No.IR.QUMS.REC.1396.346), recorded at the Iranian Registry of Clinical Trials (IRCT20180726040604N1), and conducted after obtaining the necessary permissions. All the study procedures were in compliance with the ethical guidelines of the Declaration of Helsinki 2013.

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Authors contributions

Carried out the experiments and the interpretation of the results and writing the article: Baghiatallah Salehi; Supervised the project: Jalil Azimian; Conducted the study and were in charge of overall direction and planning: Layli Yakkafallah; Designed the sampling model and the computational framework and analysed the data: Maryam Mafi.

Conflict of interest

The authors declared no conflict of interest.

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