

Evaluation of the effects of foot reflexology massage on vital signs and chemotherapy-induced anxiety in children with leukemia

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ABSTRACT

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Background: Cancer is a common disease among children. One of the most important treatment methods in this regard is chemotherapy, which leads to anxiety and negative physiological reactions in patients. This study aimed to evaluate the effects of foot reflexology massage on vital signs and chemotherapy-induced anxiety in children with leukemia.

Methods: This clinical trial was conducted on children with leukemia (aged 6-12 years), undergoing chemotherapy in the oncology center of Kerman, Iran in 2015. In total, 120 children were selected through convenience sampling and randomly allocated to three groups of 40 samples. Intervention was performed in the form of a 20-minute session of foot reflexology massage for the intervention group and simple massage for the placebo group before the injection. Vital signs and anxiety levels were estimated immediately before and after the intervention using the vital sign record form and observation scale of behavior distress (OSBD). Data analysis was performed in SPSS version 16 using Kruskal-Wallis test, Chi-square, Wilcoxon test, Mann-Whitney U, and Spearman's correlation coefficient.

Results: In this study, heart rate, systolic and diastolic blood pressures, respiratory rate, body temperature ($P < 0.0001$) and anxiety level ($P = 0.003$) significantly decreased in the intervention group after the intervention. However, this significant reduction was only observed in the systolic blood pressure ($P < 0.0001$), heart rate ($P < 0.0001$), respiratory rate ($P = 0.009$) and anxiety level ($p < 0.0001$) of the placebo group. In contrast, systolic ($P < 0.03$) and diastolic blood pressure ($P < 0.0001$) significantly elevated in the control group after the intervention.

Conclusion: According to the results of this study, foot reflexology massage could be applied as a non-pharmacological method to reduce anxiety and improve vital signs in children with leukemia during chemotherapy.

1. Introduction

Cancer is one of the most important chronic diseases due to its high prevalence during childhood.¹ Cancer is the third leading cause of mortality after cardiovascular diseases, car accidents and natural causes in Iran,² as well as the second leading cause of death in children in developing countries. According to the literature, leukemia is the most common type of cancer,³ which is known as the most frequent malignancy in childhood accounting for 31% of cancers in children aged <15 years.⁴ Since nearly 25% of the Iranian population are aged less than 15 years, cancer in children is considered a significant human health risk in the

young population. Therefore, special attention must be paid to this chronic disease.⁵

One of the most important therapeutic strategies for cancer is chemotherapy, in which antineoplastic agents are used to destroy tumor cells.⁶ Increased anxiety levels are observed in children during the first step of this effective treatment due to the necessity of finding a suitable vein and its maintenance.⁷ In a study by Perry et al. (2012), the greatest anxiety sources in children were identified as the fear and stress caused by venipuncture- or injection-related pain.⁸ In fact, children with cancer have more difficulties dealing with therapeutic interventions than the disease, which leads to fear, stress and psychological distress during and after the treatment.⁹

Anxiety and mental tensions cause disturbances in the physical and mental performance of patients.¹⁰ In this regard, anxiety could significantly affect the children's response to treatment and its clinical outcomes,⁹ which generally leads to increased heart rate, respiratory rate and blood pressure.¹¹ Therefore, preparing children to cope with stressful procedures in order to prevent physiological and behavioral disorders is of paramount importance.^{8, 12} This must be performed by nurses rather than other healthcare team member, since nurses spend more time with patients. In addition, holistic nursing care¹³ is one of the most important responsibilities of nurses.¹³

Caregivers and healthcare professionals should integrate painful procedures with intervention strategies to alleviate pain and anxiety in patients.^{14, 15} Meanwhile, there have been several non-pharmacological methods introduced to reduce stress and anxiety,¹⁶ which are mainly simple and inexpensive with low risk of complications. Moreover, these methods could be used as alternative or secondary treatments with other medications.⁵

One of the most common non-pharmacological approaches in this regard is foot reflexology massage, which is an approved ancient medical treatment.^{17- 19} Reflexologists have stated that the bottom of the feet are small maps of the whole body, reflecting all the body organs and limbs.²⁰ According to these experts, applying pressure on the reflex points of the feet (sometimes within the palms) leads to the balance and release of energy channels in the body, thereby improving physiological parameters and enhancing comfort through decreasing cortisol levels and stimulating the parasympathetic nervous system.²¹

Several studies have been conducted to evaluate the effects of reflexology on anxiety levels and some physiological parameters of different patients. However, conflicting results have been obtained, and further investigation is required in this regard. For instance, Mohamadpoor et al. (2013) indicated that reflexology massage reduced the vital signs of samples, such as heart rate.²² Nevertheless, Albert et al. (2009) marked no significant difference between this approach and physiological parameters (with the exception of systolic and diastolic blood pressure) and psychological criteria (e.g., depression, anxiety and mood).²³

In another study by Mahmoodirad et al. (2013), reflexology massage significantly decreased anxiety in patients undergoing angiography.²⁴ However, no such effect was observed in a review study by Ernest (2009).²⁵ Given the conflicting results of previous studies, most of which were performed on adults, and the importance of changes in vital signs and

chemotherapy-induced anxiety in children, this study aimed to evaluate the effects of foot reflexology massage on vital signs and chemotherapy-induced anxiety in children with leukemia.

2. Methods

2.1. Design

This clinical trial was conducted on children with leukemia aged 6-12 years, referred to the oncology center of Kerman, Iran during 2014-2015.

2.2. Participants and setting

In this study, Sample size was estimated at 40 patients per group based on the results obtained by Torabi et al. (2012)²⁶ ($Z_{1-\alpha/2} = 0.96$, $d = 0.94$, $Z_{\beta} = 0.80$, $\beta = 0.20$, $\alpha = 1.77$, $\sigma = 1.5$). In total, 140 patients were selected using available sampling and randomly allocated to three groups of intervention (foot reflexology massage), placebo (simple touch) and control. First, the number of participants and groups was entered in the software and randomly placed in 20 blocks of six items. Afterwards, the intervention was implemented for each block based on the type of study groups.

Inclusion criteria were age range of 6-12 years, available medical records at the selected oncology center, diagnosis of leukemia, healthy legs, no use of anti-anxiety medications, and no former experience of foot reflexology massage before the study. On the other hand, the only exclusion criterion was unwillingness to cooperate at any time during the research.

2.3. Instruments

Demographic questionnaires, vital sign record form and observational scale of behavioral distress-revised (OSBD-R) were used to collect data. Demographic data included age, gender, age at diagnosis, accompanied parent, and educational level of children.

Vital sign record form consists of information about systolic and diastolic blood pressure, heart rate, body temperature, and respiratory rate. Reliability of results was confirmed using a sphygmomanometer with registered brand of ISOMED, which was compared with another sphygmomanometer with the same brand after calibration and adjustment. In addition, heart rate of the participants was measured by the ISOMED stethoscope, accuracy of which was determined through the mentioned method. Respiratory rate of the subjects was counted by observing the chest wall movements for one minute. In this study, inter-rater

agreement was used to assess the reliability of the mentioned approach through the monitoring of the vital signs of patients by another nurse five minutes after evaluation by the researcher. This process was repeated for 10 samples, and reliability was confirmed at the coefficient of 90%.

Reliability and validity of observational scale of behavioral distress-revised (OSBD-R) was first confirmed by Elliott *et al.* in 1987.²⁷ This is in fact a standard scale to determine the anxiety caused by therapeutic procedures in children through the assessment of eight different behaviors, including crying, shouting, physical strength, verbal resistance, seeking mother's assistance, requesting information, predicting pain and slamming hands and legs. Within a score range of 0-4, each observed behavior was graded 0.5, while absence of the mentioned behaviors was scored zero. Scores ≤ 1 were indicative of no anxiety, while scores 1.5-2 indicated mild anxiety, and scores 2.5-3 and 3.5-4 were regarded as moderate and severe anxiety in children, respectively. Reliability and validity of this scale have been confirmed for the Iranian population through content validity and concurrent rating,²⁸ which was estimated at the Cronbach's alpha of 0.70 in the present study.

2.4. Data Collection

This was a single-blind study, and all the forms and questionnaires were completed by the research assistant, who was unaware of group assignments. Demographic questionnaires were completed by parents through interviews, followed by the evaluation and recording of the vital signs of children in the study groups. In addition, anxiety levels of the participants were calculated based on OSBD-R, and the vital signs and anxiety levels were assessed before and immediately after the intervention.

In this research, the intervention group received reflexology massage, while simple massage was applied for the placebo group, and no intervention was implemented for the control group. After 20 minutes, chemotherapy medication was administered, and the researcher was asked to evaluate anxious behaviors and vital signs of the samples during this procedure. Our research assistant entered the injection room before the intervention and after the desired time (20 minutes) in order to observe the behaviors of children (participants could not see the researcher during this process). Intervention was carried out by the researcher, who was trained in this field prior to the study. To do so, accuracy of reflexology massage points and methods of applying pressure were confirmed by an acupuncturist and a reflexologist. It

should be mentioned that the researcher did not use white lab coats to control its effect on the results.

Initially, the researcher washed his hands with warm water and applied baby oil, which has no therapeutic features and is used for massage. Afterwards, the researcher placed his thumbs on the pressure points (bilaterally on the plantar surface, between the distal shafts, and the point related to kidney and heart in the center of the sole) for monitoring the vital signs and anxiety level (the pituitary reflex point, located in the middle of each big toe) and massaged (figures 1 & 2).

In this process, the sole, surface and toes of the feet were massaged for two minutes for relaxation,²⁹ followed by eight minutes of applying pressure on specific reflex points. Each reflex point of the feet was massaged using the middle part of the first knuckle of the index and thumb fingers and the fleshy part of the thumb through applying constant pressure (0.5 cm) until one-third of the nail turned white. This massage was applied with circular movements with no interruption for 20 minutes (10 minutes for each foot).

In the placebo group, simple massage was applied for 20 minutes on both feet, and no specific reflex points were massaged.³⁰

On the other hand, no intervention was implemented on the control group before injection.

2.5. Ethical considerations

Objectives of the study were explained to the participants prior to the study, and they were assured of the safety of intervention and confidentiality terms regarding their personal and medical information.

2.6. Statistical analysis

Data analysis was performed in SPSS version 16 using Kruskal-Wallis test to compare the groups in terms of age and age at diagnosis and evaluate the vital signs and anxiety level in the groups, and Chi-square for the comparison of groups regarding gender, educational level and accompanied parent. In addition, Wilcoxon test was applied to evaluate the vital signs and anxiety level of study groups before and after the intervention, and comparison of the vital signs and anxiety level between the groups was performed via Mann-Whitney U test. Spearman's correlation coefficient was used to evaluate the relationship between the vital signs and anxiety level, as well as the associations of vital signs and anxiety levels with age and age at diagnosis. In this study, P value of less than 0.05 was considered statistically significant.

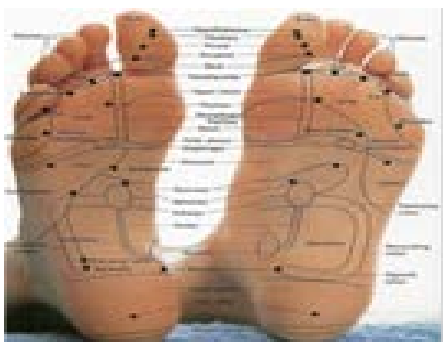


Figure 1. Pressure points related to the vital signs



Figure 2. Pressure points related to anxiety level

3. Results

Demographic characteristics of the participants are shown in Table 1. According to this table, a significant difference was observed between the groups in terms of gender ($P=0.006$) and educational level ($P=0.001$), which could not be controlled by the researcher due to the random allocation of the participants to study groups. However, this difference could be ignored since no significant correlations were observed between anxiety, systolic and diastolic blood pressure, body temperature, and respiratory rate with variables of gender and educational level. In addition, no statistically significant difference was observed between the variables of accompanied parent, age, and age at diagnosis in the study groups (Table 1).

Before the intervention, no significant differences were observed between the groups in terms of mean systolic and diastolic blood pressure,

respiratory rate, body temperature, and anxiety level. However, a significant reduction was observed in the systolic and diastolic blood pressure, heart rate, body temperature and respiratory rate ($P<0.0001$) and level of anxiety ($P=0.003$) in the intervention group after the massage. Similarly, systolic blood pressure ($P<0.0001$), heart rate ($P<0.0001$), respiratory rate ($P=0.009$) and anxiety level ($P<0.0001$) significantly decreased in the placebo group after the intervention. In contrast, a significant increase was observed in the control group in terms of the systolic ($P<0.03$) and diastolic blood pressure ($P<0.0001$) (Table 2).

According to the Kruskal-Wallis test, a statistically significant difference was observed between the three study groups in terms of mean anxiety score, systolic and diastolic blood pressure, heart rate, body temperature, and respiratory rate. While a significant difference was found between the intervention and control groups, as well as the placebo and control groups, in terms of anxiety level ($P<0.0001$), no such difference was reported between the intervention and placebo groups.

On the other hand, there was a significant difference between the intervention and placebo groups in terms of diastolic blood pressure ($P=0.006$) and respiratory rate ($P<0.0001$). Furthermore, a significant difference was found between the intervention and control groups in all the vital signs, including systolic blood pressure ($P<0.0001$), diastolic blood pressure ($P<0.0001$), heart rate ($P=0.006$), respiratory rate ($P<0.0001$), body temperature ($P=0.012$) and anxiety level ($P<0.0001$). In addition, a significant difference was observed between the placebo and control groups in terms of systolic blood pressure ($P=0.003$), diastolic blood pressure ($P=0.009$), heart rate ($P<0.0001$), and anxiety level ($P<0.0001$); meanwhile, no such difference was observed between the mentioned groups regarding respiratory rate and body temperature.

Table 1. Demographic characteristics of participants

Demographics	Group	Intervention	Control	Placebo	P-value
		N (%)	N (%)	N (%)	
Gender	Female	15 (37.5)	13 (32.5)	17 (42.5)	0.006*
	Male	25 (62.5)	27 (67.5)	23 (57.5)	
Educational level	Non-student	22 (55)	13 (32.5)	18 (45)	<0.001*
	Student	18 (45)	27 (67.5)	22 (55)	
Accompanied parent	Mother	16 (40)	20 (50)	17 (42.5)	0.2*
	Not mother	24 (60)	20 (50)	23 (57.5)	
Age (year)	M±SD	7.58±1.62	8.30±1.97	7.87±2.17	0.24**
Age at diagnosis (year)	M±SD	5.84±2.08	6.41±2.11	5.75±2.32	0.27**

*Chi-square; **Independent t-test

Table 2. Comparison of mean vital signs and anxiety level before and after intervention in three groups

Vital signs	Group	Intervention	Control	Placebo	*P-value
		M±SD	M±SD	M±SD	
Systolic blood pressure	Before intervention	95.62±7.56	95.02±8.80	95.02±1.04	0.73
	After intervention	85.72±8.16	96.42±8.12	88.85±11.76	<0.0001
	**P-value	<0.0001	0.03	<0.0001	
Diastolic blood pressure	Before intervention	47.77±5.48	47.20±5.37	47.00±6.58	0.68
	After intervention	41.20±5.10	49.20±4.48	45.75±7.02	<0.0001
	**P-value	<0.0001	<0.001	0.06	
Heart rate	Before intervention	109.90±13.84	109.90±17.02	106.92±15.78	0.19
	After intervention	100.65±13.67	110.37±14.16	96.45±12.82	<0.0001
	**P-value	<0.0001	0.59	<0.0001	
Respiratory rate	Before intervention	25.12±2.68	27.90±1.29	26.43±3.45	0.19
	After intervention	22.25±2.16	25.62±2.62	25.25±3.26	<0.0001
	**P-value	<0.0001	0.54	0.009	
Body temperature	Before intervention	36.48±0.32	36.19±1.70	36.45±0.43	0.93
	After intervention	36.18±0.52	36.50±0.40	36.32±0.52	0.017
	**P-value	<0.0001	0.15	0.12	
Anxiety level	Before the intervention	1.42±1.27	1.15±1.11	1.63±0.94	0.11
	After the intervention	0.63±0.70	1.40±2.18	0.83±1.05	<0.0001
	**P-value	0.003	0.09	0.005	

*Kruskal-Wallis test; **Wilcoxon test

4. Discussion

According to the results of the current research, reflexology and simple massage could have a positive impact on the total score of anxiety, systolic and diastolic blood pressure, heart rate, body temperature, and respiratory rate in children with leukemia within the age range of 6-12 years. Tension and mental pressure are responsible for 75% of health problems in the society. Since there are more than 700 nerves in legs, foot massage and stimulation of nervous system could result in comfort and reduction of tension in patients.³¹

In this regard, JU Myang *et al.* (2013) indicated that reflexology massage is associated with improved systolic and diastolic blood pressure.³² Moreover, Lu *et al.* (2011) reported that 60 minutes of reflexology massage alleviated heart rate in patients undergoing coronary artery bypass grafting (CABG).³³ In line with our results, Jones *et al.* (2012) denoted changes in cardiac indices, such as decreased heart rate, systolic and diastolic blood pressure, and mean arterial blood pressure, by massaging the upper half of the bottom of the feet in healthy samples.²¹ Correspondingly, it could be declared that reflexology massage leads to the calmness of hyperactive regions and stimulation of inactive body parts. Moreover, foot reflexology massage is able to stimulate the parasympathetic nervous system.³⁴

Çelebiog *et al.* (2015) conducted a study to evaluate the effects of reflexology massage on anxiety levels. According to the results, performing 10 minutes of foot reflexology massage caused a

significant reduction in the anxiety levels of children with cancer during intrathecal injection,³⁵ which is in congruence with our findings. In addition, Cushall *et al.* (2010) marked that a course of massage therapy after heart surgery positively alleviated pain in the participants.³⁶

In another study by Korhan *et al.* (2014), hand, foot and ear reflexology massage (30 minutes) for five days were reported to reduce physiological parameters and use of analgesics in patients undergoing mechanical ventilation support,³⁷ which is consistent with the results of the present study. This type of massage relaxes the muscles through improving blood flow, followed by the stimulation of parasympathetic nervous system and reduction of anxiety levels.³⁸ Therefore, application of reflexology massage is considered to be a profitable intervention, which could be used to restore tranquility and reduce patient anxiety in high-risk conditions, as well as the elevated anxiety levels of patients due to chronic diseases.³⁹ Massage therapy stimulates the secretion of norepinephrine and epinephrine from synaptic terminals, thereby decreasing cortisol levels, saliva in the bloodstream, mental pressure, and anxiety.⁴⁰

Inconsistent with the aforementioned studies, Padiyal *et al.* (2012) declared that foot reflexology massage increased heart rate in the samples.⁴¹ Furthermore, it was concluded that increased heart rate was due to the activation of sympathetic and parasympathetic nervous system after the foot reflexology massage. In the study by Padiyal *et al.* (2012), the intervention was implemented on healthy individuals three times, while study

population of the present study consisted of children with leukemia, who underwent the intervention procedure only once. This contradiction in results might be due to the differences in sample populations and intervention methods.

Sadeghi Sharame et al. (2009) reported that foot reflexology massage had no impact on physiological indices,⁴² which is not in congruence with our findings. This inconsistency might be due to the lack of a systematic method of reflexology massage. In the mentioned study, the left leg of the samples in the placebo group was massaged similar to the right leg of the subjects in the intervention group. In contrast, massage was performed based on valuable sources (left leg of samples in the placebo group similar to the left leg of samples in the intervention group) in the current research.

According to the results obtained by Kave'ee et al. (2015), foot reflexology massage had no significant impact on the anxiety and discomfort of patients undergoing open heart surgery.⁴³ This discrepancy could be due to the time of applying massage on the subjects; accordingly, reflexology massage was applied for three days before the surgery, and vital signs of the patients were almost stable in terms of anxiety level.

A clinical trial by Mehling et al. (2012)⁴⁴ was conducted on 23 children with cancer aged 5-18 years. According to the results, foot reflexology massage had no effect on the anxiety levels of children, which is not in congruence with our results. This inconsistency might be due to the differences in the sample size. On the other hand, demographics of the researcher and using white lab coats in the study by Mehling et al. might have adversely affected the anxiety level of patients.

One of the major drawbacks of this study was differences between the samples in terms of anxiety threshold, as well as cultural, social, and mental factors, which might have affected the results. Moreover, the samples were heartened by the presence of parents during injection, intervention, and data collection, which could have manipulated the effects of intervention. Another limitation of this study was the differences between the samples in terms of gender and educational level, which occurred due to random assignment of the

participants to the study groups. Given that this study was performed in only one healthcare center, generalization of the results must be carried out with caution.

5. Conclusion

According to the results of this research, foot reflexology massage significantly reduced the anxiety level and improved the vital signs of children with leukemia aged 6-12 years undergoing chemotherapy. Since nurses have long-term interactions with patients, it is recommended that nurses incorporate feet reflexology massage into care, which is safe, cost-efficient, and well tolerated by children. It is also suggested that this intervention be performed on homogenous groups (in terms of gender and educational level) at different time intervals and for more than one session in order to obtain strong evidence to support this approach.

Conflicts of interest

The authors declare no conflicts of interest.

Authors' contributions

Akram Ghazavi: study design, study implantation and drafting of the manuscript. Batool Pouraboli: participation in study design and implantation, drafting of the manuscript. Sakineh Sabzevari: study design, drafting of the manuscript. Moghadameh Mirzaei: data analysis, participation in drafting of the manuscript.

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