

Effect of Left Sole Massage on Pain Relief and Haemodynamic Condition of Patients with Chest Pain- A Randomized Controlled Trial

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ABSTRACT

BACKGROUND

Reflexology for chest pain, ache, burning or stabbing sensation in the chest is most commonly performed on the feet. Pitchfork of left sole is the cardiac reflex point. This study aimed to evaluate the effect of left sole massage on haemodynamic and pain relief in patients with chest pain.

METHODS

This cross over clinical trial study was conducted on 117 patients with chest pain admitted to Imam Khomeini hospital's emergency room in Ardabil. McGill visual pain scale was applied to measure pain intensity, and left sole massage was used for alleviating pain which was evaluated in two steps. The significance level was regarded at $p < 0.05$.

RESULTS

The results demonstrated that according to paired and independent t-test, the level of pain severity in the massage group had a significant difference with that of the control ($p = 0.011$). Furthermore, the participants in reflexology group had the mean score of 142.0 ± 4.41 for systolic blood pressure, 89.8 ± 2.78 for diastolic blood pressure, and 76.4 ± 4.20 for Pulse Per Minute before intervention; however, they changed to 138 ± 4.28 , 87.2 ± 2.70 , and 76.4 ± 3.28 (normal range), respectively. There was a significant difference in the ratings of both pre- and post-intervention ($p < 0.05$) based on the paired t-test.

CONCLUSIONS

In future, left sole massage can be used as proper supplement for medical therapies and analgesics and can reduce the number and dose of drugs administered for management of haemodynamics and narcotics for chest pain relief.

KEY WORDS

Massage Therapy, Reflexology, Haemodynamic Condition, Pain

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BACKGROUND

Chest pain, ache, and burning or stabbing sensation in the chest are some of the most common symptoms of angina. Associated symptoms such as nausea, dyspnoea or vomiting are, however, more common among women than men. (1,2) Chest pain is reported to account for 20-30% of all emergency medical admissions.(3) Reflexology is a treatment rooted in the traditional Eastern philosophy that qi, or life energy, flows through the body along pathways known as meridian. As vital energy flows through the meridians, it forms tiny whirlpools close to the skin's surface at places called acupuncture points. These points function somewhat like gates to the moderate flow of qi.(4) When the flow of energy becomes blocked or congested, people experience discomfort or pain on a physical level.(5) Reflexology is most commonly carried on on the feet. Pitchfork of left sole is the cardiac reflex point (See figure 1 for the foot reflex areas).

Massage is a simple method to ease pain as well as aiding relaxation, and promoting a feeling of wellbeing and a sense of receiving good care. It is thought that physiological and clinical outcomes can be improved by providing symptomatic relief of pain through physical and mental relaxation.(6,7,8) Indeed systematic application of touch is called massage.(9) It is also held that massage can increase the threshold of pain by releasing of endorphin.(6,7,8) Strong, sustained touch in massage can improve blood flow more than any other forms of touch. On the physical level, massage lowers blood pressure, slows heart rate, and promotes deeper and easier breathing.(10) Moreover, pharmacological and non-pharmacological sufficient interventions, assessment, as well as evaluation of the patient reaction, paves the way for effective pain management. For instance, there are various approaches to control it; the use of local anaesthesia techniques (Epidural and cry analgesia), systematic therapies

(narcotic and non-narcotic drugs), as well as complementary medicine techniques (Massage therapy and acupuncture).(11) Today, upload analgesics, even though, are the foundation of pain management, they alone are not sufficient analgesia to alleviate pain(12) and have a limited therapeutic spectrum and complications, including insufficient pain treatment, respiratory depression, as well as too much relaxation that makes the condition much more complex.(13) More care should be taken to treat pain since most heart diseases are more likely to occur by aging, and older patients are subjected to the side effects of systematic analgesia most often. Recently, the use of supplementary therapeutic techniques, including massage has been raised in treatment units, which result in pain relief, relaxation, and anxiety reduction. There is still no scientific consensus on these approaches' action mechanism. Metabolic balance to the tissues is brought through massage therapy that manipulates soft tissues.(14) Each metatarsus has more than 7,000 nerves. Reflexology experts claim that vital energy or life force is flowing alongside the pathways in the legs to all body organs, and any barrier in the flowing at the end will result in disease; in each leg, reflexology points' stimulation may breakdown such barriers in the canal flow and sources the release of energy. In each part of the body, such paths are connected with metatarsus over neural pathways. In massage therapy, touching soft tissue decreases pain so rises relaxation and comfort of the patients and also decreases muscle tension together with anxiety. Endorphins and enkephalin may be released by massage. Reflexology is a basic and invasive technique with no complication, which may be considered as a part of nursing care.(15) Then We hypothesize that massage therapy on acupuncture points in pitchfork of left sole in patients with chest pain will relieve participants' pain. This research aimed to determine left sole massage impact on pain relief in patients with chest pain.

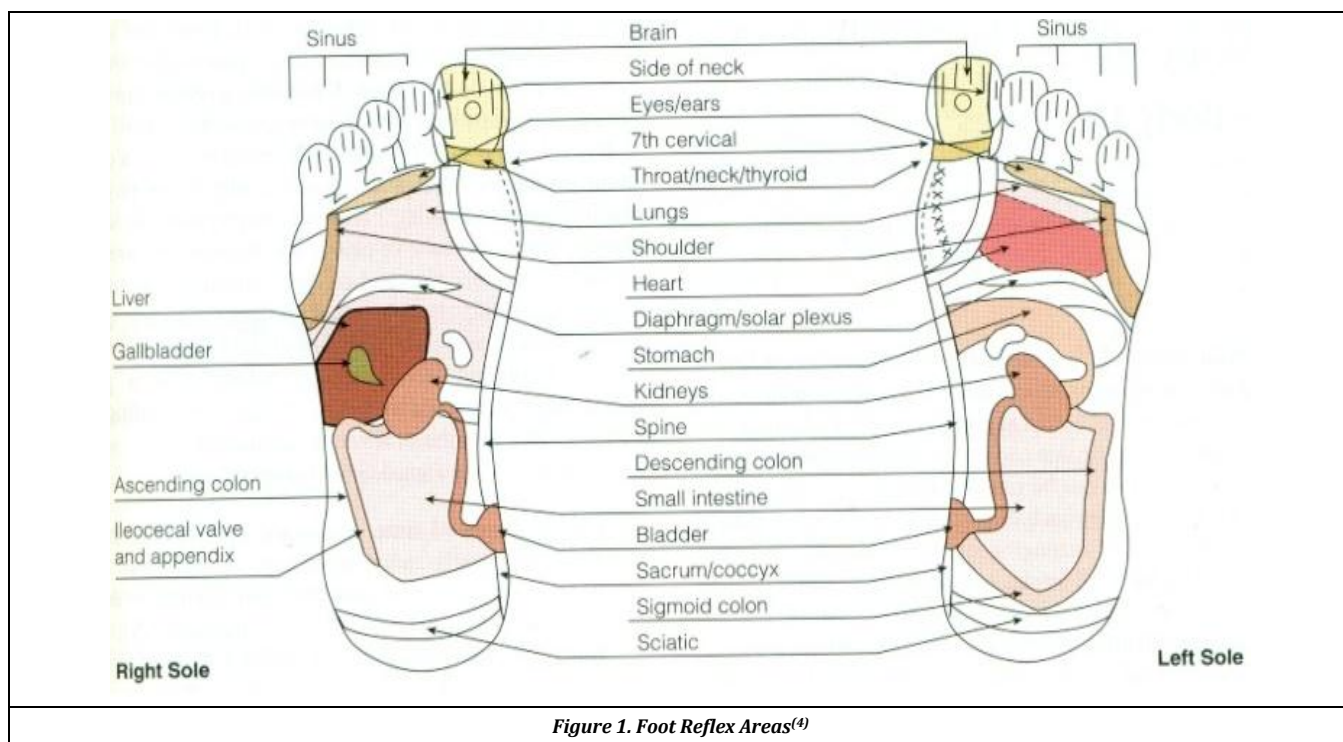


Figure 1. Foot Reflex Areas(4)

METHODS

This cross over clinical trial study was conducted between November 2015 & April 2016. The subjects were adults with chest pain. The participants (Admitted patients to emergency room of Imam Khomeini hospital in Ardebil) were evaluated taking the inclusion and the exclusion criteria. They were asked to provide informed consent written and at random were allocated to a treatment group (n=57), i.e., massage group, and a control group (n=60), placebo. Three patients in the control group left the study and went to a private hospital. The Intention to treat and the per-protocol support approaches were applied to analyze the omitted data. The sample sizes of 60 in each group were selected to achieve at least 80% power (84% actual) to detect a difference between the group proportions of 0.45. The proportion in group 1 (intervention) was assumed to be 0.35 under the null hypothesis and 0.8 under the alternative hypothesis. The proportion in group 2 (control group) was 0.35. The significance level actually achieved by this design was 0.050.

A sponsor-independent contractor made the allocation. A registration form sent to the allocation center is filled out by the researcher upon informed consent. The registration form consists of information on the criteria for inclusion and exclusion of subjects. A registration report is sent to the researcher by the allocation center upon getting the registration form. The researcher ensures that the patient meets the research requirements, and when the washout time is accomplished, and he sends a second registration form to the allocation center. The patient is randomized by the allocation center based on the above pre-defined criteria, and the researcher receives this data. At the study enrolment, randomization is performed once. Patients are allocated to two groups at the post-enrolment randomization: intervention and control group by blocked randomization. The 117 participants needed 10 blocks to get into these blocks. These 10 blocks were selected at random by placement. The first block was also randomly selected, with the researchers blindfolded and selected from a random number table. This four-digit number started with 04. This was the first block to determine the next 9 blocks, from the left of the same number, the numbers whose first two digits were in the range 1 to 6, one after the other. Numbers greater than 6 were rejected and the next number was selected. In total, 28 numbers, the first two digits of which were not under six, were rejected and 10 were selected. The modes were then written in order. This operation was checked four times to ensure it was correct.

To measure pain intensity, McGill's visual pain scale was applied. Milzak in 1975 developed McGill pain scale that has been tested in numerous investigations. Now it is regarded as being among the scales of pain gradation. In various situations, the pain intensity has been investigated via this scale.⁽¹⁶⁾ The scale of McGill visual pain, indeed, is a horizontal ruler that ranges from 0 to 10 to calculate pain intensity. 0 is painless, and 10 is very severe pain in this ruler.⁽¹⁷⁾ The patients were initially trained to apply this scale, and next, their pain intensity was registered. Furthermore, in this phase, certain haemodynamic parameters, including blood pressure and pulse were calculated. A nurse, qualified and experienced in the scope,

massaged left sole of the patients in metatarsals of 2, 3& 4 (Adductor hallucis) for 15 minutes in the massage group.

The massage intervention consisted of gentle/ light effleurage; myofascial and petrissage activate point release. The massager washed hands with warm water and pressed the point with her thumbs both, with no pause. The patient then was asked concerning the pain intensity and information was recorded. Also, the crucial signs were evaluated and recorded. In the placebo group, the patients received 3 ML normal Saline 0.9% by intravenous injection (for blinding); besides, an indeterminate point on the right foot was massaged as an alternative of the reflexology foot massage. Then patients were only checked and there was no intervention for 15 min, which was called wash out period. Afterwards we counter balanced two groups and previous control group received massage therapy as an intervention. At this stage, three patients were excluded from study because she was willing to visit a private hospital, and the study went ahead with 57 patients. Before and after intervention both groups completed visual pain scale, finally we compared the results of step 1& 2 (See figure 2). Data collectors were blinded to treatment assignment. Just before and after each treatment session by treatment providers aware of treatment assignments, immediate results were achieved. Routine cares (without analgesia) along with the identified interventions were provided for all participants (case and control).

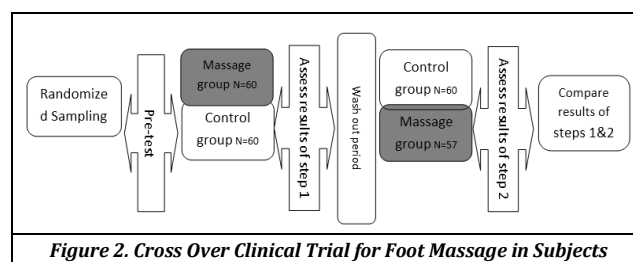


Figure 2. Cross Over Clinical Trial for Foot Massage in Subjects

Ethical Considerations

The Ethics Committee approved the study, and researchers followed the Helsinki Declaration for medical research including human subjects. Each participant signed an informed written consent form. The participants were assured that talking part in this study was voluntarily, and they can quit at any time and all information will remain confidential. The study was registered at the Iranian Registry of Clinical Trials (IRCT), available at <http://irct.ir/>, with registration number of "IRCT201503244256N5".

Inclusion Criteria

The criteria for inclusion of participants included age between 18 and 70 years, having no history of diabetes, non-addiction, having healthy feet, and full consciousness, and not suffering from mental problems.

Exclusion Criteria

Patients, prior to their visit for chest pain, who had been the subject of coronary revascularization during the previous year, were excluded.

Data Analysis

Data analysis was carried out by SPSS software version 16 through descriptive and inferential statistics such as Chi-

square, paired t-test, and independent t-test. The significance level was regarded at $p < 0.05$. Also, the Intention to treat approach and the per protocol support method applied for data analysis. But we didn't any missing value.

RESULTS

Table 1 demonstrated 117 subjects' characteristics (57 individuals in the case group and 60 individuals in control one). The control and intervention groups were similar in gender, age, educational background, economic factors, lifestyle characteristics, and medical treatments. These socio-demographic characteristics were similar for both groups and exhibited insignificant difference ($p > 0.05$) (See Table. 1). Also, independent T test result for sever of pain score between intervention and control group was no significant difference ($p = 0.88$). We changed the intervention and control group in step II. In both step I and II, there was statically significant difference ($p < 0.05$).

Characteristics	Case		Control		p Value
	N	%	N	%	
Age (mean ± SD)	59.4±1.93		58.67 ± 1.82		p>0.05
Sex					
Male	37	61.7	37	61.7	
Female	20	35	23	33.3	
Marital status					
Single, divorced...	4	6.6	12	19.4	
Married	53	86.8	48	77.4	
Habitat					
Urban	47	77	48	80.6	
Rural	10	16.4	12	19.4	
Blood pressure					
Systolic mmHg	142.0±4.41		136.2±4.23		
Diastolic mmHg	89.8±2.78		87.2±2.70		
Pulse Per Minute	76.4±4.20		76.4±3.28		
Drugs					
Aspirin/NSAIDS	56	93.3	55	91.6	
Smoking	15	25	21	35.6	
Alcohols	0.0	0.0	1	5.1	
Medical diagnoses					
Chest pain	57	96.3	60	100	
Activity					
None	51	89.4	51	85.0	
Intermediate	6	10.0	8	13.3	
Sever	0	0.0	1	1.7	
Total	57	100	60	100	

Table 1. Characteristics of Respondents (n=117)

Pain Severity (0-10)	Step I				Step II		
	Time	Before	After	Pair t Test	Before	After	Pair t Test
	Group	Mean±SD	Mean±SD		Mean±SD	Mean±SD	
Pain Severity (0-10)	Intervention	5.38 ± 1.35	4.11 ± 1.35	p=0.000	5.36 ± 1.52	4.05 ± 1.70	P=0.000
	Control	5.06 ± 1.27	5.23 ± 1.55	p=0.124	4.70 ± 1.19	4.73 ± 1.26	P=0.718
Compare intervention	Independent t-Test	t=-0.42 df=115 p=0.67	t=5.28 df=115 p<0.001	-----	t=9.42 df=115 p<0.001	t=0.82 df=115 p= 0.011	-----

Table 2. Compare of intervention and Control Group

In the foot reflexology group, their average pain severity, before massage therapy, was (5.38±1.35) which is moderate score but after the intervention decreased to (4.11±1.35). Although the control group had (5.06±1.27) pre-test pain

severity. In the post-test, it increased to (5.23 ± 1.55), and there was a meaningful difference between the scores of the groups prior to and following intervention ($p < 0.05$) based on the paired t-test.

Also the participates in reflexology group had the mean score of 142.0±4.41 for systolic blood pressure, 89.8± 2.78 for diastolic blood pressure and 76.4±-4.20 for Pulse Per Minute before intervention but they changed to 138 ± 4.28, 87.2±2.70 and 76.4 ±-3.28 (normal range), respectively, after the intervention and based on the paired t-test, a meaningful difference was observed in scores of both prior to and following intervention ($p < 0.05$) (see Table 2).

Paired t-test was done to assess the effect of left sole massage on pain severity of each group after counterbalancing them in step 2 (see table 2). The study group's pain level was upper than that of the pre-intervention control group; between post- and pre-intervention scores, a meaningful statistical difference ($p = 0.000$) was observed. Table 2 provides the Independent t-test result and compares the experimental group with the control. As it can be seen, the post intervention scores of the experimental and control groups were significantly different ($p = 0.011$).

DISCUSSION

Among the most disturbing diseases, heart disease is one that has assigned itself the highest death rate.⁽¹⁸⁾ Unrelieved pain may be transformed into psychological, emotional, as well as physical distresses, which have an adverse impact on the prognosis, as well as the disease and surgery outcome.⁽¹⁹⁾ Pain results in less motion in the patients; they attempt to decrease their pain over light breathing and less chest mobility so that they will have hypoxemia and pulmonary dysfunction, the recovery of patient will be hindered, and his/her life even threatened.⁽¹⁾ Insufficient pain relief might also enhance sympathetic response that promotes cardiac function and raises the intake of myocardial oxygen. Thus, patients with partial cardiac reserve and ventricular dysfunction may not rise oxygen supply to preserve proper balance between oxygen supply and demand, and it results in tissues without oxygen, as well as normal cell function and haemodynamic changes,⁽¹²⁾ hence, loss of pain control may have negative impacts on people health.⁽⁴⁾ The pain also triggers the nervous and cardiovascular systems sequentially. The rates of heartbeat, together with the blood pressure boost and lead to an increase in myocardium oxygen demand.

Further, the pain has an impact on the patients' activity rate.^{(1),(20)} The participants in this study suffered from chest pain, before intervention, while after intervention and following left sole massage therapy on reflex point, their pain relived and felt comfort. Numerous investigates support generally the current research findings. In the early 1900's in the south of America, Fitz Jerald introduced, for the first time some parts of body, as treatment points. Referring to the results of the investigation, the energy flows from foot to head throughout the body over vertical pathways. Pressure on a reflex point, therefore, may have an impact on whole body.⁽²¹⁾ Moreover, touching the soft tissue employed in the treatment massage may sooth pain and rise relaxation and as a result, may rise adjustment power of patients to prevailing conditions.⁽²²⁾ Reflex massage has also been used as a

supportive treatment technique in Egypt, China, as well as India for centuries.⁽²³⁾

Meanwhile gentle massage may inhibit the transmission of pain along the ascending fibers through closing the gate or activating the descending endogenous opioid and non-opioid paths to reduce nociceptive transmission and pain.⁽²⁴⁾ Reflex massage, indeed, is a non-complex and non-invasive technique, which may be taken inside patients with chest pain.⁽²⁵⁾ Some studies have demonstrated significant subsiding in pain too. Hayes established that the foot massage potentially affects the comfort and well-being sense of patients.⁽²⁶⁾ Further, Poole et al. investigated the reflex massage impact on pain decrease, as well as general health of patients with chronic back pain, and concluded that the massage affects pain alleviation significantly.⁽²⁷⁾ Lee's investigations have similarly shown that the foot massage reduces stress and anxiety effectively and may decrease the depression in patients; these may be considered the foot massage's positive side effect.⁽²⁸⁾ These results endorse our hypothesis that left sole massage has soothing impacts on pain.

In patients with chest pain in control group, there was no significant difference before and after the intervention ($p=0.124$). These participants, in spite of existing pain as duress before intervention (Placebo & uncertain point massage), felt security and comfort, which may be due to presence of caregivers, and the regular checks that they were given. Additionally, this research revealed that there is a positive association between patient's haemodynamic condition and the foot reflex massage. The subjects' mean score in reflexology group was 142.0 ± 4.41 for systolic blood pressure before intervention but it decreased to 138 ± 4.28 (normal range) after the intervention. The performed studies by Kaur J,⁽²⁹⁾ et al, 2012, & Frankal BSM,⁽³⁰⁾ 1997, and Moeini & et al,⁽³¹⁾ 2011 approve the process too. They have showed that the average systolic and diastolic blood pressure between the two groups of intervention and control had a significant difference after doing the reflex therapy. But control group's mean score was 136.2 ± 4.23 for systolic blood pressure before intervention (Placebo group received 3 ML normal Saline 0.9% via intra venous injection). Meanwhile instead of the reflexology foot massage, they were given massage on uncertain points on the right foot) and it increased to 138 ± 4.28 after the intervention that was because of their pain and full stress. Then parallel with the findings of the above studies, in the present study their blood pressure decreased (to the normal range) after intervention which can be attributed to the positive effect of left sole massage and foot reflexology on participants' haemodynamic condition.

It should be mentioned that we tried to control confounding variables and come up with more accurate results by adopting crossover method. We selected two groups and tried left sole massage therapy on pain relief in patients with chest pain in 2 steps, counterbalanced them and compared the results.

Limitations

For the present research, there were certain limitations, such as diverse deduction of every subject, personal differences and expectations. Put another way, the participants' responses to pain, as well as their physiological responses,

might have been affected by multiple confounding element, including discomfort, temperament, sleepy/awake state, and prior painful experiences even though some of these parameters were controlled in the present analyses. Despite these limitations, this study introduces an intervention that may be an effective pain management intervention and can decrease narcotics & analgesic agents' consumption. The present research, therefore, may afford a research-based intervention for health specialists.

CONCLUSIONS

As this technique is simple and cost-effective, in the future it may be applied along with medical therapies and analgesics and can reduce the number and dose of drugs administered for haemodynamic control and narcotics for chest pain relief. For examining long term effects longitudinal studies with more variables are required.

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