



Effects of Foot Reflexology on Post-sternotomy Hemodynamic Status and Pain in Patients Undergoing Coronary Artery Bypass Graft: A Randomized Clinical Trial

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Abstract

Objectives: There are contradictory results regarding the effects of foot reflexology on postoperative pain and hemodynamic status in patients undergoing coronary artery bypass graft (CABG). Therefore, the present study aimed to investigate the effects of foot reflexology on post-sternotomy pain and physiological parameters in patients undergoing CABG.

Materials and Methods: This randomized clinical trial was conducted on 40 women in Shahid Madani hospital of Tabriz in 2019. The sample size was determined based on previous studies using a formula and the participants were randomly assigned to treatment (n=20) and control (n=20) groups. In addition, all participants completed a three-part questionnaire (i.e., demographics, the visual analog scale, and hemodynamic symptoms forms) before and 40 minutes after the intervention. Then, the women in the test group received 20 minutes of left foot reflexology based on the existing method while those in the control group received no intervention. The data were statistically analyzed using the Kolmogorov–Smirnov and chi-square tests, as well as the paired sample and independent t tests at the significance level less than 0.05.

Results: The results indicated that the intervention significantly reduced systolic ($P=0.001$) and diastolic ($P=0.005$) blood pressures, along with heart ($P=0.003$) and respiratory ($P=0.041$) rates. Further, foot reflexology significantly decreased the severity of postoperative pain in the treatment group ($P=0.003$).

Conclusions: Overall, the study findings revealed that foot reflexology had positive effects on the stability of hemodynamic status and thus relieved postoperative pain in patients undergoing CABG.

Keywords: Foot reflexology, Severity of pain, Hemodynamic stability, CABG

Introduction

Cardiovascular diseases are considered as the main causes of death worldwide and are predicted to remain by 2020. According to Deyirmenjian et al (1), the drug cannot eliminate the problem in some patients with cardiovascular disease thus there is a need for surgery including coronary artery bypass graft (CABG), which accounts for 60% of all open-heart surgeries in Iran (2).

Despite the success of cardiac surgery techniques, postoperative pain is a common complication in such patients (3). Based on the results of previous research, 33%-75% of patients undergoing cardiac surgery suffer from moderate to severe pain (4). In addition, postoperative pain within the first 27-72 hours after CABG has various reasons such as surgical site incisions, chest tube insertion, tissue manipulation, and invasive procedures during the surgery (5,6).

Similarly, the hospitalization of such patients in the intensive care unit (ICU) within the first two to three days

after the surgery increases their chances of experiencing stress and anxiety, leading to an increase in their blood pressure (BP), respiratory rate (RR), and heart rate (HR), and generally, change their hemodynamic status (7).

Hence, anxiety and pain management in such patients is very essential and unavoidable for controlling their hemodynamic status (7). The use of complementary therapies including massage techniques in medical centers has increased in recent years. Soft tissue touch in massage therapy reduces pain but increases comfort in patients and relaxes them thus increasing their ability to adapt to the new situation. It is proven that there is a relationship between cardiovascular diseases and the psychological state of patients, therefore, alternative medicine is predicted to effectively promote the health and comfort of such patients (8,9).

Many studies reported the positive and beneficial effects of reflexology, therefore post-reflexology pain and the parameters of hemodynamics are controlled in

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the patients after CABG (9-12). However, Ernst found no convincing evidence in this regard in his review study (13). Pain management after CABG and hemodynamic stability in patients with cardiovascular disease are very sensitive, and pain control has positive effects on surgical outcomes. Accordingly, the present study evaluated the foot reflexology on post-sternotomy pain and physiological indices in patients undergoing CABG.

Materials and Methods

The current randomized clinical trial was performed at Shahid Madani hospital of Tabriz from January 30 to May 10, 2019. The inclusion criteria were females aged 40-80 years, complete consciousness, and full foot health, especially of the soles of the feet. Further, the exclusion criteria included affliction with peripheral arterial disease in the foot, blood disorders and thrombocytopenia, severe complications from the surgery as follows.

- Severe bleeding (more than 400 mL in an hour or more than 200 mL/h for 4 consecutive hours);
- A history of diabetes for more than 10 years;
- The implantation of an artificial cardiac pacemaker;
- Bradycardia (less than 50 beats per minute) or low BP (lower than 90.35 mm Hg);
- The use of sedatives or analgesics three hours before the intervention;
- Drug, sedative, or alcohol addiction;
- Development of postoperative cognitive or neurological disorders such as stroke.

Likewise, the sample size was calculated considering the results of previous similar studies in this field and using a sample size formula. Therefore, the sample size of 40 was selected (20 in each of the treatment and control groups) given the 0.05 level of significance and the statistical power of 0.08 (14,15). The participants were selected using a purposive sampling technique and were then randomly assigned to two groups utilizing a random number table (the random assignment was conducted by a statistician).

After visiting the participants, the researcher completed consent forms and demographic forms (including data about age, marital status, and the history of hypertension and diabetes) for all participants through conducting interviews. Then, the participants in the test group were briefed on foot reflexology and were assured that this method would not have any complication or interference with their routine treatment. In addition, the visual analog scale, applied for measuring the intensity of pain after surgery, was explained to all the participants in a simple and understandable language.

On the second day after the surgery, the assistant researcher (a trained physiotherapist) visited the ICU to measure and record the severity of pain and hemodynamic parameters (i.e., systolic BP, diastolic BP, HR, and RR) in patients after the extubation (which was performed three hours after surgery) and stabilization of their hemodynamic status (hemodynamic changes of less than

20%). Next, massage therapy was performed in silence without any conversation with the patient. The masseuse took off her watch and jewelry and washed her hands, sat in a comfortable seat at the foot of the patient's bed, and applied a lubricant cream (a transparent water-based product free of salt, alcohol, and essence that caused no allergy and had no therapeutic value) to the patient's left foot for one minute. Then, the left foot sole was massaged for 15 minutes. It began with massaging the place where the toes are connected to the rest of the foot below the third toe line by the heel of the hand from the center of the foot outwards. The solar plexus reflex point, where the foot meets the foot arch, was then pressed and massaged using both tips of the thumbs by rotational motions from the center of the foot outwards for 30 seconds. Finally, the center of the foot sole was massaged by the thumb through rotational motions with tolerable pressure so that it would not annoy the patient. The massage lasted 20 minutes. According to the principles of foot reflexology, the left areas of the body correspond to the reflex points of the left foot and hand while the right areas of the body react to the reflex points of the right foot and hand. Hence, it is necessary to stimulate the reflexes of the left foot or the left hand to reduce the pain related to the heart, which is located on the left side of the body, which is the reason for using the left foot reflexology in this study. The severity of pain and hemodynamic parameters of participants were once again measured and recorded 20 minutes after the massage therapy since the effects of foot reflexology reach their highest level 20 minutes after the massage. Those in the control group received no massage, and their hemodynamic status was measured three hours after extubation and 40 minutes later (15, 16). The researcher and the statistician were blind to the type of grouping of the patients and their group. In addition, the attrition rate during the study was equal to zero.

The participants and their first-degree relatives were briefed on the research objectives and procedures, and a written consent form was obtained from these individuals. They were also assured that the participants could discontinue the study at any stage of the research. Moreover, the ICU nurses were asked to avoid interrupting the patients' routine activities.

The data were statistically analyzed utilizing the Kolmogorov-Smirnov and chi-square tests in addition to the paired sample and independent *t* tests in SPSS-19. A *P* value of 0.05 was considered statistically significant.

Results

A total of 40 out of 63 identified patients met the inclusion criteria and thus were selected for the study. The participants were equally divided into treatment and control groups. Those in the treatment group participated in the intervention program. It is noteworthy that the attrition rate was zero throughout the study (Figure 1).

The normality of data distribution was assessed by the

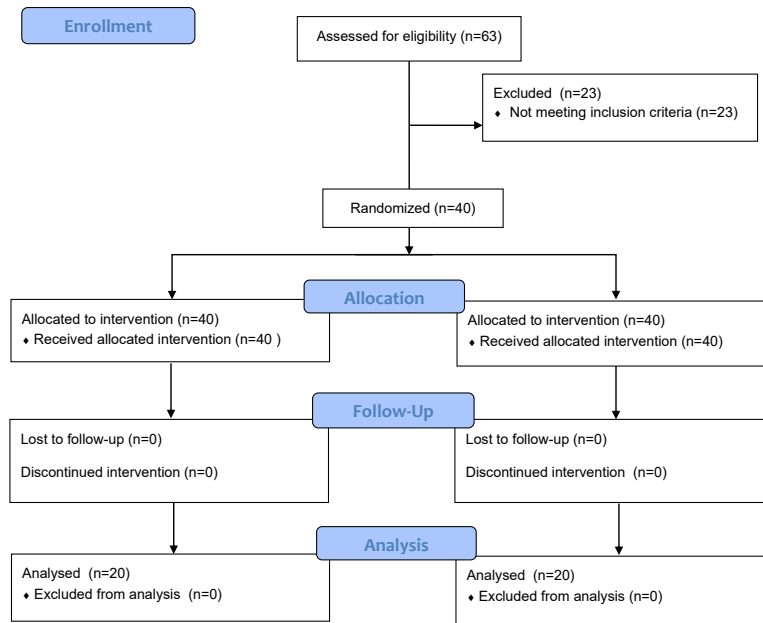


Figure 1. The Flow Chart of the Recruitment and Retention of Participants.

Kolmogorov-Smirnov test and the results showed that the data followed a normal distribution ($P < 0.05$). The data were then analyzed using parametric tests and the results were as follows.

The mean age of the participants was 57.29 ± 8.52 and 56.11 ± 8.01 years in treatment and control groups. In addition, there were no significant differences between the two groups with respect to a history of hypertension ($P = 0.001$) and diabetes ($P = 0.303$), the details of which are provided in Table 1.

There was no significant difference between the treatment and control groups in terms of pre-intervention systolic BP ($P = 1.00$), but a significant difference was observed between them after the intervention ($P = 0.041$). Moreover, there was a significant difference ($P = 0.001$) between pre- and post-intervention scores regarding systolic BP in the treatment group (Table 2).

However, no significant difference was found between the treatment and control groups regarding pre-intervention

diastolic BP ($P = 1.00$) while a significant difference was observed between them after the intervention ($P = 0.044$). In addition, there was a significant difference ($P = 0.005$) between pre- and post-intervention scores for diastolic BP in the treatment group (Table 3).

Contrarily, the results indicated no significant difference between treatment and control groups respecting HR before the intervention ($P = 1.00$) whereas a significant difference was detected between them after the intervention ($P = 0.03$). Similarly, there was a significant difference ($P = 0.003$) between pre- and post-intervention HR in the treatment group (Table 4).

As regards the RR, there was no significant difference between treatment and control groups before the intervention ($P = 0.315$). However, a significant difference was observed between the two groups after the intervention ($P = 0.001$). In addition, there was a significant difference ($P = 0.041$) between pre- and post-intervention RR in the treatment group (Table 5).

Table 1. Demographic Information of the Participants

Variables	Groups (N=40)		Test Result
	Treatment (n=20)	Control (n=20)	
Age in year (Mean±SD)	57.29±8.52	56.11±8.01	t=-0.80, df=50, P=0.911
Marital status (N)			$\chi^2=0.000^{**}$, df=1, P=1
Married	16 (80%)	15 (75%)	
Widow	4 (20%)	5 (25%)	
History of BP (N)			$\chi^2=0.000^{**}$ df=1 P=0.001
Have	18 (90%)	17 (85%)	
Not have	2 (10%)	3 (15%)	
History of diabetes (N)			$\chi^2=0.000^{**}$, df=1, P=0.303
Have	14 (70%)	15 (75%)	
Not have	6 (30%)	5 (25%)	

*Independent t test; **Chi-square test.

Table 2. Comparison of Mean Systolic Blood Pressure Before and After Foot Reflexology in Treatment and Control Groups

Group	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Paired Sample T Test
Treatment (n=20)	110.25±10.25	100.15±10.10	t=5.25, df=25, P=0.001
Control (n=20)	110.25±10.30	110.50±10.35	t=-0.612, df=25, P=0.901
Independent t test result	t=0.00, df=50, P=1.00	t=-2.50, df=50, P=0.41	

Table 3. Comparison of Mean Diastolic Blood Pressure Before and After Foot Reflexology in Treatment and Control Groups

Group	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Paired Sample T Test
Treatment (n=20)	70.25±8.11	60.10±5.75	t=0.00, df=25, P=0.955
Control (n=20)	9.85±70.25	70.20±7.60	t=2.50, df=25, P=0.005
Independent t test result	t=0.00, df=50, P=1.00	t=-2.50, df=50, P=0.44	

Table 4. Comparison of the Mean Heart Rate Before and After Foot Reflexology in Treatment and Control Groups

Group	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Paired Sample T Test
Treatment (n=20)	90.25±8.11	81.75±11.75	t=4.50, df=25, P=0.003
Control (n=20)	90.50±12.25	91.25±11.50	t=-1.41, df=25, P=0.191
Independent t test result	t=0.00, df=50, P=1.00	t=-0.711, df=50, P=0.03	

Table 5. Comparison of the Mean Respiratory Rate Before and After Foot Reflexology in Treatment and Control Groups

Group	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Paired Sample T Test
Treatment (n=20)	18.25±3.25	21.75±3.25	t=0.001, df=25, P=0.001
Control (n=20)	21.50±5.20	22.15±4.50	t=-1.33, df=25, P=0.315
Independent t test result	t=0.211, df=50, P=0.094	t=-0.060, df=50, P=0.041	

Table 6. Comparison of the Mean Severity of Pain Before and After Foot Reflexology in Treatment and Control Groups

Group	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Paired Sample T Test
Treatment (n=20)	5.25±1.20	3.15±1.55	t=0.001, df=25, P=0.001
Control (n=20)	5.08±1.20	4.91±1.85	t=-1.33, df=25, P=0.228
Independent t test result	t=-1.211, df=50, P=0.094	t=0.055, df=50, P=0.003	

As shown in Table 6, the results demonstrated that there was no significant difference between treatment and control groups regarding the severity of pain ($P=0.228$). Contrarily, a significant difference was found between them after the intervention ($P=0.001$). Likewise, there was a significant difference between pre- and post-intervention severity of pain in the treatment group ($P=0.003$).

Discussion

The present study investigated the effects of foot reflexology on post-sternotomy pain and physiological parameters in patients undergoing CABG. The findings indicated that foot reflexology tangibly improved the

hemodynamic status and reduced pain in patients.

The results regarding the reduced systolic and diastolic BP after foot reflexology in this study is consistent with the findings of Moeini et al (17), Kaur et al (18), and Eguchi et al (19). In contrast, Song et al (20) reported that foot reflexology had no positive effect on systolic and diastolic BP. These contradictory results can be attributed to the differences in intervention programs and the sample size. Although the mechanism of foot reflexology is not clearly known, relaxation and stress relief may be effective in lowering BP.

The study findings also demonstrated that foot reflexology had positive effects on reducing HR and RR. These results are in line with those of previous studies

(21,22). It seems that foot reflexology creates a relaxation effect that reduces HR and stabilizes RR.

Consistent with the findings of previous research (15), foot reflexology reduced the severity of pain in the current study. The precise mechanism of foot reflexology is not clear, but some of the theories, that explain how this technique functions, include the gate control theory of pain, the nerve impulse theory, and the theory of the increased secretion of endorphins and enkephalins (that controls the pain). Finally, the secretion of endorphins may cause morphine-like analgesic properties as well.

Conclusions

In general, foot reflexology is considered as an inexpensive, non-invasive, and simple technique that can be easily performed by a patient's companions and medical staff. Further, this method can stabilize hemodynamic status and thus reduce postoperative pain in patients who undergo CABG.

Limitations of the Study

Some of the research limitations include the small sample size, the lack of long-term repeated follow-up interventions, inattention to the results of placing the patients on cardiopulmonary bypass during the surgery, failure to record opioids which were administered to the patients, and the lack of access to a special room for the intervention program.

Suggestions for Future Studies

It is recommended that future studies attempt to eliminate the above-mentioned limitations and compare foot reflexology with the other techniques of alternative medicine.

Conflict of Interests

Authors have no conflict of interests.

Ethical Issues

The research project was approved by the Ethics Committee of Tabriz University of Medical Sciences (ethical No. IR.TBZMED.REC.1397.1059) and registered in Iranian Registry of Clinical Trials website (identifier: IRCT20190325043107N9; <https://www.irct.ir/trial/41755>).

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