## The Effect of Foot Reflexology on Fatigue, Sleep Quality, Physiological Indices, and Electrocardiogram Changes in Patients with Acute Myocardial Infarction: A Randomized Clinical Trial

#### Abstract

**Background:** Limited evidence is available regarding the effect of reflexology on Acute Myocardial Infarction (AMI). The present study evaluated the effect of foot reflexology on fatigue, sleep quality, physiological indices, and electrocardiogram changes in AMI. **Materials and Methods:** This clinical trial was conducted on 80 subjects with AMI. They were divided into an intervention (received reflexology for 3 consecutive days) and a control (received the routine care) group. The Multidimensional Fatigue Inventory, the Pittsburgh Sleep Quality Index, a pain numeric analog scale, a daily physiological indices form, and daily electrocardiogram were used to collect data. The collected data were analyzed in SPSS software. The study was conducted based on CONSORT criteria. **Results:** After controlling the covariates, a significant difference was found between the intervention and control groups with regard to the mean scores of fatigue ( $F_{5,80} = 16.33$ ; p < 0.001), sleep quality ( $F_{5,80} = 16.56$ ; p < 0.001), and chest pain intensity ( $F_{5,80} = 6.86$ ; p = 0.010); means of systolic blood pressure ( $F_{5,80} = 22.20$ ; p < 0.001), heart rate ( $F_{5,80} = 5.86$ ; p = 0.010), respiration ( $F_{5,80} = 9.37$ ; p = 0.020) and T-wave changes ( $\chi^2_{1,80} = 6.05$ , p = 0.010) on the fourth day of the intervention. **Conclusions:** Given the effectiveness of foot reflexology in different aspects of AMI patients, the implementation of this intervention is recommended for these patients in coronary care units.

Keywords: Fatigue, musculoskeletal manipulations, myocardial infarction, sleep

#### Introduction

Acute Myocardial Infarction (AMI) occurs as a result of a decrease in coronary blood flow. It may lead to ischemia and myocardial injury, manifesting in the form of inversed and flatten T-wave as well as rising or falling of the ST segment in the Electrocardiogram (ECG). Patients with AMI also experience some complications such as arrhythmia and changes in physiological indices such as hypertension, hypotension, tachypnea, and fever.<sup>[1]</sup> In addition to changes in physiological indices, some patients with Coronary Heart Diseases (CHDs) experience fatigue.<sup>[2]</sup> Average fatigue in Cardiovascular Disease (CVD) patients was reported to be mild.<sup>[3]</sup> Sleep disorders are another common complaint in patients with heart diseases. A previous study indicated that many patients admitted to Cardiac Care Units (CCUs) suffered from sleep disturbance<sup>[4]</sup> and low quality of sleep.<sup>[5]</sup> A study showed that 71.7% of AMI

patients hospitalized in CCUs had poor habitual sleep quality and 29.2% suffered from excessive daytime sleepiness.<sup>[6]</sup>

As mentioned above, AMI patients hospitalized in CCUs have manv complications and problems, which may have a poor prognosis for the disease. Thus, it is important to pay close attention to these problems and provide interventions in this regard. In recent years, Complementary and Integrative Health (CIH) therapies such as aromatherapy<sup>[7]</sup> and reflexology<sup>[8]</sup> have been considered to improve health outcomes. In the present study, a CIH therapy named reflexology has been considered. Foot reflexology is one of the most effective methods of CIH. A study demonstrated that reflexology improves sleep quality and reduces fatigue and pain in chronic conditions such as cancer.<sup>[8]</sup> Nevertheless, the question is whether reflexology can

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be effective in the acute phase of CVDs such as AMI. A review of the literature showed that reflexology improved sleep quality,<sup>[9]</sup> reduced anxiety<sup>[10]</sup> and fatigue,<sup>[11]</sup> and regulated physiological indices such as Blood Pressure (BP),<sup>[12-15]</sup> respiration,<sup>[13,14]</sup> heart rate,<sup>[15]</sup> Saturation Level (SPO<sub>2</sub>),<sup>[15]</sup> and pain<sup>[16]</sup> in Acute Coronary Syndrome patients undergoing coronary angiography and Coronary Artery Bypass Graft (CABG) surgery. However, a study demonstrated that reflexology did not affect physiological indices in CABG surgery patients.<sup>[17]</sup> These studies reported contradictory results regarding the effectiveness of reflexology in physiological indices. Additionally, they did not provide responses to the present study question, which was focused on AMI. Literature review also indicated that a limited number of researches have been conducted on the effectiveness of reflexology in AMI patients. Only one study demonstrated that reflexology for 3 consecutive days reduced chest pain in AMI.<sup>[18]</sup> However, covariates such as administration of nitroglycerin, antihypertensive drugs, and heart rate regulators and performance of coronary angioplasty and angiography on the day of data collection were not controlled in that study. Moreover, the effectiveness of reflexology on fatigue and sleep quality among patients with AMI has not been investigated in any studies. Hence, in order to improve evidence-based practice regarding the effectiveness of reflexology on AMI, the present study evaluated the effect of foot reflexology on fatigue, sleep quality, physiological indices, and ECG changes in AMI patients.

#### **Materials and Methods**

This randomized controlled trial was conducted with a pretest-posttest design and an intervention group and a control group. This trial was registered in the Iranian Registry of Clinical Trials (IRCT20130616013690N8; ID: 53975, 17-03-2021). Data were collected from May 2021 to January 2022. The study was conducted in the CCUs of Al-Zahra Heart Center affiliated to Shiraz University of Medical Sciences, Iran. The subjects were the patients who had AMI, and their diagnosis was approved by a cardiologist. The inclusion criteria of the research were being 18-75 years of age; speaking Persian language; having mental orientation in place, time, and person; and willing to participate in the study. Patients with infectious or bleeding ulcers in their legs, inability to tolerate foot reflexology, previous history of CVDs, and past history of MI; individuals who had undergone CABG surgery and percutaneous transluminal coronary angioplasty; and those who had previously had arrhythmias were excluded from the study. The convenience sampling method was used to choose the AMI patients. Then, the selected AMI patients were randomly assigned to the two groups via block randomization with four blocks. The 'create a blocked randomization list' software (Sealed Envelope Ltd.; London, UK) was applied to provide a block list. Each

block was placed in an envelope and was then numbered. After selection of an AMI patient through convenience sampling, a researcher assistant opened each numbered envelope sequentially and the AMI patient was allocated to the intervention or control group accordingly.

The sample size was determined based on the study conducted by Rambod et al.,[8] which evaluated the effect of reflexology on fatigue, pain, and sleep quality in lymphoma patients. According to the results related to fatigue and  $\mu c - \mu i = 9.14$ ,  $\sigma = 11$ ,  $\alpha = 0.05$ , and  $\beta =$ 90%, a sample size of 64 AMI patients was determined for the research (32 AMI patients in each group). Based on another study conducted by Rambod et al.[7] to determine the effect of aromatherapy on physiological characteristics in patients with AMI and considering the results related to systolic BP,  $\mu c - \mu i = 20.44$ ,  $\sigma = 14$ ,  $\alpha$ = 0.05, and  $\beta$  = 90%, a sample size of 22 subjects was estimated (11 patients in each group). Considering the maximum calculation of sample size and a dropout rate of 20%, the sample size was increased to 80 participants (40 in each group). Initially, assessment for eligibility for participation in this study was conducted on 100 AMI patients. However, 10 patients were identified as not meeting the inclusion criteria and 10 had the exclusion criteria. Thus, 80 patients participated in the research and were randomly assigned to the intervention and control groups. It is worth mentioning that all the 80 patients finished the study [Figure 1].

The intervention was conducted at 4 P.M.<sup>[8]</sup> for 3 consecutive days.<sup>[19]</sup> It should be noted that at least 2 hours must have passed since the patient entered the CCU or performed invasive procedures and the patient must be in a stable condition so that she/he can undergo daily reflexology intervention. Reflexology was performed based on the following procedure. The patient lay on a bed in a quiet place. After that, a pillow was used to elevate the AMI patient's legs and feet 6 inches. Reflexology was then conducted on each foot for 15 minutes by a certified reflexologist sitting below the patient's feet. The foot reflexology procedure involved holding, pressing, sliding, gliding, stretching, and rotations. First, the reflexologist rubbed his/her hands to warm them. In the second stage, the patient's feet were rubbed by the reflexologist's hands using sweet almond oil for 5 minutes. When the feet were suitably warm, reflexology was done based on the following points for 15 minutes: the thumb toe and solar plexus affect sleep; the inner and outer edges of the foot, sole, and heel of the ankle are related to fatigue;<sup>[8]</sup> and the ball of the foot below the big toe and the palm below the thumb are related to heart. The solar plexus is located in an area at the center of the sole, almost two-thirds of the height above the heel [Figure 2]. Subsequently, the patient's feet were rubbed for 5 minutes.<sup>[20]</sup> The reason for performing the intervention for 3 days was that patients with AMI would be hospitalized for 5 days. The intervention was



Figure 1: Flow diagram of the patients with AMI who participated in the study



Figure 2: Reflexology sites in this study

conducted for 3 days, and on the fourth day, the variables were evaluated.

The foot reflexology complications and side effects such as fatigue, foot swelling, frequent urination, and bowel movement<sup>[8]</sup> were assessed every day for 4 days. The mobile number of one of the researchers of the research team was given to the participants to report any complications. However, no complications and side effects were reported. The AMI patients in the control group did not undergo any type of reflexology and only received the routine hospital care and treatment. It should be noted that the statistician and the individual involved in the data collection were blind to the intervention and control groups.

In this study, the clinical and demographic characteristics of AMI patients were assessed. The data collection tools included the Multidimensional Fatigue Inventory (MFI)<sup>[21]</sup> and Pittsburgh Sleep Quality Index (PSQI),<sup>[22]</sup> which were completed 30 minutes before the intervention and 4 days after that at 8:00 A.M. The other collection tools of the study were physiological indices including systolic and diastolic BP, heart rate, body temperature, peripheral SPO<sub>2</sub>, chest pain intensity, and ECG parameters such as ST segment (normal, elevation, or depression), T wave (normal, inverted, or flat), and heart arrhythmia. These outcomes were evaluated 30 minutes before foot reflexology and daily up to the fourth day of the intervention at 7:00 A.M. The data were collected by a CCU nurse. She was not aware of the intervention and control groups.

MFI is a self-report instrument used to assess patients' fatigue. It includes 20 items scored on a 7-option Likert scale. The total MFI score ranges from 20 to 100. Higher scores show a higher level of fatigue. The items are divided into five dimensions including general fatigue, physical fatigue, mental fatigue, reduced motivation, and reduced activity. The validity and reliability of this inventory have been approved by Smets *et al.*<sup>[21]</sup> Accordingly, the construct and convergent validity of the scale have been confirmed.

Its Cronbach's alpha was also obtained as  $0.84^{[21]}$  and  $0.75^{[8]}$  In our study, the internal consistency of the MFI was determined using Cronbach's alpha ( $\alpha = 0.81$ ).

In order to measure the patients' quality of sleep, PSQI was used. It consists of nine items. The items are scored on a scale ranging from 0 to 3. Therefore, the total score of the PSQI could range from 0 to 21. A PSQI score over 5 shows poor sleep, and higher scores indicate poorer quality of sleep.<sup>[22]</sup> The reliability of the Persian version of the PSQI was approved by a Cronbach's alpha coefficient of 0.85.<sup>[8]</sup> In our study, the Cronbach's alpha of the index was calculated to be 0.88.

Physiological indices such as systolic and diastolic BP, heart rate, and SPO<sub>2</sub> were measured using a calibrated central digital heart monitoring device (i.e. cardioset portable patient monitor, LX 110, Isfahan Optic Industries Co., Iran). To assess BP, the AMI patient lay in a supine position and the cuff was wrapped around the upper arm based on the standard procedure. After pressing the Noninvasive Blood Pressure (NIBP) on the heart monitoring device, it worked automatically and showed the systolic and diastolic BP. To assess the heart rate, while the patient was in the supine position, a 5-minute ECG recorded strip was read. Moreover, SPO, was measured using a pulse oximeter. In doing so, the patient was asked to rest his/her hand on his/her chest at the heart level. Then, the probe of the oximeter that was connected to the central digital heart monitoring was placed on the patient's middle finger. The oximeter was kept in place for 1 minute to be stable. After that, the highest result was recorded. Furthermore, a 12-lead ECG (Yasham 635, Dahian Pezeshki Pishro Co., Tehran, Iran) was used to assess the ECG parameters such as ST segment, T wave, and heart arrhythmia. The ECG parameters were read by a cardiologist who was not in this research team. Chest pain intensity was measured using a numerical analog scale.[7] It was in fact an 11-point numerical scale numbered from 0 to 10. Finally, a noncontact infrared medical thermometer (MS5618; Mastech Digital Inc., Pittsburgh, PA, USA), which is highly accurate, was used to measure temperature. To assess the inter-rater reliability, the percentage of agreement between two independent observers was reported (ICC = 0.90).

It should be noted that the person who collected the data and a statistician who analyzed the data were blinded to the study groups. Therefore, based on the researchers' view, this was a double-blind study.

Data analysis was performed using the SPSS software (version 23; IBM Corp. Armonk, NY, USA). In this study, angiography, angioplasty, and use of nitroglycerin, antihypertensive drugs, heart rate regulators, and sleep medications were considered as confounding factors (covariates). The Kolmogorov–Smirnov test was employed to test the normal distribution of data, and Levene's test was utilized for checking the equality of

variance. Then, the data were analyzed using Chi-square, Cochran's Q test, paired *t*-test, ANCOVA, and repeated measures ANCOVA. p < 0.05 was considered statistically significant.

#### **Ethical considerations**

This study was approved by the Ethics Committee of Shiraz University of Medical Sciences (IR.SUMS.REC.1399.1278, date: 2.28.2021). Written informed consent forms were signed by all the AMI patients. The permission to conduct a study was received by all the AMI patients. In fact, they were made aware of the aim, duration, and outcomes of the study and the possible side effects of the intervention. Information regarding the voluntary nature of the research was also provided. The participants also had the right to discontinue their participation in the study at any stage.

#### Results

The mean (SD) age of the AMI patients was 57.42 (8.76) years in the intervention group and 59.50 (8.02) years in the control group. Most participants in the control and intervention groups were married men aged over 56 years. As can be seen in Table 1, the two groups were homogeneous with regard to the demographic and clinical characteristics. All the participants in both groups took antihyperlipidemic drugs, heart rate-regulating drugs, and aspirin.

As seen in Table 2, no significant difference was observed between the two groups concerning MFI and its dimensions, except for mental fatigue, prior to the intervention. However, a significant difference was found between the intervention and control groups concerning MFI and its dimensions such as general fatigue, physical fatigue, and reduced activity after the intervention.

Based on the results presented in Table 2, the mean (SD) score of total sleep quality was 11.10 (5.41) in the intervention group and 12.06 (5.59) in the control group before the intervention, and the difference was not statistically significant ( $F_{1,80} = 1.87$ ; p = 0.17). The results also showed no significant difference between the two groups regarding the sleep quality dimensions, except for habitual sleep efficiency, before the intervention. After the intervention, however, a significant difference was observed between the two groups with respect to the mean scores of total sleep quality and all its dimensions, except for habitual sleep efficiency and use of sleeping medications (p < 0.05).

As Table 3 depicts, no significant difference was found between the two groups regarding the means of physiological indices including systolic and diastolic BP, heart rate, and SPO<sub>2</sub> and chest pain intensity before the intervention (p > 0.05). On the fourth day of the intervention, however, a significant difference was observed between the two groups in terms of all the physiological indices, except for diastolic BP and SPO<sub>2</sub> (p < 0.05).

Variable	Grou	Test*,		
	Intervention	Control	df, <i>p</i>	
	n (%)	n (%)		
Age (years)				
41-55	16 (40.0)	10 (25.0)	2.05, 1,	
56-70	24 (60.0)	30 (75.0)	0.15	
Gender				
Male	30 (75.0)	29 (73.0)	0.07, 1,	
Female	10 (25.0)	11 (27.0)	0.80	
Marital status				
Single	3 (7.0)	4 (10.0)	1.57, 1,	
Married	37 (93.0)	36 (90.0)	0.69	
Undergoing angiography				
During the 1st day	11 (40.75)	16 (53.33)	2.00, 3,	
During the 2 <sup>nd</sup> day	3 (11.11)	5 (16.67)	0.57	
During the 3rd day	10 (37.03)	7 (23.33)		
During the 4 <sup>th</sup> day	3 (11.11)	2 (6.67)		
Undergoing angioplasty				
During the 1 <sup>st</sup> day	3 (23.07)	1 (7.15)	3.58, 3,	
During the 2 <sup>nd</sup> day	2 (15.38)	5 (35.71)	0.30	
During the 3rd day	7 (53.84)	5 (35.71)		
During the 4 <sup>th</sup> day	1 (7.69)	3 (21.43)		
Having diabetes				
Yes	10 (25.0)	16 (40.0)	2.05, 1,	
No	30 (75.0)	24 (60.0)	0.15	
Having hypertension				
Yes	16 (40.0)	12 (30.0)	0.88, 1,	
No	24 (60.0)	28 (70.0)	0.35	
Using nitroglycerine				
Yes	18 (45.0)	20 (50.0)	0.20, 1,	
No	22 (55.0)	20 (50.0)	0.65	
Using antihypertension drugs				
Yes	28 (70%)	34 (85%)	2.58, 1,	
No	12 (30%)	6 (15%)	0.11	
Using sleep medications				
Yes	34 (85.0)	32 (80.0)	0.34, 1,	
No	6 (15.0)	8 (20.0)	0.55	

Table 1: Demographic and clinical chara	acteristics of the
AMI patients in the intervention and o	control groups

\*Chi-square

Moreover, the results of repeated measures ANCOVA showed a significant difference between the study groups regarding systolic BP and body temperature during the study.

According to the results presented in Table 4, no significant difference was found between the two groups regarding the incidence of arrhythmia and the percentage of ST-segment and T-wave changes. However, the results revealed a significant difference between the two groups concerning the percentage of ST-segment changes on the third day and the percentage of T-wave changes on the third and fourth days. In the intervention group, Cochran's Q-test showed a significant trend of the ST-segment and T-wave changes during the study.

#### Discussion

Our study results showed that foot reflexology could be used to reduce fatigue in patients with AMI. A meta-analysis study<sup>[23]</sup> and a clinical trial<sup>[8]</sup> also revealed that foot reflexology relieved fatigue. Similarly, another study indicated the effectiveness of hand reflexology in decreasing fatigue after coronary angiography.<sup>[11]</sup> Reflexology leads to the release of endorphin, which is a relaxant and painkiller substance.<sup>[24]</sup> In fact, endorphin has potent analgesic effects, reduces stress, and regulates the brain pathway,<sup>[25]</sup> which may decrease fatigue in patients with AMI.

Our study findings indicated that foot reflexology improved sleep quality in patients with AMI. Previous studies have demonstrated that reflexology promoted the quality of sleep in patients with ACS<sup>[9]</sup> and lymphoma.<sup>[8]</sup> The release of endorphin as a result of conducting reflexology has been found to modify the sleep-wakefulness cycle.<sup>[25]</sup> Moreover, reflexology relieved chest pain<sup>[18]</sup> and reduced anxiety in patients with ACS.<sup>[18,26]</sup> The abovementioned improvements in the physical and psychological dimensions of life might have regulated the quality of sleep among the patients in the present investigation.

The current study results demonstrated that foot reflexology regulated physiological indices such as systolic BP, heart rate, respiration, and body temperature. The results of some studies also indicated that reflexology regulated BP,<sup>[12,13]</sup> heart rate,<sup>[27]</sup> and respiration<sup>[13]</sup> in cardiovascular or other diseases. Moreover, a meta-analysis showed that foot reflexology was effective on vital signs such as BP, heart rate, respiratory rate, and pulse oxygen saturation.<sup>[28]</sup> Therefore, as a result of using reflexology, modifications in vital signs might be expected.

In this study, the trend of the ST-segment and T-wave changes was significant in the reflexology group during the study. This implied that conducting reflexology might reduce myocardial injury and ischemia that could occur as a result of AMI. To date, no study has reported the impact of reflexology on ST-segment and T-wave changes. Only one study conducted on patients with AMI indicated that other kinds of CIH such as inhalation aromatherapy with lemon reduced myocardial injury and ischemia.<sup>[9]</sup> Generally, the occurrence of AMI is accompanied by changes in physiological indices including tachycardia, hypertension, tachypnea, and sometimes fever.<sup>[1]</sup> In the present study, reflexology regulated physiological indices such as BP, heart rate, respiration, and body temperature. Thus, this intervention might improve the coronary artery blood flow and heart perfusion. Performance of reflexology improved SPO,

	Grou	Test****, df, <i>p</i>		
	Intervention	Control		
	Mean (SD)	Mean (SD)		
MFI*				
Before	67.47 (11.01)	69.30 (10.66)	1.71****, 5, 0.19	
After	62.37 (10.50)	68.85 (10.48)	16.33****, 5, < 0.001	
Test**, df, p	26.09, 79, < 0.001	1.82, 79, 0.06		
General fatigue				
Before	13.58 (2.14)	14.00 (2.14)	2.03****, 5, 0.15	
After	11.95 (2.06)	13.93 (2.14)	33.35****, 5, < 0.001	
Test**, df, p	20.96, 79, < 0.001	1.78, 79, 0.08		
Physical fatigue				
Before	14.58 (2.53)	14.72 (2.50)	0.45****, 5, 0.50	
After	12.97 (2.14)	14.65 (2.42)	23.13****, 5, < 0.001	
Test**, p	17.14, 79, < 0.001	1.78, 79, 0.082		
Reduced activity				
Before	15.60 (2.46)	15.92 (2.43)	1.45****,5, 0.23	
After	13.58 (2.43)	15.83 (2.46)	29.44****, 5, < 0.001	
Test**, p	22.42, 79, < 0.001	1.67, 79, 0.10		
Reduced motivation				
Before	12.75 (2.00)	12.78 (2.07)	0.11****, 5, 0.73	
After	12.67 (1.98)	12.70 (2.00)	0.17****. 5. 0.67	
Test** n	1 77 79 0 08	1 78 79 0 08		
Mental fatigue	1,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	1110, 12, 0100		
Before	10.97 (2.07)	11.83 (1.71)	7.64****. 5. 0.007	
After	10.90 (2.02)	11.75 (1.63)	0.50*****. 5. 0.48	
Test** n	1 78 79 0.08	1 77 79 0.08	,,,,,,,,	
Total sleep quality	1.70, 79, 0.00	1.77, 79, 0.00		
Before	11.10 (5.41)	12.06 (5.59)	1.87****. 5. 0.17	
After	8 40 (4 91)	12.05(5.42)	1656 * * * * 5 < 0.001	
7*** n	-5.29 < 0.001	0.00 1.00	10.50 , 5, 30.001	
Subjective sleep quality	-5.27, < 0.001	0.00, 1.00		
Before	1 58 (0 93)	1 82 (0 87)	4 18**** 5 0 04	
Δ ffer	1.17 (0.90)	1.78 (0.92)	19.03****5 < 0.001	
7*** n	4.02 < 0.001	1 41 0 16	19.05 , 9, < 0.001	
$\Sigma$ , $p$ Sleen latency	-4.02, < 0.001	-1.41, 0.10		
Before	1.93 (0.76)	1 90 (0 78)	0.002**** 5.0.96	
After	1.23 (0.80)	1.85 (0.89)	14.43****5 < 0.001	
7***	5.20 < 0.001	0.50, 0.62	14.45 , 5, < 0.001	
$\Sigma^{abc}, p$	-5.29, < 0.001	-0.50, 0.02		
Before	1.88 (0.79)	1 78 (0 73)	0 17**** 5 0 68	
After	1.36(0.79)	1.78 (0.75)	0.17, $5, 0.00$	
Alter	1.15 (0.38)	1.83 (0.75)	25.93****, 5, < 0.001	
$Z^{***}, p$	-5.21, < 0.001	-1.41, 0.16		
nabilital sleep elficiency	1.50 (0.00)	1.05 (0.00)	0.054444 5 0.005	
Beiore	1.58 (0.90)	1.85 (0.86)	8.25****, 5, 0.005	
Atter	1.45 (0.96)	1.88 (0.85)	0.51*****, 5, 0.47	
$Z^{***}, p$	-1.37, 0.08	-1.00, 0.32		

# Table 2: Comparison of the mean scores of fatigue and sleep quality and their dimensions in the intervention and control groups before and after the intervention

Contd...

Table 2: Contd						
	Grou	ıps	Test****, df, <i>p</i>			
	Intervention	Control				
	Mean (SD)	Mean (SD)				
Sleep disturbances						
Before	1.70 (0.72)	1.93 (0.88)	3.69****, 5, 0.058			
After	1.28 (0.82)	1.97 (0.80)	24.04****, 5, < 0.001			
Z***, p	-4.12, < 0.001	-1.41, 0.16				
Use of sleeping medications						
Before	1.15 (0.77)	1.33 (0.99)	2.11****, 5, 0.15			
After	1.08 (0.73)	1.30 (1.02)	3.62****, 5, 0.06			
Z***, p	-1.70, 0.08	-1.00, 0.32				
Daytime dysfunction						
Before	1.30 (0.91)	1.43 (0.84)	0.89****, 5, 0.34			
After	0.95 (0.88)	1.47 (0.82)	11.37****, 5, 0.001			
Z****, p	-3.74, < 0.001	-1.41, 0.16				

\*MFI: multidimensional fatigue inventory;\*\* Paired t-test,\*\*\* Wilcoxon test,\*\*\*\* ANCOVA (performance of coronary

angiography and angioplasty and administration of sleep and analgesic medications 24 hours before the assessment of variables as covariates);\*\*\*\*\* ANCOVA (performance of coronary angiography and angioplasty and administration of sleep medications on the 3<sup>rd</sup> day of the intervention and the mean score of mental fatigue before the intervention as covariates)

as well.<sup>[13]</sup> These effective consequences might reduce T inversion and ST elevation in patients with AMI.

The current study findings showed that reflexology decreased the severity of chest pain in AMI. Similarly, Sayari *et al.*<sup>[18]</sup> reported that foot reflexology reduced chest pain in AMI. Kardan *et al.*<sup>[16]</sup> also reported that reflexology reduced back pain after coronary angiography. In the present research, reflexology regulated vital signs and reduced myocardial ischemia and injury. Hence, using reflexology might decrease the severity of chest pain, which is related to myocardial perfusion impairment.

The strong points of the present study were determining and controlling the covariates during the study and controlling them in the SPSS software. This study also had practical implications; using reflexology might decrease fatigue, improve the quality of sleep, regulate physiological indices, and reduce myocardial ischemia and injury. Therefore, reflexology can be suggested as an easy and valuable intervention for AMI in clinical settings. Nonetheless, in order to generalize the results, more evidence-based practices are required.

One of the limitations was the length of time of this study that was 3 consecutive days. This might have affected the ineffectiveness of the foot reflexology on SPO<sub>2</sub> and diastolic BP on the fourth day. Therefore, it is suggested that a study be conducted with a longer duration and at the time of the patient's discharge from the hospital and during the recovery period at home. Since the multidimensional Post-Myocardial Infarction Fatigue (PMIF) questionnaire is also available, it is suggested that this scale be used in future studies. In this study, no limitations were considered for drug addicts and people suffering from sleep disorders. It is suggested that this point be considered in future studies.

#### Conclusion

The findings demonstrated that foot reflexology for 3 consecutive days reduced fatigue, improved sleep quality, regulated physiological indices, and decreased the incidence of ST-segment and T-wave changes in AMI. Therefore, the use of foot reflexology is recommended in AMI. Yet, further studies are needed to be performed on patients with AMI admitted to CCUs in order to improve the generalizability of the results.

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#### **Conflicts of interest**

Nothing to declare.

Group	Before		After the intervention			
•	1 <sup>st</sup> day	2 <sup>nd</sup> day	3 <sup>rd</sup> day	4 <sup>th</sup> day		
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
Systolic blood pressure						
Intervention	133.10 (10.52)	127.83 (9.18)	124.78 (7.80)	121.58 (7.58)	8.25, 1, 0.005	
Control	135.20 (10.74)	133.60 (10.26)	132.38 (9.94)	130.95 (9.20)		
Test *, df, p	0.56, 5, 0.45	6.42, 5, 0.01	13.97, 5, <0.001	22.20, 5, <0.001		
Diastolic blood pressure						
Intervention	70.18 (7.54)	69.83 (7.54)	69.10 (7.01)	68.35 (6.92)	0.002, 1, 0.96	
Control	71.60 (7.54)	71.23 (7.63)	70.03 (7.57)	69.10 (7.01)		
Test *, df, p	0.009, 5, 0.45	0.02, 5, 0.86	0.004, 5, 0.95	0.09, 5, 0.76		
Heart rate						
Intervention	79.78 (10.88)	77.68 (11.06)	75.75 (10.62)	72.73 (10.34)	1.72, 1, 0.19	
Control	80.48 (10.45)	79.95 (10.46)	79.50 (10.26)	78.93 (10.30)		
Test *, df, p	0.02, 5, 0.86	0.65, 5, 0.42	2.31, 5, 0.13	5.86, 5, 0.01		
Respiratory rate						
Intervention	15.33 (2.40)	15.00 (2.11)	14.80 (1.99)	13.87 (1.73)	1.53,1, 0.22	
Control	15.50 (2.51)	15.40 (2.39)	15.38 (2.36)	15.30 (2.07)		
Test *, df, p	0.06, 5, 0.80	0.25, 5, 0.61	1.50, 5, 0.22	9.37, 5, 0.003		
SPO <sub>2</sub> **						
Intervention	95.30 (1.77)	95.52 (1.68)	95.65 (1.67)	95.85 (1.64)	0.20, 1, 0.65	
Control	95.38 (1.67)	95.40 (1.74)	95.43 (1.71)	95.48 (1.66)		
Test *, df, p	0.01, 5, 0.92	0.25, 5, 0.61	0.43, 5, 0.51	1.78, 5, 0.18		
Body temperature						
Control	36.96 (0.24)	36.86 (0.26)	36.82 (0.26)	36.76 (0.22)	5.65, 1, 0.02	
Intervention	36.98 (0.23)	36.97 (0.22)	36.98 (0.22)	36.97 (0.23)		
Test *, df, p	- 0.38, 5, 0.70	- 2.008, 5, 0.04	- 2.88, 5, 0.005	- 4.23, 5, <0.001		
Chest pain intensity						
Control	4.30 (2.68)	3.65 (2.45)	3.40 (2.63)	2.70 (2.20)	1.83, 1, 0.17	
Intervention	4.43 (2.80)	4.30 (2.79)	4.35 (2.67)	4.25 (2.59)		
Test *, df, p	0.008, 5, 0.92	0.94, 5, 0.33	2.32, 5, 0.13	6.86, 5, 0.01		

Table 3: Comparison of the means of physiological indices in the intervention and control groups before and after the
intervention

\* ANCOVA (performance of coronary angiography and angioplasty and administration of sleep and analgesic medications 24 hours before the assessment of variables as covariates); \*\* SPO<sub>2</sub>: peripheral blood oxygen saturation level; \*\*\* RM-ANCOVA

Table 4: Comparison of th	ne frequenc	y of arrhy	ythmia and	d ST-segm	ent and T-	wave cha	nges durin	g the 4-da	y study period
	Before 1 <sup>st</sup> day		After the intervention						Test **, df, p
			2 <sup>nd</sup> day		3 <sup>rd</sup> day		4 <sup>th</sup> day		
	Yes n (%)	No n (%)	Yes n (%)	No n (%)	Yes n (%)	No n (%)	Yes n (%)	No n (%)	
Having arrhythmia									
Intervention	4 (10)	36 (90)	3 (7)	37 (93)	2 (5)	38 (95)	2 (5)	38 (95)	4.72, 3, 0.18
Control	6 (15)	34 (85)	6 (15)	34 (85)	5 (12)	35 (88)	4 (10)	36 (90)	4.71, 3, 0.39
Test*, df, p	0.48, 1, 0.49		1.18, 1, 0.28		1.45, 1, 0.23		0.74, 1, 0.39		
Having ST-segment changes									
Intervention	24 (60)	16 (40)	22 (55)	18 (45)	19 (47)	21 (53)	15 (37)	25 (63)	18.40, 3, <0.001
Control	28 (70)	12 (30)	28 (70)	12 (30)	26 (65)	14 (35)	25 (63)	15 (37)	7.36, 3, 0.06
Test*, df, p	0.88, 1, 0.35		1.92, 1, 0.17		2.49, 1, 0.11		5.00, 1, 0.02		
Having T-wave changes									
Intervention	27 (67)	13 (33)	24 (60)	16 (40)	18 (45)	22 (55)	15 (37)	25 (63)	25.71, 3, <0.001
Control	29 (72)	11 (28)	27 (67)	13 (33)	27 (67)	13 (33)	26 (65)	14 (35)	6.33, 3, 0.09
Test*, df, p	0.24, 1, 0.63		0.11, 1, 0.74		4.11, 1, 0.04		6.05, 1, 0.01		

\*Chi-square; \*\*Cochran's Q test

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