Review Paper

The Effect of Foot Reflexology on Sleep Conditions of Cardiac Patients: A Systematic Review of Randomized Clinical Trials in Iran

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ABSTRACT

Background and Objective: Due to the importance of sleep for the quality of life of cardiac patients, there is a need to find effective methods to improve their sleep quality. One of these methods is the foot reflexology (FR). This study aims to investigate the FR effects on the sleep conditions of cardiac patients.

Materials & Methods: This is a systematic review study that was conducted in 2023. After searching in the national and international databases for studies published from 1980 to 2023, 162 studies were assessed according to the inclusion and exclusion criteria, of which 147 were excluded. Finally, three randomized clinical trials that used FR were included, two were for patients with coronary artery bypass graft surgery (CABG) and one for patients with acute myocardial infarction (MI).

Results: The time of FR for each foot was in the range of 15-20 minutes and its duration ranged 2-4 days. The results of one study indicated that FR had a significant effect on sleep quality and quantity. However, other studies reported that FR was not significantly effective in improving sleep quality and quantity.

Conclusion: FR may improve the cardiac patients' sleep quality and quantity. It seems that 15-minute FR at night is effective for improving the sleep conditions of CABG patients. However, further research is required on MI patients.

Keywords: Reflexology, Massage, Sleep, Heart disease

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Introduction

Cardiovascular diseases (CVDs) are the main cause of death globally. In 2020, about 19 million death cases were attributed to CVDs globally, indicating an increase by 18.7% since 2010 [1]. The prevalence of CVDs in Iran is 1,027 per 100,000 individuals [2]. Sleep is one of the main human needs and critical moderators. Sleep problems can lead to reduced activity and a burden on heart. Sleep deprivation can result in weakened immune system, higher release of inflammatory markers (e.g. c-reactive protein, interleukin-6), adrenal insufficiency, and high blood pressure, and cardiovascular diseases [3]. The death rate of people with sleep disorders that induced heart disease is twice as those without sleep disorders [4]. Medication therapy is the gold treatment for sleep disorders, but can cause severe side effects including drug resistance, drug dependence, and drug addiction [1]. A study reported no significant difference in the sleep quality between the patients taking drugs and those with no sleep medication use. The effectiveness of drug-free treatment was lower than that of drug therapy; however, it was more permanent with no side effects [5]. Insomnia can be treated with complementary medicine [6], therapeutic touch [7], psychotherapy [8], aromatherapy [9], acupuncture [10], acupressure [11], and massage therapy [12]. Among these methods, massage therapy as a traditional, cheap, simple and non-invasive method can stimulate blood flow, relax muscles, increase oxygen supply, raise the disposal of waste products such as lactic acid, release energy, relieve fatigue, and finally, improve the quality of sleep [13]. Tensions are responsible for 75% of mental pressures. Since there are 7000 nerve endings on each foot, foot massage can lead to relaxation and removal of tension [14]. Foot reflexology (FR) has been used as a complementary and alternative therapy in Egypt and China for thousands years [15]. It is a type of massage therapy which involves applying pressure by fingers, especially the thumb, to reflex points, usually on the feet. It unblocks vital energy channels from the foot to the affected organ [16]. FR is assumed to facilitate relaxation and release endorphins, dopamine, and serotonin for relieving pain, stress, and anxiety, which consequently results in promoting the sleep quality [17]. One study evaluated the effect of FR on sleep status and reported its efficacy in patients with coronary artery bypass graft surgery (CABG) [18], while another study reported its ineffectiveness in improving sleep quality in people with CABG [12]. In a study on patients with myocardial infarction (MI), FR was ineffective among the groups, but effective within groups [19]. Thus, due to the contradictory results drawn from the studies on the effect of FR on sleep among the patients with heart diseases, an evidence-based clinical guidelines can be beneficial. Therefore, the present study aims to investigate the effect of FR on sleep quality in patients with CVDs.

Material and Methods

The is a systematic review study that was conducted in 2023. The PICO (patient, intervention, comparison, and outcome) strategy was used for extracting the related studies. This approach is commonly used to identify the components of clinical evidence and to conduct systematic reviews in evidence-based medicine [20]. Using the PICO model, we considered the randomized clinical trials (RCTs) with the following criteria: Population (patients with an accurate diagnosis of CVDs with no restriction on the types of CVDs), intervention (the intervention included only FR used for improving the quality, quantity, and depth of sleep), comparison (comparing patients received a placebo or no intervention and those received intervention regarding their sleep quantity), and outcome (assessing sleep using a valid subjective tool with favorable validity and reliability).

Two authors separately searched the Iranian databases such as SID, MagIran, and Barakat Knowledge Network System and the international databases including Web of Science, ProQuest, Medline, Springer, and Scopus using the keywords: Foot reflexology (FR), Sleep, Heart, Cardiac, Coronary, Myocardial infarction (MI), Valve, Coronary artery bypass graft (CABG), Acute coronary syndrome (ACS) for related studies published from 1980 to May 9, 2023. MeSH terms and Boolean operators (AND, OR) were also used. The reference lists of the articles were also searched. The search strategy was conducted using the preferred reporting items for systematic reviews and meta-analyses (PRISMA) checklist (Figure 1).

The relevant intervention studies in Persian or English with available full-texts were included in the study. The descriptive/analytical studies, qualitative studies, review study, abstracts of conference papers, those with inadequate report of results, and those with poor quality, particularly methodological quality (RCT studies with a score less than 3 based on JADAD scale and quasi-experimental studies with negative rating; i.e. less than 50% of the criteria met) were excluded.The JADAD Scale was used to qualitatively assess RCTs, which includes five items of randomization, method of randomization, blinding, method of blinding, and dropouts/withdrawals. Each item is scored as 0 or 1. The total score is

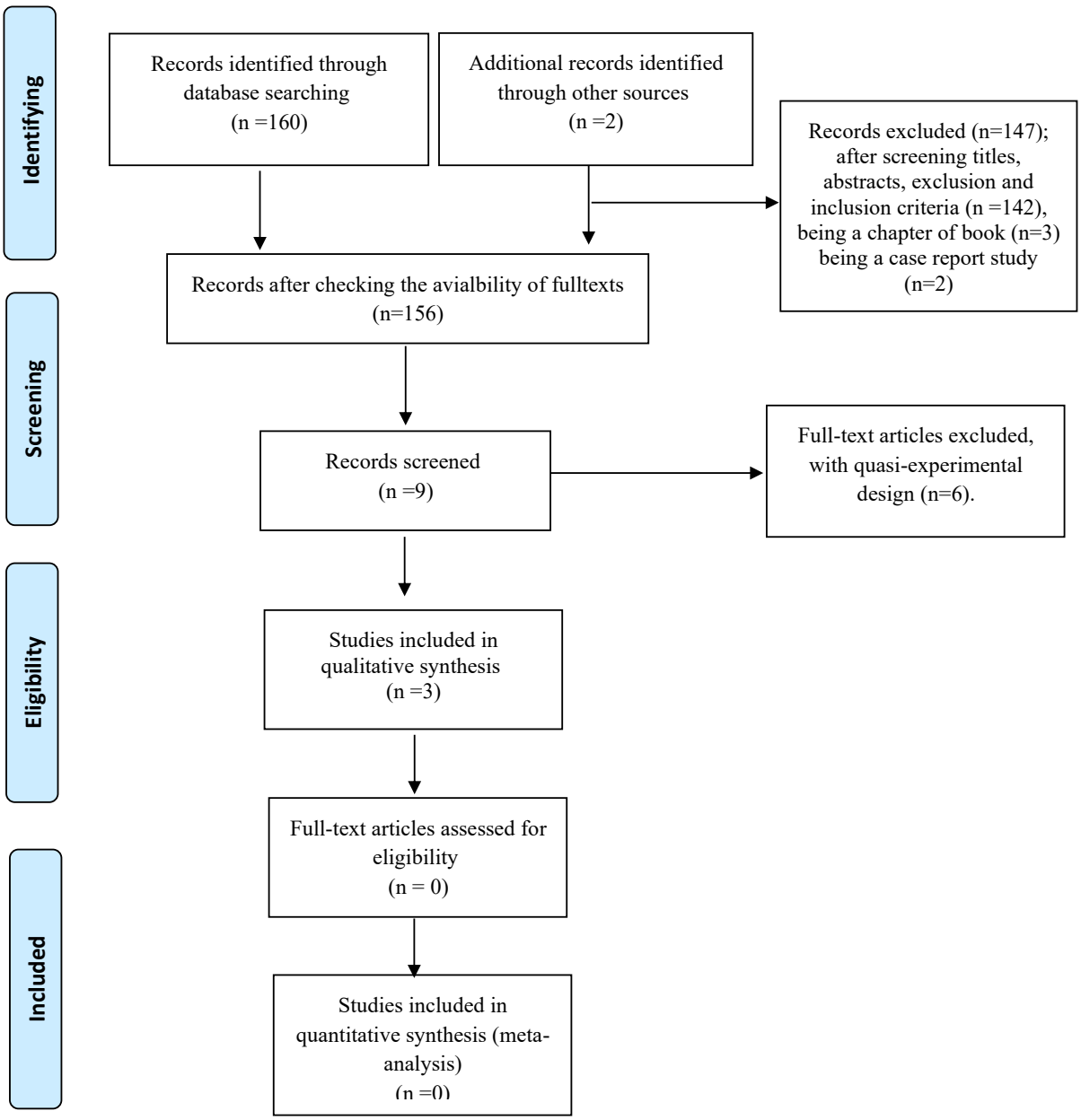

Figure 1. Flowchart of the screening process

Current Psychosomatic Research

5; a score less than 3 indicates a poor quality and a score higher than 3 shows good quality. The RCTs with a score of 3-5 points were considered included in this present study [21]. Risk of bias assessment was assessed using the ten-item checklist developed by Downs and Black with high internal consistency, good test-retest and interrater reliability, and good face and criterion validity. Positive ratings (more than 50% of the met criteria), neutral (50% of the met criteria), or negative (less than 50% of the met criteria) were determined after reviewing the studies [22]. The studies with positive ratings were included in the review. The extracted data included the author's name, year of publication, type of study, study population, sample size, the intervention duration, results, conclusions. One author completed the data extraction for all selected articles and another author randomly double-checked the articles for more accuracy.

Results

Overall, 162 article were found, of which 156 had available full-text. Then, 147 articles were excluded after the primary screening. Among the remaining 9 studies, three were RTCs [12, 18, 19] and Three studies were quazi experimental [18, 23-24] and three were hand reflexology [25-27]. Finally, three RCTs were reviewed.

Table 1. Details of reviewed studies (n=3)

Author (y)/ Study Design	Population/ Sample Size	Age of Participants	Time of Intervention	Duration of Intervention	Variable/ Instrument	Results	Conclusion
Hoseini et al. (2020)/ RCT [18]	Patients with CABG in two grupos of FR (n=20) and acupressure (20	54.2 years	15-min FR for each foot 21-min acupressure	4 consecutive nights	Sleep condition/SMHSQ	Mean hours of sleep in the FR group at baseline =23.6±23.5; Mean post-test hours of sleep in the FR =22.9±23; Mean difference =0.7; hours of sleep in the control group at baseline =23.7±24; Mean post-test hours of sleep in the control group=23.8±24 Mean difference =0.1; Mean depth of sleep at baseline in the FR group =4.9±5, Mean post-test depth of sleep in the FR group =2.8±3; Mean difference =2.1; Mean depth of sleep at baseline in control group =5.1±5, Mean post-test depth of sleep in the control group=4±4, Mean difference =1.1; Mean amount of sleep at baseline in the FR group=5.5±4, Mean post-test amount of sleep in the FR group=8.6±3, Mean difference =3.1; Mean score of satisfaction with sleep at baseline in the FR group =3.7±3.5 Mean post-test score of satisfaction with sleep in the FR group =2±3 Mean difference =1.7	FR can improve Sleep condition
Fazlollah et al. (2021)/ RCT [12]	Patients undergoing open coronary artery bypass surgery in two groups of intervention (n=30) and control (n=30)	64.29	15 min for each foot	Daily for two consecutive days	Sleep quality/ RCSQ	**Mean of deep sleep** Mean of RCSQ scores 2nd day in intervention group = 68.32±10.41 Mean of RCSQ scores 2nd day in control group = 62.80±11.86 Mean difference =5.52 **Mean of sleep latency** Mean of RCSQ scores 2nd day in intervention group = 67.00±14.89 Mean of RCSQ scores 2nd day in control group = 60.00±15.53 Mean difference =7.00 **Mean Number of awakenings** Mean of RCSQ scores 2nd day in intervention group = 69.00±12.68 Mean of RCSQ scores 2nd day in control group = 64.33±14.30 Mean difference =5.33 **Mean Ease of return to sleep** Mean of RCSQ scores 2nd day in intervention group = 70.00±10.17 Mean of RCSQ scores 2nd day in control group = 64.33±16.12 Mean difference =6.33 **Mean quality of sleep** Mean of RCSQ scores 2nd day in intervention group = 70.66±17.40 Mean of RCSQ scores 2nd day in control group = 77.00±7.49 Mean difference =7.66	

Author (y)/ Study Design	Population/ Sample Size	Age of Participants	Time of Intervention	Duration of Intervention	Variable/ Instrument	Results	Conclusion
Sayari et al. (2021)/ RCT [19]	Patients with acute MI, three groups of 30	24% aged <50 years, 38% aged 50-69 years, and 11% aged >70 years	20 min for right foot in the intervention group, 20 min for left foot in the placebo group	Daily for 3 consecutive days	Sleep quality/ PSQI and VAS	Mean PSQI score before right-foot reflexology 2nd day =8.37±0.77, Mean PSQI score after right-foot reflexology in the 3rd day =6.97±0.70, Mean difference =1.4; Mean PSQI score before left-foot reflexology as a placebo 2nd day =8.83±0.77, Mean PSQI score after left-foot reflexology as a placebo 2nd day =7.50±0.76, Mean difference =1.33; Mean PSQI score before intervention in the control group 2nd day =8.03±0.62, Mean PSQI score after intervention in the control group 2nd day =7.37±0.71, Mean difference =0.66; Mean VAS score before right-foot reflexology 2nd day =4.40±0.42, Mean VAS score after right-foot reflexology 2nd day =6.30±0.42, Mean difference =1.9 Mean VAS score before left-foot reflexology 2nd day =4.93±0.44, Mean VAS score after left-foot reflexology 2nd day =6.13±0.43, Mean difference =1.2; Mean VAS score at baseline in the control group 2nd day =5.10±0.46, Mean VAS score after intervention in the control group 2nd day =5.43±0.49, Mean difference =0.33	Foot reflexology did not show a significant effect on the sleep quality among the groups. While comparing within the groups, it was effective.

Current Psychosomatic Research

Abbreviations: RCT: Randomized clinical trial; CABG: Coronary artery bypass graft surgery; FR: Foot reflexology; SMHSQ: St. Mary's hospital sleep questionnaire; RCSQ: Richard-Campbell sleep questionnaire; MI: Myocardial infarction; PSQI: Pittsburgh sleep quality index; VAS: Visual analogue scale.

The participants in the reviewed studies included the patients with CABG [12, 18] and MI [19]. The sample size ranged from 60 to 90. The mean age of participants were 52-59 years. Sleep quality was measured with various scales such as Pittsburgh sleep quality index (PSQI), and Richard-Campbell sleep questionnaire (RCSQ), St. Mary's hospital sleep questionnaire (SMHSQ) and visual analogue scale (VAS). Similar to RCSQ, PSQI evaluates the sleep depth, the ability to fall asleep, the number of awakenings, and sleep quality. The SMHSQ evaluates the rate of satisfaction with sleep, alertness, and trouble waking up early. The VAS was a 10-cm horizontal line measuring sleep quality. The scales used in the included studies had favorable validity and reliability [12, 18, 19, 24]. In the studies by Hoseini et al. [18] and Fazlollah et al. [12], both feet were massaged, while in the study by Sayari et al. [19], only one foot was massaged. The duration of FR for each foot was 15-20 minutes for 2-4 days, usually every night before bedtime. The study conducted by Hoseini et al. [18] reported that FR was significantly effective in improving sleep quality. Sayari et al. [19] claimed that FR had no significant effect on the sleep quality of patients; however, within-group comparison revealed the FR as effective. Fazlollah et al. showed that FR was not effective in improving sleep quality [12]. Other details of the studies are presented in Table 1.

Discussion

The results of the studies reported FR had significant effect on improving the sleep quality of cardiac patients [12, 18, 19] . Hoseini et al. showed that FR can enhance sleep quality following CABG [18], which is inconsistent with the results achieved by Fazlollah et al. [12] who reported that FR was not able to promote sleep quality after heart surgery. It seems that the duration and time (night or day) of massage therapy play can affect the results of the present studies [12, 18]. In Hoseini et al.'s study, FR was done for four nights before sleep, each session lasted for 15 minutes. In Fazlollah et al.'s study, FR was performed for two days each session for 15 minutes. However, they used different scales that can affect

the quality of sleep. Hoseini et al. used SMHSQ while Fazlollah et al. used RCSQ. SMHSQ has more subscales compared to RCSQ. SMHSQ measures the amount of daytime and night time sleeps, the depth of sleep, the quality of sleep, the feeling after getting up, alertness, the number of awakenings, trouble waking up early, and difficulty falling sleep again, and difficulty sleeping the previous night. RCSQ measures the depth of sleep, the ease of falling asleep, the number of awakenings, and the subjective sleep quality. The duration of FR (15 minutes) was the same in two studies [12, 18], which can lead us to conclude that performing FR overtime, at nights before bedtime can be effective for CABG patients with sleep disorders. However, the use of SMHSQ is an important factor that can affect the results. Sayari et al. investigated the effect of FR on sleep quality in patients with MI. According to their results, FR was not effective. However, the within-group comparison showed that FR was an efficient approach. In their study, only one foot (left foot) was massaged, while in the two studies [12, 18] both feet were massaged. Although different results may be due to different time of intervention (night or day), Sayari et al.'s study applied daytime FR. Sayari et al.'s results are consistent with the results of Fazlollah et al., where FR showed no positive effects on sleep quality. Conversely, Hoseini et al. used nighttime FR which showed positive impact. Another study applying FR before bedtime also showed the beneficial effect of FR on sleep quality [27]. The use of different instruments may be reason for the difference in the results. In Sayari et al.'s study, PSQI and VAS were used to measure sleep quality, while in Hoseini et al.'s study, SMHSQ was used to measure sleep quality. Therefore, it can be said that measuring sleep quality using a suitable scale assessing more aspects of sleep quality and conducting 15-minute nighttime FR on both feet before going to bed positively affects the sleep quality of cardiac patients. It seems necessary to identify the proper duration and time for FR to obtain better sleep quality.

Conclusion

The FR as a cost-effective and easy nursing intervention seems to be effective in improving the quality and quantity of sleep among the cardiac patients. A 15-minute FR before bedtime at consecutive nights can has a positive impact on the sleep quality of patients undergoing CABG and MI. It is recommended to carry out further studies to achieve the most efficient duration, time, and number of sessions for FR for improving the sleep quality of patients with heart diseases. The meta-analysis of the included studies are also recommended.

Ethical Considerations

Compliance with ethical guidelines

All publication ethics including the avoidance of scientific misconducts (data fabrication, plagiarism, and re-submitting work for duplicate publication) were observed.

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Authors' contributions

Writing and searching: Maedeh Moradpour Ivaki; Review: Masoumeh Bagheri Nesami.

Conflict of interest

The authors declared no conflict of intervention

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