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Araştırma Makalesi / Research Article

The Effect of Post-Coronary Angiography Foot Massage on Back Pain: A Randomized Controlled Study

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Abstract
This research was conducted to assess the impact of foot massage on back pain following transfemoral angiography. This randomized controlled study was carried out with 41 patients (20 in the intervention group and 21 in the control group) who underwent transfemoral angiography in the Angiography Unit between 15 May- 30 June 2023. Data were collected using a questionnaire and a visual analog scale. In the intervention group, a 20-minute foot massage, with 10 minutes for each foot, was administered two hours after the procedure. The control group received standard pharmacological treatment. Pain assessments for all participants were conducted immediately after angiography (1st measurement), at 30 minutes (2nd measurement), at the second hour (3rd measurement), at the fourth hour (4th measurement), and at the sixth hour (5th measurement). The control group, back pain intensity at the 3rd, 4th, and 5th measurements was significantly higher than at the 1st measurement (immediately after angiography) ($p < 0.001$). In the intervention group, pain intensity at all measurements (2nd, 3rd, 4th, and 5th measurements) was significantly higher than at the 1st measurement ($p < 0.001$). Between-group comparisons indicated that, except for the 1st measurement ($p = 1.00$), back pain intensity scores at the 4th and 5th measurements in the intervention group were significantly lower than those in the control group ($p < 0.001$). Foot massage administered for 20 minutes, which is easy, without side effects, and requires no additional materials, can reduce back pain in patients following transfemoral angiography.

Keywords: Back pain, foot massage, nursing, transfemoral angiography

1. Introduction

In the treatment of coronary artery disease, catheterization procedures are commonly employed. The most widely used interventional method for this purpose is coronary angiography, which is considered the gold standard for diagnosing coronary artery disease (Baig et al., 2023; Grubic et al., 2020). Coronary angiography involves the radiological visualization of coronary arteries using a radio-opaque substance during cardiac catheterization, with the recorded images subsequently evaluated. Transradial or transfemoral approaches are preferred during coronary angiography, and the choice of approach depends on the assessment of both the patient and the physician. Studies comparing the use of femoral and radial approaches have shown that transradial artery procedures are associated with longer duration, higher radiation exposure, and greater contrast agent usage compared to transfemoral procedures, while the success rate is lower. However, transradial procedures are known to result in less hematoma, bleeding, and shorter hospital stays (Collet et al., 2017; Zhu et al., 2021). Although Transfemoral Coronary Angiography (TFA) is generally considered a safe diagnostic procedure, it can lead to complications such as hematoma, bleeding, distal embolism, and arterial thrombosis after the procedure (Aghili et al., 2022). To minimize the risk of complications following TFA, approximately 6 hours of complete bed rest is recommended. During this 6-hour bed rest period, the patient should lie in a flat position and avoid rapid movements. Complete bed rest following TFA can be an uncomfortable experience for patients, and immobility is often cited as a major contributor to post-TFA discomfort. Such immobility can lead to pain. A recent meta-analysis has identified back pain as one of the most common complaints following TFA (Busca et al., 2023; Chaiyagad et al., 2023; Elsaman, 2022; Türen et al., 2022). Post-TFA back pain can increase sympathetic stimulation, potentially raising heart rate, blood pressure, cardiac workload, and myocardial oxygen consumption. These issues can, in turn, lead to or exacerbate myocardial ischemia (Matte et al., 2016; Niknam Sarabi et al., 2021). Therefore, the management of post-TFA back pain is crucial, especially in patients with significant heart conditions. Nursing care standards for patients undergoing TFA vary. Care instructions typically used in hospitals are based on experiential knowledge rather than evidence. Hence, there is a need for research and the development of evidence-based safe care protocols for patients undergoing coronary angiography. Various pharmacological and non-pharmacological methods are available to reduce pain. Pain-relieving medications are the most common pain reduction method. However, these medications are associated with various side effects such as inadequate pain relief, respiratory depression, nausea, vomiting, and paralytic ileus. Therefore, many healthcare providers have turned to non-pharmacological methods that have the potential to reduce pain without causing serious side effects (Chaiyagad et al., 2023; Maurovich-Horvat et al., 2022). Massage is one of the non-pharmacological interventions used in nursing care. Massage is considered one of the complementary therapies with potential pain-reducing effects. It is suggested that massage can reduce pain by lowering cortisol and norepinephrine levels, increasing serotonin levels, stimulating endorphin release, facilitating blood flow, and improving oxygenation in soft tissues (Fitri et al., 2021; Hassan and Ahmed, 2022). Among massage techniques, foot massage is one of the most commonly used. Foot massage involves applying pressure to areas such as the sole and the top of the foot. Studies suggest that foot massage applied through this pressure can support blood flow in different parts of the body, thus enhancing balance and promoting relaxation (Alameri et al., 2020; Aslan and Altin, 2022). Additionally, foot massage has been shown

to have positive psychological effects, inducing relaxation (Alameri et al., 2020; Aslan and Altin, 2022). Foot massage is a simple, inexpensive, non-invasive procedure that can be used anywhere without the need for special equipment and without compromising patient privacy. Previous studies have reported the positive effects of foot massage on sleep quality, vital signs, and anxiety (Aslan and Altin, 2022; Hassan and Ahmed, 2022; Pakaya and Nento, 2023). Moreover, some studies have suggested that foot massage can have positive effects on back pain (Türen et al., 2022; Şanli and Satilmiş, 2023). However, there is a lack of sufficient research on back pain, which is the most common complaint in patients undergoing TFA. Therefore, this study aims to evaluate the effect of foot massage on back pain that occurs after TFA. This research could provide valuable evidence for nursing care plans. This research has been conducted to assess the effect of foot massage on back pain that develops after TFA.

2. Materials and Methods

2.1. Study design

This randomized controlled study was conducted in the Angiography Unit of a hospital located in western Turkey, between 15 May and 30 June 2023. To conduct the research, institutional permissions were obtained, and ethical approval was obtained from the Yalova University Human Research Ethics Committee (Date: 08/05/2023, Decision No: 2023/84). After informing the participating patients about the research, written and verbal consent was obtained from those who voluntarily wished to participate. Throughout the research, the principles of the Helsinki Declaration on Human Rights were followed. The study population consisted of patients who underwent Transfemoral Coronary Angiography (TFA) in the hospital's Angiography Unit during the specified time frame. The sample size was determined based on a similar study (Kardan et al., 2020) using G*Power 3.1.9.2 statistical software. With an effect size of d=0.99 (high effect size), power of 0.95, and α=0.05, the minimum number of patients required for inclusion in the study was determined to be 20 for the intervention group and 20 for the control group, totaling 40 patients. Inclusion criteria for the study were as follows: being 18 years of age or older, having no communication barriers, undergoing TFA, not reporting back pain prior to TFA, having no conditions such as open wounds or bone deformities that could hinder foot massage, not having any medical conditions that could cause back pain, and voluntarily agreeing to participate in the research. A total of 50 patients who met the research criteria were approached, and 42 patients willingly agreed to participate in the study. During the data collection phase, one patient from the intervention group voluntarily withdrew from the study, resulting in a total of 41 patients completing the research. After data collection, power analysis was conducted with d=0.99 (high effect size), power of 0.95, and α=0.05.

2.1.1. Randomization

Randomization was carried out using a 1:1 method. The allocation of the first patient's group was determined by drawing lots by the researcher, and after assigning the first patient to the intervention group, the remaining patients were randomized 1:1 to either the intervention or control group, resulting in a total of 21 patients in each group, totaling 42 patients for the study. One patient from the intervention group expressed a desire to withdraw from the study voluntarily, and the study was completed with a total of 41 patients. Data collection and foot massage were performed by the researcher. Since the patients were in single rooms for 6 hours of bed rest after TFA, they had no knowledge of other patients' conditions.

2.2. Data collection tools

Data collection tools were questionnaire and visual analog scale. The questionnaire, consisting of 10 questions,

was prepared by the researcher based on previous similar studies and the literature. The questionnaire assessed individual demographic data and vital signs (Alameri et al., 2020; Kardan et al., 2020). Visual analog scale (VAS*)* VAS is a scale that allows scoring from 1 to 10. VAS pain scores are evaluated as "pain-free" (score=0) and "worst pain" (score=10). Scores less than 3 are defined as mild pain, scores between 3-6 as mild to moderate pain, and scores greater than 6 as moderate to severe pain (Crichton, 2001).

2.3. Data collection

The researcher individually met with patients waiting for the TFA procedure in the patient room. Patients were informed about the purpose of the study, and those who wished to participate voluntarily were randomized into groups and asked to fill out the questionnaires. After TFA, patients were met by the researcher in their rooms, vital signs were recorded, and pain scale assessments were conducted at specified time intervals during the study procedure. Foot massage was applied to the intervention group, while the control group received standard treatment procedures. Pain assessments for all participants were conducted immediately after the TFA procedure, at 30 minutes, and then at the second, fourth, and sixth hours. In the intervention group, foot massage was applied at the beginning of the second hour, and pain assessment was performed at the end of the second hour.

2.3.1. Intervention group

Massage therapy is included in the nursing education curriculum and is one of the nursing care procedures. Foot massage was applied by the researcher. Patients assigned to the intervention group through randomization received foot massage two hours after TFA. According to information obtained from the literature review, it is observed that pain is most intense within the first four hours after the TFA procedure (Busca et al., 2023; Maurovich-Horvat et al., 2022). Based on this information, foot massage was applied by the researcher for a total of 20 minutes to each foot, with 10 minutes per foot, starting two hours after the TFA procedure. Foot massage procedure: Hands were washed, the patient was in a supine position with the foot area exposed. The researcher stood at the end of the bed facing the patient, and the researcher stroked from the distal part of the foot to the ankle three times. The same procedure was repeated three times for both the upper and lower surfaces of the foot. The researcher grasped the foot by the ankle and applied effleurage, petrissage, friction, tapotement, and vibration sequentially, with each movement being repeated three times for both the upper and lower surfaces of the foot. Finally, stroking was performed from the distal part of the foot to the ankle three times, and the procedure was completed. The same procedures were applied to the other foot in the same order. A lubricating gel, cream, or lotion was not used during the massage.

2.3.2. Control Group

Patients in the control group received the hospital's standard post-TFA treatment. Pain measurements were made according to the study procedure timing.

2.4. Data Analysis

Data were analyzed using SPSS software (version 16.0) at a significance level of 0.05. Normality distribution was assessed with the Kolmogorov–Smirnov test. Nonparametric tests were used due to the data not being normally distributed. Descriptive characteristics were presented as numbers and percentages. Group differences were evaluated using the chi-square test, and some data were presented as mean values. Intergroup variance analyses were evaluated using the Kruskal–Wallis test and Mann–Whitney U test. In-group differences were tested using the Friedman F test, and differences between sessions were tested using the Wilcoxon signed ranks test.

3. Results

3.1. Distribution of in the foot massage and control group by demographic variables

Initially, 42 patients were recruited to the study and equally allocated to two groups. A patient from the intervention group wanted to withdraw from the study voluntarily. Consequently, final data analysis was performed on the data collected from 41 patients—20 patients in the intervention group 21 patients in the control group. Age mean in the control was 54.21±5.79 and the intervention group was 53.25±6.15. Coronerarter diseases duration in these groups was 9.42±5.87 and 9.84±5.13, respectively. There were no significant differences between these groups respecting participants' age, gender, marital status, educational level, coronerarter diseases duration and ($p > 0.05$;Table 1).

Table 1. Distribution of in the foot massage and control group by demographic variables

Variables	**Intervention Group (n=20)**	**Control Group (n=21)**	**Total (n=41)**
Age mean (years) $\bar{X}\pm SD$	53.25±6.15	54.21±5.79	53.73±6.19
p*	Z=-1.557 p=0.120		
Gender			
Female	9 (45.0)	10(47.6)	19(46.3)
Male	11(55.0)	11(52.4)	22(53.7)
p**	$\chi 2$=0.414 p=0.735		
Marital status			
Married	17 (87.0)	20(95.2)	37(78.7)
Single	3(15.0)	1(4.8)	4(21.3)
p**	$\chi 2$=1.458 p=0.797		
Educational			
Literate	4(20.0)	3(14.3)	7(17.1)
Primary	11(55.0)	15(71.4)	26(63.4)
High school	5(25.0)	3(14.3)	8(19.5)
p**	**$\chi 2$**=0.597 p=0.988		
Coronerarter disease duration (years) $\bar{X}\pm SD$	9.42±5.87	9.84±5.13	9.63±5.46
p*	Z=-0705 p=0.481		

*Mann-Whitney U test, ** Chi squared, $p<0.05$.

3.1. Distribution of in the foot massage and control group by demographic variables

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Table 2. Vital signs distribution ın the groups during the first 6 hours post-TFA

Vital sings *(X±SD)*	**Intervention Group (n=20) X±SD**	**Control Group (n=21) X±SD**	**Comparison of groups p***
Heart rate (b/min)	77.05±1.43	76.09±1.81	Z=-1.914 p=0.056
Respiratory rate (c/min)	18.80±2.70	20.47±2.27	Z=-1.822 p=0.680
Sistolic Blood Pressure	129.95±2.21	131.09±3.91	Z=-0.680 p=0.497
Diastolic Blood Pressure	83.95±3.31	84.23±3.11	Z=-0.224 p=0.823
Temperature (°C)	37.35±0.2	37.27±04	Z=-0.794 p=0.427

* Mann-Whitney U test, p<0.05

3.2. Vital signs distribution ın the groups during the first 6 hours post-TFA

Table 2 presents the distribution of vital signs in the intervention and control groups during the first 6 hours post-TFA. The findings did not vary statistically significantly between the two groups ($p > 0.05$).

Table 3. The comparison of the presence of lower back pain between groups within the first 6 hours post-TFA

Pain n(%)	**Total (n=41)**	**Intervention Group (n=20) X±SD**	**Control Group (n=21) X±SD**	**Comparison of groups p***
Lower back pain n (%)				
No pain	9(22.0)	5(25.0)	4(19.5)	0.212 p=0.645
Mild pain	13(31.7)	7(35.0)	6(28.6)	0.196 p=0.658
Moderate pain	9(21.2)	6(30.0)	3(14.3)	1.476 p=0.224
Severe pain	10(24.4)	2(10.0)	8(38.1)	**4.385 p=0.036**

* Chi squared, p<0.05

3.3. The comparison of the presence of lower back pain between groups within the first 6 hours post-TFA.

Table 3 presents the comparison between the intervention and control groups based on the lower back during the first 6 hours post-TFA. Compared to the intervention group, the control group had no statistically significant no pain (5(25.0%) and 4 (19.5.0%)), mild pain (7(35.0%) and 6(28.6%)), moderate pain (6(30.0%) and 3 (14.3%)) and severe back pain (2(10.0%0) and. 8 (38.1%)). The intervention group had a statistically significant of sever pain than the control group ($p<0.05$).

Table 4. Comparison of within-and betwee group back pain average

Time	**Intervention Group (n=20) X±SD**	**Control Group (n=21) X±SD**	***Test**
1.Measurement (Immediately the after TFA)	0.00±0.00[a]	0.00±0.00[a]	Z=0.000 p*=1
2. Measurement (Thirty minutes after the TFA)	2.10±2.95[b]	1.14±2.43[a]	Z=-1.125 p*=0.261
3. Measurement (Two hours after the TFA)	3.10±1.02[b]	3.76±2.25[b]	Z=-0.123 p*=0.902
4. Measurement (Fours hours after the TFA)	2.85±1.66[b]	5.23±2.21[b]	**Z=-3.821 p*=0.001**
5.measurement (Six hours after the TFA)	3.50±1.31[b]	5.61±2.78[b]	**Z=-2.478 p*=0.013**
****Test**	**χ2=36.965 p**< 0.001**	**χ2=54.816 p**< 0.001**	

TFA: trnasfemoral anjiography * Mann-Whitney U test results for comparison of the mean scores of the two groups at each time point. ** Friedman test results for comparison of the mean scores of the within-group, Wilcoxon signed-rank test, a<b, p<0.05,
Different letters or combinations of letters on the same line represent statistically significant differences.

3.4. Comparison of within-and betwee group back pain average

The results of the Friedman test illustrated significant changes in the scores of back pain intensity in both groups across the five measurement time-points ($p < 0.001$;Table 4). Post-hoc analysis using the Wilcoxon signed-rank test was used to compare 1.Measurement (Immediately the after TFA) with other time points. Statistical analysis showed that in the control group, back pain intensity at 3., 4. and 5. measurement was significantly greater than 1.Measurement (Immediately the after TFA) ($p < 0.001$), while in the intervention group, pain intensity at all measurements (2.,3.,4. and 5. measurement) were significantly greater than 1.Measurement ($p < 0.001$). Between-group comparisons using the Mann-Whitney *U* test revealed that except for 1.Measurement ($p = 1.00$), back pain intensity scores at the 4., and 5., measurements in the intervention group was significantly less than those of the control group ($p < 0.001$; Table 4).

4. Discussion

This study was conducted to evaluate the effect of foot massage on back pain that develops after TFA. In this study, there was no statistically significant difference in vital signs between the intervention group, who received foot massage after TFA, and the control group, who received standard pharmacological treatment. These findings are consistent with the results of Elsama's study (2022), which supports the idea that there is a need for large-scale studies evaluating the effect of foot massage on vital signs after TFA (Elsama, 2022). Long periods of immobile bed rest after TFA typically involve nursing interventions such as placing sandbags instead of an invasive pillow and encouraging patients to rest in bed for at least six hours. The most commonly encountered problem during prolonged immobile bed rest is back pain (Elsama, 2022; Kardan et al., 2020; Suggs et al., 2017). In this study, almost half of the patients (45.6%) reported experiencing moderate to severe pain after TFA, and the number of patients experiencing severe pain in the intervention group was significantly lower than in the control group. Similar studies have also shown that the frequency of back pain after TFA varies between 11-27% (Cha and Sok, 2016; Türen et al., 2022). Prolonged bed rest increases pressure on tissues, reduces blood flow to muscles and tissues, and can lead to muscle fatigue and weakness (Niknam et al., 2021;

Fereidouni et al., 2019). It can be argued that prolonged bed rest after TFA leads to back pain by causing muscle fatigue and weakness. Studies focus on when back pain develops during bed rest, aiming to guide nursing care planning in this regard (Chaiyagad et al., 2023; Elsaman, 2022; Türen et al., 2022). The data obtained from the study showed an increase in back pain levels from the second hour after TFA in both the intervention and control groups. In the second hour, the back pain felt with foot massage in the intervention group significantly decreased compared to the control group, where no intervention was performed. The pain level in the control group increased over time. In other words, patients in the intervention group reported significantly lower levels of back pain at the fourth and sixth hours compared to patients in the control group. Different studies have reported the positive effects of foot massage on pain in various patient groups. Elsabely et al. (2022) found that foot massage applied to children undergoing chemotherapy reduced pain and fatigue levels (Elsabely et al., 2022). Şanlı and Satılmış (2023) determined that foot massage applied to postpartum women reduced back pain (Şanlı and Satılmış, 2023). Findings in the literature also indicate that foot massage applied to osteoarthritis patients significantly reduces pain (Yakout et al., 2022). Although the patient population in this study is different from other foot massage studies, the results of many studies support the effectiveness of foot massage in reducing pain intensity. There are various explanations for the positive effects of foot massage on back pain. The most widely accepted explanation, as mentioned earlier, is that prolonged hours of immobile bed rest can increase tissue pressure, reduce tissue and muscle blood flow, lead to muscle fatigue, weakness, and spasms, and result in back pain. Specific pressure applied to the soles of the feet is believed to reduce stress and, therefore, may have positive effects on back pain. Stress can increase the perception of pain, and a decrease in stress can significantly reduce the perception of pain. Another explanation for the positive effect of foot massage is the stimulation of endorphin release. The mechanism by which massage reduces pain is explained by the Gate Control Theory. According to this theory proposed by Melzack in 1965, thick touch fibers (A-alpha and A-beta) are faster than thin fibers (A-delta and C) that transmit pain sensations. In this context, touch receptors and fibers in the skin, which are stimulated through massage, activate mechanoreceptors and fibers that inhibit signal transmission to T cells (the gate closes) and prevent the sensation of pain. When substantia gelatinosa cells are stimulated, they release endorphins, known as endogenous opioids. Endorphins inhibit the release of substance P, which plays a role in the transmission of pain, and block the passage of pain stimuli (Yağı and Saygın, 2019). The reduction in pain levels similar to previous studies suggests that foot massage can be effectively used in alleviating back pain after TFA.

5. Conclusion

Nurses can use foot massage to reduce back pain that develops due to bed rest in patients undergoing TFA. With a simple, side-effect-free, and 20-minute application of foot massage, patients can alleviate their back pain. Additionally, the findings of this study may provide evidence for meta-analysis studies on the effects of foot massage on post-TFA back pain.

5.1. Limitations

The strengths of this study include its randomized controlled design and the patient-perceived effectiveness of the pain visual scale used. However, the limited number of patients and the lack of evaluation of the effect of foot massage on post-discharge pain represent limitations of the study. It is recommended that future research includes larger-scale studies and evaluates post-discharge pain levels in this regard.

Ethical Committee Approval

To conduct the research, the decision of the Academic Board was made by obtaining the ethics committee permission and Institutional Permission from the Clinical Research Ethics Committee where the study was conducted (Date: 08/05/2023, Decision No: 2023/84). The patients participating in the study were also informed about the study and their verbal and written informed consent was obtained.

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