



RESEARCH ARTICLE

Effect of Aromatherapy on Pain Intensity for Patients Undergoing Arterial Sheath Removal after Percutaneous Coronary Intervention: A Randomized Controlled Trial

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ABSTRACT

Coronary artery disease is estimated to have the highest rate of morbidity and mortality in the world. Invasive percutaneous coronary intervention restores blood flow in constricted or occluded coronary arteries. However, many patients suffer pain while the catheter that was entered into the femoral area is being removed. Non-pharmacological approaches, such as aromatherapy using lavender essential oil, have gained attention for pain management in various medical settings, but the efficacy of aromatherapy following arterial sheath removal remains understudied. This research aims to assess the effect of aromatherapy on reducing pain intensity in patients undergoing arterial sheath removal following percutaneous coronary intervention and examine the influence of demographic factors on the response to aromatherapy as a pain management intervention after arterial sheath removal. The study design was Randomized Controlled Trial Research. Conducted at Ibn AL-Nafees Hospital in Baghdad city. The minimum sample size is 77 selected samples from the population by simple random method from 2 February to 15 March. Using aromatherapy for patients undergoing arterial sheath removal post-percutaneous coronary intervention. Data was collected by using a visual analog scale, and analysis the data by descriptive and inferential statistics. the result of the study shows there are significant differences between the study and control groups in two periods of the measure after the intervention of aromatherapy at ($p= 0.000$), and there is no significant difference between demographic characteristics and pain in two periods of measure. In conclusion, The findings showed that lavender aromatherapy can reduce pain intensity for patients undergoing arterial sheath removal.

INTRODUCTION

The condition that affects the heart and blood vessels is known as cardiovascular disease (CVD), and it is estimated to have the highest rate of morbidity and mortality in the world (Malakar et al.,2019, Mansour 2014). CVDs include many conditions that affect the heart and blood arteries one of these conditions is coronary artery disease CAD (Al-Mayahi et al). The most common kind

of CVD is CAD (Mastoi et al.,2018). CAD is the narrowing or clogging of the coronary artery brought on by atherosclerosis, spasms, or a mix of them together (Wicaksono et al.,2020).

Percutaneous coronary intervention (PCI) is used When the coronary arteries are narrowing or blocked which an invasive procedure, not surgical, and getting access to the bloodstream via the femoral or radial artery (Obaid & Mohammed,2020). PCI is used to restoration of the blood flow, decrease complications, and decrease the death rate (Skal& Ahmed). In the United States, about 600,000 PCIs are conducted each year (Ghods et al.,2022). femoral artery access is still preferred for vascular access since it has some advantages such as the ability to employ larger-diameter catheters for complicated procedures, simplicity of use, a decrease in the frequency of technical issues related to artery diameter, and usability in emergencies (Bakhshi et al.,2014).

The artery sheath is often removed 4-6 hours following a trans-femoral PCI treatment to wait for heparin reversal (Hassan et al.,2015). However, many patients suffer pain while the catheter that was previously entered into the femoral area is being removed (Kurt & Kaşıkçı,2019). Pain is characterized as an unpleasant emotional and sensory experience with actual or potential tissue damage (Majeed et al.,2021, Hasan et al 2020). After PCI, pharmacological therapy is one method of pain management (Valikhani et al.,2023). Another method that uses non-pharmacological techniques to ease pain following PCI (Seifi et al., 2018). Nurses play a crucial role in assessing and managing pain by using many ways, including pharmaceutical interventions like analgesics and sedatives, as well as non-pharmacological methods (Majeed et al.,2023).

Aromatherapy, which uses extracts from various plant components, is one of the non-pharmacological therapeutic options (Lin et al., 2019). When compared to other complementary therapies, the usage of aromatherapy as a complementary and non-pharmaceutical method of pain management has greatly increased recently (Bikmoradi et al., 2017). That can be administered through a variety of routes, including inhalation, massage, topical applications on the skin's surface, and very rarely, oral ingestion (Ali et al., 2015).

Malloggi et al, (2023) stated the use of lavender aromatherapy for alternative or supplementary purposes from antiemetic to calming and pain treatment has become immensely popular. Lavender can operate as a circulatory stimulant, which enhances heart function and has favorable effects on coronary blood flow (Seifi et al., 2018). According to a review of the literature, the study examined the effects of aromatherapy on patients undergoing PCI's anxiety, vital signs, and sleep quality (Cho et al.,2013). seifi et al, (2018) stated that a substantial effect of aromatherapy utilizing lavender to lessen pain following CABG, And the effect of aromatherapy on open heart surgery patients' levels of pain in the surgical site (Darzi et al., 2020; Jam et al., 2013).

However, there are no studies about the effect of aromatherapy on reducing pain after arterial sheath removal for patients undergoing PCI. Furthermore, the studies suggested that additional research was required to confirm the findings that the administration of aromatherapy, particularly lavender, can significantly decrease pain in patients undergoing heart surgery (Abdelhakim et al., 2022; Jam et al., 2014). Based on this gap, the researcher decided to conduct this study to assess the effect of lavender essential oil on pain intensity after arterial sheath removal following PCI.

METHODS

Research design and sample

Randomized control trial design (RCT), is used in this study to find out the effect of lavender essential oil on pain intensity for patients undergoing arterial sheath removal after PCI. The sample size was 77 patients at Ibn AL-Nafees Hospital in Baghdad city. The inclusion criteria were composed the adult patients above 18 years old, undergoing PCI, both male and female, and conscious patients. The excluded criteria in this study, are patients who have chronic respiratory disorders such as asthma and chronic obstructive pulmonary disease. Patients with diabetes

militias, patients with uncontrolled blood pressure. Additionally, individual's sensitive to the inhalation of perfumes that could lead to airway irritants, as well as those with allergies to plants and perfumes, are also excluded. Furthermore, patients with mental state disorders are not included, as the study requires participants to be attentive and willing volunteers, unconscious patients and those with olfactory disorders are excluded because the study is based on the inhalation of lavender. Also, visual impairments are excluded due to the instrument used, which relies on self-reporting.

MEASUREMENT INSTRUMENT

The scale used is a visual analog scale (VAS) to assess the pain intensity that the patients experienced when sheath removal. pain intensity consists of a line, most often 100 mm long, with 2 descriptors representing extremes of pain intensity (e.g., no pain and extreme pain) at each end, the scores classified as following no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm) (Jensen et al.,2003). First used by Hayes and Patterson in 1921(Couper et al.,2006). It's widely used as a measure of pain intensity globally. It has been shown that VAS is valid, reliable, and interval scale (Gupta et al.,2016). According to the assessment of Intraclass Co-relation (ICC), the VAS for measuring acute pain has a high degree of reliability. ICC for all paired VAS scores was 0.97 (Bijur et al.,2001). The general information questionnaire included the VAS and demographic characteristics (Age, sex, Occupation, Educational Level, and previous PCI).

Data Collection and Intervention

Data collection was through a questionnaire containing demographics and VAS. The consent of all patients to participate in the study was obtained after explaining the procedure to them and the objectives of the study and informing them that all their data would remain confidential and would only be used for research purposes. The sample was selected by divided into two groups, the study group and the control group, also by randomization. The blue card represented the study group and the red card represented the placebo group. Upon signing the consent forms, patients are allocated into groups. Then the procedure for the intervention group is applied. All patients were male and female lying in the supine position in the catheterization unit following PCI, the arterial sheath was removed after 4 hours post-PCI, and manual pressure was placed by a nurse for 20 minutes on a femoral artery in the groin area. The three drops of lavender oil by dropper on sterile gauze which was tied to the collar of the participants for inhalation before arterial sheath removal for 20 minutes. After that, the VAS was measured to assess the intensity of pain that was assessed when the patient mentioned a point on the VAS line that represents the perception of pain used two times immediately and after 20 minutes post arterial sheath removal. VAS was used with a placebo group, which received 3 drops of distilled water applied on sterile gauze, and also tied to the collar of participants at the same time as the intervention group. after that measuring pain intensity by using VAS at the same time to measure pain in the intervention group. The study is single-blinded since the participants are intentionally kept unaware of which of the two groups have been assigned. This type of study reduces bias in the result, as a participant might unknowingly act differently if they knew their group assignment.

DATA ANALYSIS

Data was analyzed by using the Statistical Package of Social Sciences (SPSS) version 26. In which descriptive and inferential statistic measures were employed. Descriptive statistics were used to describe the demographic variables including Frequency (F), Percentage (%), Mean Score, and Standard Deviation. Mann-Whitney U Test to determine statistically significant differences between experimental and placebo control groups regarding pain score. Spearman Correlation test to find the correlation between age and pain score, and the correlation between pain score immediate arterial sheath removal and post 20 minutes post arterial sheath removal. chi-square

test to find out the difference between demographic characteristics (sex, educational level, occupation), and total pain.

Ethical Consideration

Official permissions were obtained from relevant authorities before collecting the study data as started by getting the approval of the Council of the Nursing College/University of Baghdad for this study on 22/11/2023. The researcher submitted a detailed description of the study including the objectives and methodology of the study to the Iraqi Ministry of Planning\Central Statistical Organization). The researcher submitted a detailed description of the study to the Al-Rusafa Health Directorate Training and Development Center to obtain official permission to carry out the study. and registered in the Iranian Registration of Clinical Trials under code: IRCT20231027059870N1. The final step was getting permission to collect the data from the Ibn Al-Nafees Educational Hospital for Cardiovascular Surgery in Baghdad City. The ethical issues have been applied to promote professional study conduct when the researcher obtained approval from all patients without mentioning the patient's name, also the researcher explained the objective of the study to all patients. The researcher told all participants that the results of the questionnaire would be utilized specially for research purposes, also told that all participants are autonomous individuals who have the right to refuse involvement. The participants in the study gave the researcher written and oral approval.

RESULT

The results showed that the mean age of patients undergoing PCI was 57.11 years with an SD of 8.82. The majority of the patients were males respectively 66.2 % from the study sample. Regarding education, the highest percentage was at the primary educational level 35.1%, and regarding occupation the highest percentage was employed 32.5 % According to the history of previous PCI, the findings showed that 40.3 % of patients have a history of previous PCI, and 59.7 % do not have a history of PCI. Finally, the statistical measures for pain over two periods show differences. The first period (pain1) had a higher mean of 27.41 with a larger standard deviation of 20.27. In contrast, the second period (pain2) had a lower mean 21.05, and a slightly smaller standard deviation 18.00, suggesting less variability compared to the first period. This indicated a change in pain levels with reduced variation in the second period.

Table1: Demographic Profile

Characteristics	F	%
Age M ± SD 57.11 ± 8.82		
Sex		
Male	51	66.2
Female	26	33.8
Total	77	100%
Educational level		
Illiterate	7	9
elementary	27	35.1
middle school	9	11.7
high school	15	19.5
Bachelors	19	24.7
Total	77	100%
Occupational		
Freelancer	12	15.6
Employed	25	32.5

Unemployed	17	22
Housewife	23	29.9
Total	77	100%
Previous PCI		
Yes	31	40.3
No	46	59.7
Total	77	100%
Pain1		
M ± SD 27.41 ± 20.27		
Pain2		
M ± SD 21.05 ± 18.00		

F= Number of frequencies, % = Percentage, M = Mean, SD = Standard Deviation

Comparing the Aromatherapy group and control group regarding pain score after Immediate arterial sheath removal, and post 20 minutes after arterial sheath removal.

Table 2: Aromatherapy group

Pain score after immediate arterial sheath removal (pain1)	Group	N	Mean rank	Sig.	Mann-Whitney
	Aromatherapy	35	26.46	0.000	296.000
	Control	42	49.45		
	Total	77	75.91		
Pain score after 20 minutes post arterial sheath removal (pain2)	Aromatherapy	35	19.19	0.000	41.500
Control	42	55.51			
Total	77	74.7			

Sig. = Significant, N = Number of participants.

Table 2 shows the results of the Mann-Whitney U Test when comparing the difference in pain score after arterial sheath removal between the two groups. The finding showed that significant difference between the study and control groups regarding pain score after immediate sheath removal at (p=.000). Also, a significant difference between the two groups at (p=.000) after 20 minutes' post-sheath removal.

Table 3: Correlation between pain score immediate arterial sheath removal and post 20 minutes post arterial sheath removal.

Groups	N	Spearman's correlate pain1&pain2	Sig.
Aromatherapy	35	.434	.009
Control	42	.485	.001

Sig. = Significant, N = Number of participants.

Table 3 shows there is a significant relationship between pain score in two periods of measure immediate and post-20-minute post arterial sheath removal in the aromatherapy group at (P=.009). and a significant relationship between pain score in two periods of measure immediate

(pain 1) and post-20-minute after arterial sheath removal (pain 2) in the control group at (P= .001)

Table 4: Correlation between age with total pain scores.

Demographic	Spearman's correlation	Total pain
Age N=77	-.140	Sig. = .226

Sig. = significance, N = Number of participants.

In Spearman's correlation test, table 4 shows the correlation between the Age and total pain score, the results revealed there is no statistically significant correlation between Age and pain in a period of measures at (P= .226).

Table 5: Differences among Sex, Education level, Occupation, and previous PCI with total pain score.

Demographic	Chi-square	Sig.
Sex	44.58	.758
Education level	215.50	.346
Occupation	155.23	.50
previous PCI	52.74	.445

Sig. = significance.

Table 5 used the chi-square test to find out the difference between demographic characteristics (sex, educational level, occupation, previous PCI), and total pain, the results show there is no significant difference between demographic characteristics and pain in two periods of measure.

DISCUSSION

According to the studies, older people frequently experience a greater ischemia burden than the younger, which suggests that they have a greater potential to benefit from coronary revascularization therapy (Shanmugam.,2015). In current study found the mean age of the study participants was 57.11 years. Similar findings appear in a study conducted by Heidaranlu et al. (2021). This study found the mean age for the experimental group was 57.23 and 59.32 years for the control group. Lafta and Tahseen (2023) found that the mean age for the study group was 50 and 51 for the control group. Another study conducted by Mousa and Mansour (2020) found a mean age of 54 in the study group and 60 in the control group. According to sex, the study revealed with advanced age in men, testosterone levels will decrease the level so the male is at a higher risk of cardiovascular disease (Yeap.,2019). The decrease of sex hormones plays an important role in the development of CVD (Rodgers.,2019). So in the current study found the majority of the participants in the study sample were males 66.2%. A study conducted by Sokhanvar et al. (2023) this study found a high percentage was males in the experimental group 80%, and in the control group 76.6%. Furthermore, Sallal and Mousa (2023) found the highest percentage in the study sample was male 63.3% in the experimental group, and 53.3% in the control group. When comparison between the Aromatherapy group and the control group regarding pain in two periods of measurement. The finding showed that aromatherapy by using lavender essential oil has a significant effect on reduced pain intensity after arterial sheath removal after two periods of measure. This result was similar to the findings of the study conducted by Seifi., et al. (2018) also found a significant effect of aromatherapy. Moreover, the study found that time plays an important role in reduced pain similar to the study conducted by Khalil et al. (2019) which found

that time has benefits in reduced pain intensity. According to the correlation and differences among age, Sex, Education level, and Occupation with pain intensity that patients experience due to arterial sheath removal in this study, there is no significant correlation between age and pain score, and there are no differences between sex, educational level, and occupation with pain intensity that experienced due to arterial sheath removal. This finding similar to the study was conducted by Rejeh et al. (2020) also found there is no significant association between age and pain score and no significant differences between sex, educational level, and occupation with pain score. When showing the difference between previous PCI and the patients who had PCI last time with pain scores after two periods of measures. The results show there is no significant difference between previous PCI with pain scores in two periods of measures. This finding similar to the study was conducted by Bayindir et al. (2017) who also found there are no significant differences between previous PCI and pain scores in different periods of measure.

CONCLUSION

In conclusion, the findings showed that lavender aromatherapy can reduce pain intensity for patients undergoing arterial sheath removal, provide comfort, and facilitate nurses to provide comfort through simple methods of pain management for patients.

RECOMMENDATIONS

Based on the findings, it is recommended to incorporate aromatherapy as an adjunctive therapy with nursing practice care for patients undergoing arterial sheath removal. Also, further research conducting the study in a multi-center with a high sample size is recommended to generalize the results.

CONFLICT OF INTEREST

The author declares that they have no conflict of interest.

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