Original Article

Compare the Effect of Aromatherapy with Lavender and Valerian Essential Oil on Headache Caused by Nitroglycerin Infusion, Vital Signs, and Narcotic Use in Patients with Coronary Artery Disease: A Three-Blind, Randomized Controlled Trial

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Abstract

Background: Most patients receiving nitroglycerin infusion experience some degree of headache. This study aimed to determine the effect of aromatherapy with lavender and valerian essential oil on the severity of headaches caused by nitroglycerin infusion, vital signs, and narcotic use in patients with coronary artery disease admitted to CCU wards. **Materials and Methods:** This three-blind clinical trial was performed with the participation of 90 patients with consent. Patients were randomly divided into three groups (lavender, valerian, and control). Samples of lavender and valerian groups were inhaled cotton soaked in 3 drops of fragrance for 30 minutes. In the control group, no intervention was performed and only the usual methods of pain control were performed for these patients. The severity of patients' headaches in four time periods (before the intervention and 15, 30, and 60 minutes after the intervention) was measured using the visual scale of pain and vital signs before and after the intervention. **Results:** The results showed that in all three groups, there was a statistically significant difference between the different stages of pain measurements and the headache score had reduced (df: 4, $p < 0.05$) ($X^{2:}$ 5.98). There was no difference between the mean scores of the pain levels in the two fragrance groups after the intervention. But there was a significant difference between the fragrance and control groups (df: 6, $p < 0.001$) ($X^{2:}$ 49.04). **Conclusions:** Aromatherapy with lavender and valerian essential oils is effective in reducing headaches in patients receiving nitroglycerin infusion and reducing their use of painkillers and narcotics.

Keywords: *Aromatherapy, headache, lavender oil, nitroglycerin, valerian*

Introduction

Among cardiovascular diseases, coronary heart disease is the most common life-threatening disease that causes disability, economic problems, and mortality more than any other disease.[1] To relieve pain in these patients, various drug combinations have been suggested, the most important of which are nitrates, especially nitroglycerin.[2] Nitrates have a great impact on the venous system. Dilation of the veins causes more blood to accumulate in them and, as a result, reduces the return of venous blood to the heart, which eventually leads to a decrease in heart function and a decrease in the supply of oxygen to the body tissues.[3]

The pain relief medications are often associated with side effects such as hypotension, impaired vital functions such as respiration and heart rate, and sometimes allergic reactions and shock.[4] Nitroglycerin and other organic nitrates are no exception and have side effects, the most common of which are severe headaches and hypotension.[5] Nowadays, various therapies have been proposed to control drug combinations' side effects, especially nitroglycerin. Clinical aromatherapy is one of the complementary therapies used along with conventional therapies to improve or treat diseases.[6] One of the herbs used in aromatherapy is lavender, which has long been used in traditional medicine. This plant is effective in treating headaches, especially headaches caused by tension.[7] Lavender contains linalool alcohol ketone esterswaleid, which effectively reduces pain and inflammation.[8] Besides, it improves

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heart function and stimulates blood circulation causing mental peace.[9]

Another herb traditionally used in the treatment of headaches is valerian, which is one of the native medicinal plants of Asia and is found almost everywhere in Iran. The medicinal properties of the plant are in its roots and rhizomes. Its active ingredients are mainly valerianic acid and valepotriates, which exert their sedative and analgesic properties by acting on GABA receptors, adenosine, and benzodiazepines.[10] No complications or allergies to valerian have been reported in clinical trials.[11,12] Valerian is considered safe even during pregnancy and lactation and is recognized as a Group A food in Australia, and its existence in foods has been declared unimpeded by the Food and Drug Administration of USA.[13]

Despite the high severity of headaches,[2,3] unpleasant and numerous side effects due to the administration of nitroglycerin, and, on the other hand, the urgent need for new, effective, and low-complication treatments, limited studies have been performed on the effect of lavender and valerian on headache induced by nitroglycerin infusion.

This study aimed to determine the effect of aromatherapy with lavender and valerian essential oil on the severity of headaches caused by nitroglycerin infusion, vital signs, and narcotic use in patients with coronary artery disease admitted to CCU wards.

Materials and Methods

This study was a three-blind three-group randomized clinical trial (IRCT20210516051316N1), which was performed on patients admitted to the CCU wards of the Boo Ali Sina Hospital in Qazvin from September 2021 to September 2023. The sample size was estimated assuming the first type error α =0.05 (95% confidence) and the second type error β =20% (80% power) and according to the study of with the similar studies (2013)[2] and considering the minimum error d = 0.7.

Taking into account 10% of the sample drop, 30 people were calculated for each group and finally, the total sample size was considered 90 people.

Inclusion criteria included no previous history of nitrate use, no history of allergies and respiratory problems, no use of painkillers 6 hours before the intervention, no headache before the intervention, no use of perfume or cologne before or during the intervention, no history of drug addiction according to individual's statements, no pregnancy, no olfactory disorder, no colds, and nasal congestion that affect the sense of smell. Exclusion criteria included withdrawal from the study, headache before nitroglycerin infusion, decreased level of consciousness during the study, allergy to essential oils of valerian and lavender or herbal extracts during the study, and discontinuation of nitroglycerin infusion by the attending physician for any reason. The intervention was started after obtaining informed written consent and explaining the research objectives performed on patients who suffered from headaches after receiving intravenous nitroglycerin and met the inclusion criteria; they were selected and entered into the study using the convenience method. In this study, eligible patients were randomly divided into three groups, (1) lavender, (2) valerian, and (3) control, using the random sampling method (bag and colored balls) [Figure 1].

This process was performed by one nurse who was not aware of the research. Both groups did not know the type of fragrance used, and instead of naming the fragrance, numbers 1 and 2 were assigned by someone outside the research team, and even the researcher was not aware of this numbering. Moreover, the statistical consultant did not know the names of the fragrances, and only the analysis was done with numbers 1 and 2 and the control group. It should be noted that the number 1 fragrance was valerian and the number 2 was lavender. The intervention was done in this way with the start of nitroglycerin infusion; the patient was instructed to report side effects. After complaining of a headache, patients in the test groups (lavender and valerian) inhaled (30 minutes) cotton soaked in 3 drops of lavender essential oil 1.5% and valerian essential oil 1.5%, prepared by Kazerun Agro-industry Company, which was attached to their clothes collar. In the control group, no intervention was performed and only the usual methods of pain control were performed for these patients. The severity of patients' headaches in four periods (before the intervention and 15, 30, and 60 minutes after) was measured using the visual pain scale. Vital signs, including blood pressure, heart rate, body temperature, and the percentage of peripheral oxygen saturation before and after the intervention, were measured in three groups too. It should be noted that if the nitroglycerin infusion was stopped by the physician for any reason, the patient would be excluded from the study and sampling would continue until the sample size was complete. The data were collected by one the researcher, and the collection tool included a demographic information checklist containing age, gender, underlying disease, diet, and the information including vital signs before and after

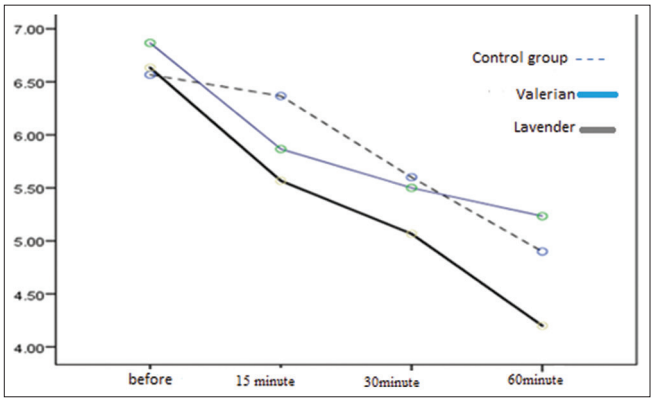

Figure 1: Comparison of pain intensity (visual scale) in three groups

the intervention, respiration rate, blood pressure, heart rate, body temperature, percentage of the peripheral oxygen saturation, nitroglycerin dosage, and intake dosage of narcotic, headache occurrence time, visual pain scale, digital clock, and a dropper. The validity of the demographic information form was confirmed through content validity; in this way, the questionnaire was given to 10 faculty members of the School of Nursing and Midwifery, specialists in traditional medicine, and cardiology of Qazvin University of Medical Sciences. After reviewing and applying their opinions, their validity was confirmed. The validity and reliability of the visual pain scale have been confirmed in various previous studies.[14] To be surer, the reliability of this tool was evaluated using the test–retest method; the scale was completed for 10 patients by the researcher in two stages with an interval of 30 minutes and its reliability was obtained, $r = 0.89$. To determine the reliability of the digital clock, the duration between the start and end of the intervention was measured with a digital clock with a reputable brand (Nixon Regulus); due to the similarity of the results, its reliability was confirmed. The reliabilities of the sphygmomanometer (Alpikado model alpk2), pulse oximetry (Choice Mod model MD 300C29), thermometer (Wintect model WT550), and heart rate monitoring (VECTRA) were determined in the same way. To determine the reliability of the dropper, the number of droplets was measured with a new and reputable brand dropper (Kidzemi KM210147) and with an insulin syringe (1 drop = 0.1 cc); due to the similarity of the results, its reliability was confirmed. Version 24 of SPSS software was used to analyze the data. To evaluate the homogeneity of groups in terms of demographic variables, Chi-square and one-way analysis of variance were used, and, if necessary, the Kruskal–Wallis test was used. The normality of the data was assessed using the Shapiro test; to compare the mean scores of headaches in the three groups, analysis of variance test was used; and to compare the data before and after the intervention, paired *t*-test was used. The significance level in all tests was considered 0.05.

Ethical considerations

After obtaining the code of ethics (IR.QUMS.REC.1398.200) and IRCT code, the researchers started the research with the necessary permits from Qazvin University of Medical Sciences and entered the samples into the study.

Results

Demographic characteristics

In this study, 43 individuals out of 90 samples were female (47.77%) and the rest were male. The result of the Chi-square test showed that the frequency of the gender variable in the three groups was not statistically significant ($p = 0.956$) and the three groups were homogeneous in this regard. The mean age and standard deviation of the subjects were 59.86 ± 9.80 years ($p = 0.569$). Furthermore, other demographic variables in the three groups indicated the similarity of the participants [Table 1].

Clinical characteristics

According to the results of the Friedman test, the mean scores of headaches in all three groups were significantly different in the three stages after the intervention ($p < 0.05$) and the headache score decreased. But in the meantime, the headache scores after the intervention in the lavender group were lower than those of the other groups [Table 2].

Further, according to the results of the Mann–Whitney U test, there was a significant difference between the control and valerian groups in the preintervention, 30 minutes after the intervention, and 60 minutes after the intervention, and in comparison, with the control and lavender groups in the preintervention and 60 minutes after the intervention, there was a significant difference between the control group and intervention groups [Table 3].

Pain reduction charts of all three groups have been drawn [Figure X].

Patients in all three groups were evaluated for vital signs before and after the intervention. There was no significant difference between the means of all preintervention scores in the three groups ($p > 0.05$). These results indicated that the participants' matching had been performed correctly. In comparing respiratory rate (RR) in the three groups after intervention, it revealed that the mean scores of RR in the control group were significantly lower than those of the other groups ($p < 0.001$). Despite the low mean differences before and after the intervention in the group of valerian and lavender, these differences were not significant ($p > 0.05$).

There was a significant difference between the mean of all scores (respiratory rate, body temperature, percentage of saturation of peripheral oxygen) after the intervention in the three groups ($p < 0.01$). The mean difference in vital signs scores before and after the intervention was not significantly different in the three groups ($p > 0.05$). According to the paired *t*-test in the valerian group, the mean scores of systolic blood pressure and heart rate decreased significantly. One of the notable points of this study was that the mean rate of diastolic pressure after the intervention, although significantly reduced in all three groups, the rate of this reduction was greater in the lavender group than in the valerian group. Although no significant difference was observed between the three groups in reducing systolic blood pressure after the intervention, the reduction in systolic blood pressure was greater in the lavender group than in the valerian group. Comparing the percentage of saturation of peripheral oxygen and body temperature in the three groups, the difference after the intervention was significant; but before and after the intervention, it was not significant. Furthermore, comparing the heart rate in the three groups, it was lower in the valerian group, but the difference before and after the study was not significant ($p = 0.006$) [Table 4].

Table 1: Demographic characteristics of subjects by three groups

Variables		Lavender (fragrance 2) The numbers (%)	Valerian (fragrance 1) The numbers (%)	Control group The numbers (%)	*p*
Age		30 (age average=58 years)	30 (age average=61 years)	30 (age average=59 years)	0.569
Gender	Female	14 (46.66%)	14 (46.66%)	15 (50%)	0.956
	Male	14 (53.33%)	16 (53.33%)	15 (50%)	
Diet	Normal	14 (50%)	12 (40%)	8 (26.66%)	0.143
	Low salt	11 (36.66%)	8 (26.66%)	15 (50%)	
	Low fat				
	Diabetic	4 (13.33%)	10 (33.33%)	7 (23.33%)	
Background disease	Acute coronary syndrome	11 (36.66%)	11 (36.66%)	17 (56.66%)	0.196
	Hypertension	13 (43.33%)	11 (36.66%)	20 (66.66%)	0.051
	Diabetes	11 (36.66%)	6 (20%)	11 (36.66%)	0.274
	Hyperlipidemia	4 (13.33%)	2 (6.66%)	0 (0%)	0.159
	Other	1 (3.33%)	3 (10%)	6 (20%)	0.118
Work shift	Morning	8 (26.66%)	12 (40%)	11 (36.66%)	0.816
	Evening	10 (33.33%)	7 (23.33%)	9 (30%)	
	Night	12 (40%)	11 (36.66%)	10 (33.33%)	

*Chi-square test

Table 2: Comparison and test of pain intensity (visual scale) between different measurement stages by three groups

	Before intervention	15 minutes	30 minutes	60 minutes	Type of statistical test and *p*
Control group	6.57 (1.22)	6.37 (1.29)	60/5 (1.29)	4.90 (1.18)	*p*=0.001 df=3
Valerian	6.86 (1.31)	5.87 (1.31)	5.50 (1.41)	5.23 (1.59)	*p*=0.001 df=3
Lavender	6.63 (0.96)	5.57 (1.17)	5.07 (1.07)	4.20 (0.96)	*p*=0.001 df=3

*Friedman test

Table 3: Comparison and test of pain intensity (visual scale) between different stages of two-by-two measurements of groups

Vital sign	Respiratory rate			Systolic blood pressure			Diastolic blood pressure		
Intervention group	Before the intervention	After the intervention	*p*	Before the intervention	After the intervention	*p*	Before the intervention	After the intervention	*p*
Control	15.26 (1.11)	15.13 (1.63)	0.536	137.66 (23.80)	126.50 (20.34)	0.001	91.33 (29.24)	82.00 (16.48)	0.005
Valerian	18.96 (2.42)	18.60 (1.97)	0.250	138.96 (21.32)	133.73 (17.15)	0.012	73.26 (14.33)	71.36 (11.83)	0.110
Lavender	19.96(3.75)	19.73 (3.00)	0.601	135.16 (18.78)	129.20 (23.10)	0.031	72.26 (16.47)	69.63 (9.46)	0.218
p	0.001	0.001		0.784	0.384		0.001	0.001	
Vital sign	**Heart rate**			**Body temperature**			**The percentage of the peripheral oxygen saturation**		
Intervention group	**Before the intervention**	**After the intervention**	***p***	**Before the intervention**	**After the intervention**	***p***	**Before the intervention**	**After the intervention**	***p***
Control	84.16 (11.30)	82.90 (11.00)	0.034	36.54 (0.30)	36.50 (0.28)	0.003	95.63 (1.29)	95.86 (1.27)	0.129
Valerian	74.93 (14.97)	73.36 (14.81)	0.006	36.97 (0.44)	36.98 (0.36)	0.854	93.16 (2.05)	92.43 (5.69)	0.454
Lavender	76.86 (15.39)	75.66 (14.77)	0.143	36.85 (027)	36.89 (0.23)	0.460	94.00 (1.74)	94.00 (1.96)	1.000
p	0.31	0.022		0.001	0.001		0.001	0.001	

*Paired samples statistics

According to the statistical results regarding the dosage of narcotics received, 24 individuals (79%) in the control group received narcotics. Meanwhile, 4 individuals (13.4%) in the valerian group and 1 individual (7.1%) in the lavender group received narcotics to relieve headaches. This indicated that the effect of fragrance prevented the patient from needing additional analgesia ($p < 0.001$) [Table 5].

Discussion

The results showed the application of lavender and valerian essential oils to reduce nitrates-induced headaches is

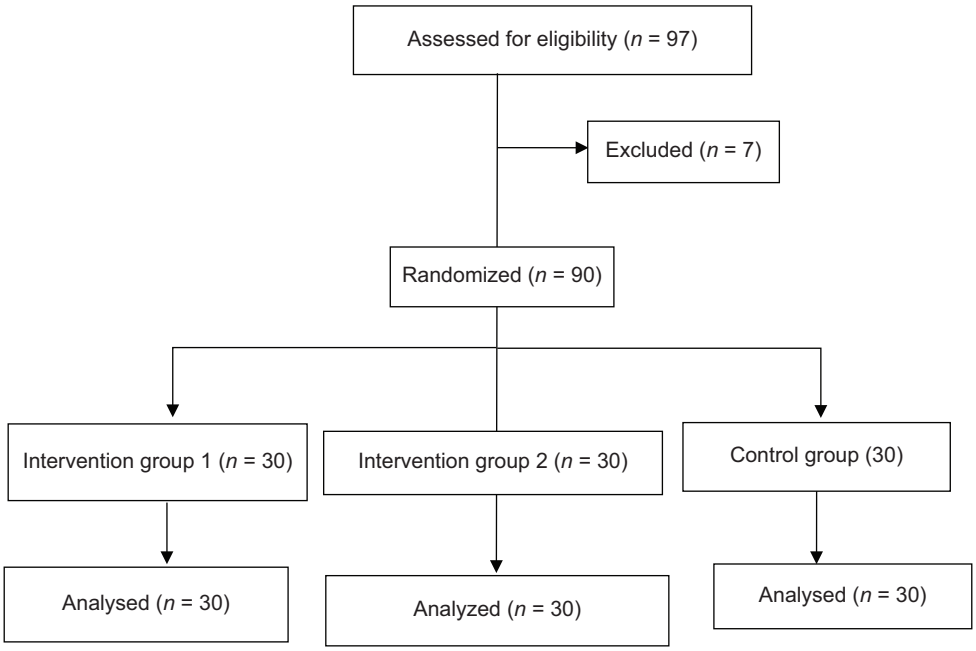

Figure X: The flow diagram of this study

Table 4: Evaluation of vital signs (respiratory rate, blood pressure, heart rate, body temperature, percentage of peripheral oxygen saturation) before and after the intervention in three groups

	Before intervention		15 minutes		30 minutes		60 minutes	
	Z	*p*	*Z*	*p*	*Z*	*p*	*Z*	*p*
Groups of control and valerian	–2.582	0.010	–0.899	0.369	–2.198	0.028	–3.503	0.001
Groups of control and lavender	–2.132	0.033	–0.590	0.555	–1.668	0.095	–3.227	0.001
Groups of valerian and lavender	–0.930	0.352	–0.589	0.556	–1.189	0.234	–1.324	0.186

*Statistical test: Mann–Whitney

Table 5: Comparison of received narcotic in three groups

Statistical test Pearson and Chi-Square	Lavender number (%)	Valerian number (%)	Control group number (%)	*p*
Number of patients who received narcotic dosage	1 (7.1%)	4 (13.4%)	21 (79%)	*p*=0.001

effective. However, this study did not show the superiority of one essential oil over the other in reducing nitrates-induced headaches. In the present study, although a reduction in headache was observed in the control group too, the rate of this reduction was greater in both groups receiving the fragrance. So far, studies have been conducted on the effect of lavender on dysmenorrhea[15,16] or pain relief from surgery[17] and migraines. In this regard, the results of Zarifnejad *et al*. (2015) showed that there was a significant difference between the severity of headaches in the three groups of lavender, acetaminophen, and placebo after the intervention. In the aromatherapy group with lavender essential oil, the rate of headache was significantly low.[2] In the aforementioned study, sampling among patients was performed in the summer, while in the present study, Rafiei *et al*. (2016) also found in their study that lavender essential oil can also reduce the rate of disability and the number of headaches caused by migraine. The results of the present study were consistent with these studies in terms of the effect that lavender essential oil significantly had on reducing nitroglycerin-induced headaches. The present study also showed the effect of valerian in reducing headaches in patients receiving nitroglycerin. In this regard, the study of Azizi *et al*.[10] showed that valerian capsules can be effective in reducing the severity of tension headaches. Mirzaee *et al*.[11] too studied the effect of aromatherapy with lavender essential oil on anxiety and hemodynamic changes in 64 patients who were candidates for surgery and found that the number, duration, and severity of migraine attacks in patients significantly decreased. In the present study, both essential oils were effective in reducing pain, but neither was superior to the other in terms of the rate of reducing headache. However, in a study conducted by Kamalifard *et al*.,[12] comparing the effect of these two essential oils in reducing pain in the acute phase of labor, the results showed that valerian was superior to lavender in reducing pain, which

was not in line with this study. Since no other study was found in the researcher's research to investigate and compare this case with the present study, in justifying this case, it can be said that the affecting mechanism of the valerian on reducing pain in different parts of the body is probably different. The present study measured the effect of this herbal essential oil on headaches, while the study of Kamalifard *et al*.[12] measured the reduction of pain in the acute phase of labor. Regarding the effect of lavender essential oil on patients' vital signs, studies have been performed on patients after open-heart surgery[18,19] or patients admitted to general wards.[20] One of the significant points in the present study was the reduction of systolic and diastolic pressure in the lavender group compared to the valerian group, but this relationship was not significant. Nategh *et al*.[21] in a study compared the effect of lavender essential oils and almond oil with a placebo on hemodynamic parameters in 110 patients with acute coronary syndrome. They found that although both systolic and diastolic pressures were reduced in the lavender group, this difference was not significant. This result was not consistent with the present study. Mirbastegan and colleagues[22] similarly studied the effect of aromatherapy with lavender essential oil on the vital signs of myocardial infarction patients admitted to intensive care units. Their results at the end of the intervention indicated a statistically significant decrease in blood pressure. In another study, Moradi *et al*.[23] found that aromatherapy with two drops of lavender essential oil in patients with ischemic heart disease could make a significant reduction in diastolic and systolic blood pressure. The results of these two studies were in line with the results of the present study. In the study of Moradi *et al*.,[23] it was further found that lavender essential oil can cause a significant reduction in the respiratory rate and heart rate in patients. Similarly, in the present study, the average of respiratory rate in the lavender group was lower than that of the other two groups, but this difference was not significant. Seifi *et al*.[24] in their study evaluating the effect of lavender on 60 patients after CABG surgery found that aromatherapy with lavender inhalation had no significant effect on vital signs, which was not consistent with our study. In justifying disparities, it can be said that this difference could be because of the different type of study plus the different duration of inhaling the fragrance. In the mentioned study, 2% lavender essential oil was inhaled by patients for 20 minutes, but in the present study, 1.5% essential oil was inhaled by patients for 30 minutes. Another notable finding in our study was the need to receive fewer narcotics in both aromatherapy groups. The results of a study by Kim *et al*. (2007) entitled "The effect of lavender essential oil treatment on the need for narcotic in the post-anesthesia care unit and on obese patients undergoing laparoscopic gastric banding surgery" stated that patients in the placebo group needed more narcotic to relieve postoperative pain (82%), which was significantly higher in comparison to the lavender group (46%) ($p = 0.007$).[25] The results of the aforementioned study were consistent with the present study. Given that the use of narcotics is common in CCU wards, while these drugs have many side effects such as respiratory depression, nausea, and vomiting and, on the other hand, are economically expensive,[26] the use of these alternative methods can be useful in relieving pain. Although the researcher tried to minimize the disturbing effects of these factors, they may affect the participants' vital signs. For example, medications, the unique atmosphere of the intensive care unit, and other unknown factors, such as participants' moods, may affect the effectiveness of aromatherapy. Therefore, it is recommended that further multicenter studies be conducted in different wards and hospitals, as well as in the general wards of coronary heart care, taking into account the unique and significant characteristics of the participants. One limitation was that a single center that is conducting the study is in only one hospital and one ward. The other limitation was disturbing and uncontrollable factors. Since the study and interventions were carried out in the ward environment, the noise of the environment, the sound of the personnel involved with the patient, the presence of a sick patient in the ward, and the time of the infusion may affect the results of the study.

Conclusion

The results of the present study revealed that both lavender and valerian essential oil could reduce the headache caused by nitrates intake, and therefore, these two fragrances may be a proper alternative medication for pharmacological methods to reduce this type of headache. Although aromatherapy interventions in the lavender group had a greater effect on patients' vital signs than those of the valerian group, both fragrances did not significantly affect patients' vital signs. However, lavender and valerian aromatherapy can be used as a simple, safe, and inexpensive alternative treatment. In addition, due to the cost and side effects of narcotics, the use of some alternative methods such as these two fragrances can be effective in reducing headaches in patients with coronary artery disease.

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Conflict of interest

Nothing to declare.

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