

The effects of sesame oil on the prevention of amiodarone-induced phlebitis

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ABSTRACT

Background: Phlebitis is the most common complication associated with peripheral intravenous infusion of amiodarone. The purpose of this study is to determine the effects of sesame oil on the prevention of amiodarone-induced phlebitis.

Materials and Methods: This is a double-blind randomized controlled trial. Thirty-six patients hospitalized in a coronary care unit were randomly allocated into two groups using a convenience sampling method. Following peripheral intravenous cannulation, five drops of pure sesame oil were applied to the skin within a 10 cm radius of the infusion site prior to the administration of amiodarone in the intervention group. Sesame oil was rubbed on the skin at the infusion site every 6 h in the 24-h period of amiodarone infusion. In the control group, liquid paraffin, used as a placebo, was rubbed on the skin at the infusion site of amiodarone. Both groups were monitored for the development of phlebitis and its degree within the 24-h period of amiodarone infusion as well as 6 h after its administration. The incidence of phlebitis was confirmed and recorded by an assessor who was blind to the two groups. Data were analyzed using Statistical Package for Social Science (SPSS) version 18, and descriptive and inferential statistics such as Chi-square test, Kaplan–Meier, Hazard ratio, independent *t*-test, and Fisher's exact test.

Results: There was a statistically significant difference between the two groups in their catheter survival after 30 h and 10 min ($P < 0.001$). Over 60% of the patients (61.1%) in the intervention group did not show any sign of phlebitis, while 16.7% and 22.2% of the patients manifested signs of grade 2 and 3 phlebitis, respectively. In the control group, 22.2% of the patients showed no signs of phlebitis, while 5.6%, 27.8%, and 44.4% of the patients exhibited signs of grade 2, 3, and 4 phlebitis, respectively. The statistical analysis showed significant differences in the degree of phlebitis ($P = 0.006$) and the onset of phlebitis development ($P < 0.001$) between the two groups.

Conclusions: It is recommended to apply sesame oil topically to the infusion site of amiodarone so as to reduce the rate of the development of amiodarone-related phlebitis.

Key words: Amiodarone, Iran, phlebitis, sesame oil

INTRODUCTION

Phlebitis is the most common complication of intravenous injections,^[1,2] with symptoms including painful swollen vein; warmth, erythema, tenderness;

with a red line streaking along the vein. Chemical, mechanical,^[3] and infectious agents can cause phlebitis^[4,5] and can lead to clotting, thrombophlebitis,^[5] bacteremia, and even death.^[6]

One of the drugs that can cause phlebitis is amiodarone, administered through intravenous infusion.^[7-10] Amiodarone is used in the treatment of cardiac arrhythmias and angina.^[11] The current guideline for peripheral intravenous infusion of amiodarone recommends less than 2 mg/ml, which has been developed for diluting the drug and reducing the risk of phlebitis.^[8] Yet, the prevalence of phlebitis has been reported as 67%,^[9] 13.6%,^[8] and 55%^[4] in these patients, which can lead to increased costs, patient discomfort, delayed administration of intravenous drugs, and delayed patient discharge.^[4] Meanwhile, according to the Intravenous Nurses Society, the accepted level of phlebitis for any population has been reported as 5% or less.^[12,13] Accordingly, application of central venous catheters and drug dilution has been recommended for administration of amiodarone. However, these methods are often not applicable, as amiodarone is administered in an emergency

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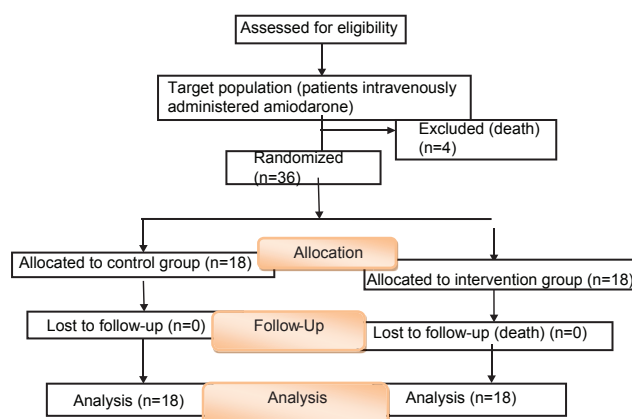
over a short period of time,^[9] and further dilution of the drug is not applicable due to concerns about increased circulating fluid volume for cardiac patients.^[14]

Various procedures have been suggested to prevent phlebitis, including administering heparin,^[15] dilution of drugs, and use of topical corticosteroids,^[16] none of which is without complications. Heparin is associated with the risk of bleeding at the operation site and thrombocytopenia, and corticosteroids are followed by increased risk of infection through impaired defense system.^[17] Thus, it is recommended to use simpler, more economical, and available methods. One of these methods seems to be the use of complementary and alternative medicine, an example of which is applying sesame oil. This oil has antioxidant, anti-inflammatory, and antibacterial properties, and contains various lignans such as sesamin and sesaminol that prevent the release of pro-inflammatory agents including interleukin-8 and endothelin-1, which ultimately prevent inflammation.^[18] According to available databases, no papers have been published in relation to the effect of sesame oil in preventing amiodarone-induced phlebitis. In this area, there has only been one study conducted in Iran, which aimed to examine the effect of sesame oil in preventing chemotherapy-induced phlebitis. Sixty patients undergoing chemotherapy entered this randomized controlled clinical trial. Results indicated significant differences between the two groups in terms of severity and timing of phlebitis.^[12] Since chemotherapy-induced phlebitis is a chemical type of phlebitis and amiodarone is also a chemical, it seems sesame oil can be as effective on amiodarone-induced phlebitis as it is on chemotherapy-induced phlebitis. Thus, this study was conducted with the aim to determine the effect of sesame oil on the prevention of amiodarone-induced phlebitis.

MATERIALS AND METHODS

This study is a double-blind randomized controlled clinical trial, which was conducted following approval of the Ethics Committee of Mazandaran University of Medical Sciences, coded IRCT201308127494N7, on patients admitted to the cardiac and CCU departments of Shahid Yahyanejad Hospital, Babol, who received intravenous infusion of amiodarone protocol according to doctors' orders. Inclusion criteria were being ≥ 18 years of age,^[19] having no allergy to sesame, and use of upper limbs for intravenous catheterization. Exclusion criteria included having autoimmune diseases, constant use of analgesics and opiates for pain relief, use of other drugs or herbal oils to prevent phlebitis,^[12] bradycardia,^[7,20] and patient's death^[21] (consort follow chart).

Sample size was estimated at 36 patients (18 in each group), based on a pilot study conducted on 12 patients,



Flow chart: Consort follow chart

with 16% phlebitis in the intervention group and 83% phlebitis in the control (considering the loss to follow-up). After obtaining written consents, patients were randomly divided into a sesame oil group (intervention group) and a liquid paraffin group (control group) according to the RANDBETWEEN function in Microsoft Excel. Then, their medical and demographic details were recorded.

In this study, data collection tools included demographic and medical details' questionnaires, containing variables of age, gender, group allocated (intervention or control group), diagnosis, type of background disease (diabetes and hypertension), and patient's dominant hand.^[22]

In this study, Visual Infusion Phlebitis Scale (VIPS) was used to assess phlebitis and its severity, which was first introduced by Jackson in 1998.^[5,23] This is a numerical scale from 0 to 5, with 0 indicating a healthy IV (intravenous) site; 1 identifying slight pain or redness near the IV site; 2 involving two of the following as evident, pain, redness, and swelling at the IV site; 3 including symptoms such as pain along the path of the cannula, redness around the cannula site, and swelling; 4 identifying pain along the cannula path, redness around the cannula insertion site, swelling, and a palpable venous cord; and 5, which has all the symptoms in 4 plus pyrexia.^[5] In the VIPS, patients with grade 2 or greater phlebitis should have their catheter removed or replaced.^[5] This scale has been used in various studies.^[1,2,12,24] Nekuzad *et al.* confirmed the reliability of this scale with a correlation coefficient of 0.93.^[12] Content validity was used to assess validity of the demographic and medical questionnaire through confirmation received from five expert academic staff. In the present study, reliability of the VIPS was confirmed using equivalence or inter-rater reliability.^[25] A phlebitis checklist was recorded for 10 patients by five nurses, separately and without knowledge of each other's evaluation scores, and internal consistency in Cronbach's alpha test was found to be 0.984.

The amiodarone administration protocol involves infusion of 1050 mg over 24 h. Amiodarone is diluted with dextrose 5% solution. In the first 10 min, 150 mg (1.5 mg/ml) of amiodarone is administered as a bolus. The next dosage of 360 mg (1.8 mg/ml) is infused immediately afterward (over 6 h). The 540 mg (1.8 mg/ml) maintenance dose is infused over 18 h. This protocol takes a total of 24 h and 10 min to complete.^[11]

In both groups, the IV line was inserted in the upper limbs using a size 20 cannula from Mediplus Company, Haryana, India. This was specifically used for amiodarone infusion, and no other injection was performed through this vein. To prevent bias, all sampling stages were performed equally for every patient by the same researcher. In the intervention group, catheterization was performed with aseptic considerations, and before the first injection of amiodarone, five drops of pure sesame oil (from Barij Essence Company, Kashan, Iran,^[18] with quality certificate No. ISO9001:2008 and production license No. 0227500) were rubbed within a 10 cm radius of the infusion site (without any massage or manipulation of the infusion site).^[12] With the onset of infusion, sesame oil was topically rubbed every 6 h (4 times in 24 h). In the control group, liquid paraffin (from Merck, Darmstadt, Germany; Code: 1.07160) was rubbed on the skin as placebo, exactly as the sesame was applied for the intervention group.^[26,27] Patients in both groups were regularly monitored over the 24 h of amiodarone infusion and also 6 h after (making a total of 30 h and 10 min) to assess catheter survival in terms of incidence and severity of phlebitis. Once the incidence of phlebitis was confirmed by the assessor (blind to the groups), grade of phlebitis, duration of the survival of catheter, and the onset and completion of the infusion were recorded. In the course of the study, patients were blind to the use of sesame oil or paraffin.

Data were analyzed with Statistical Package for Social Science (SPSS) software program (v. 18) using descriptive statistics such as relative and absolute frequencies, mean and standard deviation, and inferential statistics such as Chi-square, Kaplan–Meier, Hazard ratio, independent *t*-test, and Fisher's exact test.

RESULTS

Thirty-six patients participated in this study. Demographic and medical details of patients are presented separately for the two groups in Table 1. Eleven patients (61.1%) in the sesame oil group and 14 patients (77.8%) in the liquid paraffin group had atrial fibrillation, with the remaining patients experiencing other cardiac arrhythmias. Catheterization was performed in patients' left hand in 83.3% ($n = 15$) of the sesame oil group and 77.8% ($n = 14$) of the liquid paraffin group, and for the

rest of the patients, in the right hand. Considering that there was a random allocation of patients into groups, there were no significant differences between the two groups in terms of age, gender, diagnosis, background diseases, diabetes, hypertension, and site of IV line ($P > 0.05$) [Table 1].

In the first 10 min of catheterization, no patient in either group contracted phlebitis. Phlebitis incidence rate and its comparison between the two groups on occasions of the first 10 min to 6 h after catheterization, from 6 h and 10 min to 24 h and 10 min, and from 24 h and 10 min to 30 h and 10 min are presented in Table 2. In total, the phlebitis rate over 30 h and 10 min after catheterization was 38.9% ($n = 7$) in the sesame oil group and 77.8% ($n = 14$) in the liquid paraffin group.

According to Chi-square test, there was a significant difference between the two groups in terms of the grade of phlebitis over 30 h and 10 min after catheterization ($P = 0.006$, $\chi^2 = 12.37$). Grade of phlebitis in the first 10 min was zero in both groups. When comparing the grade of phlebitis in the two groups, a significant difference was found in the first 10 min to 6 h and 10 min ($\chi^2 = 13.84$, $P = 0.003$), from 6 h and 10 min to 24 h and 10 min ($\chi^2 = 11.97$, $P = 0.008$) and Chi-square's test showed no significant difference between the two groups from 24 h and 10 min to 30 h and 10 min after catheterization.

It can be seen from Figure 1 that possible catheter survival in the sesame oil group was linear in the first 18 h, and then reduced stepwise. Catheter survival in the liquid paraffin group was linear in the first 2 h, and steeply reduced stepwise until 9 h after catheterization, then stayed constant until the 18th hour, and reduced once again. Kaplan–Meier showed a significant difference in catheter survival between the two groups over 30 h and 10 min after catheterization ($P < 0.001$). Mean survival time in the sesame oil group was 22.286 (1.34) h with a confidence interval 19.659–24.912 and in the liquid paraffin group was 6.571 (1.028) h with a confidence interval 4.556–8.587.

It can be seen from hazard function figure that in the sesame group, the Cumulative Hazard in the first 18 h was linear and equal to zero, and increased stepwise afterward. In the liquid paraffin group, the Cumulative Hazard was linear and equal to zero in the first 2 h, and steeply increased afterward. This figure demonstrates greater hazard ratio in the control group compared to the intervention [Figure 2].

DISCUSSION

In the present study, mean age in the sesame and liquid paraffin groups was 68.5 (13.01) and 70.27 (13.52) years, respectively. In a study aiming to investigate the incidence

Table 1: Demographic and medical details of patients in the intervention and control groups

Group Variables	Intervention group (sesame oil)		Control group (liquid paraffin)		Statistical test	P value
	Mean	Standard deviation	Mean	Standard deviation		
Age	68.50	13.01	70.27	13.52	Independent t-test	0.690
Mean time of phlebitis development	22.28	3.54	6.57	3.54	Independent t-test	<0.001
Gender						
Male	38.9%		44.4%		Chi-square	0.735
Female	61.1%		55.6%			
Catheter site						
Wrist	16.7%		27.8%		Chi-square	0.464
Forearm	77.8%		72.2%			
Anti-cubital	5.6%		0%			
Diabetes	27.8%		16.7%		Fisher's exact test	0.691
Hypertension	50%		38.9%		Chi-square	0.171

Table 2: Phlebitis incidence rate at different times in the intervention and control groups

Incidence of phlebitis Group	From the first 10 min to 6 h and 10 min		From 6 h and 10 min to 24 h and 10 min		From 24 h and 10 min to 30 h and 10 min		The entire 30 h and 10 min	
	Number	%	Number	%	Number	%	Number	%
Intervention group (sesame oil)	0	0	6	33.3	1	8.3	7	38.9
Control group (liquid paraffin)	10	55.6	4	50	0	0	14	77.8
Statistical test	Fisher's exact test		Fisher's exact test		Fisher's exact test		Kaplan-Meier	
P value	<0.001		0.664		1		<0.001	

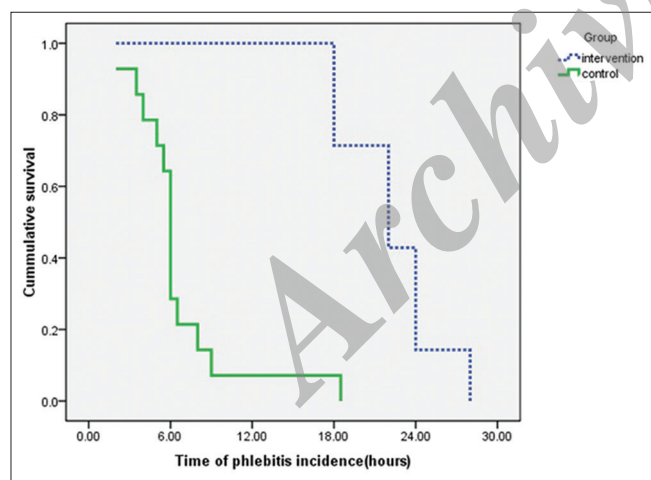


Figure 1: Catheter survival rate (hours) in the intervention and control groups

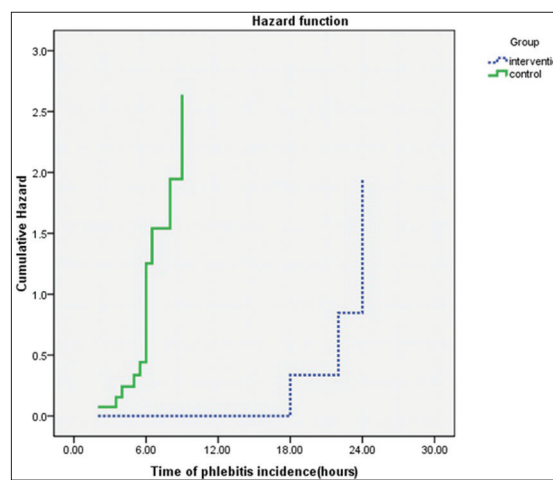


Figure 2: Risk of phlebitis (hours) in the intervention and control groups

of amiodarone-related phlebitis, patients' mean age was 65.1 (11.3) years.^[8] Considering that the present study was conducted in cardiac and CCU departments, and that prevalence of cardiovascular diseases is greater in older age, this finding is rational. In the present study, according to *t*-test results, there was no significant difference in the age of patients who contracted phlebitis and those who did not (*P* = 0.671), and this finding is supported

by similar studies.^[8,28,29] Unlike the results of the present study, another study reported age as a phlebitis risk factor.^[4] Given this difference, conducting descriptive studies with larger sample size to assess the relationship between age and phlebitis rate appears necessary.

In the present study, 11 patients (61.1%) in the sesame oil group and 10 (55.6%) in the liquid paraffin were female. Chi-square test showed no significant difference between

men and women in terms of contracting phlebitis. Unlike the present study, in a study conducted in the United States, aiming to investigate the incidence of phlebitis, male gender was associated with increased incidence of phlebitis.^[30] According to another study conducted in the United States on 188 catheterized patients to assess the onset of phlebitis, women who received higher doses of intravenous medications were at greater risk of phlebitis.^[31] Considering such conflicting results, it is recommended to conduct an extensive epidemiological study with a large sample size to examine the relationship between gender and the incidence of phlebitis.

In the first 10 min, from the first 10 min to 6 h and 10 min, from 6 h and 10 min to 24 h and 10 min, and from 24 h and 10 min to 30 h and 10 min after catheterization, the incidence rates of phlebitis in the intervention group were 0, 0, 33.3%, and 16.7%, respectively, and in the entire 30 h and 10 min after catheterization, the incidence rate of phlebitis was estimated at 38.9%. Similar to the present study, Nekuzad *et al.* conducted a study to investigate the effect of external use of sesame oil in the prevention of chemotherapy-induced phlebitis, in which the rate of phlebitis in the intervention group was reported to be 10%,^[12] which is less than that in the present study. This is probably due to continuous administration of high concentration of amiodarone over 24 h, which has a molecular weight of 643.3 and contains 37% iodine.^[4] However, in Nekuzad *et al.*'s study, chemotherapy medications were administered with a different protocol, and thus, the type and duration of drug contact with vein were different, which can explain the difference in phlebitis rate.

In the first 10 min, from the first 10 min to 6 h and 10 min, from 6 h and 10 min to 24 h and 10 min, and from 24 h and 10 min to 30 h and 10 min after catheterization, the incidence rates of phlebitis in the control group (liquid paraffin) were 0, 55.6%, 50%, and 0, respectively, and in the entire 30 h and 10 min after catheterization, the incidence rate of phlebitis was estimated at 77.8%. The present study results showed a significant statistical relationship between the two groups in terms of contracting phlebitis. These results are consistent with the results obtained by Nekuzad *et al.*,^[12] and thus confirm the effect of sesame oil on phlebitis. Boyce *et al.* reported the incidence of amiodarone-induced phlebitis as 67%.^[9] However, the phlebitis scale used to assess the severity of phlebitis in Boyce *et al.*'s study was different from that in the present study, and this rate was less in the control group compared to that in the present study (77.8%).

In a study by Junying *et al.* entitled "MEBO (Moist Exposed Burn Ointment) for treating skin injury and phlebitis caused by extravasation of chemotherapeutic drugs," 72.2% of

patients in the sesame group were reported to have healed after 3 weeks, while only 33.4% healed in the control group.^[32] In a study by Cho *et al.* entitled "Successful combined treatment with total parenteral nutrition fluid extravasation injuries in preterm infants," sesame oil was shown to have therapeutic effects on phlebitis.^[33] Results of these studies confirm the anti-inflammatory effects of sesame oil in the treatment of venous damages. Thus, it can be concluded that in addition to preventive effects, sesame oil has therapeutic effects on phlebitis.

The present study results showed increasing severity of phlebitis with time in the sesame oil group, especially in the period from 6 h and 10 min to 24 h and 10 min, when the highest dose of amiodarone (540 mg) was administered, phlebitis severity was the highest. In the intervention group, phlebitis grade 1, 4, or 5 did not occur in the entire 30 h and 10 min, and 61.1% did not contract phlebitis. But 16.7% contracted phlebitis grade 2 and 22.2% contracted grade 3. In a similar study, the mean phlebitis score in the intervention group was 0.1, and was less than that in the control group.^[12] The present study results showed increasing scores of phlebitis with time in the control group. In a similar study, the mean score of phlebitis in the control group was 1.9.^[12] Boyce and Yee reported various grades of phlebitis among patients.^[9] In the present study, the grades of phlebitis were not examined for different amiodarone protocol times. From the first 10 min to 6 h and 10 min, and from 6 h and 10 min to 24 h and 10 min, a significant difference was observed in terms of phlebitis scores between the two groups. In line with the present study results, this difference was also reported by Nekuzad *et al.*^[12]

In the present study, catheter survival was higher in the intervention group than in the control group. Minimum and maximum times for the incidence of phlebitis in the sesame oil group were 18 and 28 h, respectively, and in the liquid paraffin group were 2 and 18.5 h, respectively. These results show that use of sesame oil delays the onset of phlebitis induced by peripheral intravenous infusion of amiodarone in the intervention group. In line with the present study results, in Nekuzad *et al.*'s study, time of development of phlebitis in the intervention group had been delayed compared to the control group.^[12] Results of a study conducted by Sharifipour *et al.* to assess the topical effects of sesame oil on severe corneal alkali burn in rabbits showed that the application of topical sesame oil can delay rupture of the cornea in severe alkali burn, with 29.6 days in the sesame oil group and 25.6 days in the control group ($P = 0.01$).^[18]

CONCLUSION

According to the results, topical use of sesame oil is recommended to reduce progress of amiodarone-induced

phlebitis, particularly because sesame oil is plentiful in Iran, has no side effects, and is economical.

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