Science Press

Journal homepage:
www.jcimjournal.com/jim
www.elsevier.com/locate/issn/20954964
Available also online at www.sciencedirect.com.


• Research Article

# Efficacy of topical chamomile on the incidence of phlebitis due to an amiodarone infusion in coronary care patients: a double–blind, randomized controlled trial

**Maryam Sharifi-Ardani[1], Leili Yekefallah[1], Saeed Asefzadeh[2], Marjan Nassiri-Asl[3]**

1. School of Nursing and Midwifery, Qazvin University of Medical Sciences, Qazvin 341197-5981, Iran
2. Social Determinants of Health Research Center, Qazvin University of Medical Sciences, Qazvin 341197-5981, Iran
3. Cellular and Molecular Research Center, Department of Pharmacology, Qazvin University of Medical Sciences, Qazvin 341197-5981, Iran

## ABSTRACT

**BACKGROUND:** Amiodarone is a useful antiarrhythmic drug. Phlebitis, caused by intravenous amiodarone, is common in patients in coronary care units (CCUs).

**OBJECTIVE:** The aim of this study was to evaluate the effect of topical chamomile on the incidence of phlebitis due to the administration of an amiodarone infusion into the peripheral vein.

**DESIGN, SETTING, PARTICIPANTS AND INTERVENTIONS:** This was a randomized, double-blind clinical trial, conducted on 40 patients ($n$ = 20 per group) in two groups—an intervention group (chamomile ointment) and a control group (lanoline, as a placebo), hospitalized in the CCUs and undergoing an amiodarone infusion into the peripheral vein over 24 h. Following the cannulation and commencement of the infusion, placebo or chamomile ointment was rubbed in, up to 10 cm superior to the catheter and repeated every eight hours for three days. The cannula site was then assessed based on the phlebitis checklist.

**MAIN OUTCOME MEASURES:** The incidence and time of occurrence of phlebitis, relative risk, severity of phlebitis were the main outcome measures.

**RESULTS:** Nineteen patients (19/20) in the control group had phlebitis on the first day of the study and one patient (20/20) on the second day. In the intervention group, phlebitis occurred in 13 cases (13/20) on the first day and another two (2/7) was found on the second day. The incidence of phlebitis was significantly different between two groups ($P$ = 0.023). The cumulative incidence of phlebitis in the intervention group (15/20) is significantly later and lower than that in the control group (20/20) during two days ($P$ = 0.008). Two patients in the intervention group did not develop phlebitis at all during the 3-day study. Also, the relative risk of phlebitis in the two groups was 0.68 ($P$ = 0.008 5). A significant difference was not observed with regard to phlebitis severity in both groups.

**CONCLUSION:** It seems that phlebitis occurred to a lesser extent and at a later time frame in the intervention group compared to control group. Topical chamomile may be effective in decreasing the incidence of phlebitis due to an amiodarone infusion.

http://dx.doi.org/10.1016/S2095-4964(17)60358-3
**Received** April 1, 2017; **accepted** May 26, 2017.
**Correspondence:** Prof. Marjan Nassiri-Asl; E-mail: mnassiriasl@qums.ac.ir

**TRIAL REGISTRATION:** This protocol was registered in the Iranian Registry of Clinical Trials (IRCT2014042017361N1).

**Keywords:** phlebitis; amiodarone; prevention; chamomile; clinical trial; plants, medicinal

**Citation:** Sharifi-Ardani M, Yekehfallah L, Asefzadeh S, Nassiri-Asl M. Efficacy of topical chamomile on the incidence of phlebitis due to an amiodarone infusion in coronary care patients: a double-blind, randomized controlled trial. *J Integr Med*. 2017; 15(5): 373–378.

## 1 Introduction

Amiodarone is one of the most effective drugs for the treatment of supraventricular tachyarrhythmia and specifically appropriate in patients with life-threatening ventricular tachyarrhythmia.[1] This drug is widely used in clinical practice for the treatment of ventricular tachyarrhythmia, wide-complex tachycardia and atrial fibrillation and for rhythm control after surgery.[2] The use of amiodarone is recommended in the cardiopulmonary resuscitation algorithm of the American Heart Association.[3]

The incidence of phlebitis, caused by intravenous amiodarone, varies in different studies from 8% to 55%.[4] However, according to the Infusion Nurses Society, an acceptable phlebitis rate is reported to be ≤ 5% for a population.[5] Intravenous amiodarone is administered via a peripheral catheter that causes mild to severe thrombophlebitis at the infusion site.[6,7] To prevent phlebitis due to an amiodarone infusion, a central venous catheter is preferred.[6] However, it is not always possible to administer a drug via central catheter, especially in emergency situations or for short periods. Moreover, the use of this method may expose patients to other risks, such as thrombotic events and mechanical complications.[6]

Chamomile is a herb that is widely used and included in the herbal medicine pharmacopoeia of 26 countries.[8] Amino acids, polysaccharides, fatty acids, essential oils, minerals, flavonoids, and phenolic compounds are the main elements of chamomile.[9] Chamomile has various pharmacological properties including antioxidant, gasteroprotective and hepatoprotective effects and antibacterial and wound healing activities.[10–13]

Chamomile flowers contain 1%–2% volatile oil, including α-bisabolol, α-bisabolol oxides A and B, matrisin (which usually turns to kamazolen) and other flavonoids with anti-inflammatory and anti-edema properties.[14]

Chamomile extract (2.5%) is most therapeutically effective when treating phlebitis grade II.[15] It has been suggested that chamomile's therapeutic effects are attributable to its anti-inflammatory properties.[15] Moreover, chamomile ointment has been demonstrated to promote wound healing in episiotomy in nulliparous women.[16] The aim of this study was to determine the effect of chamomile ointment on the incidence of phlebitis due to amiodarone therapy in patients in the coronary care units (CCUs) of selected hospitals in Qazvin, Iran.

## 2 Material and methods

### 2.1 Study design

This study was a randomized, double-blind, placebo-controlled trial. The patients of the CCUs in Qazvin (Buali-Sina, Velayat, and Razi Hospitals), Iran, from March 2014 to March 2015 were selected for the study population. Based on data from a previous study,[6] and using a sample size formula with a power of 90%, $\alpha$ equal to 0.05, and an attrition rate of 20%, the sample size in this study was calculated to be at least 20 patients in each group.

### 2.2 Inclusion and exclusion criteria

Inclusion criteria were patients between 18–78 years old, who had been treated with amiodarone due to ventricular or supraventricular arrhythmias. Patients with any concomitant disease, such as diabetics mellitus and peripheral vascular disease were excluded, as this could affect the risk of phlebitis occurrence.

### 2.3 Intervention

Chamomile ointment (Soha-Jissa Pharmaceutical Company, Salmanshahr, Mazandaran, Iran) containing 1.5 g chamomile extract per 100 g (1.5%) was used as the intervention in this study. Pharmaceutical lanoline (Farabi, Hashtgerd, Iran) with color additives was used as the placebo. It was prepared and placed in the same container by a pharmacist so that the containers' contents with regard to color, smell, consistency and appearance would be the same. The rapid infusion of 150 mg amiodarone (Ebewe Pharma, Vienna, Austria) was commenced within 10 min in all patients, and continued for the first six hours at 1 mg/min, and for the next 18 h at 0.5 mg/min. All the patients received a single drug and no other injection was administered. A 20-gauge needle was used in the arm, back of the hand, wrist, forearm and elbow for both groups and was fixed by transparent adhesive.

Forty patients who had been treated with amiodarone for 24 h were placed in the intervention (chamomile ointment) and control (lanoline) groups after random selection, with 20 patients in each group (Figure 1). An independent researcher generated simple randomization by means of computer-generated random numbers, which were placed in sealed opaque envelopes. This researcher