Effects of injection-site splinting on the incidence of phlebitis in patients taking peripherally infused amiodarone: A randomized clinical trial

Farah Ayat-Isfahani, Mina Pashang, Bita Davoudi, Saeed Sadeghian, and Arash Jalali

*Intravenous amiodarone is considered an effective treatment option for cardiac ventricular and atrial arrhythmias. Peripheral infusion of amiodarone may cause blood vessels irritation and phlebitis that is the most common complication of this drug by this route even when it is administered within recommended dosing limits. The effect of injection-site splinting on the occurrence of phlebitis among a group of cardiac arrhythmia patients receiving peripherally infused amiodarone. This research is a clinical trial on patients of Tehran Heart Center who were hospitalized due to cardiac arrhythmias. A sample of 60 patients with mean age 65 ± 14 years were randomly divided into control and test groups. In the experimental group with close splint and restrict the movement of the injection site until the end of the infusion and control groups without closing brace, at the same time received amiodarone. Injection protocol was similar for both groups. The results were analyzed with Spss18. The results of this research still significantly reduced the incidence of amiodarone injection-site phlebitis in the injection time (*P = *.005).* (J Vasc Nurs 2017;35:31-35)

Intravenous amiodarone is considered an effective treatment option for cardiac ventricular and atrial arrhythmias.[1] A meta-analysis of randomized controlled trials of amiodarone showed that prophylactic amiodarone was able to decrease arrhythmic death in high-risk patients and that this effect led to an overall reduction of 13% in total mortality.[2] The preferred route of administration is by a central catheter using an in-line filter; however, this method is often not feasible since the drug is injected in emergent situations for a short period of time.[3] On the other hand, the peripheral infusion of amiodarone may cause the irritation of the blood vessels, which is technically termed "phlebitis" and is somehow the most common complication of this drug via this route even when it is administered within recommended dosing limits.[1,4,5] Phlebitis causes significant pain, failure of the peripheral intravenous cannula, interruption to the prescribed drug, and requirement for the insertion of a new peripheral intravenous cannula. Moreover, it has harmful impacts on both patients and the health care system necessitating additional diagnostic interventions and therapies, long periods of hospitalization, excess costs, stress for patients and their families, and further workload for the nursing staff.[3,6] In addition, it leads to loss of future venous access[7] and untreated bacterial phlebitis, which may eventually cause sepsis.[8] Most importantly, phlebitis can result in thrombus formation (thrombophlebitis) and even death.[9] In general, phlebitis may be categorized as postinfusion, bacterial, chemical, and mechanical phlebitis[10] based on its causes. In this regard, amiodarone-induced phlebitis has been ascribed to the mechanical and chemical effects of the particulate matter introduced during injection.[11] Many factors are believed to contribute to the development of amiodarone-induced phlebitis, among which the following are more outstanding: size, length, material of the cannula used, insertion technique and skill of clinicians, pH, and osmolarity of the solution, rate of infusion, duration of treatment, and frequent handling of intravenous dressings.[12–14] All these previously mentioned factors have been repeatedly modified on different occasions to see their impact on the occurrence of phlebitis; nevertheless, nonsignificant change has been observed.[4,10,15] What can, however, clearly be witnessed is that any movement such as the bending and straightening of the arm may dislodge the cannula and cause the infiltration of the infusion fluid, extravasation of the drug, or mechanical phlebitis.[1,10,16] Accordingly, researchers have proposed the fixation of the injection site to see whether this would reduce the incidence of phlebitis. Therefore, the objective of the present study was to investigate the effect of injection-site splinting on the occurrence of phlebitis among a group of cardiac arrhythmia patients receiving peripherally infused amiodarone.

From the Tehran Heart Center, Tehran University of Medical Sciences, North Kargar St, Tehran.

Corresponding author: Farah Ayat-Isfahani, Tehran Heart Center, Tehran University of Medical Sciences, North Kargar St, Tehran 1411713138, Iran (E-mail: rose8a2001@yahoo.com).

1062-0303/$36.00

http://dx.doi.org/10.1016/j.jvn.2016.11.001

METHOD

This randomized clinical trial was conducted with the approval of the Institutional Review Board of Tehran University of Medical Sciences (January 11, 2012), in accordance with the Declaration of Helsinki, and was registered with the www.irct.ir protocol registration system (IRCT2015061622768N1). The population of the study consisted of 64 random consecutive

patients with cardiac arrhythmia presenting during daytime working shifts at the coronary care unit. All patients had ventricular tachycardia or atrial fibrillation requiring intravenous amiodarone during hospitalization. The exclusion criteria were comprised of age <18 years, history of chemotherapy, history of radiotherapy, history of deep vein thrombosis, any varicose veins, and renal failure. Patients receiving intravenous antibiotics and/or steroid drugs were also excluded. Furthermore, four patients were excluded from the study: two of them owing to a history of chemotherapy (one patient with lymphadenopathy and one with bladder cancer) and two due to refusal to participate in the study after completing the written informed consent form. Although the nature of the intervention precluded the blinding of the investigators, the randomization of the patients was performed depending on whether the last digit of the patients' code was odd or even. After obtaining written informed consents from all participants, we randomly divided 60 patients into an intervention group and a control group, each with 30 subjects. In the intervention group, a cannula (18 or 20 gauge sizes depending on the patient's vessel size) was inserted and dressed with sterile gauze by a bedside nurse. The injection site was immobilized using a splint that was designed by the research nurse, based on the location of the catheter (Figures 1 and 2). Two kinds of splints were designed by the research team: the first kind was used for the hand and the other kind for the forearm, taking a neutralization angle to the wrist and elbow for both. The splints were made of fiberglass. In order to avoid sweating, the researchers covered the splints with cotton. In the control group, the same technique was applied except for the fact that no splint was used to fix the injection site. All patients in both groups received intravenous amiodarone through a peripheral vein access. Intravenous amiodarone is typically given as a bolus of 150 mg in 50 cc of normal saline serum for 10 minutes and then 1 mg/min (75 mg in 50 cc of normal saline serum) of intravenous infusion for 6 hours followed by 0.5 mg/min (75 mg in 50 cc of normal saline serum) intravenously for 18 hours (a total dose of 300 mg/24 h). The venous access site was examined 30 minutes and subsequently 3, 6, 12, and 24 hours after amiodarone administration for signs of phlebitis. Each patient's temperature was recorded by a trained nurse. Phlebitis, the outcome variable, was diagnosed by the documented presence of tenderness, edema, redness, and temperature at the intravenous site as noted at least by two members of the medical team. Upon noting the phlebitis sign, the bedside nurse was to inform the other nurse. In case of disagreement between the two nurses, a third nurse from another ward would have the final say. (In the present study, such conflict did not arise.) Upon the confirmation of phlebitis, the patients had their catheters removed and replaced. For those in the intervention group, a splint was used to fix it once again. Other drugs were given through separate cannula.

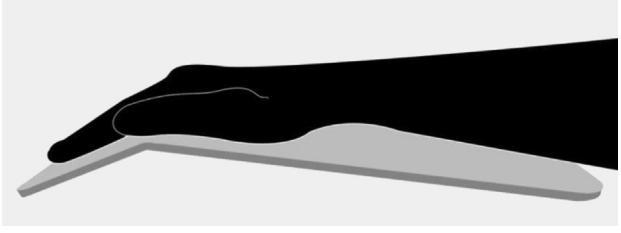

Figure 1. *Wrist splint.*

Figure 2. *Forearm splint.*

Data collection

Qualified nurses collected data on a data collection form on prespecified data elements, including baseline demographics, potential risk factors of phlebitis (eg, diabetes mellitus, hypertension, and cigarette smoking), and type and cause of arrhythmia. The starting and ending times of amiodarone infusion, location of the catheter (ie, the hand, forearm, wrist, or elbow), phlebitis occurrence, time to the onset of phlebitis, and catheter size were also taken into consideration.

Statistical analysis

The data were analyzed using PASW Statistics for Windows, version 18.0. (Chicago: SPSS Inc.). As a power analysis based on the results of a pilot study suggested, a sample size of 30 patients for each group was required to achieve a power of 90% at a 0.05 level of significance for the detection of a 30% reduction in phlebitis incidence attributed to splint usage. The continuous variables are described as means $\pm$ SDs or medians with interquartile range boundaries, and they were compared between the intervention and comparison groups using the Student *t*-test or the Mann–Whitney *U*-test. The categorical variables are expressed as frequencies with percentages, and they were compared between the two groups using the χ^2 test or the Fisher exact test. The variables that were simultaneously associated with the intervention group and phlebitis incidence with a $P < .2$ were considered potential confounders. For the continuous variables, the log-transformation method was drawn upon to approximately normalize the values that were highly skewed, and the transformed values were used in the analyses. A logistic regression model was applied to adjust for the potential confounders. If a patient developed the event of phlebitis more than once, each one was considered an independent phenomenon.

RESULTS

Sixty patients were included in the statistical analysis of the data. Overall, the average age of the patients was 65 $\pm$ 14 years, and 44 of the subjects (73.3%) were men. The reason for the intravenous amiodarone injection was atrial fibrillation in 28 (74.7%) patients and ventricular tachycardia in 32 (53.3%). The intervention and control groups could be considered similar with respect to their baseline characteristic data except for the point that the patients in the control group more frequently received aspirin (Table 1). In both groups, the average duration