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The Effect of Intravenous Administration with Body Temperature on Indwelling of Peripheral Venous Catheters

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ABSTRACT

Background: Intravenous (IV) catheter insertion is the most common invasive hospital procedure and its related complications are costly for both patients and the healthcare system. Phlebitis or inflammation of the vein is an important cause of premature catheter failure.

Objective: This study aimed to determine the effect of IV administration with body temperature on indwelling of peripheral venous catheter.

Methods: This randomized controlled clinical trial was conducted among 106 patients who required IV administration and were admitted to internal wards of Imam Ali Hospital in Sarayan, Iran in 2016. The patients were randomly divided into an intervention (n = 53) and a control (n = 53) group via permuted block randomization with four blocks. The solutions and medications were infused by infusion pump SN-1500SERIAL at body temperature (37 °C) in the intervention group and at a mean temperature of 24 °C in the control group. The insertion sites were observed every two hours for evidence of phlebitis according to the Infusion Nurses Society. The indwelling of the peripheral vein catheter was also recorded every two hours. The data were collected using an information sheet and were analyzed by t-test and chi-square test using the SPSS 16 software. $P < 0.05$ was considered to be statistically significant.

Results: There were no significant differences between the two groups in terms of age, sex, education level, marital status, underlying diseases, addiction, Body Mass Index (BMI), and the mean received volume of infused fluids. The results also showed no significant differences between the two groups in terms of occurrence of phlebitis ($P = 0.28$). Despite the increase in the indwelling of the peripheral vein catheter in the two groups, the differences were not statistically significant ($P = 0.13$).

Conclusion: Although IV administration with body temperature has been reported to be slightly effective in indwelling of the peripheral venous catheter, this study showed no significant evidence. Thus, further studies are recommended to be conducted on lower and higher degrees than body temperature (37 °C).

1. Background

Among hospitalized patients, intravenous therapy is the most common invasive procedure and is associated with a phlebitis rate of 2.3 - 60% (1). Direct administration of fluids and drugs into the bloodstream is necessary. In this context, placing catheters is the most common invasive hospital intervention in the world, such a way that 60 - 90% of patients need an intravenous catheter during hospitalization. Intravenous catheter is the most commonly used intravenous device for administration of drugs, intravenous fluids, and blood products (2). It has been estimated that 150 million peripheral intravenous catheters are inserted in the United States annually, with an increasing use of medication therapy that is toxic to the veins. In many instances, patients experience several unsuccessful attempts before a peripheral line is successfully inserted, which increases their stress, discomfort, and costs (3). Despite the vast majority of controlled studies, total catheter failure rates have been reported to be 35 - 50%. Catheter failure and its associated complications are costly for the

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healthcare system (4, 5). Catheter failure or ineffectiveness refers to the exit of the catheter before the target time or the time determined by the Center of Disease Control (96 - 72 hours) following phlebitis, tissue infiltration, obstruction or mechanical failure, random catheter withdrawal, or infection (alone or in combination) (6, 7). Phlebitis has been mentioned in numerous studies on intravascular catheter complications to be one of the most important reasons for catheter failure (8). Phlebitis is a serious health problem that affects a large proportion of hospitalized patients receiving intravenous therapy (9).

Most studies have reported the incidence of phlebitis to vary from 18% to 35% in different regions (10). However, according to the Nursing Association standards, the accepted phlebitis rate in any population has been declared to be 5% or less (7, 11).

According to medical and nursing texts, clear reasons have been introduced for phlebitis as follows:

- Chemical phlebitis, which is related to the nature of injectable solutions and drugs (osmolality and pH), insertion of catheter on the wet skin (impregnated with liquid disinfectant), and type and material of the catheter.
- Mechanical phlebitis, which is related to catheter size and flexibility, ratio of catheter size to vein diameter, location of installation, insertion technique, catheter fixation method, repeated use of a site for catheter insertion, and injection speed.
- Bacterial phlebitis, which is associated with defective disinfection of the skin before catheterization and taking care of the catheter, including dressing of the catheter site, changing the dressing, fixing the catheter, duration of catheter indwelling, and replacement time of the infusion set.
- Patients' demographic factors, including age, gender, and race, and their underlying conditions, including malnutrition, neutropenia, use of immunosuppressant agents, and circulatory dysfunction.
- The therapeutic skill of catheter insertion also plays an important role in creation of phlebitis (12, 13).

Good practice when inserting a cannula, including appropriate choices of device and site, can help prevent phlebitis. Good infection control techniques are also vital in preventing the condition (14).

Evidence has suggested that some preventive measures can reduce the prevalence rate of cardiovascular disease (15). For example, heparin 100 U/mL was effective in the maintenance of peripheral venous catheters. It reduced the number of catheter-related phlebitis/occlusions as well as the number of catheters per patient, with potential advantages to both patients and the health system (16).

According to published studies about the risk factors of phlebitis, soluble temperature is one of the factors that influence phlebitis (17). The local effects of moist temperature compress on phlebitis have been studied. Local hot compresses have been reported to affect phlebitis symptoms due to the peripheral catheter (18). The results of another study showed that the incidence of phlebitis and vascular injury was declined via warm infusion of mannitol (19).

Despite the impact of heat on the incidence of phlebitis, few studies have explored the impact of the local temperature of the injection solution on preventing the symptoms of phlebitis. Heat dilates the arteries and reduces the risk of clot formation in the vessels. In fact, increased blood flow occurs following the use of local heating, which reduces clots as an inflammatory agent in the vessel wall. It prevents the inflammation of the vessel wall, as well (13).

2. Objectives

Considering the importance of this issue and the lack of sufficient studies on the effects of temperature on occurrence of phlebitis and indwelling of peripheral vein catheters, the question arises whether temperature of the injectable solution affects the indwelling of peripheral venous catheters. Therefore, this study aims to determine the effect of intravenous infusion with body temperature on indwelling of peripheral venous catheter.

3. Patients and Methods

3.1. Trial Design

This randomized controlled clinical trial was approved by the Regional Ethics Council of Gonabad University of Medical Sciences (IR.GMU.REC.57, 1395) and was registered in the Iranian Registry of Clinical Trials (code: IRCT2017022632779N1). The clinical trial was reported based on the CONSORT statement 2010 checklist (20) (Figure 1).

3.2. Participants and Setting

This study was done on the patients admitted to the internal medicine ward of Imam Ali hospital, Sarayan, South Khorasan, Iran in 2016. The study population included all patients who were admitted to the internal ward of Imam Ali hospital and were treated with intravenous solutions and drugs.

3.3. Sample Size and Randomization

Based on the study performed by Haji Hosseini et al. and considering the power of 80% and confidence level of 95%, a 96-subject sample size was calculated for the study (n = 48 in each group) (18). By taking a 10% loss rate into account, 53 participants were considered for each group. Totally, 106 patients were selected via convenience sampling and were randomly assigned to intervention and control groups using permuted block randomization with four blocks.

The inclusion criteria of the study were signing informed consents for taking part in the research, aging 18 - 65 years, complete awareness, not having underlying diseases such as leukemia, immunodeficiency, and dermatitis, having healthy upper limbs, not having received immunosuppressive drugs and chemotherapy, having an intravenous catheter for at least 72 hours, not consuming intravenous irritant drugs and hyperosmolar solutions that are accompanied with high levels of phlebitis after injection (some antibiotics, such as vancomycin, azithromycin, levofloxacin, beta-lactams, and amphotericin, and some electrolytes, such as potassium) (21), not having the history of injection drug abuse, and not having fever > 37.5 °C. The exclusion criteria of the study were unwillingness to continue cooperation, need for injection of irritating drugs and hyperosmolar solutions during the study, receiving liquids and intravenous drugs

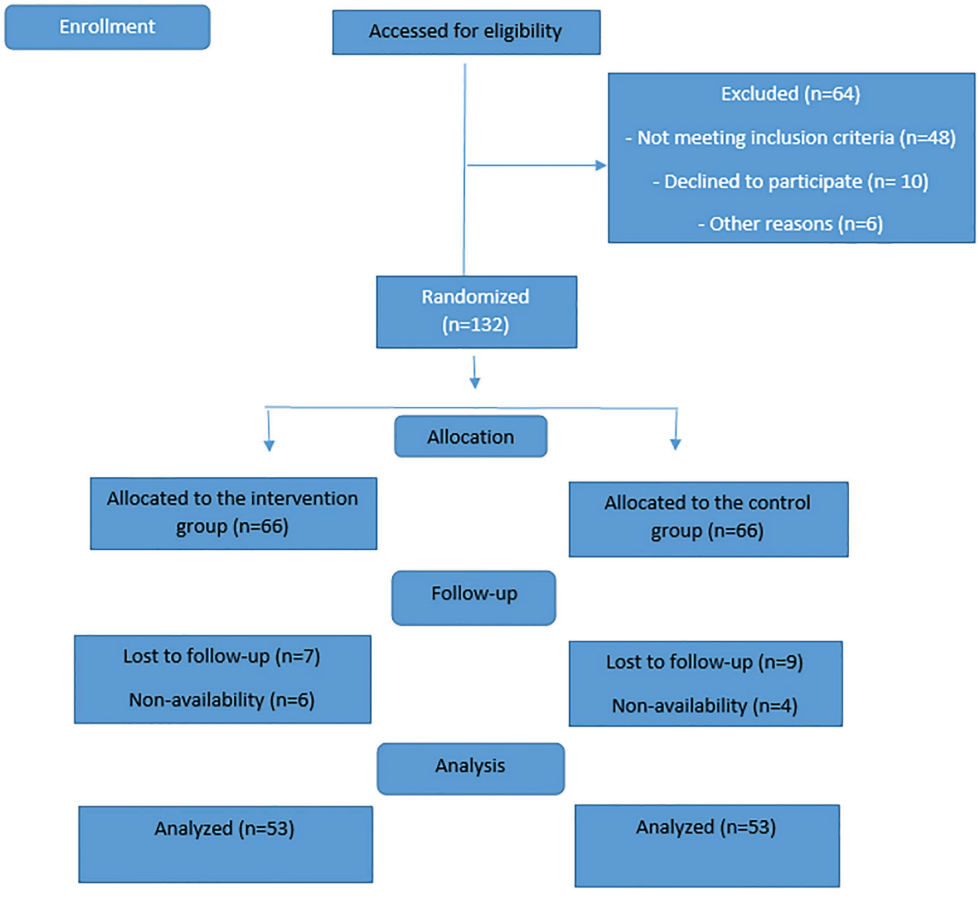

Figure 1. CONSORT Flowchart of the Study

for less than 72 hours, transfer to other centers, adhesion sensitivity (transparent dressing), and suffering from febrile illness with temperature above 37.5 °C.

3.4. Intervention and Outcomes

Intravenous catheter number 22 (blue) was installed in the veins at the patients' forearms by trained nurses who had two-six years of clinical experience and were trained about the catheterization process based on the standards of Infusion Nurses Society, including disinfecting the catheter site, selecting an appropriate intravenous catheter, selecting a suitable catheter for the vein, and dressing the catheter site. After disinfection with 70% alcohol, the catheter was installed in the appropriate site. The catheter was established by transparent dressing. In the intervention group, the solutions and prescriptions were prepared by a volumetric infusion pump (MDT SINO SN-1500 serial models) with the ability to heat the infused solution within the range of body temperature. The infused solution was administered in the intravenous catheter at the temperature of 37 °C just prior to its entrance into the vein. In the control group, on the other hand, the solutions and medications were placed in the patients' rooms for two hours before infusion (the temperature of the patients' rooms was about 24 °C). Then, a contact thermometer was stuck on the microcet by its adhesive layer. It should be noted that the average temperature of the infused solutions was 24 °C that was prescribed for the total infusion time.

Isotonic solutions included normal saline and 3.3% normal saline plus 33.3% dextrose combined with the intravenous drugs with average volumes of 2, 1.5, and 1 liter on the first, second, and third days, respectively. If necessary, an intravenous drug including cefotaxime 2 gr was administered every eight hours. Acetaminophen diluted with 100 mL distilled water was also administered and infused by the microset within 30 minutes. Immediately after the beginning of infusion, hematoma and accuracy of catheterization were investigated. In case of complications, the patients were excluded from the study. Then, the catheter site was assessed every two hours after installation using the phlebitis criteria of the Infusion Nurses Society whose validity and reliability were confirmed by a researcher's assistant who was unaware of the study groups (13, 22). These criteria included five degrees from zero to 4, as follows: grade 0: no symptoms, grade 1: redness with or without pain, grade 2: pain with redness or edema, grade 3: pain with redness or edema plus reddening of the streaks along the path of the vein and a touchable rope-shaped vein sized less than one inch, and grade 4: symptoms of grade 3 plus a touchable rope-shaped vein sized more than 1 inch and secretion. As soon as the occurrence of phlebitis symptoms with grade 2, the catheter was removed and the case was recorded as catheter removal by phlebitis. The catheter remained in place until it worked safely and did not show the clinical signs of damage. As soon as any events of catheter failure occurred, they were removed from the site.

Data collection forms were completed by nurses based on the records and statements. The first part of the form

included demographic characteristics, such as disease diagnosis, having or not having diabetes, smoking, and body mass index. The second part of the form contained information about catheterization, complications, and factors related to phlebitis and catheter removal, which was provided by the researcher using sources, books, and related publications. The face and content validity of this form was confirmed by 10 faculty members.

3.5. Statistical Analysis

The data were analyzed using the SPSS statistical software, version 16. First, Kolmogorov-Smirnov test was performed to determine the normality of the data. Parametric tests were used in case of normal distribution and non-parametric tests were used in case the data did not follow normal distribution. Independent t-test was used to compare the two groups regarding mean age, body mass index, and the received volume of infused fluids. Besides, chi-square test was used to compare the two groups in terms of gender, education level, marital status, underlying diseases, addiction, phlebitis, and indwelling of the peripheral venous catheter. $P < 0.05$ was considered to be statistically significant.

3.6. Ethical Considerations

The trial protocol was approved by the regional Ethics Committee (code: IR.GMU.REC57, 1395). Written informed consents for participation in the study were obtained from all participants. Besides, the data were gathered and analyzed anonymously.

4. Result

The mean age of the patients in the two groups was 44.05 ± 11.05 years and the majority of the patients were female (58.5%). The two groups were homogeneous in terms of age ($P = 0.66$), sex ($P = 0.43$), body mass index ($P = 0.18$), education level ($P = 0.85$), marital status ($P = 0.02$), underlying diseases ($P = 0.17$), addiction ($P = 0.91$), and the mean received volume of infused fluids [first 24 hours ($P = 0.65$), second 24 hours ($P = 0.55$), and more than 48 hours ($P = 0.333$)] (Tables 1 and 2). The results of chi-square test showed no significant difference between the two groups regarding the cause of catheter withdrawal ($P < 0.05$) (Table 3).

The results indicated a decrease in the frequency of phlebitis in the intervention group, but it was not significant statistically. Indeed, the injectable solution with normal body temperature did not have any significant effects on indwelling of peripheral catheters although it increased the indwelling of the peripheral catheters (Table 4).

5. Discussion

This study aimed to determine the effect of intravenous injection with body temperature on indwelling of peripheral catheters. Although temperature equalization with normal body temperature (37 °C) improved the incidence of phlebitis and peripheral catheter indwelling, it caused no significant difference between the two groups. On the contrary, Lakshmi et al. reported a significant difference in the level of superficial phlebitis in the group receiving warm compress. Thus, warm compress was effective in treatment of phlebitis (18). The obtained result might be attributed to utilization of temperatures higher than normal body temperature for heating the vein. Increasing the temperature beyond the natural body temperature causes vascular expansion. This dilatation reduces blood flow, thereby preventing inflammation in the vein wall.

Pan Li et al. conducted a study in China to determine the effect of heated mannitol 20% on prevention of phlebitis. They reported that hotter mannitol infusion had a significant effect on reducing the incidence of phlebitis (19). These results were not consistent with those of the present study. The difference might be related to the potential of serum mannitol 20% for causing phlebitis due to its hyperosmolar nature. It also contains a solid crystalline suspended in the serum as a stimulant for the vein wall at lower temperatures. These crystals gradually shift from solid to fluid state. In that study, increasing the temperature caused a decrease in crystals and reduced the incidence of phlebitis in the intervention group. However, the difference in the temperature of the injectable solution in the control and intervention groups differed from that in the present investigation (less than 10 degrees in one group and 37 degrees in the other group).

Table 1. Comparison of the Two Groups regarding the Means and Standard Deviations of Age, Body Mass Index, and Received Volume of Infused Fluids

Variable	Control Group (Mean ± Standard Deviation)	Intervention Group (Mean ± Standard Deviation)	T-test
Age	43.5 ± 10.43	42.51 ± 11.73	t = 0.42 df = 104 P = 0.66
Body mass index	23.6 ± 3.76	25 ± 3	t = 1.34 df = 99.1 P = 0.18
Average received volume of infused fluids (first 24 hours)	1.97 ± 1.05	2.06± 0.96	t = 0.45 df = 104 P = 0.64
Average received volume of infused fluids (second 24 hours)	0.88 ± 0.98	0.9 ± 1.09	t = 0.59 df = 104 P = 0.55
Average received volume of infused fluids (more than 48 hours)	0.57 ± 0.32	0.63 ± 0.43	t = 0.96 df = 104 P = 0.23

Table 2. Comparison of the Frequency Distribution of the Variables in the Two Groups

Variable	Frequency of the Control Group (%)	Frequency of the Intervention Group (%)	χ2 Test
Sex			
Female	33 (62.3)	29 (54.7)	χ2 = 0.62 df = 1 P = 0.43
Male	20 (37.7)	24 (45.3)	
Education level			
Illiterate	14 (26.4)	16 (30.2)	χ2 = 1.34 df = 4 P = 0.85
Primary school	12 (22.6)	13 (24.5)	
Middle school	5 (9.4)	4 (7.5)	
Diploma	11 (20.8)	7 (13.2)	
Academic	11 (20.8)	13 (24.5)	
Marital status			
Single	9 (17)	9 (17)	χ2 = 0/0 df = 1 P = 1
Married	44 (83)	44 (83)	
Underlying disease			
Any disease	11 (20.8)	18 (34)	χ2 = 7.57 df = 5 P = 0.17
Diabetes	14 (26.4)	13 (24.5)	
Hypertension	10 (18.9)	7 (13.2)	
Respiratory disease	10 (18.9)	10 (18.9)	
Cardiopulmonary disease	3 (5.7)	5 (9.4)	
Others	5 (9.4)	0 (0)	
Addiction			
No addiction	35 (66)	37 (69.8)	χ2 = 0.17 df = 2 P = 0.19
Injection drug abuse	10 (18.9)	9 (17)	
Oral drug abuse	8 (15.1)	7 (13.2)	

Table 3. Comparison of the Two Groups regarding the Causes of Catheter Withdrawal

Group	Control Group		Intervention Group		χ2 test
Cause of catheter withdrawal	**N**	**Frequency**	**N**	**Frequency**	χ2 = 2.34 df = 4 P = 0.65
Phlebitis	18	34	13	24.5	
Tissue infiltration	15	28.3	19	35.8	
Mechanical obstruction	12	22.6	14	26.4	
Random departure	7	13.2	7	13.2	
Infection	1	1.9	0	0	
Total	53	100	53	100	

Table 4. Comparison of the Two Groups regarding Peripheral Venous Catheter Indwelling

Variable	Control Group (Mean ± Standard Deviation)	Intervention Group (Mean ± Standard Deviation)	Independent t-test
Indwelling time of the peripheral venous catheter	43.41 ± 21.62	49.76 ± 21.67	t = 1.5 df = 104 P = 0.13

The current study findings revealed no significant difference between the two groups with respect to demographic characteristics and the incidence of phlebitis. These results were in line with those of the study performed by Peterson (23). The results of the studies by Rego Furtado (2) and Rickard et al. (24) also showed no gender differences in the occurrence of phlebitis. Nonetheless, some studies have reported a higher incidence of phlebitis in males (24).

The limitation of this study was the unpredictability of the type and dose of the drugs received by the patients. The researchers tried to select the patients who consumed conventional drugs with conventional doses.

5.1. Conclusion

The results of this study showed that temperature equalization with body temperature did not have any significant effects on the incidence of peripheral vein phlebitis and indwelling of peripheral venous catheters. However, a reduction was observed in the incidence of phlebitis during the first 48 hours. Hence, further investigations are recommended to be conducted on the effects of higher and lower temperatures on the incidence of phlebitis and indwelling of the peripheral venous catheter.

5.2. Ethical Considerations

The trial protocol was approved by the regional Ethics Committee (code: IR.GMU.REC57, 1395). The study was also registered in the Iranian Registry of Clinical Trials (code: IRCT2017022632779N1).

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Authors' Contribution

Study design and concept: M M, A P, and M S; data acquisition: A P; analysis and interpretation: M M and M S; drafting of the manuscript: M M. All authors have read the draft of the manuscript and have confirmed its final version.

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