Clinical and Experimental Health Sciences

Effect of Skin Antiseptics Used in Peripheral Intravenous Catheter Application on Phlebitis Development: A Double-Blind Randomized Controlled Trial

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ABSTRACT

Objective: This study aimed to examine the effect of antiseptics used in peripheral intravenous catheter (PIVC) application on phlebitis development.

Methods: This is a double-blind randomized controlled trial that is suitable for the Consolidated Standards of Reporting Trials (CONSORT) statement. The study was carried out at a University Hospital in Turkey. The study participants were 60 patients (experiments 30 and control 30). 2% chlorhexidine was used as a skin antiseptic in the intervention group and 70% alcohol was used in the control group. In both groups, the catheter insertion site was observed every 8 hours for 72 hour. Data were obtained using the "Personal Information Form" and "Phlebit Scale". Independent samples t-test (t-table value), Mann–Whitney U test (Z-table value) and Fisher's exact test, continuity correction, or Pearson's χ2 cross tables were used for data analysis.

Results: No statistically significant difference was found between 2% chlorhexidine and 70% alcohol in preventing the development of phlebitis after PIVC application ($p > 0.05$).

No statistically significant relationship was found between the intervention and control groups in terms of sex, BMI, substance abuse, alcohol use, smoking, chronic disease, or PIVC application area ($p>0.05$). The highest degree of phlebitis that developed in the intervention and control groups was 1st degree. There was also no statistically significant difference between the groups in terms of degree of phlebitis and phlebitis development time ($p > 0.05$).

Conclusions: In line with the findings obtained from this study, it is thought that both skin antiseptics used when inserting a peripheral intravenous catheter are effective in preventing the development of phlebitis and will guide healthcare personnel in the selection of antiseptics.

Keywords: Nursing, phlebitis, antiseptic, peripheral intravenous catheter

1. INTRODUCTION

Peripheral intravenous catheter (PIVC) application and care are very important for the maintenance and success of treatment in individuals receiving healthcare (1). PIVC insertion is one of the most common and highly invasive nursing interventions (2). It has been reported that 58%–87% of patients receive treatment via PIVC during hospitalization (3). Although PIVC is of great benefit to patients and is lifesaving, problems such as infiltration, extravasation, and phlebitis may arise owing to damage to the endothelial layer as a result of inadequate care or erroneous applications. Studies have shown that the rate of complications necessitating premature removal of PIVC has reached 50% in Turkey (4,5). Such complications increase the risk of infection in individuals, prolong hospitalization, threaten patient safety, and cause unnecessary labor and material expenditures in healthcare institutions, thereby increasing the healthcare cost (6,7).

Phlebitis is a state of inflammation in the intima layer of the vein and develops in response to tissue damage. This condition is characterized by pain, erythema, redness, edema, and vascular hardening (8). In the literature, phlebitis has been reported to be one of the most common complications, with incidence rates ranging from 1.25% to 80% in patients with PIVC (9). PIVC-related phlebitis development is recognized as a major problem in clinical practice. A study including data from 51 countries shows that the development of phlebitis remains a global threat (10).

The incidence of phlebitis can increase because of patient-related factors such as age, sex, and certain chronic diseases

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as well as other causes such as dose and osmolarity of the drugs administered, the technique used for establishing vascular access, and the knowledge level of the nurses (11). One of the many factors that can cause PIVC-related phlebitis is microorganisms in the skin that are transported first to the catheter surface and then to the bloodstream with the catheter, thereby leading to infection in the intima layer of the vein and also systemic infection. Therefore, to ensure antisepsis in the area of application, the INS and the healthcare infection control practices advisory committee (HICPAC) recommend that the area of PIVC application be cleaned with 70% alcohol, povidone–iodine, or 2% chlorhexidine. Moreover, the antiseptic must fully contact the skin and then be allowed to dry for at least 2 minutes (5,8,12).

The guidelines prepared by The Centers for Disease Control and Prevention (CDC) and Infection Prevention Society emphasize that the principle of surgical asepsis should be considered during and after PIVC application and that symptoms of phlebitis should be monitored at 8-hour intervals (13). In accordance with INS and HICPAC, the National Vascular Access Management Guideline recommends the use of 70% alcohol solution, povidone–iodine, or 70% alcohol containing >0.5% chlorhexidine as antiseptic in the PIVC application area (4,5).

When scientific studies are examined, no study examining the effect of skin antiseptics used in PIVC applications in preventing phlebitis has been found in Turkey. When studies in the world on this subject are examined, some studies reported that disinfection method of chlorhexidine in isopropyl alcohol before the implementation is the more effective than alcohol (14-17). However some studies reported there is no significant difference between the two antiseptics(18-20). Therefore due to controversy in this area, comprehensive study is required. Therefore, this study aimed to investigate the ability of 2% chlorhexidine and 70% alcohol, which are antiseptics commonly used in PIVC applications, to prevent phlebitis development.

The following hypotheses are proposed:

H0: The use of 2% chlorhexidine or 70% alcohol while inserting PIVC has no superiority over each other in reducing the development of phlebitis.

H1: Using 2% chlorhexidine or 70% alcohol when placing PIVC is superior to each other in reducing the development of phlebitis.

2. METHODS

2.1. Ethical Considerations

The study was reviewed and approved by the ethics committee of university faculty of medicine in November 2019 (14/ 01.11.2019). Ethical standards founded on informed and voluntary consent were adhered to. Written consent was obtained from the participants prior to their inclusion in the study (Declaration of Helsinki, 2013). Participation was voluntary. Participant withdrawal from the study was respected without any disadvantage to or repercussions for the participant. The randomization of participants ensured that all participants had an equitable chance of being allocated to either the intervention or control arm. The study protocol was reviewed and approved by on Clinical Trials.gov (NCT04817020).

2.2. Trial Design

This study was a double-blind randomized controlled trial. The study was carried out between January 2020 and September 2020 at a University Medical Faculty Hospital General Surgery Clinics. The hospital is a university hospital located within the provincial border of Adana. Based on similar studies in the literature, the sample size was calculated using G Power 3.0.10 program based on 95% confidence range, 0.81 power level, 0.05 margin of error, and 0.75 effect size. Sixty patients are determined to be sufficient to represent the research population (18,19).

Considering that patients may withdraw from the study, their treatments may change, and they may be discharged before 72 hours, the maximum number of patients that can be included within the period and meet the criteria has been reached.

From the population determined within the scope of the research, 79 patients who accepted the research were reached. Among 85 patients, 79 patients met the study criteria. Nineteen patients were not included in the study due to being discharged before 72 hours, being admitted to the intensive care unit after surgery, and changing antibiotic treatments. Phlebitis development status was evaluated using the phlebitis scale every 8 hours after the application. The scale was applied for 72 hours.

2.3. Participants

2.3.1. Inclusion Criteria: The participants consisted of patients who met the following inclusion criteria: (a) 18 years or older; (b) newly admitted to the clinic; (c) vascular access established in the clinic; (d) upper extremity available for PIVC; (e) administration of antibiotics and/or analgesics containing the same active substance as part of intravenous (IV As drug therapy only (antibiotics with ceftriaxone and ornidazole as active ingredients and analgesics with paracetamol as active ingredients); (f) no problems in terms of state of consciousness or sensory organs.(g) Not being discharged or transferred to a different unit before 72 hours.

2.3.2. Exclusion Criteria: The exclusion criteria were as follows: (a) PIVC inserted by someone other than the researcher; (b) having hematological, oncological, or allergic disease (c) having peripheral vascular disease; (d) having any incision or scar tissue in the IV region.

2.4. Interventions

All patients in the intervention and control groups were treated with 20G intravenous catheters made from the same material (Vialon), and transparent, non-allergic, 6 cm × 7 cm transparent covers (Tegaderm; 3M, St Paul, MN, USA) were used to stabilize and secure the PIVC. The upper extremity was selected in all patients for PIVC application.

After applying skin antiseptic from top to bottom along the vein in the PIVC application area, it was dried for 2 minutes according to INS (2016) and HICPAC (2011) recommendations, and PIVC insertion was performed. All PIVCs were washed with a 5-mL ready-to-use injectable saline solution (BD PosiFlush™) before, during, and after different types of treatment and were secured with PIVC cover. A special label was attached to the arm of the patient receiving the PIVC, which indicated that the PIVC application was for research purposes, and all nurses at the clinic were informed about it.

To prevent or minimize the formation of treatment-induced chemical phlebitis, antibiotics with only ceftriaxone or ornidazole as the active substance and analgesics with only paracetamol as the active substance were infused through the PIVC. If the patient was about to receive a different treatment, consent was obtained and a second catheter was inserted to the other arm.

Phlebitis development was evaluated 8 hours after the application with the "Phlebitis Scale" recommended by INS (2016). Within the scope of this evaluation, millimetric measurement was performed with a transparent ruler and the degree of phlebitis was determined and recorded. The scale was applied every 8 hours for 72 hours. According to many studies, it has been observed that prolonged stay of PIVC's in the vein increases the risk of phlebitis, and as a result of these studies, it has been decided to routinely change PIVC's every 72-96 hours worlwide (8,13). When the researcher was not present, the measurement was carried out by nurses who were informed about the research. PIVC was completely removed in case of phlebitis development before 72 hours. Forms filled out before PIVC removal were included in the research.

2.5.Outcomes

The primary outcome measure is the rate of phlebitis development according to the antisepsis used. In addition, the degree of phlebitis according to the antisepsis used in the primary results and the time it develops are included.

As secondary results, it was aimed to examine the development of phlebitis among some variables. These variables are; age, gender, body mass index, alcohol smoking habits, chronic disease status and the region where the catheter is inserted, and the development of phlebitis was examined according to these variables.

2.6. Randomization

The randomization of patients into 2% chlorhexidine and 70% alcohol groups was made by a statistician other than the researcher. Block randomization method was used for randomization of the patients. Within the research population, 79 patients were included in the study. The patients were evaluated according to the inclusion and exclusion criteria. In the first stage, 79 people we randomly selected (n=39) formed the intervention group and (n=40) the control group. This randomized trial adhered to the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines. A flow diagram of the study is shown in Figure 1.

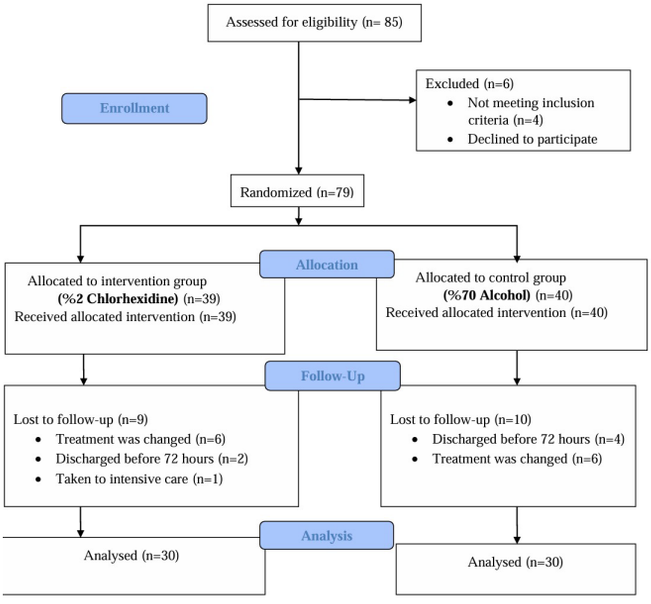

Figure 1. *Consort 2010 Flow Diagram fort the data collection procedure*

2.7. Validity and Reliability

Since the researcher was working in the same institution as a nurse, all PIVC initiatives and antiseptic applications were performed by the researcher to minimize errors that may result from differences in application. Another nurse who was on the infection control committee volunteered to observe the researcher's compliance with the PIVC implementation directive and determined the accuracy of the intervention. PIVC applications and data collection were performed at time points suitable to the participants, and all data were maintained in a confidential manner. In addition, the data were checked by both researchers to ensure accuracy before performing statistical analyses.

2.8. Instruments

2.8.1. Personal Information Form

Data on age, sex, body mass index (BMI), chronic disease, current medical diagnosis, substance or alcohol use, smoking, and PIVC application area were collected for both groups.

2.8.2. The INS Phlebitis Scale

The scale was developed by Gallant and Schultz and published by the INS (21). Psychometric properties of the scale were evaluated by Groll et al. (2010). The Phlebitis Scale has been recognized as a valid, clinically applicable, and reliable scale to determine when intravenous catheters should be removed (22).

2.9. Blinding of Research

Participants were randomly assigned to the intervention and control groups by a statistician other than the researcher. The groups were named Group I and Group II instead of the intervention and control groups. The researcher was blinded to the groups. To eliminate possible differences, the solutions were prepared only by the nurse responsible for the General Surgery-1 Clinic. Both solutions were placed in light-proof bottles of the same color and the same size. Group I (intervention group) was treated with 2% chlorhexidine (solution in blue-labeled bottle), and Group II (control group) was treated with 70% alcohol (solution in pink-labeled bottle). The solutions were indistinguishable in terms of color and smell. Thus, both researchers and participants were blinded to the solutions used.

After statistical analysis was performed, the researcher was informed by the clinical nurse that Group I was the intervention group treated with 2% chlorhexidine (blue-labeled solution), while Group II was the control group treated with 70% alcohol (pink-labeled solution).

2.10. Data Analysis

Statistical analysis was performed using SPSS package program (IBM SPSS Statistics 24). Independent samples t-test (t-table value) was used to compare the measurements between the two independent groups when parametric test conditions were met, and Mann–Whitney U test (Z-table value) was used otherwise. Fisher's exact test, continuity correction, or Pearson's χ^2 cross tables were used to examine the relationship between two qualitative variables. The significance level was accepted as $p<0.05$.

3. RESULTS

3.1. Patients and PIVC Characteristics

Thirtynine patients were assigned to the experimental group (2% chlorhexidine) and 40 patients to the control group (70% alcohol). 9 of 39 patients included in the control group were excluded from the application. Among the reasons for exclusion: Treatment changes were made in 6 patients, 2 patients were discharged before 72 hours, and 1 patient was transferred to a different clinic. In the control group; Among the 40 patients who accepted the application, a total of 10 patients were excluded from the application because 4 patients were discharged before 72 hours and the treatment of 6 patients was changed. A total of 30 patients in both groups were included in the application.

The mean age of the participants in the intervention group was 50.07 ± 10.82, and the mean age of the participants in the control group was 46.53 ± 12.57 years. It was noted that 56.7% of the participants were men and that the mean BMI was 25.03 ± 5.74 kg/m^2 (overweight). Substance abuse was observed in only one participant. Furthermore, 11.7% of the participants used alcohol and 30% were smokers. Moreover, 26.7% of the participants included in the study had a chronic disease. Of these participants, 37.5% had diabetes mellitus (DM) and hypertension simultaneously.

The most commonly used area for PIVC insertion was the forearm (61.7%). No statistically significant relationship was found between the intervention and control groups in terms of sex, BMI, substance abuse, alcohol use, smoking, chronic disease, or PIVC application area ($p > .05$). The groups were found to be independent and homogeneous in terms of the specified characteristics (Table 1).

3.2. Outcome Measures

After PIVC application, five patients (16.7%) in the intervention group that was treated with 2% chlorhexidine developed phlebitis, whereas eight patients (26.7%) in the control group that was treated with 70% alcohol developed phlebitis. No statistically significant difference was found between 2% chlorhexidine and 70% alcohol in preventing the development of phlebitis after PIVC application ($p > 0.05$). In line with this result, the H0 hypothesis was approved. The highest degree of phlebitis that developed in the intervention and control groups was 1st degree. Although phlebitis development occurred at all time intervals, it was most frequent between 32 and 40 hours (37.5%). There was also no statistically significant difference between the groups in terms of degree of phlebitis and phlebitis development time ($p >.05$) (Table 2).

Table 1. *Patient Characteristics*

Variable	Intervention group (2% chlorhexidine) (n = 30) n %		Control group (70% alcohol) (n = 30) n %		Total (N = 60) N %		Statistical analysis* Significance level
Mean Age	50.07±10.82		46.53±12.57		49.5±11.6		t=1,167 p=0.248
Sex							
Male	15	50.0	19	63.3	34	56.7	χ^2=0.611 p=0.434
Female	15	50.0	11	36.7	26	43,3	
BMI class (kg/m²)					2		χ^2=1.714 p=0.634
Underweight (<18.5)	1	3.3	1	3.3	28	3.3	
Normal (18.5-24.9)	12	40.0	16	53.3	16	46.7	
Overweight (25.0-29.9)	8	26.7	8	26.7	14	26.7	
Obese (≥30.0)	9	30.0	5	16.7		23.3	
Average BMI	26.80±5.32kg/m²		26.40±6.22kg/m²		25.03±5.74kg/m²		Z=-0,591 p=0.554
Substance abuse							
Yes	-	-	1	3.3	1	1.7	p=1.000
No	30	100.0	29	96.7	59	98.3	
Alcohol use							
Yes	3	10.0	4	13.3	7	11.7	p=1.000
No	27	90.0	26	86.7	53	88.3	
Smoking							
Yes	8	26.7	10	33.3	18	30.0	χ^2=0.079
No	22	73.3	20	66.7	42	70.0	p=0.778
Chronic disease							
Yes	9	30.0	7	23.3	16	26.7	χ^2=0.000
No	21	70.0	23	76.7	44	73.3	p=1.000
Name of the disease							
Diabetes mellitus	3	33.3	2	28.58	5	31.25	χ^2=5.623
Hypertension	-	-	2	28.58	2	12.5	p=0.229
DM+hypertension	5	55.6	1	14.28	6	37.5	
Hepatitis B	1	11.1	1	14.28	2	12.5	
Epilepsy	-	-	1	14.28	1	6.25	
Catheter area							
Back of the hand	5	16.7	7	23.3	12	20.0	χ^2=3.577
Wrist	6	20.0	3	10.0	9	15.0	p=0.311
Forearm	17	56.6	20	66.7	37	61.7	
Inside the elbow	2	6.7	-	-	2	3.3	

** "Pearson – χ2"; "Independent Samples t-test" (t-table value); "Mann–Whitney U test" (Z-table value)*

Table 2. *Phlebitis Development, Degree of Phlebitis, and Phlebitis Development Time in the Intervention and Control Groups*

Variable	Intervention group (2% chlorhexidine) (n = 30)		Control group (70% alcohol) (n = 30)		Statistical analysis* Significance level
	n	%	n	%	
Phlebitis development status					
Positive	5	16.7	8	26.7	χ^2=0.393
Negative	25	83.3	22	73.3	p=0.531
Degree of Phlebitis					
1	3	60.0	5	62.5	χ2=0.008
2	2	40.0	3	37.5	p=0.928
Phlebitis development time					
8–16 hours	1	20.0	-	-	χ^2=2.790
32–40 hours	1	20.0	3	37.5	p=0.732
40–48 hours	1	20.0	1	12.5	
48–56 hours	-	-	1	12.5	
56–64 hours	1	20.0	1	12.5	
64–72 hours	1	20.0	2	25.0	

** "Pearson-χ2"*

4. DISCUSSION

This study was conducted to highlight the importance of skin antisepsis in preventing phlebitis, which causes tissue damage as a result of inflammation in the vein's intima layer. It was done to compare the effectiveness of two different solutions. The findings were discussed in line with the relevant literature. In the present study, both antiseptics used in the groups were similarly effective in preventing the development of phlebitis. Similar to our results, there are studies in the literature reporting no difference between the use of 2% chlorhexidine and 70% alcohol (18,23), among 70% alcohol, 2% chlorhexidine, and povidone-iodine (19), between 2.5% chlorhexidine containing 70% alcohol and 70% alcohol (20), and between 2% chlorhexidine and 2% nitroglycerin (24) as antiseptics for PIVC application in terms of preventing the development of phlebitis.

When other studies in the literatüre similar to our study were examined, phlebitis development was observed in 36.7% of the patients in the chlorhexidine group and 53.3% of the patients in the alcohol group, and no significant difference was found in terms of phlebitis development between the groups (18). In another study investigating the effects of alcohol, chlorhexidine and povidone–iodine on preventing phlebitis, no significiant difference was found between the groups (19). Kaur et al. (2012) examined the effect of chlorhexidine and alcohol on phlebitis. Although fewer patients developed in the chlorhexidine group, no statistically significant difference was found between the groups in line with our study (20).

In order to use 2% chlorhexidine containing 70% alcohol solution more reliably, there are studies on whether solutions with lower concentrations are reliable enough (25,26). In a study, the effectiveness of 2% chlorhexidine containing 70% alcohol and 0,5% chlorhexidine containing 70% alcohol on staphylococcus epidermis biofilm formation was investigated in witro, and it was reported that the 2% chlorhexidine solution had a higher efficiency (27).

There is also study reporting less phlebitis development in patients treated with 2% chlorhexidine when compared with those treated with 70% alcohol (14). Furthermore, 2% chlorhexidine solution containing 70% alcohol has been reported in a study to be more effective in preventing phlebitis compared with 70% alcohol and chlorhexidine only (15).

Another study has observed less phlebitis development in patients treated with 70% alcohol–5% chlorhexidine solution compared with patients treated with 70% alcohol solution (16).

In the study in which Maki et al. (2014) looked at its effectiveness in antisepsis, they reported that a 2% aqueous chlorhexidine solution was statistically superior to 70% isopropyl alcohol or 10% povidone-iodine for the prevention of catheter-related bloodstream infections with catheters (28).

In the present study, phlebitis development was most frequent in the time period of 32–40 hours. In the study conducted, phlebitis development was most frequently observed between 40 and 49 hours (6). In another study, it was reported that the incidence of phlebitis was highest within the first 48 hours; this rate decreased between 48 and 96 hours and was the lowest between 96 and 120 hours (29,30). In the present study, only 1st degree and 2nd degree phlebitis development was observed in the patients. These results emphasize the importance of monitoring phlebitis development every 8 hours in line with the CDC report. Furthermore, the findings highlight that chemical and mechanical variables that can cause phlebitis in the early hours as well as patient groups with comorbid diseases should be examined separately for phlebitis development.

This study was conducted during the COVID-19 pandemic. Therefore, hospitalization of urgent and complicated cases was prioritized in clinics, which posed difficulties in reaching a greater number of participants meeting the inclusion criteria. At the same time, the study will be particularly relevant for low – and middle-income countries where chlorhexidine skin preparation may not always be available. The results of the study are limited to the patients who were given antibiotics and/or analgesics containing the same active substance in drug therapy (antibiotics whose active substance is ceftriaxone and ornidazole and analgesics whose active ingredient is paracetamol).

5. CONCLUSIONS

According to the results of this study, It was found that 2% chlorhexidine and 70% alcohol used for skin antisepsis before PIVC application were not superior to each other in terms of preventing the development of phlebitis. The results of this study will help reduce the dilemma of nurses and other healthcare professionals in choosing the type of antiseptic to avoid phlebitis development and also assist healthcare institutions in selecting antiseptics from a cost-effectiveness perspective. Future studies should be conducted with different antiseptics and larger samples, evaluating different time intervals with more groups. In addition, further studies that examine patient groups with different diagnoses and receiving different treatments, together with individual variables, should be planned.

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Acquisition of data for the study: AK
Analysis of data for the study: AK, ZE
Interpretation of data for the study: AK, ZE
Drafting the manuscript: AK, ZE
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