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Comparison of the Effects of Alcohol, Chlorhexidine and Alcohol-Chlorhexidine on Local Catheter-Related Infections Rate: A Double-Blind Clinical Trial Study

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Abstract

Background: Although it is vital to prevent catheter-related infections (CRIs) as the most common cause of hospital infections, there is still no agreement on the best antiseptic agent.
Objectives: The aim of the present study was to compare the effects of chlorhexidine, alcohol, and alcohol-chlorhexidine solutions on local CRIs in patients admitted to coronary care units (CCUs).
Methods: This randomized double-blind clinical trial was performed on 150 patients admitted to the CCUs of the hospitals affiliated to Zahedan University of Medical Sciences, Iran, in 2017. The subjects were selected using the convenience sampling method and randomly divided into three groups of 50, including groups A (alcohol), B (chlorhexidine), and C (alcohol-chlorhexidine). The injection site was disinfected with 70% alcohol, chlorhexidine solution, chlorhexidine-alcohol solutions in groups A, B, and C at a radius of 5 cm from the center. Local CRIs rate was assessed based on results of a culture test. After removing the catheter from the vessel, the tip was separated with a scissor and transferred to the culture medium under sterile conditions. It was then sent to laboratory for microbiological evaluation, and the culture results were compared. In case of growth of more than 15 colonies in each plate, the colony was considered to be positive. Patients and laboratory experts who reviewed and reported the results of the culture were blind to the group allocations. Data were then analyzed by using Chi-square test and Fisher's Exact test in SPSS, version 16.
Results: We found a significant difference between the three groups in terms of local CRIs (A: 20%, B: 22%, and C: 4%; P: 0.024). There was a significant difference between the chlorhexidine and alcohol-chlorhexidine groups (P = 0.007) and between the alcohol and alcohol-chlorhexidine groups in this regard (P = 0.014). The prevalence of local CRIs was significantly lower in the alcohol-chlorhexidine group than the alcohol and chlorhexidine groups.
Conclusions: Since the findings of the present research showed that skin cleansing with alcohol-chlorhexidine solution compared to alcohol and chlorhexidine could more effectively reduce local CRIs, it is recommended to use this formulation for disinfection of the intravenous catheterization site.

Keywords: Disinfection Solution, Local Catheter-Related Infection, Peripheral Venous Catheterization, Alcohol, Chlorhexidine, Hospital Infection

1. Background

Intravenous devices are essential in modern medical treatments and are used in most hospitalized patients, especially those admitted to special care units. Peripheral venous catheters (PVC) are the most frequently used medical devices during hospital care (1). Results of studies conducted in several countries show that the global frequency of PVCs is between 30% and 80%. Although it is not possible to accurately determine the global use of PVCs, its global sale reaches 1.2 billion a year (2). PVC is the origin of 10% - 50% of blood infections due to *Staphylococcus aureus* (3).

Results of a meta-analysis study revealed that the risk of local catheter-related infections (CRIs) is 0.1 to 0.5 per 1000 catheter days (4). There is no exact information on the rate of local CRIs in Iran because most studies are car-

ried out in a specific hospital or city and no research has been carried out at the national level.

Although local CRIs rate is negligible compared to central venous catheter (CVC) infections, it can lead to infection in a large number of patients due to the high frequency of PVCs (5). The most important catheterization-induced complication is sepsis and the most probable mechanism of such complication is colonization and biofilm formation on catheters. Catheter contamination can occur when it is being attached or later when it is being used. The incidence of PVC-induced sepsis is 0.2 to 0.7 per 1000 catheter days and a total of 0.08 for each catheter (6, 7).

Blood-borne hospital infections are the eighth cause of mortality in the United States, which increase the rate of hospitalization; cost of treatment for blood-borne hospital infections is 36,441 to 37,078 dollars each year (8). PVC-induced infections include local CRIs such as cellulitis, soft tissue infection, osteomyelitis, phlebitis, thrombophlebitis, supportive thrombophlebitis, and septicemia or bacteremia (9). PVCs cause several major and minor complications with local CRI being considered as one of its major complications (10). Although common, these practices are not devoid of complications, which may lead to mortality and morbidity, increased duration of hospital stay, and significant costs (11). Immigration of skin organisms at the catheter insertion site is the most common transmission route of local CRIs and catheter tip colonization. Microorganisms can access the IV catheter through the skin around the catheter insertion site (12). Extensive efforts have been made to reduce these complications, including the use of prophylactic antibiotics, but the use of systemic antibiotics is not possible due to the risk of drug resistance (13, 14); therefore, there is a dire need to use optimal therapeutic strategies and appropriate local CRI control tools to reduce the prevalence of these organisms in each society (15).

Since the treatment of hospital infections imposes great costs on the treatment sector of the country, implementation of an infection control program or even a small but effective change in nurses' performance seems to be very useful and cost-effective in controlling hospital infections from the viewpoint of health economics (16). The selected disinfectant must be capable of performing the required task. Selection is dependent on the conditions in which the disinfectant must function, such as duration of exposure, temperature, pH, and the presence or absence of neutralizing agents (17). So far, various solutions have been introduced and used for this purpose, including alcohol and povidone iodine. Chlorhexidine solution has been introduced to the healthcare community as a new disinfectant during the last several decades. Nursing reference books, journals, and scientific papers present different opinions about choosing a disinfectant solution; however, the question regarding the best disinfectant for the catheter insertion site remains unresolved (18).

There are few studies on venous catheter disinfection in Iran, which cannot be generalized to the whole society due to their limited sample sizes or specific wards where they were conducted in.

2. Objectives

We decided to carry out the present study to compare the effects of alcohol, chlorhexidine, and alcohol-chlorhexidine on infections caused by venous catheterization in CCU patients admitted to the hospitals in Zahedan.

3. Methods

The present double-blind clinical trial was conducted after being approved by the Ethics Committee of Zahedan University of Medical Sciences and registered under the code no. IR:ZAUMS.REC.2017.37. The study was performed among patients hospitalized in CCUs of the hospitals affiliated to Zahedan University of Medical Sciences. The study sample size was determined according to similar studies (19) with a confidence level of 95%, test power of 80%, P1: 0.15, and P2: 0.62. The standard sample size was calculated at 102, but considering the probability of sample attrition, it was increased to 150 (50 per group).

The inclusion criteria included being aged above 18 years, being admitted on the sampling day, being consciousness and having collaboration on the first day of admission, and not having any underlying diseases such as lupus, renal failure, chronic obstructive pulmonary disease, or liver diseases based on patient report. The exclusion criteria were receiving antibiotics, blood products, or hypertonic materials, not being willing to participate in the study, or being discharged before 24 hours. The subjects were selected using the convenience sampling method and randomly assigned to three groups of A (alcohol), B (chlorhexidine), and C (alcohol-chlorhexidine).

The randomization was carried out using a total of 150 cards as follows: 50 red cards for the alcohol group, 50 blue cards for the chlorhexidine group, and 50 white cards for the alcohol-chlorhexidine group. When a patient was hospitalized, a card was picked up by the patient and s/he was placed in a group based on the color of the card selected, and the patient's IV catheter was then fixed after disinfection of the site by a special disinfectant.

The data collection instrument used in this study was a demographic and clinical characteristics form containing items on gender, marital status, hospitalization history, catheter fixation site, sustainability, and cause of catheter removal. Catheter insertion and disinfection of the catheterization site were performed after the patient was assigned to the related group by the researcher in accordance with Taylor's Handbook of Clinical Nursing Skills reference book (20). Disinfection was the same in all the groups and was carried out rotationally from the center to the surrounding for 5 seconds. In all the patients, antiseptic solutions of the same brand were used. All the research subjects were given the same training on catheter care. Also, it was mentioned in the patients' index card that the patient has been enrolled in a research test so that coordination can be made regarding replacing the IV catheter and/or performing any other intervention by the ward personnel.

The dressing was changed by the researcher if the previous dressing was wet or bloody, and the serum set was then replaced for patients of the three groups according to the hospital routine. In case of definitive diagnosis of phlebitis (score 2 or higher according to the nursing association's phlebitis checklist) (19) or 72 hours after catheter fixation, the IV catheter was removed by removing the band-aid while ensuring it is not in contact with the surrounding skin. For catheter replacement, immediately the part of the catheter that was inserted into the vein was separated from the tip using sterilization technique by scissors and then transferred to a pre-prepared sterile test tube. Considering the fact that the three solutions are very similar in color, odor, and other important properties, and the same pads were used to disinfect the skin of the catheterization site in the three groups, it was possible to blind patients to the type of disinfection used. Therefore, the intervention was carried out in such a way that the patient was blind to group allocations. In addition, the laboratory expert who evaluated the presence of infection was also blind to the assignment of samples to the three different groups. All laboratory cultures were performed, interpreted, and reported by one person. Local CRI was considered as a colony count of more than 15 in each plate (21).

A semi-quantitative culture technique was used with a sensitivity of 85% according to the Ministry of Health (21). IV catheter tip culture was carried out in agar medium using semi-quantitative culture. The number of colonies appeared on the culture medium 48 hours later was counted. The colonies were also analyzed in terms of the type of microorganisms. Statistical analysis was carried out using Chi-square and Fisher's Exact test in SPSS version 16.

4. Results

The mean age of the subjects was 50.8 $\pm$ 6.1 years, ranging from 35 to 59 years old. Overall, 48% of the patients were men and 52% were women. The majority of the subjects were married in all the three groups (78.6%). The majority of research subjects were admitted (53%) due to diagnostic angiography or percutaneous coronary intervention (PCI). There was no significant difference between the three groups in terms of demographic and clinical characteristics (Table 1).

The prevalence of local CRI in the alcohol, chlorhexidine and alcohol-chlorhexidine groups was 20%, 22%, and 4%, respectively. The results of the Chi-square test revealed a significant difference between the three groups in terms of local CRI (P = 0.024; Table 2). Chi-square test also showed such a difference between the chlorhexidine and alcohol chlorhexidine groups (P = 0.007) and the alcohol and alcohol-chlorhexidine groups (P = 0.014). The findings of this study showed that the prevalence of infection in the alcohol-chlorhexidine group was significantly lower than those of the alcohol and chlorhexidine groups (Table 2). *Staphylococcus epidermis* was the most common cause of infection (11%), and infection rate in the three groups of alcohol, chlorhexidine, and alcohol-chlorhexidine was 20%, 22%, and 4%, respectively. The prevalence of the above microorganism was 14% in the alcohol and chlorhexidine groups and 2% in the alcohol-chlorhexidine group. Results of Fisher's Exact test showed no significant correlation between group and type of microorganism (P = 0.463).

5. Discussion

The findings of the present study showed that the prevalence of local CRIs in the alcohol-chlorhexidine group was lower than those of the alcohol or chlorhexidine groups. Some studies have reported similar results. Mimoz et al. in a study in France showed that the use of chlorhexidine-alcohol solution was more effective in reducing the incidence of central venous CRIs in ICU patients compared to the use of alcohol or povidone iodine alone (22). Sarani et al. compared the effectiveness of alcohol and povidone iodine and ascribed that povidone iodine, following alcohol application, can better control local CRI in CCU patients (23). Although that study did not investigate the effect of alcohol-chlorhexidine, the use of a combination of antiseptic substances was found more effective than using them alone as was also evidenced in the present study.

Lai et al. revealed that the use of combined solutions such as chlorhexidine and povidone iodine or chlorhexidine + alcohol was more effective in reducing local CRIs

Table 1. Demographic and Clinical Characteristics of Patients in the Alcohol, Chlorhexidine and Alcohol-Chlorhexidine Groups[a]

Variable	Alcohol	Chlorhexidine	Alcohol-Chlorhexidine	P Value
Age (y), mean ± SD	51.5 ± 6.0	50.4 ± 8.5	50.7 ± 6.5	0.638[b]
Gender				0.78[c]
Male	23 (46)	26 (52)	23 (46)	
Female	27 (54)	24 (48)	27 (54)	
Marital status				0.59[d]
Married	43 (86)	35 (70)	40 (80)	
Single (single, divorced, widowed)	7 (14)	15 (30)	10 (20)	
Hospitalization history				0.97[c]
Yes	28 (58)	28 (58)	29 (58)	
No	22 (44)	22 (44)	21 (42)	
Catheter location				0.83[b]
Forearm right hand	40 (80)	40 (80)	42 (84)	
Forearm left hand	10 (20)	10 (20)	8 (16)	
IV Permanence time				0.772[b]
48 h	18 (36)	20 (40)	20 (40)	
60 h	22 (44)	16 (32)	18 (36)	
72 h	10 (20)	14 (28)	12 (24)	
IV D/C cause				0.568[c]
Phlebitis	5 (10)	10 (20)	7 (14)	
Patient discharge	33 (66)	24 (48)	30 (60)	
Inefficiency	8 (16)	12 (24)	11 (22)	
72 h	4 (8)	4 (8)	2 (4)	

[a] Values are expressed as No. (%) unless otherwise indicated.
[b] ANOVA.
[c] Chi-square.
[d] Fisher Exact.

Table 2. Comparison of Frequency of Local Catheter-Related Infections in Alcohol, Chlorhexidine and Alcohol-Chlorhexidine Groups[a]

Group	Positive[a]	Negative[a]	P Value
Alcohol	10 (20)	40 (80)	0.024[b]
Chlorhexidine	11 (22)	39 (78)	
Alcohol-chlorhexidine	2 (4)	48 (96)	

[a] Values are expressed as No. (%).
[b] Chi-square.

in special care units compared to using disinfectant solutions such as povidone iodine or alcohol alone or not using any disinfectants (24). In a study on the prevention and control of local CRIs in ICU patients in France, Timsit et al. reported that the use of disinfectants such as chlorhexidine solution, as compared with the absence of any disinfectants, was more effective in preventing and controlling local CRIs caused by arterial and venous catheters (18). In their review study, Ho and Litton confirmed more positive effects of chlorhexidine disinfectant solution compared to placebo or povidone iodine in reducing local CRIs (25). Kinirons et al. achieved similar results in a comparative study on the use of chlorhexidine and povidone iodine solutions in reducing CRIs in children in France. They showed that chlorhexidine solution was more effective in controlling CRIs as compared to povidone iodine solution (26).

The culture results showed that *S. epidermis* was the most frequent microorganism with a frequency of 14% in alcohol and chlorhexidine groups and 2% in the alcohol-chlorhexidine group. In this regard, *S. epidermis* was introduced as the most common cause of temporary pacemaker catheter infection in a review study carried out by McCann et al. (27). Kasuda et al. (28) also referred to *S. epidermis* as the only type of bacteria cultured from the tip of epidural catheters. Similar results were also obtained

in Mimoz et al.'s study (22), which showed lower growth of Gram-positive cocci, coagulase-negative staphylococci (CoNS), and Gram-negative bacilli in a chlorhexidine group as compared to a povidone iodine group. The highest bacterial growth rate was reported for CoNS in some other studies (29). The discrepancy between the results of the above studies and those of the present study can be due to the difference in catheter type, placement procedure, application of catheter, and site of catheter insertion.

5.1. Conclusion

In general, the findings of the present study showed that skin disinfection with alcohol-chlorhexidine solution, as compared to skin cleansing with alcohol and chlorhexidine, can cause a greater reduction in the rate of local CRIs. Therefore, given the lack of common guidelines in this area, further studies are recommended to reach an agreement on the overall view and provide a specific standard.

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Footnote

Authors' Contribution: Hamed Sarani, primary design of the research, participation in data collection, and monitoring the research process; Nezarali Moulaei, data analysis and drafting of the manuscript; Ebrahim Ebrahimi Tabas, participation in research design and data collection; Enayatollah Safarzai, was responsible for the study design, data collection, and drafting of the manuscript; Somayeh Jahani, culture and identification of the microorganisms and antibiogram.

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