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Durability of the two-lumen catheter in hemodialysis patients; Ethanol 70%-heparin versus cefazolin-heparin: a randomized, double-blind clinical trial study

Hadi Yousefi[1], Mehdi Hosseinifard[2], Mojgan Falaki[3], Fariba Asadi Noghabi[2], Hamidreza Samimagham[4], Mohsen Yousefi[5], Hossein Mardanparvar[6], Jahanbakhsh Vahdatnejad[7*]

[1]Department of Community Medicine, Faculty of Medicine, Hormozgan University of Medical Sciences, Bandar Abbas, Iran
[2]Mother and Child Welfare Research Center, Hormozgan University of Medical Sciences, Bandar Abbas, Iran
[3]Department of Internal Medicine, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[4]Cardiovascular Research Center, Hormozgan University of Medical Sciences, Bandar Abbas, Iran
[5]Student Research Committee, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[6]Department of Nursing, Faculty of Nursing and Midwifery, Hormozgan University of Medical Sciences, Bandar Abbas, Iran
[7]Clinical Research Development Unit, Imamsajad Hospital, Yasuj University of Medical Sciences, Yasuj, Iran

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ABSTRACT

Introduction: Maintenance of hemodialysis catheters is essential for the patients and medical staff due to their repeated use for hemodialysis and other therapeutic interventions in the hospital.
Objectives: This study aimed to comprise the effect of ethanol 70%-heparin versus cefazolin-heparin on the catheter durability time of hemodialysis patients.
Patients and Methods: The study population consisted of 73 hemodialysis patients referred to Shahid Mohammadi hospital in Bandar Abbas. Patients were divided into two groups cefazolin (cefazolin 5 mg/dL, and heparin 2500 IU/mL) and ethanol (ethanol 70%, and heparin 2500 IU/mL). In both groups, after each hemodialysis session, 2.9 to 3.3 mL of the locking solution was locked in the catheter lumen and remained until the next session. This intervention was conducted for all patients continuously for five months. The time of catheter durability was calculated from the time of catheter placement in the central vein until the time that it has been taken out according to the doctor's diagnosis. Data were collected and analyzed by SPSS version 26.
Results: Results showed that demographic characteristics, including age, weight, gender, marital status, catheter type, underlying diseases, and dialysis adequacy between the two groups were similar ($P > 0.05$). In the ethanol group, the mean time of the catheter durability was 27.5 days, and in the cefazolin group was 26.98 days. Although the time of the catheter durability was slightly higher in the ethanol group, this difference was not significant ($P = 0.194$).
Conclusion: Cefazolin and ethanol 70% did not show a significant difference in the catheter durability time of hemodialysis patients.
Trial Registration: The trial protocol was approved by the Iranian Registry of Clinical Trials (IRCT20210811052145N1; https://en.irct.ir/trial/58037, ethical code; IR.HUNS.REC.1398.052).

Implication for health policy/practice/research/medical education:
In a clinical trial study on 73 hemodialysis patients, we found no significant difference in the effect of cefazolin versus ethanol 70% on catheter durability in hemodialysis patients.
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Clinical Trial

Introduction

Vascular catheters in hemodialysis patients are used for several purposes, including injection of fluids, drugs, and hemodialysis (1). The maintenance of these catheters is essential for the medical staff due to their repeated use for hemodialysis and other therapeutic interventions in the hospital (2). The durability of catheters is unclear based on the conducted studies. Various factors such as the type of catheter (size and manufacturer brand), place of placement, skin preparation method, ways of keeping it open, and kind of disease affect the time of catheter durability (3). Catheters will block due to the

***Corresponding author**: Jahanbakhsh Vahdatnejad, Email: Jahan.vahdat@gmail.com, vahdatnejad.jahan@yums.ac.ir

accumulation of fibrin and clot formation at the cannula access site (4). Catheter blockage is one of the factors that reduce the durability of the intravenous catheter, which can be identified by symptoms such as the impossibility of fluid injection and no blood return (5). In case of repeated catheter replacements, besides the painful procedure and increasing infection risk, the time of hospitalization and more costs are imposed on the patient (6). There are several ways to improve the durability of catheters, including injection of sodium chloride or sodium chloride combined with heparin after hemodialysis and the flushing technique (7). This study aimed to evaluate the effect of ethanol 70%-heparin versus cefazolin-heparin on the durability of the two-lumen catheters in hemodialysis patients.

Objectives

No previous studies assessed the effect of ethanol and cefazolin on the time of catheter durability of hemodialysis patients. This study aimed to comprise the impact of ethanol 70%-heparin versus cefazolin-heparin on the catheter durability time of hemodialysis patients.

Patients and Methods

Study design

This randomized, double-blind clinical trial study was conducted on hemodialysis patients referred to Shahid Mohammadi hospital of the Hormozgan University of Medical Sciences in Bandar Abbas, Iran.

Participants

Eighty patients were included in the study by inclusion criteria and randomly (Random sample allocation software) assigned to two groups named the cefazolin group (n = 40) and the ethanol group (n = 40). Written consent was obtained from all patients, and demographic characteristics were collected. Inclusion criteria included having a permanent or temporary dual lumen catheter, informed written consent to participate in the study, and an age of more than 18 years. Exclusion criteria included premature removal of the catheter for reasons other than infection, the patient's unwillingness to continue participating in the study, and death for any reason.

Intervention

Before each hemodialysis session, the patients were first evaluated for weight, blood pressure, and body temperature by a trained nurse. For all patients, routine and standard care, including catheter washing with normal saline and hemodialysis, was performed under the supervision of a dialysis physician. After hemodialysis, the catheter was rewashed with normal saline. In the cefazolin group, a solution of heparin lock-cefazolin was prepared with a ratio of 2 cefazolin (5 mg/dL) to 1 heparin (2500 IU/mL) (8). in the ethanol group, a solution of heparin lock-ethanol 70% with a ratio of 2 ethanol 70% to 1 heparin (2500 IU/mL) was prepared (9). These two solutions were locked in the catheter lumen by a trained nurse with the amount of 2.9 to 3.3 mL, considering the catheter lumen volume. In both groups, the solution remained in the catheter until the next session, and this intervention was performed on patients continuously for five months. The time of catheter durability was calculated from the time of catheter placement in the central vein until the time that it has been taken out according to the doctor's diagnosis. In the ethanol group, two patients were excluded due to migration and two patients due to using systemic antibiotics. In the cefazolin group, one patient was excluded due to migration, and two patients were excluded due to kidney transplantation. Finally, 36 patients in the ethanol group and 37 patients in the cefazolin group were evaluated for analysis (Figure 1).

Blinding

This study is a double-blind study. Patients, a trained nurse, dialysis physicians, and the person who assessed the results had no information about the two groups' allocation.

Statistical analysis

Data were analyzed by SPSS (version 26). Quantitative variables were used to describe the data center means, and standard deviations were used to describe the data distribution. Frequency and percentage were used to describe the data. The normal distribution of data was evaluated by the Kolmogorov–Smirnov tests. Chi-square test, independent *t* test, Fisher's exact test, and Mann–Whitney U test were used to analyze the data. *P* values less than 0.05 were considered significant.

Results

Results showed that of all 73 hemodialysis patients who participated in this study, 47% (n = 34) were male, and 53% (n = 39) were females with a mean age of 52.27 ± 13.25 years. The ethanol group consisted of 15 (42%) males and 21 (58%) females with a mean age of 51.94 ± 11.51 years. In the cefazolin group, 19 patients (52%) were male and 18 (48%) were females, with a mean age of 58.51 ± 14.17 years. No significant was difference found between the two groups in terms of age, weight, gender, marital status, catheter type, underlying diseases, and dialysis adequacy. In other words, the two groups were similar (Table 1).

The results showed that the time of catheter durability in the ethanol group was 27.5 days and in the cefazolin group was 26.98 days. Although the time of the catheter durability was slightly higher in the ethanol group, the Mann–Whitney U showed that this difference was not significant (Table 2).

The results showed that catheter durability time by variables including gender, underlying disease, catheter site infection, and catheter type between two groups of ethanol and cefazolin were not significant (Table 3).

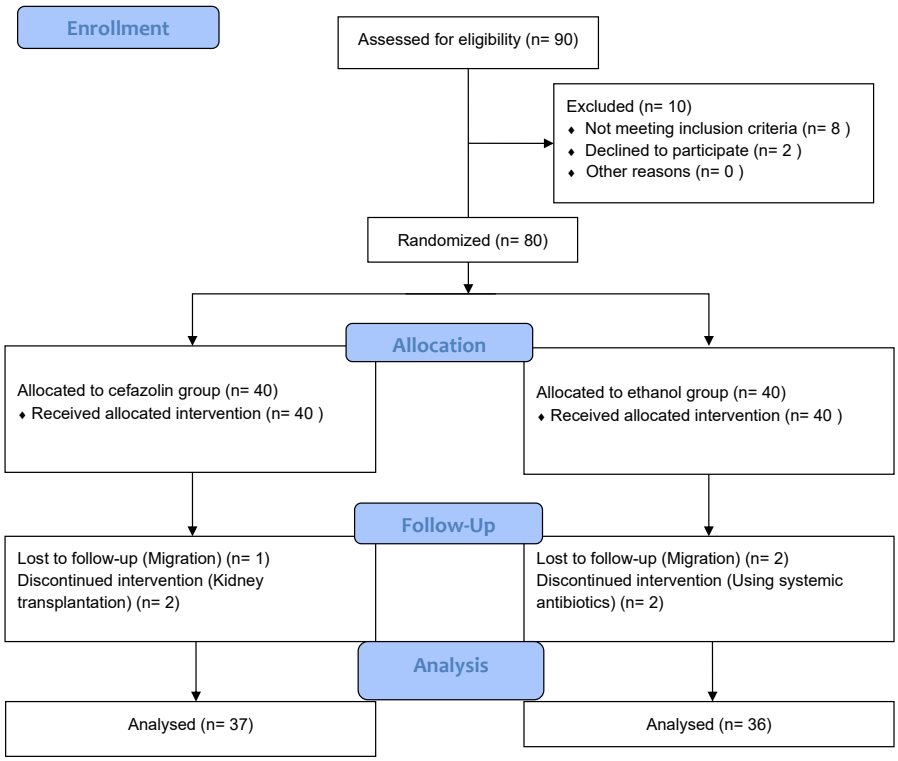

Figure 1. CONSORT flow chat diagram.

Discussion

Results showed that demographic characteristics, including age, gender, underlying disease, dialysis adequacy, and catheter type between the two groups were similar. The data of this study are in line with other studies in terms of age, gender, underlying diseases, and catheter type (10,11). This study is the first clinical trial study that compares the effect of ethanol 70% and cefazolin on catheter durability time in hemodialysis patients. In this study, the result showed that, although the time of the catheter durability was slightly higher in the ethanol group, this difference was not significant. As mentioned, this study is the first, and no study has been found to compare its result with the present study. Results also demonstrated that the catheter durability time in the ethanol group was 27.5 days and in the cefazolin group

Table 1. Comparison of demographic characteristics including age, weight, gender, underlying disease, marital status, catheter type, and dialysis adequacy between two groups of ethanol and cefazolin

Variable	Group		*P* value
	Ethanol (n=36) No. (%)	Cefazolin (n=37) No. (%)	
Gender			
Male	15 (42)	19 (52)	0.407[a]
Female	21 (58)	18 (48)	
Marital status			
Single	1 (2.8)	2 (3.4)	0.117[a]
Married	35 (97.2)	35 (94.6)	
Underlying diseases			
Yes	8 (22.2)	13 (35.1)	0.223[a]
No	28 (77.8)	24 (64.9)	
Catheter type			
Permanent	27 (75)	30 (81.1)	0.530[a]
Temporary	9 (25)	7 (18.9)	
Age (y), Mean ± SD	51.94 ± 11.51	58.51 ± 14.17	0.126[b]
Weight (kg), Mean ± SD	66.79 ± 13.63	68.8 ± 14.66	0.323[b]
Dialysis adequacy (Kt/V), Mean ± SD	1.31 ± 0.35	1.33 ± 0.41	0.352[b]

[a] Chi-square. [b] Independent *t* test.

Table 2. Comparison of catheter durability time between two groups of ethanol and cefazolin

Variable	Group				*P* value[a]
	Ethanol (n=36)		Cefazolin (n=37)		
	Mean	Standard deviation	Mean	Standard deviation	
Durability time (day)	27.52	2.83	26.89	3.28	0.194

[a] Mann–Whitney U.

Table 3. Comparison of catheter durability by variables including gender, underlying disease, catheter site infection, and catheter type between two groups of ethanol and cefazolin

Variable		Group				*P* value[a]
		Ethanol (n=36)		Cefazolin (n=37)		
		Catheter durability time (day)		Catheter durability time (day)		
		Mean	Standard deviation	Mean	Standard deviation	
Underlying Disease	Yes	28	0.001	25.46	4.89	0.154
	No	27.39	3.21	27.66	1.63	0.934
Gender	Male	28	0.001	25.84	4.38	0.632
	Female	27.19	3.7	28.1	0.012	0.355
Catheter type	Temporary	27.8	0.001	28	0.013	0.228
	Permanent	27.37	3.27	26.63	3.61	0.212
Catheter site infection	Yes	11	1.2	17.75	21.1	0.157
	No	28	0.001	28	0.001	1

[a] Mann–Whitney U.

was 26.98 days. Develter et al stated that this period was 61.5 days, which is significantly higher than the catheter durability time in our study (12).

Ivan et al reported no significant difference in catheter survival in the cases of using high-concentration heparin lock and low-concentration, and the survival rate was 73% in high-concentration versus 71% in low-concentration (13). In our study, the dose of used heparin in both ethanol and cefazolin groups was similar. Thus, the anticoagulant effect of heparin could not be practical on the difference in catheter durability time between the two groups. On the other hand, one of the other factors that could affect the catheter durability time was the antibacterial effect of cefazolin and ethanol. Although the catheter durability time was slightly higher in the ethanol group, this difference was not statistically significant. Therefore, we conclude that ethanol and cefazolin also have a similar infection prophylaxis effect.

Conclusion

Catheter durability time in this study was similar to previous studies. Cefazolin and ethanol 70% didn't show a significant difference in the catheter durability time of hemodialysis patients.

Limitations of the study

The number of studied patients was insufficient because, with the increase in the number of patients, the difference in some variables may become statistically significant. However, in terms of variables such as age, weight, gender, marital status, underlying diseases, catheter type, and dialysis adequacy, the two groups were similar, which is one of the strengths points of the present study.

Authors' contribution

MH, FA, HY, and HS prepared the concept and design. Data was collected by MH, HS, MY, and FA. Methodology and formal analysis were performed by HY. JV, MF, and HM prepared the initial draft. FA, HS, and HM reviewed and edited the initial draft. JV was the project administration, and HY was Supervisor. Validation and investigation performed by HM and HS. Funding and resources were provided by all authors. All authors participated in preparing the final draft of the manuscript, revised the manuscript, and critically evaluated the intellectual contents. All authors have read and approved the manuscript's content and confirmed the accuracy or integrity of any part of the work.

Conflicts of interest

The authors declare no conflict of interest.

Ethical issues

The research was conducted in accordance with the tenets of the Declaration of Helsinki. This study resulted from the MSc nursing thesis with Ethical code (IR.HUNS.REC.1398.052), approved by the ethics committee of Hormozgan University of Medical Sciences, Bandar Abbas, Iran. Accordingly, written informed consent was taken from all participants before any intervention. The study protocol was also registered as a clinical trial at the Iranian Registry of Clinical Trials (identifier:

IRCT20210811052145N1; https://en.irct.ir/trial/58037). Ethical issues (including plagiarism, data fabrication and double publication) have been completely observed by the authors.

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