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Address: Mashhad Nursing and Midwifery School, Ebn-e-Sina St., Mashhad, Iran
P.O.Box: 9137913199
Tel.: (098 51) 38591511-294
Fax: (098 51) 38539775
Email: EBCJ@mums.ac.ir

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Comparing the Effect of Continuous and Intermittent Irrigation Techniques on Complications of Arterial Catheter and Partial Thromboplastin Time in Patients Following Coronary Artery Bypass Grafting Surgery

Sedegheh Arta[1], Seyed Reza Mazloum[2]*, Shahram Amini[3], Fatemeh Hajiabadi[4]

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Abstract

Background: Different approaches are available to irrigate the arterial catheter, such as continuous and intermittent techniques. However, there is a disagreement regarding the most appropriate method.

Aim: this study aimed to compare the effect of two continuous and intermittent irrigation methods on complications of arterial catheter and partial thromboplastin time (PTT) in patients with coronary artery bypass (CABG) surgery.

Method: This randomized clinical trial was conducted on 60 participants undergoing coronary artery bypass grafting surgery in open-heart surgery ICU at Imam Reza hospital in Mashhad, Iran, in 2016. In continuous group, the arterial catheter was continuously irrigated with heparin solution at the rate of 2cc/h, and in the intermittent group with a syringe containing 5cc heparin solution every 3 hours. In both groups, catheter was monitored and recorded every 3 hours (until 48 hours and 3 times from enrollment) in terms of complications of partial thromboplastin time. Data were analyzed using SPSS version 16.

Results: The findings of independent t-test showed that the two groups are homogeneous in age (P =0.48). The result of Fisher's exact test revealed no significant difference between the two groups in terms of average incidence of complications during the first 24 hours (P=0.55) and second 24 hours (P=0.55) after catheterization. Also during the 48 hours after surgery, independent t-test results showed no statistically significant difference in partial thromboplastin time (P=0.53) between the two groups.

Implications for Practice: According to the results of the research based on the lack of difference between continuous and intermittent irrigation methods up to 48 hours after catheter replacement in terms of arterial catheter complications, further long-term follow-up researches are recommended.

Keywords: Arterial catheter, Catheter irrigation, Coronary artery bypass grafting, Partial thromboplastin time

1. MSc Student in Adults Critical Care Nursing, Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences, Mashhad, Iran
2. Evidence based Caring Research Center, Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences, Mashhad, Iran
3. Associate Professor of Anesthesia, Faculty of Medical, Mashhad University of Medical Sciences, Mashhad, Iran
4. PhD Student in Nursing, Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences, Mashhad, Iran
* Corresponding author, Email: mazloumr@mums.ac.ir

Introduction

Open-heart surgery is one of the most common surgeries around the world, and Iran is among the top 10 countries in terms of specialties related to this surgery (1). Open-heart surgery saves the lives of many patients; but because of several pre- and post-operative complications, it is an important and potential hazard to patients' health and endangers their health (2). Therefore, continuous cardiovascular monitoring system in critically ill patients in intensive care unit (ICU) is very important to manage their complex and difficult situations. This important information can be obtained from various ways including invasive monitoring of pulmonary artery pressure, central venous pressure and blood pressure (3).

Blood pressure is one of the critical parameters in monitoring patients after heart surgery. Arterial blood pressure control is considered as a golden standard when the patient is susceptible to hemodynamic changes (4). Besides many advantages of this method, it also has some complications like any other therapeutic or care method (5). One of its problems is blockage in catheter that it is necessary to be washed to prevent it (6).

Different solutions and methods such as heparin, heparinized distilled water, heparinized normal saline and 0.9% normal saline are suggested to flush catheters (6-8); two of them are intermittent and continuous irrigation of catheter with heparin solution. Since the arterial catheter is connected to a transducer, which does not allow solution to flow continuously at usual pressure (9), so the use of intermittent irrigation with heparin by a syringe is common (4). Given the occurrence of many blockages in the artery,, replacement of a new arterial catheter is ignored despite the need for patient monitoring and because of its difficulty and complications as well as the risk for patient (10, 11). In addition, some recent studies have shown that manually actions on irrigation system in intermittent method can reduce the efficiency of this approach and increase the risk of infection (12, 13).

In continuous irrigation, a 300-mmHg pressurized cuff is used to create a 2-ml/h continuous flow of heparinized normal saline in the route of artery catheter. Therefore, there is no need to use syringes for intermittent bolus of heparinized solution. The possibility of backflow of blood, clot formation and related complications occur less frequently because of the steady stream of irrigation solution (14).

Given that heparin solution is used for washing the catheter in both methods, the incidence and intensity of these complications are mainly resulting from the amount of injected heparin (15). The most common complications are hemorrhage and hematoma (5-7 percent) caused by increased partial thromboplastin time (PTT) (16). Other reported complications include reversible alopecia, allergy, osteopenia, thrombocytopenia and paradoxical thromboembolism. The important part is to choose the most appropriate method with fewer incidences of complications which serves medical purposes better. This objective is usually expressed in the forms of value and duration of PTT and how to increase it (17).

In this regard, Adib and Fatourchi (2005) showed that the PTT value in continuous infusion of heparin is more stable and durable in the required therapeutic duration compared to intermittent method. They concluded that continuous method is more appropriate for the prevention of thrombosis and other complications such as bleeding (16).

However, there is limited evidence to indicate the effectiveness and practicability of intermittent method and studies have not showed any significant differences between the complications of two intermittent and continuous methods in maintenance of arterial catheter (12). On the other hand, in these studies, two methods of intermittent and continuous have not been compared with each other (13). Witkowski et al. (2013) showed that both intermittent and continuous infusion of heparin can be used to keep the intra-arterial catheter open after heart surgery in children and the most common complications in both groups were bleeding and catheter blockage, and there was no significant difference between the two methods (14). However, Robertson-Malt et al. (2014) compared the effect of heparin and saline to keep arterial catheter open with review of seven articles. In these studies, only the intermittent washing method was used. They concluded that existing evidence does not have the needed quality because of the possibility of bias; therefore, there is no sufficient confidence to confirm the effectiveness of intermittent irrigation of arterial catheter using heparinized solution at a concentration of 1-2 IU/ml (15).

Given the frequent use of intermittent method in all intensive care units of open-heart surgery at hospitals in Mashhad, limited studies comparing the effect of washing arterial catheter methods and

their contradicting results and unclear effective irrigation methods to prevent or reduce the complications of these methods in washing arterial catheter after surgery in patients undergoing open-heart surgery, the present research was conducted to determine the effect of two continuous and intermittent irrigation methods on complications of arterial catheter and partial thromboplastin time of patients after coronary artery bypass grafting surgery.

Methods

The current study was a randomized clinical trial of two groups by post-test design in 2016. The study population included all patients undergoing CABG surgery whom were hospitalized in the ICU at Imam Reza Hospital in Mashhad, Iran. The participants were easily chosen and enrolled in the study after obtaining written informed consent, and then were randomly (using a table of random numbers) assigned into two continuous and intermittent irrigation groups. The minimum sample size was calculated using formula of "comparison of two independent groups", so that a pilot study was conducted on 20 patients (10 patients in each group) and then the sample size was obtained based on each studied variables. Therefore, the sample size was estimated at 26 people in each group according to hemorrhage variable (P1 = 0.51, P2= 0.89) by 95% confidence level and 80% sensitivity of test; finally, 30 patients were studied in each group. Inclusion criteria were age less than 70 years, cardiovascular disorders (e.g., Raynaud syndrome), no preoperative coagulation disorders (PT<13 seconds and PTT<45 seconds) and the normal rate of postoperative bleeding (according to the protocol of postoperative bleeding). Exclusion criteria included lack of willingness to continue cooperation in research, accidental exiting of arterial catheters, improper function of arterial catheters (lack of acceptable curve on the monitor), postoperative bleeding more than normal level (with regards to postoperative bleeding protocol), need to reoperation for any reason and the death of patient.

Study tool included researcher-made checklist to record complications of arterial catheter and PTT level. The first part of this tool contained medical background information consisting of 12 multiple choice questions and supplementary questions on age, gender, drug addiction, history of diabetes, history of hypertension, aspirin consumption, plavix consumption, site of catheter , type of catheter, level of heparin used during surgery, postoperative use of protamine and duration of surgery. The checklist of recording complications for arterial catheter and PTT level contained two items about the complications of hemorrhage and hematoma and one item about the PTT. The content validity of these two means was reviewed and approved by 10 faculty members of Department of Medical-Surgical Nursing, School of Nursing and Midwifery of Mashhad, Iran. PTT level obtained from agreement among raters by calculating Cronbach's alpha coefficient was used to assess the validity of checklist recording arterial catheter complications with reliability coefficient of 0.84 (r=0.84). Meanwhile, the competence of the researcher and researcher assistant to complete the checklist was approved by a specialist of intensive care as a member of the research team; the researchers and researcher assistant had several years of experience in cardiac surgery intensive care unit.

The participants were chosen easily based on the inclusion criteria and enrolled in the study among patients hospitalized during study period, and then were randomly categorized into two control group (intermittent irrigation) and intervention group (continuous irrigation) based on a table of random numbers.

In the intervention group (continuous irrigation), serum containing heparin was pressured by inflatable cuff (cuff transfusion), at a rate of 300 mmHg, because the opening of transducer route requires a pressure of 300 mm Hg. Under this pressure, the catheter route was continuously washed by heparin serum at the rate of 2 ml/h. In intermittent irrigation group, catheter was washed every 3 hours by nurses through 5 ml syringes connected to a tee related to serum containing heparin. Thus, after opening the tee toward arterial catheter and aspirating blood from the arteries, 5 ml of solution containing heparin was aspirated to ensure patency of the catheter and was injected into the catheter as the bolus form. In both groups, monitoring of arterial catheter was performed and recorded in checklist of arterial catheter every 3 hours until catheter working and maximum up to 48 hours in terms of occurrence of complications, including hematoma and hemorrhage. In case of malfunctions in catheter caused by any reason, including the incidence of blockage, the catheter was removed under supervision of doctor; process of recording information was stopped. The malfunctions of catheter happened due to blockage in the 2 cases in the intervention group and in 14 patients in control group

at different times of second 24 hours after the study. Therefore, their data were recorded before removing catheter, and then data recording process was terminated in order to remove catheter. Observation of continuous curve of the arterial wave on monitor provides the possibility of evaluating the catheter performance at every moment.

The venous blood samples were taken from patients to measure PTT upon entry of the patient's in intensive care unit (up to three times from baseline to transfer patient to the ward); the results of lab tests were recorded in the checklist. According to the checklist, the catheter should be washed by bolus method after each sampling (for gasometry and other tests), washing method was similar in both groups and the amount of heparin serum used was recorded.

Ethical considerations included approval of ethics committee of Mashhad University of Medical Science and written informed consent of participants. Once the data are collected and coded, they were inserted into computer. After ensuring the accuracy of data entry, SPSS version 16 software and descriptive statistics (for summarizing data) and tests of Kolmogorov-Smirnov, independent t-test, Mann-Whitney, chi-square, Fisher's exact, chi-square and repeated measures ANOVA were used to analyze the data.

Results

A total of 60 studied patients included 63.3% (n=19) male and 36.7% (n=11) female in continuous irrigation group, and 66.7% (n=20) male and 33.3% (n=10) female in the intermittent irrigation group. The chi-square test results showed no significant difference between the two groups in this regard (P=0.79). The mean age of patients was 57.7± 7.8 years in continuous irrigation group and 56.1 ± 9.5 years in intermittent group (range: 29-70 years). The result of independent t-test indicated no significant difference between the two groups in terms of age (P=0.48). The site of catheter replacement in 100.0 percent (n=30) of patients was the radial artery and its type was peripheral venous catheter No. 20 in both intermittent and continuous irrigation groups; given that the site and type of catheter were the same in all patients, statistical analysis was impossible. Other background characteristics and information on the disease and the result of their homogeneity in the two groups obtained from independent t-test, Mann-Whitney and chi-square were investigated and listed in Table 1.

Table 1. Comparison of medical background characteristics of participants in the two continuous and intermittent irrigation groups

Variable	Continuous (n=30)	Intermittent (n=30)	Test result
Gender			
Male	19 (63.3%)	20 (66.7%)	*P= 0.79
Female	11 (36.7%)	10 (33.3%)	
Age (year)	57.7 ± 7.8	9.5 ± 56.1	**P= 0.48
Drug addiction			
Yes	7 (23.3%)	9 (30.0%)	*P= 0.56
No	23 (76.7%)	21 (70.0%)	
History of hypertension			
Yes	23 (76.7%)	14 (46.7%)	*P= 0.12
No	7 (23.3%)	16 (53.3%)	
History of diabetes			
Yes	14 (46.7%)	14 (46.7%)	*P= 1.00
No	(53.3%) 16	16 (53.3%)	
Aspirin consumption			
Yes	23 (76.7%)	18 (60.0%)	*P= 0.22
No	7 (23.3%)	12 (40.0%)	
Plavix consumption			
Yes	5 (16.7%)	5 (16.7%)	*P= 1.00
No	25 (83.3%)	25 (83.3%)	
Intraoperative level of heparin (unit)	166.8 ± 56.9	149.7 ± 47.2	***P= 0.25
Postoperative level of protamine (unit)	165.8 ± 56.9	148.0 ± 48.7	***P= 0.21
Surgical duration (hours)	0.9 ± 4.8	0.7 ± 4.7	***P= 0.99

*: Chi square, **: Independent t test, ***: Mann-Whitney

Table 2. Comparison of frequency distribution of patients' arterial catheter complications within the first 48 hours after surgery in the two continuous and intermittent irrigation groups

Arterial catheter complications		Continuous	Intermittent	Test result
Fourth three hours	No complication	30(100)	29(96.7)	*P= 1.00
	Hematoma	0(0.0)	1 (3.3)	
Fifth three hours	No complication	30(100)	29 (96.7)	*P= 1.00
	Hematoma	0(0.0)	1 (3.3)	
Sixth three hours	No complication	30(100)	25 (89.3)	**P= 0.18
	Hemorrhage and hematoma	0(0.0)	1 (3.6)	
	Hematoma	0(0.0)	(7.1) 2	
Seventh three hours	No complication	30(100)	25 (96.2)	*P= 0.46
	Hematoma	0(0.0)	1 (3.8)	
Eighth three hours	No complication	30(100)	25 (96.2)	*P= 0.46
	Hematoma	0(0.0)	(3.8) 1	
Ninth three hours	No complication	30(100)	22 (95.7)	*P= 0.43
	Hematoma	0(0.0)	(4.3) 1	
Tenth three hours	No complication	29 (96.7)	20 (95.2)	**P= 0.34
	Hemorrhage and hematoma	1 (3.3)	0(0.0)	
	Hematoma	0(0.0)	1 (4.8)	

*: Fisher's exact test, **: Exact chi square

In the first 12 hours after surgery, no related complications of arterial catheter occurred in patients of either group. In fourth and fifth three hours, hematoma was observed in arterial catheter of 7.1% (1) of patients in intermittent group, but there were no complications in the continuous irrigation group. Fischer's exact test indicated no significant difference between the two groups in this regard (P=1.000). In the sixth to tenth three hours, Fischer's exact test and exact chi-square results showed that there is no significant difference between the two groups in the incidence of complications of arterial catheter in both groups (P>0.05). In the eleventh to seventeenth three hours, no complication was observed among the patients in continuous and intermittent irrigation groups whose arterial catheter had not been still blocked and removed (Table 2). Given that, no complication was occurred during the first 12 hours in both groups, which is not mentioned in Table 2 as well as the eleventh to seventeenth three hours for the same reason.

The mean admission PTT of patients was 9.34±6.5 seconds in continuous irrigation group and 9.35 ± 4.6 seconds in the intermittent group. The independent t-test results at this stage showed that there is no significant difference between the PTT of two patients' groups (P=0.55). Also the result of independent t-test in the first time (the first 24 hours) and second time (the second 24 hours) indicated no significant statistically difference for the mean PTT between the two continuous and intermittent statistically significant difference between the mean admission and second time PTT in two groups (P=0.62). The result of repeated measures analysis of variance (ANOVA) tests showed that during the various stages of PTT assessment, there was no statistically significant difference for the PTT between the two studied groups (Table 3).

Table 3. Comparison of patients' partial thromboplastin time within 48 hours after surgery in the two continuous and intermittent irrigation groups

Partial Thromboplastin time (seconds)		Continuous	Intermittent	Test result
		Mean ± SD	Mean ± SD	
Admission		34.9 ± 5.6	35.9± 6.4	*P= 0.55
First 24 hours		37.2 ± 9.2	39.3± 8.0	*P= 0.39
Second 24 hours		37.6 ± 9.9	38.0± 8.7	*P= 0.87
Test result	Total effect			*P< 0.001
	Group effect			**P= 0.70
	Effect of PTT measurement			**P= 0.09
	Interaction between group and assessment of PTT			**P= 0.53

*: Independent t test, **: repeated measure ANOVA

Discussion

The results of present study demonstrated that the two groups did not differ in terms of the frequency of side effects incidence (hemorrhage and hematoma) in both continuous and intermittent irrigation groups and the mean incidence of complications was similar in both groups .In this regard, the study results of Witkowski et al. (2013) titled " Lack of difference between continuous versus intermittent heparin infusion on maintenance of intra-arterial catheter in postoperative pediatric surgery: a randomized controlled study" showed that 1.6% (n=1) of continuous irrigation group had hematoma. However, none of the patients in irrigation group suffered from this complication; from this point of view, there was also no significant difference between the two groups. Therefore, the side effects of catheter irrigation methods were similar in both groups (14). The results of this study were consistent with the findings of present study and indicated lack of difference in the incidence of complications level. Although it seems that irrigation is a more convenient method to control the volume of parenteral solution, this method probably has more safety level (18). In intermittent method, within one to two hours after injection, blood levels of heparin was in the desirable range; but earlier (immediately after injection), its blood level was higher than the required blood level to prevent the formation of blood clots. This can predispose the person to bleeding (16). This issue probably was the cause of hemorrhage in the intermittent irrigation group in this study and Witkowski's study. Other studies have been carried out in this field. Shah et al. (2011) examined the effect of continuous irrigation method on bleeding complications and infection in central venous catheter. They showed that continuous irrigation method had no significant correlation with the risk of bleeding and infection in central venous catheter. Although this confirms the undeniable advantages of continuous irrigation of catheter such as continuous flow of heparinized solution to prevent clotting, there has been no comparison with other alternatives. The results of studies such as Del Cotillo et al.(2008) entitled " Heparinized solution vs. saline solution in the maintenance of arterial catheters: a double blind randomized clinical trial"(19), Goh et al. (2011) entitled "Heparinised saline versus normal saline in maintaining patency of arterial and central venous catheters"(20), and Haydari et al. (2015) entitled " Comparison the Effect of Heparin and 0.9% sodium chloride to maintain central venous catheter patency"(21), have examined the incidence of complications level following the use of the heparinized and non- heparinized solutions in intravenous or arterial catheters irrigation. All these showed no significant difference between incidence of complications and type of used irrigation solution and they are in line with the present study. Although in these studies, neither of the intermittent and continuous methods have been studied; the use of heparin as probably an important factor affecting the incidence of complications such as bleeding and hematoma is a common ground of these studies with the present study. According to the results of the above-mentioned studies, a safe and proven dose of heparin for venous or arterial catheters irrigation does not cause major side effects (16). If the catheter is not blocked, it will not necessary take time to open or replace it. On the other hand, taking the required actions and cares on time can reduce the patients' duration of hospitalization. According to the results of present study, the incidence of complications makes no difference in two catheter irrigation methods.

Concerning the partial thromboplastin time, the results showed that there is no statistically significant difference for PTT level between the two intermittent and continuous irrigation groups. In this regard, the result of Adib and Fatourchi (2005) entitled "Comparative Survey Effect of Continuous and Intermittent Heparin infusion on Partial Tromboplastin Time" indicated no significant difference between the two methods of heparin infusion (16). The results of this study are consistent with the findings of present study. Although in the intermittent injection method of heparin (every 3 hours), the level close to the therapeutic desire in the interval of 1 to 1.5 hours after the injection is usually achieved and the PTT levels at the time before the above time were higher and were lower than therapeutic range and optimum levels at the times after that; the mean PTT within 6 hours was similar to continuous infusion group. However, the PTT level was almost consistent in continuous infusion method. Since the PTT level in the group with continuous infusion was more consistent compared to interrupted injection which was more stable in the required therapeutic range (16), it is clear that this form of treatment is desired pharmacodynamically (17). Therefore, continuous method is preferable to prevent the incidence of thrombosis or recurrence, and complications such as bleeding as well as reduction in the need for repeated PTT measurement (16).

Study limitations included short-term duration of patients' follow-up. Given that these patients were hospitalized in ICU for 48 hours and the complications usually rise within the second day, if follow-up of the complications of irrigation methods were examined for longer period, further and better outcomes could have been achieved. Nevertheless, this was impossible due to limitations of time and financial resources. This issue is suggested to be considered in future studies.

Implications for Practice

The results of this research showed that the incidence rate of arterial catheter complications including hematoma, hemorrhage and partial thromboplastin time has no statistically significant difference between the two continuous and intermittent groups and these two methods are not preferred to each other in terms of the examined variables. Regarding the limitations of this study based on catheter monitoring only for 48 hours and possibility of incidence of complications after this period, further long-term follow-up researches are recommended.

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Conflict of interest

The authors declare that there is no conflict of interest.

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