

Original Research Article

Effectiveness of Standardized Nursing Care Protocol Post Cardiac Catheterization to Reduce Hematoma Development

ABSTRACT

BACKGROUND

Hematoma development is the most common vascular access complication among post-cardiac catheterization patients. It requires safe and standardized nursing care protocol, as well as qualified and skilled health providers to obtain good outcomes of management. The vascular complications were severe and increased the length of stay in the hospital. Timely recognition and management can diminish their burden.

OBJECTIVES

1. To evaluate the effectiveness of Standardized Nursing Care Protocol Post cardiac catheterization to reduce hematoma development.
2. To assess the association of hematoma development between procedure site (radial and femoral) and comorbidities (diabetes, hypertension, and obesity) among post-cardiac catheterized patients. Hypothesis

METHODOLOGY

This quasi-experimental (post) study was conducted at Coronary Care Units at tertiary care hospitals in Karachi. In this study, a total of 108 post-cardiac catheterized patients participated. The patients were divided into two groups; the interventional group and the control group. In the control group, 54 post-cardiac catheterized patients were selected and data were taken based on inclusion criteria who received routine holistic nursing care post-procedure and have been discharged. Besides 54 patients participated in the interventional

group who received Standardized Nursing Care Protocol post-cardiac catheterization including proper patient assessment, compression techniques, interventions pre, during and post sheath and TR-band removal to discharge instruction by the principal investigator (PI). The data was collected through patients' assessment sheets and hematoma scales for the identification of hematoma development rate among post-cardiac catheterized patients. The non-probability consecutive sampling technique was accomplished for the collection of data.

FINDINGS

The rate of hematoma development in the (control) group was reflected at 18 (33.3 %) while after the implementation of the standardized nursing care protocol the rate of hematoma development was 9 (16.6%) in the (interventional) group out of 54 (50%) post-cardiac catheterized patients. There was a significant difference between the (control) and (interventional) groups regarding the rates of hematoma development post-cardiac catheterization i.e. the P values were $0.037 < 0.05$. Thus, the standardized nursing care protocol post-cardiac catheterization was effective in the reduction of hematoma development.

Furthermore, the radial site procedure reflected fewer rates of hematoma development 8 (14.81%) as compared to the femoral site procedure 19 (35.1%) among post-cardiac catheterized out of 54 (50%). The P-value was $0.058 > 0.05$ there was no association between hematoma development and procedure site in the (interventional and control) groups post-cardiac catheterization. Similarly, the P-value was greater than 0.05 hence there was no association between hematoma development and comorbidities (diabetes, hypertension, and obesity) post-cardiac catheterization.

CONCLUSION

The implementation of Standardized Nursing Care Protocol post-cardiac catheterization was effective for the reduction of hematoma development in the (intervention) group while there was an association of hematoma development between the (control and interventional) groups. However, there was no association between hematoma development and site procedure (radial and femoral) and comorbidities (diabetes, hypertension, and obesity) post-cardiac catheterization.

Keywords: Cardiac Catheterization, **Standardized nursing care protocol, Hematoma.**

BACKGROUND

Cardiac catheterization, including coronary angiography and angioplasty, is a standard diagnostic and therapeutic strategy for the evaluation of cardiovascular diseases⁽¹⁾. Even in the United States, more than one million patients undergo percutaneous coronary intervention (PCI) each year⁽²⁾. It can be performed via radial, ulnar, femoral, or brachial arteries through a sheath⁽³⁾. The sheath is a small flexible catheter, introduced as a guide for wires, stents, and balloons during diagnostic and (PCI)⁽⁴⁾. Similarly, the Trans radial (TR)-band is a compression device that maintains hemostasis of the radial artery after a Tran's radial procedures⁽⁵⁾. Despite being a popular procedure, vascular puncture access complications are experienced by MI (Myocardial infarction) patients after removals of arterial sheath and TR-band⁽⁶⁾. The prevalence of hematoma development ranges from small hematoma 30.6% to medium hematoma 37.6% and large hematoma 16.5% with the major bleeding occurrence at the rate of 1.7% post-cardiac catheterization⁽⁷⁾. Similarly, as per statistics, there is an association between hematoma development between procedure sites (radial, femoral) and comorbidities (diabetes, hypertension, and obesity) post-cardiac catheterization⁽⁸⁾. As per statistics, the Trans radial access associated local hematoma rate is 1.2% to 2.6%, which is 60% lower than in the

transfemoral puncture site ⁽⁹⁾. Tran's radial artery access is associated with a lower hematoma rate than Tran's femoral artery access ⁽¹⁰⁾. In the USA hematomas were 14.5% in the transfemoral approach and none developed in the radial approach ⁽¹¹⁾. Similarly, in India forearm hematoma was developed in 187 (10.7%) patients Grade I hematoma was most common (3.53%), Grade II (3.08%), Grade III (2.83%) and Grade IV (1.25%) hematoma ⁽¹²⁾. Additionally, in Jordan (38%) developed vascular complications such as small hematoma (20%) and then large hematoma 9.3% ⁽¹³⁾. This may occur due to improper digital compression when a sheath is removed from the access site which requires specialized nursing care, training, and competency. Digital pressure is the best method to achieve hemostasis ⁽¹⁴⁾. Furthermore, there is an inadequate 40% in the nurse's knowledge, and 87.1% of nurses were observed doing unsatisfactory practices which are related to post-cardiac catheterization at tertiary care hospitals in Pakistan and Egypt ^{(15), (16)}. The nurses should be experts in the monitoring of warning signs, proper assessment, compression techniques, interventions pre, during and post sheath and TR-band removal to discharge instruction. Nurses need to develop safe nursing care protocols post cardiac catheterization based on evidence research. In United states 3% of vascular access site complications almost 90,000 patients are affected annually in 3 million procedures ⁽¹⁷⁾. Comparatively, as per evidence, the rate of hematoma development between comorbidities (hypertension, diabetes and obesity) are the factors of the vascular site complications ⁽¹⁸⁾. The rate of hematoma development among hypertensive patients was (73%), in diabetes (49%) post coronary interventions ⁽¹⁹⁾. Moreover, obesity has been identified as a correlated factor with hematoma development post coronary intervention ⁽²⁰⁾. The ratio of hematoma was indicated 22% after sheath removal which required for additional manual compression. As a result, patients face additional difficulties such as extended hospital stay and financial constraints ⁽²¹⁾.

These complications are best prevented by the development and implementation of standardized protocols for the removal of femoral sheath and TR-band which are based on scientific evidence. Thus, it is recommended that the development and implementation of standardized nursing care protocols can reduce the rate of hematoma development⁽¹⁵⁾. Therefore, this study was conducted to evaluate the effectiveness of standardized nursing care protocol post-cardiac catheterization in reducing hematoma development and to identify the association of hematoma development between site procedure (radial and femoral) and comorbidities (diabetes, hypertension, and obesity) among post-cardiac catheterized patients.

METHODS

The quasi-experimental post-study was conducted from March 2020 to July 2021. The study's target population was post coronary angiography and angioplasty both radial and femoral single access puncture of the artery, hemodynamically stable and both males and females between 18 years and above were included. While the patients with previous surgery of iliac, femoral, and radial arteries, peripheral vascular diseases, hemodynamically unstable with bleeding disorders, and patients on thrombolytic therapy within 24 hours were excluded from the study. The sample size was calculated the rate of no hematoma post-cardiac catheterization patients was taken (Control group) 13(15.3%) and post-implementation of standardized nursing care protocol (Intervention group) 35(41.5%)⁽⁷⁾. It was calculated by taking a 95% confidence interval and 80% of the power. The total sample size was 108, 54 in each group. The non-probability consecutive sampling technique was used for the collection of data. Patient assessment sheet and hematoma scale post removal of the femoral, radial arterial sheath, and TR-band among post-cardiac catheterized patients were used after the pilot study. The rate of hematoma was identified in the control group, 54 post-cardiac who received routine holistic nursing care post-procedure

and have been discharged. 54 patients participated in the interventional group who received Standardized Nursing Care Protocol post-cardiac catheterization including proper patient assessment, compression techniques, interventions pre, during and post sheath and TR-band removal to discharge instruction by the principal investigator (PI). Then, the rate of hematoma development was assessed after the implementation of standardized nursing care protocol and a comparison was made between the interventional group and control group. The (PI) was experienced and well trained under interventional cardiologists and certified for sheath and Trans radial band removal. The development of hematoma was measured through a 12-hour follow-up post-procedure after that time has gone undetected among the interventional group. The standardized nursing care protocol of the study was qualitatively validated by an interventional cardiologist according to the standard guideline after reading and discussing the related articles.

The Ethical clearance was obtained from the Clinical Research Committee (CRC), Ethics Research Committee (ERC), and Board of Advanced Study Research (BASR) of Ziauddin University. Furthermore, permission from the hospital was obtained. The participant's confidentiality was assured and written informed consent was obtained for voluntary participation. SPSS software version 22.0 was used for data analysis. Descriptive statistics were shown in frequency and percentage. The association of hematoma development between interventional and non-intervention groups, procedure site (radial and femoral) and comorbidities (diabetes, hypertension, and obesity) was assessed by chi-square. **There was no biasness between the control group and interventional group the control group, 54 post-cardiac catheterized patients who received routine holistic nursing care post-procedure and have been discharged.**

RESULT

In this study total of 108 male and female post-cardiac catheterized patients were selected. The patients were divided into two groups (a control) group and an (interventional) group. The (control) group contained 54 patients and 54 in the (intervention) group.

The number of male patients was higher (62%) as compared to the number of females (38%). Similarly, the highest number of participants 47 were falling in the 61-80 years age group, and the lowest number of participants 6 were falling 81-100 years. Moreover, there were (88%) of angiography and (12%) of angioplasty patients participated. Besides, the highest number of the patients did not receive the injection of heparin according to different units, and the lowest number of participants have received heparin doses out of 108 participants. Further, standard 6F sheath was used in all patients and the normal values of PTT and APTT patients were selected. Furthermore (54) radial puncture site procedures and (54) femoral site punctures were nominated from the study. The radial site procedure patients had fewer rates of hematoma developed eight (14.8%) than the femoral site procedure 19 (35.1%) among post-cardiac catheterized patients (n=108). Besides, 78 were diabetic and 30 were nondiabetic patients participated. The rate of hematoma development identified in diabetic patients was 19 (24.3%) and in the non-diabetic, the hematoma ratio was eight (26.6%). The large established hematoma development rate was 03 (3.8%) in diabetic patients while it was not developed in non-diabetic patients. Comparatively, 52 patients were hypertensive but 56 patients were not. The rate of hematoma developed among

hypertensive patients was eight (15.3%) and 19 (33.9%) in non-hypertensive patients. Correspondingly the rate of hematoma development was recognized in 24 (24.7%) out of 97 obese patients. Similarly, in non-obese, the hematoma ratio was three (27.3%) out of 11 patients.

Table: 01 Association of Hematoma Development between Intervention and Control Group (n=108).

Hematoma	Groups		Chi-square P-value
	Control Group n (%)	Interventional Group n (%)	
No Hematoma	36 (66.7)	45 (83.3)	0.037*
Small Hematoma	08 (14.8)	08 (14.8)	
Medium Hematoma	07 (13)	01 (1.9)	
Large Hematoma	03 (5.6)	00	
Total	54 (50)	54 (50)	

* Significant level at 0.05

Table 01. Shows a significant difference between the (Control) and (Interventional) groups regarding hematoma development post-cardiac catheterization i.e. the P values were $0.037 < 0.05$. The rate of hematoma development in (Control) group was indicated at 18 (33.3%) while after the implementation of standardized nursing care protocol the rate of hematoma development in the (Interventional) group was 9 (16.6%) out of 54 (50%) participants. Thus, there was an association of hematoma development between the (Control) group and the (Interventional) group. Furthermore, in the (Control) group, a large hematoma was developed 03 (5.6%) patients but after the implementation of standardized nursing care protocol, the large hematoma had not developed in the (Interventional) group. Moreover, the (Control) group

reflected the highest percentage of 18 (33.3 %) of hematoma development as compared to the (Interventional) group 9 (16.6%).

Table: 02 Association between Hematoma Development and Site Procedures of study Subjects (n=108)

Hematoma	Site Procedures		Chi-square P-value
	Radial n (%)	Femoral n (%)	
No Hematoma	46 (85.2)	35 (64.8)	0.058
Small Hematoma	06 (11.1)	10 (18.5)	
Medium Hematoma	02 (3.7)	06 (11.1)	
Large Hematoma	00	03 (5.5)	
Total	54 (50)	54 (50)	

Table: 02. Points out that there was no significant difference between hematoma development and site procedure in (interventional and Control) groups i.e. P-value was $0.058 > 0.05$. The radial site procedure reflected fewer rates of hematoma development 8 (14.81%) as compared to the femoral site procedure 19 (35.1%) out of 54 (50%) post-cardiac catheterized patients. So, there was no association of hematoma development between control and interventional groups. Apart from that in the radial approach 46 (85.2%) of patients were free of hematoma while in the femoral approach 35 (64.8%) patients were no hematoma out of 54 (50%). Similarly, the large hematoma did not develop in radial site procedure while 3 (5.5%) developed in femoral access.

Table: 3 Association between Hematoma Development and Comorbidity (Diabetes Mellitus) of Study Subjects (n=108)

Hematoma	Diabetes Mellitus		Chi-square P-value
	Yes n (%)	No n (%)	
No Hematoma	59 (75.6)	22 (73.3)	0.582
Small Hematoma	10 (12.8)	06 (20)	
Medium Hematoma	06 (7.7)	02 (6.7)	
Large Hematoma	03 (3.8)	00	
Total	78	30	

Table: 3. This table elucidates that there was no significant difference between hematoma development and co-morbidity (diabetes mellitus) post-cardiac catheterization i.e. P-value was $0.582 > 0.05$. Therefore, there was no association between hematoma development and co-morbidity (diabetes mellitus). The rate of hematoma development was established 19 (24.3%) out of 78 diabetes patients while 8 (26.6%) out of 30 non-diabetic patients. The large hematoma 03 (3.8%) was established in a diabetic while wasn't developed in the non-diabetic patients.

Table: 4, Association between Hematoma Development and Comorbidity (hypertension) of Study Subjects (n=108)

Hematoma	Hypertension		Chi-square P-value
	Yes n (%)	No n (%)	
No Hematoma	44 (84.6)	37 (66.1)	0.102
Small Hematoma	05 (9.6)	11 (19.6)	

Medium Hematoma	03 (5.8)	05 (8.9)	
Large Hematoma	00	03 (5.4)	
Total	52	56	

Table: 4, this table shows that there was no significant difference between hematoma development and co-morbidity (hypertension) post-cardiac catheterization i.e. P-value was 0.102 > 0.05. Hence, there was no association between hematoma development and comorbidity (hypertension). The rate of hematoma development among fifty-two hypertensive patients was eight (15.38%) and 19 (33.9%) in non-hypertensive fifty-six patients. The highest score of small hematomas development appeared in 11 (19.6%) in non-hypertensive patients while the small hematomas development rate was identified in five (9.6%) among hypertensive patients post cardiac catheterization.

Table: 5. Association between Hematoma Development and Comorbidity (obesity) of Study Subjects (n=108)

Hematoma	Obesity		Chi-square P-value
	Yes n (%)	No n (%)	
No Hematoma	73 (75.3%)	08 (72.7%)	0.468
Small Hematoma	13 (13.4%)	03 (27.3%)	
Medium Hematoma	08 (8.2%)	00	
Large Hematoma	03 (3.1%)	00	
Total	97	11	

Table:5. This table presents that there was no significant difference between hematoma development and co-morbidity (obesity) post-cardiac catheterization i.e. P-value was $0.468 > 0.05$. Thus, there was no association between hematoma development and comorbidity (obesity). The rate of hematoma development was recognized in 24 (24.7%) out of 97 obese patients. Similarly, in non-obese patients, hematoma development was mentioned three (27.3%) out of 11 patients. The highest ratio of small hematoma 13 (13.4%) was established among obese patients although 03 (27.3%) was recognized among non-obese patients post cardiac catheterization.

DISCUSSION

This study revealed that there was a significant difference between the hematoma development in (Control) group and (Interventional) group. The rate of hematoma development in (Control) group was indicated at 18 (33.3%) while after the implementation of standardized nursing care protocol the rate of hematoma development in the (Interventional) group was 9 (16.6%) out of 54 (50%) participants. Thus, there was an association of hematoma development between the (Control) group and the (Interventional) group. As per statistics, the implementation of standardized nursing care protocol post-cardiac catheterization is an effective role in reducing bleeding, and hematoma as well as improving patient safety, outcomes, saving treatment time and cost⁽²²⁾. Furthermore, there was a positive association between nurses' knowledge about the practice and a lower rate of vascular site complications which requires safe and standardized care, as well as qualified and skillful health providers⁽²³⁾. The rate of hematoma development post coronary intervention was reduced after the implementation of good nursing care⁽²⁴⁾.

The current study points out the radial site procedure reflected fewer rates of hematoma development 8 (14.81%) as compared to the femoral site procedure 19 (35.1%). So, there was no association between hematoma development and site procedure. As per evidence, the femoral access has shown 14.5% hematoma versus radial route 0% (11) as well as the hematomas were significantly higher in the femoral approach ⁽¹⁰⁾.

The current study identified that the large hematoma was not developed in the radial site procedure while 3 (5.5%) had developed in femoral access. As per statistics, Tran's radial artery access is associated with lower hematoma than Tran's femoral artery access ⁽⁸⁾. Such as evidenced hematoma occurred 1.4% in transradial approach and 7.2% in femoral access, which is 60% lower than in Transfemoral puncture sites ⁽¹⁰⁾. In the USA the vascular complications rate was in Tran's radial approach (0.24%) Tran's femoral approach (1.12%) ⁽²⁵⁾. Moreover, radial hematoma development is preventable and easy to treat by the utilization of proper techniques that could reduce the occurrence and severity of complications ⁽²⁶⁾. As per contradicting findings radial artery spasm, and radial artery occlusion, are the common complications while radial artery perforation and compartment syndrome are rare complications in TRA ⁽²⁷⁾.

The current research interprets the rate of hematoma development was established at 19 (24.3%) while 8 (26.6%) non-diabetic patients. Therefore, there was no association between hematoma development and co-morbidity (diabetes mellitus). As per the **investigation, the radial hematoma was in diabetes mellitus 67 (35.8%) and hypertension 68 (36.4%) out** of 1754 patients ⁽¹²⁾. Manual compression method with standardized nursing care measured a low rate of hematoma development as compare to the vascular closer device. Diabetes mellitus and hypertension were not a significant variable of hematoma development. The hematoma ratio was 2 (0.3%) in

hypertension and 1 (0.2%) diabetes⁽²⁸⁾. The incidence rate of vascular complications was 40.6% in diabetes, hypertension 87(89.7) and 24(24.7) in obese patients⁽²⁹⁾.

The present study shows the rate of hematoma development among hypertensive patients was eight (15.38%) and 19 (33.9%) in non-hypertensive. Hence, there was no association between hematoma development and comorbidity (hypertension). As per the investigation systolic blood pressure of more than 160 mmHg significant predictor of hematoma development⁽³⁰⁾. The investigator proved that high blood pressure may increase the length of time to achieve hemostasis, as medically antihypertensive is required before the sheath is removable⁽³¹⁾. High blood pressure is a higher risk for hematoma development due to the difficulty of compressing an artery with elevated intraluminal pressure⁽¹³⁾.

This study presented that there was no significant difference between hematoma development and comorbidity (obesity) post-cardiac catheterization. The rate of hematoma development was recognized in 24 (24.7%) non-obese and three (27.3%) obese. Thus, there was no association between hematoma development and comorbidity (obesity). As per statistics obesity is not a significant factor of vascular complications, non-obese had 4 times more complications than obesity⁽³²⁾. As per previous studies, obesity was associated with an increased risk of vascular complications⁽³³⁾. Overweight and obesity were not independent predictors of short-term outcomes in over weight 187 (7.2) in obese 149 (5.3)⁽³⁴⁾. The hematoma development was obesity noted 7 (1.1%), hypertensive BMI ≥ 23 kg/m² indicated 395 (62.3%) and in diabetes 143 (22.6%)⁽³⁵⁾.

STRENGTH OF THE STUDY

The current study has various strengths, which are as follows:

- The essential feature of the study was its design, quasi-experimental (post), which facilitated in carrying out of interventional research.
- The implementation of the standardized nursing care protocol and data collection carried out by the researcher herself, she was experienced in dealing with post-cardiac catheterized patients besides well trained under interventional cardiologists and certified for sheath and Trans radial band removal.
- Standardized nursing care protocol was effective for the reduction of hematoma post-cardiac catheterization, which has not been studied earlier in Pakistan.
- The study adopted a valid data collection tool which was further validated by experts and pilot tested on 10% of the sample size of post-cardiac catheterization patients.

LIMITATIONS

- It is a single-center study with a small sample size hence it cannot be generalized.
- Data for the current study were collected through a 12-hour follow-up post-cardiac catheterization within this time was recorded but any hematoma development after that time has gone undetected.

RECOMMENDATION FOR NURSES

- Standardized Nursing Care protocol on post-cardiac catheterization associated training and certification should be necessary for nurses.
- In this study, the digital approach is an effective and safe method for the removal of femoral arterial sheaths thus nurses should implement the manual digital compression method on post-cardiac catheterized patients instead of vascular close devices (VCD).
- Nurses should be identified patients' health-related issues besides gaps then fill the gap through advanced-based literature.

RECOMMENDATION FOR HOSPITAL MANAGEMENT

- The finding of the study addressed that the hospital management should provide simulation for hospital site nurses to up to date their knowledge and practice related to new research.
- Refresher courses follow-up to check nurses' knowledge and displayed checklist protocol in areas.
- It is recommended to the hospital management or policy creator to implement the standardized nursing care protocol post-cardiac catheterization for the reduction of hematoma development in the hospital, as a result, can patient free from hematoma, diminish hospitalization, reduce financial constraints, release patient's discomfort, increase patient satisfaction and also nurses can manage these patients easily.

RECOMMENDATION FOR RESEARCH

- Randomized control trial (RCT), with a large sample size to confirm the effectiveness of standardized nursing care protocol on post-cardiac catheterized patients and also to reassess the association of hematoma development between procedure site (radial and femoral) and comorbidities (diabetes, hypertension, and obesity) on large sample size.

CONCLUSION

The implementation of standardized nursing care protocol post-cardiac catheterization was effective for the reduction of hematoma development in the (intervention) group while there was an association of hematoma development between (control and interventional) groups. However, there was no association of hematoma development between procedure site (radial and femoral) and comorbidities (diabetes, hypertension, and obesity) post-cardiac catheterization.

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