

## 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), comorbidities (diabetes, hypertension, and obesity) among post-cardiac catheterized patients.

#### **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 were participated in the interventional group who received Standardized Nursing Care Protocol post-cardiac catheterization including for 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.

## **Results**

The rate of hematoma development in the (control) group was reflected 18 (33.3 %) while after implementation of the standardized nursing care protocol the rates 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 for 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), comorbidities (diabetes, hypertension, and obesity) post-cardiac catheterization.

**Keywords:** Femoral arterial sheath and TR-band removal, nurses' knowledge and practice, standardized nursing care protocol, Cardiac Catheterization, and hematoma.

### **Introduction**

Cardiac catheterization, including coronary angiography and angioplasty, is a standard diagnostic and therapeutic strategy for the evaluation of cardiovascular diseases<sup>1</sup>. Coronary angiography is performed by cardiologists for evaluation of the extent of coronary artery disease or blockage<sup>2</sup>. Even in the United States, more than one million patients undergo percutaneous coronary intervention (PCI) each year<sup>3</sup>. It can be performed via radial, ulnar, femoral, or brachial arteries through sheath<sup>4</sup>. The sheath is a small flexible catheter, introduced as a guide for wires, stents, and balloons during diagnostic and (PCI's)<sup>5</sup>. Similarly, the Trans radial (TR)-band is a compression device that maintains hemostasis of the radial artery after a Tran's radial procedures<sup>6</sup>. Despite being a popular procedure, vascular puncture access complications are experienced by MI (Myocardial infarction) patients after removals of arterial sheath and TR-band<sup>7</sup>. The most common complications are grade II or III hematoma<sup>8</sup>. It occurs when blood gets

trapped underneath the skin around the insertion site due to improper digital compression which requires 18-20 minutes<sup>9</sup>. Post-cardiac catheterization patients are at high risk of vascular site complications<sup>10</sup>. 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<sup>11, 12</sup>. Similarly, as per statistics, there is an association of hematoma development between procedure sites (radial, femoral) and comorbidities (diabetes, hypertension, and obesity) post-cardiac catheterization<sup>13,14</sup>. As a result, patients face additional difficulties such as extended hospital stay and financial constraint<sup>15</sup>. These complications are best prevented by the development and implementation of standardized protocols for removal of femoral sheath and TR-band which are based on scientific evidence<sup>16</sup>. The protocols should be based on patients' assessment, compression techniques, interventions pre, during and post sheath and TR-band removal to discharge instruction<sup>17</sup>. The Manual compression method of sheath removal is considered the golden standard technique than vascular closure devices which obligate higher vascular site complications<sup>18</sup>. The nursing actions ensure an excess of blood return around the sheath<sup>19</sup> especially severe vascular complications can increase illness and death 32% rate as well as expenses of the patients<sup>20, 21</sup>. Recognition, as well as appropriate management, is dependent on the nurse's competence. Hence standardized nursing care protocols should be established to run nursing training where they are following certain strategies to be utilized<sup>22, 23</sup>. The lack of universally recognized scientific guidelines or protocol may increase the complication rates if nurses are unaware of how to detect and respond to a hematoma, are unaware of the cause that placing patients at greater risk of complications<sup>24</sup>. As per statistics, 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<sup>25,26</sup>. The nurses should be experts in the monitoring of warning signs, proper assessment, documentation, and proper evaluation of puncture site after removal of the femoral sheath and TR band<sup>27</sup>. The post-cardiac catheterized patients are at a high risk of vascular site complications<sup>28</sup>. In the United States of America (USA) the rate of large hematoma was 3% and bleeding was 1.7% post-cardiac catheterization<sup>29,30</sup>. Additionally, in Jordan (38%) developed vascular complications out of 114 patients<sup>31</sup>. Comparatively in India forearm hematoma 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<sup>32</sup>.

Digital pressure is the best method to achieve hemostasis when a sheath is removed from the access site which requires specialized nursing care, training, and competency. 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<sup>33,34</sup>. Tran's radial artery access is associated with a lower hematoma rate than Tran's femoral artery access<sup>35</sup>. In USA Tran's radial approach, the rate of hematoma development was (2.9%) and in Tran's femoral approach (7.7%)<sup>36</sup>. Similarly, in India forearm hematoma was developed in 187 (10.7%) patients<sup>37</sup>. In elderly and hypertensive patients, there is a greater risk of hematoma or bleeding, which requires closer monitoring of the access site during and after sheath removal<sup>38</sup>. As per evidence, the rate of hematoma development between comorbidities (hypertension, diabetes and obesity) are the factors of the vascular site complications. High blood pressure may increase the length of time to achieve hemostasis, antihypertensive is required before sheath removal<sup>39,40</sup>. High blood pressure, 180 mmHg before sheath removal more likely to develop femoral complications<sup>41</sup>. The rate of hematoma development among hypertensive patients was 65 (73%) out of 118 after sheath removal post coronary interventions<sup>42</sup>. Similarly, diabetes is one of the factors which increase

the risk of access site complications among post-cardiac catheterization<sup>43, 44</sup>. Additionally, it is revealed that diabetes was the significant variable of hematoma development 44 (49%) out of 118 patients<sup>45</sup>. Moreover, obesity has been identified as a correlated factor with hematoma development post coronary intervention<sup>46</sup>. Comparatively, the study revealed that obesity is associated with an increased risk of vascular complications post-cardiac catheterization<sup>47, 48</sup>. Procedure protocols and staff education regarding complications not only ensure the patients' safety and comfort but also reduce the costs. At the same time, it also improves the effectiveness of cardiac catheterization<sup>49</sup>.

Thus, it is recommended that the development and implementation of standardized protocols of arterial sheath and TR-Band can reduce the rate of hematoma development<sup>50</sup>. 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.

## **Methodology**

The study setting was conducted at cardiac units (Cath-lab, CCU, Cardiac Ward) at tertiary care hospital in Karachi, Pakistan. The study's target population was post coronary angiography and angioplasty male and female patients who were falling in the inclusion criteria were selected.

Quasi-experimental (post) design was employed to determine the effectiveness of the Standardized Nursing Care Protocol for the reduction of hematoma development and to evaluate the association of hematoma development between procedure site (radial and femoral), comorbidities (diabetes, hypertension, and obesity) among post cardiac catheterization. The whole study period was accomplished from March 2020 to July 2021. The sample size was

calculated by using OpenEpi software version 3 based on statistics. 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%)<sup>52</sup>. 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.

#### Sample Selection

##### **Inclusion Criteria**

- Post coronary angiography of both radial and femoral punctures site patients.
- Post coronary angioplasty only for radial puncture site patients.
- Both male and female patients between 18 years and above will be able to join and consent to take part in the study.
- Normal Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) test.
- Single access puncture of the artery will be included.

##### **Exclusion Criteria**

- Post coronary angioplasty femoral puncture site patients were excluded due to the non-availability of the ACT machine.
- Patients with previous surgery of iliac, femoral, and radial arteries.
- Patients with peripheral vascular diseases.
- Hemodynamically unstable patients with bleeding disorders.
- Patients on thrombolytic therapy within 24 hours.

### **Pilot Study**

The pilot study was conducted in March 2020 and April 2020 on 10% of the sample size on post-cardiac catheterization patients. The reliability of the tool according to Cronbach alpha value was ( $r=0.722$ ) including patients' assessment sheet and hematoma scale post removal of TR band and femoral sheath.

### **Data Collection Procedure**

The data were collected by utilizing a patient assessment sheet and hematoma scale post removal of the femoral, radial arterial sheath, and TR-band among post-cardiac catheterized patients. The data was collected among 108 post-cardiac catheterized patients 54 in each group. 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 were 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). She 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. 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.

### **Ethical Consideration**

The study was approved by the Clinical Research Committee (CRC), Ethics Research Committee (ERC), and Board of Advanced Study Research (BASR) of the Ziauddin University. Furthermore, permission from the hospital was obtained. To accomplish the participant's right of autonomy, informed consent was taken the background, purpose, possible risks of the study, and their right to refuse participation were discussed with the participants.

## Result

In this study total of 108 male and female post-cardiac catheterized patients were selected. The patients were divided into two groups (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%) as shown in graph 2. 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 as shown in graph 1. Moreover, there were (88%) of angiography and (12%) of angioplasty patients participated. Besides, the highest number of the patients did not receive the injection 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) as displayed in table 4. 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

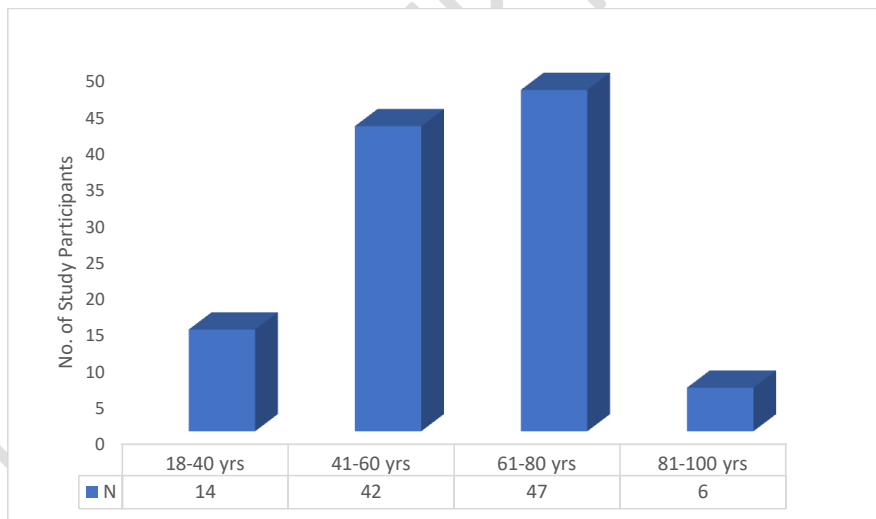
**Comment [1]:** Add ethical clearance certificate number by CRC, HRC and BASR

What are the consequences if the control group does not use the Standardized Nursing Care Protocol?  
How to explain to two groups that there is a difference in treatment?

development rate was 03 (3.8%) in diabetic patients while it was not developed in non-diabetic patients (table 5). 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 (table 6). 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 7).

### **Distribution of Age Category among Study Participants**

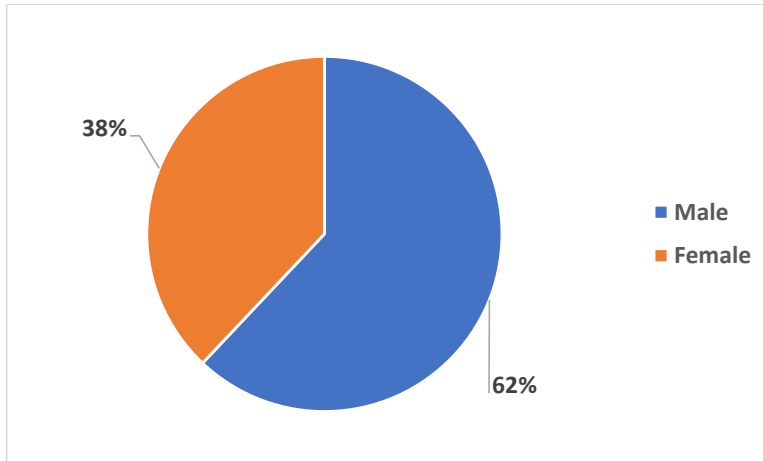
In this study 108 post-cardiac catheterization patients participated, the highest number of participants 47 were falling in the 61-80 years age group, Similarly, the lowest number of participants 6 were falling 81-100 years age group as shown in graph 1.



**Graph: 1 Bar Chart Represents Age Distribution of Study Participants**

### **Gender Distribution**

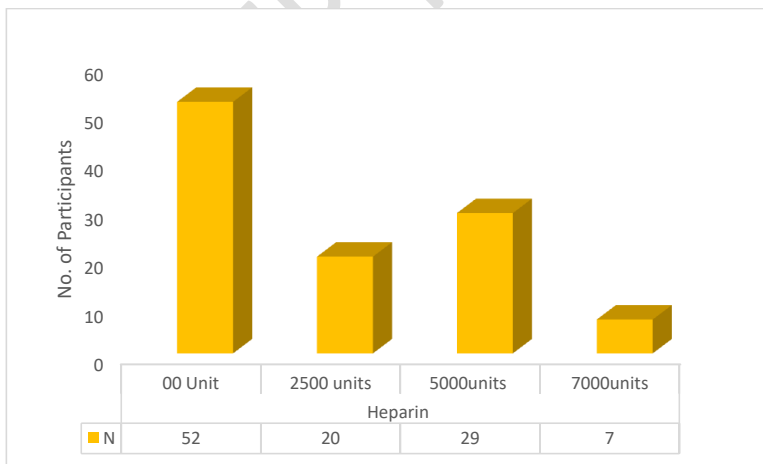
The numbers of male patients were higher i.e. n= (62%) as compared to the female for the given study.



**Graph: 2 Pie Chart Represents Gender Distribution of Study Participants**

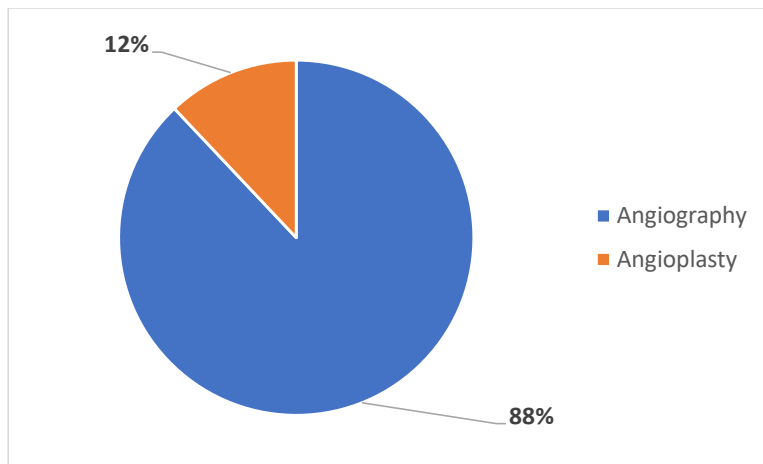
### **Distribution of Heparin**

**Graph: 3** shows the injection heparin received by the participants according to different units, the highest number of patients who have not received heparin and the lowest number of participants 7 received heparin dose out of 108 participants.



**Graph: 3 Bar Chart represents Frequency of Heparin used for Study Participants.**

**Graph: 4.** Reflecting most of the patients were treated by angiography procedure 88%, on the other hand, angioplasty patients were 12%.



**Graph: 4** Pie Chart Represents Type of Procedures used for Study Participants

**Table: 1** Association of Hematoma Development between Intervention and Control Group (n=108).

Hematoma	Groups		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	
<b>Total</b>	54 (50)	54 (50)	

\* Significant level at 0.05

**Table 1.** 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: 2 Association between Hematoma Development and Site Procedures in Control**

**Group (n=54)**

Hematoma	Site Procedures		P-value
	Radial n (%)	Femoral n (%)	
No Hematoma	22 (81.5)	14 (51.9)	0.087
Small Hematoma	03 (11.1)	05 (18.5)	
Medium Hematoma	02 (7.4)	05 (18.5)	
Large Hematoma	00	03 (11.1)	
Total	27 (50)	27 (50)	

**Table: 2.** This table illustrates that there was no significant difference between hematoma development and site procedures in the (Control) group post-cardiac catheterization i.e. P-value was  $0.087 > 0.05$ . So, there was no association between hematoma development and site

procedure in the (control) group among post-cardiac catheterized patients. Although the rate of hematoma development was represented higher in the femoral approach than the radial approach; such as in the femoral site procedure the highest number of patients 13 (48.1%) had developed hematomas. However, the rate of hematoma development was signifying 5 lowest (18.5%) in radial approach out of 27 (50%). Additionally, the large hematomas had developed three (11.1%) in femoral access, but did not develop in radial access among post-cardiac catheterized patients.

**Table: 3 Association between Hematoma Development and Site Procedures in**

**Interventional Group (n=54)**

Hematoma	Site Procedures		P-value
	Radial n (%)	Femoral n (%)	
No Hematoma	24 (88.8)	21 (77.7)	0.087
Small Hematoma	03 (11.1)	05 (18.5)	
Medium Hematoma	00	01 (3.7)	
Total	27 (50)	27 (50)	

**Table: 3.** Clarifies that there was no significant difference between hematoma development and site procedure in (Interventional) group post-cardiac catheterization i.e. P-value was  $0.087 > 0.05$ . Hence, there was no association between hematoma development and site procedure in the (Interventional) group. The rate of hematoma development in radial site procedure represented 3 (11.1%) out of 27 (50%) while the medium and large hematoma did not develop in an (Interventional) group. However, in the femoral approach, 6 (22.2%) patients had developed hematomas and large hematoma had not developed. The table revealed that in the radial site procedure 24 (88.8%) patients were free from hematoma as compared to the femoral site 21 (77.7%) patients were free from hematoma development post cardiac catheterization.

**Table: 4 Association between Hematoma Development and Site Procedures of study**

**Subjects (n=108)**

Hematoma	Site Procedures		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: 4.** 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: 5 Association between Hematoma Development and Comorbidity (Diabetes**

**Mellitus) of Study Subjects (n=108)**

Hematoma	Diabetes Mellitus		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	

<b>Total</b>	78	30	
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**Table: 5.** 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: 6 Association between Hematoma Development and Comorbidity (hypertension) of Study Subjects (n=108)**

<b>Hematoma</b>	<b>Hypertension</b>		<b>P-value</b>
	<b>Yes</b>	<b>No</b>	
	<b>n (%)</b>	<b>n (%)</b>	
<b>No Hematoma</b>	44 (84.6)	37 (66.1)	0.102
<b>Small Hematoma</b>	05 (9.6)	11 (19.6)	
<b>Medium Hematoma</b>	03 (5.8)	05 (8.9)	
<b>Large Hematoma</b>	00	03 (5.4)	
<b>Total</b>	52	56	

**Table: 6,** 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 five (9.6%) among hypertensive patients post cardiac catheterization.

**Table: 7. Association between Hematoma Development and Comorbidity (obesity) of Study**

**Subjects (n=108)**

Hematoma	Obesity		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:7.** 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 24 (24.7%) out of 97 obese patients. Similarly, in non-obese patients, the hematoma development 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

Table 1. This study revealed that there was a significant difference between the hematoma development in (Control) group and after the implementation of standardized nursing care protocol (Interventional) group. The rate of hematoma development in (Control) group was indicated 18 (33.3%) while after implementation of standardized nursing care protocol the rate of hematoma development in the (Interventional) group was 9 (16.6%) out of 54 (50%) participants which support the alternative hypothesis. Thus, there was an association of hematoma

**Comment [12]:** Should be added to the analysis of researchers and comparisons with other studies that have been done previously

development between the (Control) group and the (Interventional) group. It's proved by the statistic that implementation of standardized nursing care protocol post-cardiac catheterization is an effective role in reducing bleeding, hematoma as well as improving patient's safety, outcomes, saving treatment time and cost <sup>51</sup>. Furthermore, there was a positive association between nurses' knowledge about the practice and lower the rate of vascular site complications among patients in the intervention group which requires safe and standardized care, as well as qualified and skillful health providers <sup>52</sup>. The rate of hematoma development post coronary intervention was reduced after implementation of good nursing care <sup>53</sup>. Additionally, another study was in Lahore Pakistan (Feroze et, al) found a positive correlation between the skills and knowledge regarding patient's safety post-cardiac catheterization, adequate skills, and knowledge which reflected on enhanced patient safety <sup>54</sup>.

**Comment [13]:** Citation should be adjusted to the citation guide

Table 2. This study has revealed that there was no significant difference between hematoma development and site procedures in the (control) group post cardiac catheterization. Although the rate of hematoma development was represented higher in the femoral approach than the radial approach; such as in the femoral site procedure the highest number of patients 13 (48.1%) had developed hematomas. However, the rate of hematoma development was signifying 5 lowest (18.5%) in radial approach out of 27 (50%). So, there was no association between hematoma development and site procedure in the (control) group post-cardiac catheterization. Similarly, as per statistics, Tran's radial artery access is associated with lower hematoma than Tran's femoral artery access <sup>55</sup>. Such as evidenced by small hematoma 60 (20%) then large hematoma 28 (9.3%) in femoral approach <sup>56</sup>. Additionally, in this study, the large hematoma had developed three (11.1%) in femoral access but had not developed in radial access besides 77% reduction in major vascular complication by using Trans radial approach <sup>57</sup>. Moreover, the radial hematoma

development is preventable and easy to treat by the utilization of proper techniques that could reduce the occurrence and severity of complications<sup>58,59</sup>.

Table 3. It clarifies that there was no significant difference between the rate of hematoma development and site procedure in (interventional group) post-cardiac catheterization. Hence, there was no association between hematoma development and site procedure in the (Interventional) group. The rate of hematoma development in radial site procedure represented 3 (11.1%) while in femoral site 6 (22.2%) out of 27 (50%). The Trans radial access associated local hematoma rate is 1.2% to 2.6%, which is 60% lower than in Transfemoral puncture sites<sup>60,61</sup>.

**Comment [14]:** Should be added with the author's analysis and also add some other research that underlies.

Table 4. Points out that there was no significant difference between hematoma development site procedure in (Control and Interventional) groups post-cardiac catheterization. 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. As per evidence, the radial access has shown a less vascular access complication rate of 27% versus femoral route 45% as well as the large hematomas were significantly higher in the femoral approach<sup>62,63</sup>. In the USA the hematoma development rate was in Tran's radial approach (2.9%) Tran's femoral approach (7.7%)<sup>64</sup>. In India forearm hematoma developed in 187 (10.7%) patients<sup>65</sup>. Similarly, this 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 contradicting findings radial artery spasm, radial artery occlusion, are the common complications while radial artery perforation and compartment syndrome are rare complications in TRA<sup>66</sup>.

Table 5: interpret that there was no significant difference between hematoma development and co-morbidity (diabetes mellitus) post-cardiac catheterization. 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. Therefore, there was no association between hematoma development and co-morbidity (diabetes mellitus). As per the investigation, diabetes is one of the factors which increases the risk of access site complications among post-cardiac catheterization<sup>67, 68</sup>. As per statistics, those patients who had diabetes mellitus were prone to groin complications development post coronary intervention<sup>69, 70</sup>. Another study has shown that diabetes mellitus was not a significant predictor for hematoma development<sup>71</sup>. Diabetes is a significant variable of hematoma 44 (49%) out of 118 patients.

Table 6: shows that there was no significant difference between hematoma development and co-morbidity (hypertension) post-cardiac catheterization. The rate of hematoma development among fifty-two hypertensive patients was eight (15.38%) and 19 (33.9%) in non-hypertensive fifty-six patients. Hence, there was no association between hematoma development and comorbidity (hypertension). As per statistics hypertension was found to be a not significant variable of vascular complications<sup>72, 73</sup>. Correspondingly, hypertension is not a predictor for hematoma formation<sup>74</sup>. The investigator proved that high blood pressure may increase the length of time to achieve hemostasis, as medically antihypertensive is required before sheath removable<sup>75, 76</sup>. It's proved by investigators that a history of hypertension and diabetes mellitus is an associated factor of hematoma development<sup>77-83</sup>. Additionally, it's concluded that high blood pressure, 180 mmHg before sheath removal more likely to develop femoral complications<sup>84</sup>. In hypertensive patients, the rate of hematoma development was 65 (73%) out of 118 post coronary interventions<sup>85</sup>.

Table 7: Presented that there was no significant difference between hematoma development and comorbidity (obesity) post-cardiac catheterization. The rate of hematoma development was recognized 24 (24.7%) out of 97 obese patients. Similarly, in non-obese patients, the hematoma development mentioned three (27.3%) out of 11 patients. Thus, there was no association between hematoma development and comorbidity (obesity). As per statistics obesity is not a significant factor of vascular complications post-cardiac catheterization<sup>86</sup>. As per previous studies, obesity was associated with an increased risk of vascular complications post-cardiac catheterization<sup>87, 88</sup>. Additionally, obesity was associated with hematoma development<sup>89</sup>. Furthermore, obesity has been identified as a correlated factor with hematoma development post coronary intervention<sup>90</sup>.

### **Strength of the Study**

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

- The essential feature of the study was its design, quasi-experimental (post), which facilitated in carrying out interventional research.
- The implementation of the standardized nursing care protocol and data collection carried out by the researcher herself, she was experienced 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.
- In this study the manual digital method was used for the removal of the femoral arterial sheath thus its evidence that the digital approach is an effective and safe method for the removal of femoral arterial sheaths.

- The study adopted a valid data collection tool which was further validated by experts and pilot tested on 10% of sample size on 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), 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), comorbidities (diabetes, hypertension, and obesity) post-cardiac catheterization.

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