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Comparison of Closure Device with Manual Compression in Patients Undergoing Percutaneous Coronary Intervention Through Femoral Access Site

Ayesha Rehman, Abdul Hameed Siddiqui, Andaleeb Khan*, Muwahhid Rasheed, Sohail Zafar, Kamil Rehman Butt*****

Department of Resident Cardiology, Armed Forces Institute of Cardiology/National Institute of Heart Diseases/National University of Medical Sciences (NUMS) Rawalpindi Pakistan, *Department of Internal Medicine, FTC Lipa Pakistan, **Department of Internal Medicine, Combined Military Hospital, Quetta/National University of Medical Sciences (NUMS) Pakistan, ***Department of Internal Medicine, FTC Goma Pakistan

ABSTRACT

Objective: To compare the complications between closure device and manual compression in patients after percutaneous coronary intervention through femoral access site.

Study Design: Comparative cross-sectional study.

Place and Duration of Study: Armed Forces Institute of Cardiology, from Mar to Nov 2021.

Methodology: Eighty patients who underwent percutaneous coronary intervention through the femoral access site during the study period were recruited in this analysis. Patients were randomly divided into two groups for the procedure adopted for hemostasis after percutaneous coronary intervention. Group-A underwent manual compression of the femoral access site, while hemostasis in Group-B was achieved with the help of a closure device. Hematoma formation, pseudo-aneurysm, AV fistula and bleeding were compared in both groups.

Results: Eighty patients participated in this analysis. Of them, 50(62.5%) were male and 30(37.5%) were female. The mean age of patients was 48.85±8.93 years. In 35(43.75%) patients, hemostasis was achieved by manual compression (Group-A), while in 45(56.25%) patients, by vascular compression device (Group-B). Both groups did not differ statistically significantly in Hematoma formation, AV fistula formation, bleeding, and pseudo-aneurysm formation (*p*-value: 0.05).

Conclusion: There was no statistically significant difference in the complications studied among the closure device method and manual compression of hemostasis in PCI through femoral vein access.

Keywords: Closure device, Femoral artery, Hemostasis, Manual compression, Percutaneous coronary intervention.

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INTRODUCTION

Interventional cardiology has been an emerging speciality in Pakistan. The number of intervention procedures has been increasing with each passing day.[1] The Burden of Cardiac surgeons has been reduced tremendously after the evolution of interventional cardiology, and a lot of diagnostic and therapeutic work related to one of the most vital organs of the body has been dealt with with minimum intervention via vascular access.[2,3]

The percutaneous coronary intervention has been the most commonly performed diagnostic or therapeutic procedure by cardiac physicians.[4] Femoral artery is the main vessel used for this purpose despite this procedure is very good safety profile. Still, several local and systemic complications have been reported by patients undergoing percutaneous coronary intervention for various cardiac procedures.[5]

Correspondence: Dr Ayesha Rehman, Department of Resident Cardiology, AFIC/NIHD, Rawalpindi Pakistan

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Various methods have been used globally for hemostasis of access sites after percutaneous coronary intervention, with different merits and demerits.[6] Access site bleeding has been a major concern after percutaneous coronary intervention and occurs in around 2-3% of the patients undergoing this procedure for any indication.[7] A systematic review of vascular closure devices for femoral artery puncture sites by Noori *et al*. summarized that major complications were seen less in patients with closure devices than those with manual compression. Infections and thrombotic events were seen slightly more in patients who used vascular closure devices. No conclusive data was generated to recommend using any particular method by them.[8] Gewalt *et al*. compared vascular closure devices and manual compression after femoral artery puncture in women undergoing transfemoral catheterization. They revealed that manual compression and vascular closure devices were equally effective in achieving hemostasis. However, the time required to achieve the

optimum level was reduced in patients managed with vascular closure devices.[9]

The percutaneous coronary intervention has been a routine procedure in all the cardiac centres of Pakistan. Complications, may they be local, would pose a burden on patients as well as the health care system. A local study conducted at Agha Khan University Hospital in 2020 concluded that around 2% of the patients undergoing percutaneous coronary intervention had local access site complications.[10] The rationale for planning this study was to compare the complications between closure devices and manual compression in patients after percutaneous coronary intervention through the femoral access site.

METHODOLOGY

The comparative cross-sectional study was conducted at the Armed Forces Institute of Cardiology, from March to November 2021 after approval from Armed Forces Institute of Cardiology committee (Letter no 27/12/R&D/2021/132). The population proportion of femoral access site complications in patients undergoing PCI, 3.5%, was used to calculate the sample size.[11] The non-probability Consecutive sampling techniques were used to gather the sample.

Inclusion Criteria: Patients of either gender, aged 18 to 65 years, who underwent PCI via femoral artery access site for various diagnostic and therapeutic cardiac indications were included. Referred patients from other primary and secondary care units for the same purpose were also included after the initial assessment.

Exclusion Criteria: Patients with poorly controlled comorbid illnesses, patients with known neoplastic conditions, leukaemia, or lymphomas, those undergoing the redo procedure, patients with known bleeding or clotting disorders or taking medications that could interfere with hemostasis were excluded.

Patients undergoing PCI via femoral artery access fulfilling the inclusion and exclusion criteria mentioned above were included in the study after consent. Patients were randomly divided into two groups via lottery method before the procedure. Group-A received manual compression after the surgery, while Group-B received a vascular closure device for hemostasis. Routine medications were given to each patient per the hospital protocol and condition. The consultant cardiologist of our unit performed PCI as per the set protocol.[12] The extravascular vascular closure device (Proglide) was used by the consultant who did the procedure via an aseptic technique. Patients undergoing manual compression underwent sheath removal and local compression via set protocol by a consultant cardiologist who performed the procedure.[13] A pressure bandage was applied 2 hours after VCD implantation and 6 hours after manual compression. Both groups' complications were observed 6 hours after the procedure and noted in a proforma designed for this study.

Statistical Package for Social Sciences (SPSS) version 23.0 was used for the data analysis. Quantitative variables were expressed as Mean±SD and qualitative variables were expressed as frequency and percentages. Chi-square test was applied to explore the inferential statistics. The *p*-value lower than or up to 0.05 was considered as significant.

RESULTS

Eighty patients who underwent the procedure were included in our final analysis. Of them, 50(62.5%) were male and 30(37.5%) were female. Table-I summarises the general characteristics of the participants. 48.85±8.93 years was the mean age of the participants we included**.** 35(43.75%) underwent manual compression, while 45(56.25%) used vascular compression devices for hemostasis. Out of the total of 80 patients, 06(7.5%) had hematoma formation, 15(18.75%) had AV fistula, 05(6.25%) had pseudo aneurysm, and 14(17.5%) suffered from bleeding.

Table-I: Characteristics of Patients Undergoing Percutaneous Coronary Intervention Through Femoral Access Site (n=80)

Study Parameters	n(%)
Age (years)	
Mean±SD	48.85±8.93 years
Range (min-max)	20 years-64 years
Gender	
Male	50(62.5%)
Female	30(37.5%)
Mode of Presentation	
Chronic stable angina	29 (36.25%)
Stable angina	27 (33.75%)
STEMI	14 (17.5%)
NSTEMI	08 (10%)
Others	02 (2.5%)
Complications	
Hematoma	06 (7.5%)
AV fistula	15 (18.75%)
Pseudo-aneurysm	05 (6.25%)
Bleeding	14 (17.5%)
Technique Used	
Manual Compression	35 (43.75%)
Vascular Closure Device	45 (56.25%)

Table-II shows the results of the statistical analysis. Hematoma formation was found in 3(8.6%)

patients in the manual compression group and 3(6.7%) patients in the devising group (*p*-value-0.749), and AV fistula formation was seen in 8(22.9%) patients in the manual compression group. In comparison, it was seen in 7(15.6%) patients in the devise group (*p*-value-0.408). The same was the case for bleeding and pseudo-aneurysm formation, and they did not occur statistically significantly different (*p*-value; 0.268 and 0.086, respectively) in both groups.

Table-II: Comparison of Various Complications Among Study Groups (n=80)

Complications	Manual compression group	Vascular device closure group	*p*-value
Hematoma Formation			
No	32(91.4%)	42(93.3%)	0.749
Yes	03(8.6%)	03(6.7%)	
AV Fistula Formation			
No	27(77.1%)	38(84.4%)	0.408
Yes	08(22.9%)	07(15.6%)	
Pseudo-Aneurysm Formation			
<3 days	31(88.6%)	44(97.7%)	0.086
>3 days	04(11.4%)	01(2.3%)	
Bleeding			
No	27(77.1%)	39(86.6%)	0.268
Yes	08(22.9%)	06(13.4%)	

DISCUSSION

The use of cardiac interventions has been increasing, and hundreds of PCIs have been done daily in big cardiac centres worldwide.13 Access intervention sites have always been an interest for cardiac physicians. However, most cardiologists prefer femoral access for PCI.[14] Prevention of local complications and achieving adequate and quick hemostasis have been the goals of the treating team. Several methods have been used to assess the best way of achieving hemostasis at access sites after PCI, but there is still a consensus on one method. In our study, we tried to compare the complications between closure devices and manual compression in patients after percutaneous coronary intervention through the femoral access site.

Hermanideset *et al*.[15] conducted randomized comparison of closure devices or manual compression in patients undergoing percutaneous coronary intervention. They concluded that both methods were equally effective for hemostasis, except that patients with hypertension benefitted more from the closure device method. We did not study patients with regard to comorbid illness, but overall, there was not much difference regarding complications of both procedures in our data set. A comparison of vascular closure devices vs manual compression after femoral artery puncture in patients on oral anticoagulation was published by Mayer *et al*.[16] in 2021. They revealed that vascular closure devices were slightly better in terms of pseudo-aneurysm formation and time taken for hemostasis; otherwise, neither of these modalities had much difference in terms of complications. Our results supported the results of Mayer *et al*. as no complications, including e-aneurysm formation, were found with any difference in the groups.

Mankerious *et al*. conducted a post-hoc analysis of a large-scale randomized clinical trial in 2018 regarding manual and closure device compression for hemostasis.[17] They found that the use of the FemoSeal vascular closure device was associated with fewer complications and better hemostasis than manual compression. Our results differed in this regard, as no clear superiority was established for any method in our analysis.Gabrielli *et al*.[18] published a study regarding the safety and efficacy of a vascular closure device for hemostasis after PCI. They found the device safe and efficacious for the said purpose, but there was no comparison group, so results remain unclear for generalization. Ours was a better design, and we compared the two methods. We could not generate any positive and conclude that any of the methods studied were superior to others in terms of post-procedure complications.

LIMITATION OF STUDY

We studied short-term complications in a small set of patients. This uses our data set, which is very limited for generalising the local population. No data was generated regarding difficult PCI or the cost-effectiveness of methods.

CONCLUSION

There was no statistically significant difference in the complications studied between the closure device method and manual compression of hemostasis in patients undergoing PCI through femoral vein access.

Conflict of Interest: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

AR & AHS: Data acquisition, data analysis, data interpretation, critical review, approval of the final version to be published.

AK & MR: Study design, data interpretation, drafting the manu-script, critical review, approval of the final version to be published.

SZ & KRB: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity

of any part of the work are appropriately investigated and resolved.

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