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Occurrence of Bleeding Complications of Radial and Femoral Artery Routes in Patients Undergoing Percutanous Coronary Intervention

Huma Naeem Tareen[1*], Mohsin Saif[2] and Faiza Parveen Baloch[3]

[1]*Assistant Professor Cardiology Department Bolan Medical College Balochistan, Post fellowship PGR, Interventional Cardiology, AFIC & National Institute of Heart Diseases Rawalpindi, Pakistan.*

[2]*Classified Cardiologist, Cardiology, AFIC & National Institute of Heart Diseases Rawalpindi, Pakistan.*

[3]*Senior Registrar Family Medicine, Dow University of Health Sciences Karachi, Pakistan.*

[*]Correspondence:

Dr. Huma Naeem Tareen, Assistant Professor Cardiology Department Bolan Medical College Balochistan, Post fellowship PGR, Interventional Cardiology, AFIC & National Institute of Heart Diseases Rawalpindi, Pakistan.

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ABSTRACT

Background: *Percutaneous coronary angiography and percutaneous trans-luminal coronary angioplasty are the standard diagnostic and therapeutic strategies for coronary artery disease [1]. Angiography/percutaneous coronary intervention (PCI) is usually performed by the femoral and radial artery routes. However, the ulnar artery can also be used [2]. Conventionally, the femoral route has been favored for coronary angiography and percutaneous coronary intervention, but there is growing interest for radial access due to reduced hemorrhagic complications during and after the procedure. This is due to the fact that severe bleeding is considered a determinant of poor prognosis in patients with acute coronary syndrome [3]. In the current practice of interventional cardiology, it has been recognized that bleeding has become the most common early complication associated with PCI [4].*

Objective: *To determine the frequency of bleeding complications of radial and femoral artery routes (major bleeding and localized hematoma formation) in patients undergoing Percutanous Coronary Intervention.*

Setting: *This cross sectional study Department of Cardiology, Cardiology, AFIC & National Institute of Heart Diseases Rawalpindi.*

Methodology: *Patients fulfilling the inclusion criteria was recruited for the study after informed consent and explanation about risks and benefits of the procedure. Bleeding complications was determined in transradial or transfemoral access groups undergoing Percutanous Coronary Intervention. The data was gathered through a pre-tested questionnaire after informed consent. Every patient was given an ID, Privacy of the patient was ensured. Post procedure patient was examined immediately for localized swelling, hematoma formation and hemoglobin were assessed.*

Results: *Total 205 patients were included according to the inclusion criteria of the study. Mean age (years) in the study was 53.51 ± 13.97 whereas there were 146 (71.2) male and 59 (28.8) female patients who were included in the study according to the inclusion criteria. Frequency and percentage of localized haematoma among radial and femoral artery was 02 (2.1) and 06 (5.6) respectively and retroperitonial haematoma among radial and femoral artery was 8 (8.2) and 17 (15.7) respectively.*

Conclusion: *The study concluded that common bleeding complications were observed more in femoral artery route then radial artery route. Future studies must be conduct at multiple setups to know the proportion of bleeding complication either in radial or femoral artery route, so that to suggest a uniform protocol for the management of patients undergoing percutaneous coronary intervention (PCI).*

Keywords
Percutaneous Coronary Intervention, Coronary Angiography, Hematoma Formation, Radial Access, Femoral Access.

Introduction

Percutaneous coronary angiography and percutaneous transluminal coronary angioplasty are the standard diagnostic and therapeutic strategies for coronary artery disease [1]. The femoral and radial artery routes usually perform angiography / percutaneous coronary intervention (PCI). However, the ulnar artery can also be used [2]. Conventionally, the femoral route has been favored for coronary angiography and percutaneous coronary intervention, but there is growing interest for radial access due to reduced hemorrhagic complications during and after the procedure. This is because severe bleeding is considered a determinant of poor prognosis in patients with acute coronary syndrome [3]. In the current practice of interventional cardiology, it has been recognized that bleeding has become the most common early complication associated with PCI [4].

According to recent data from the USA, major bleeding occurs at a rate of 1.7% after PCI. Of this about half occur from the site of arterial access and half from non-access sites [4]. Bleeding complications in patients with ACS were significantly lower in procedures performed via radial artery route (7.8%) [5], as compared to femoral routes (12.2%); this encompasses both major and minor bleeds [5]. In an another study reported in American Journal of Cardiology in 2016, bleeding complications were 1.5% in transradial verses 4.8% in transfemoral artery group [6]. Other complications include arterial embolization with loss of distal pulses, hematomas accompanied by significant blood loss, arterial pseudo aneurysms and arteriovenous fistulas [3].

Major bleed and localized hematoma formation are the two main vascular complications encountered during the access through radial or femoral route. In case of femoral access, large hematoma formation occurs in 3% of patients, while localized hematoma formulates in 1.2 % of patients undergoing PCI through radial route. Bleeding risk was significantly reduced (by more than half) in radial access as compared to femoral access [4]. The aim of this study is to find local data (statistics) about the common bleeding complications of radial and femoral artery route as there is variability in proportion of complications with different studies done in the past.

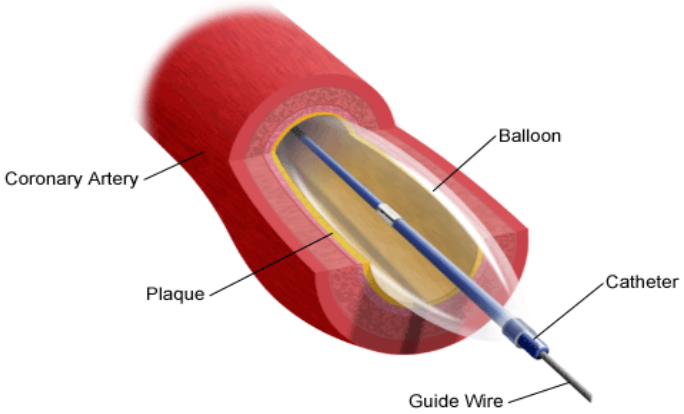
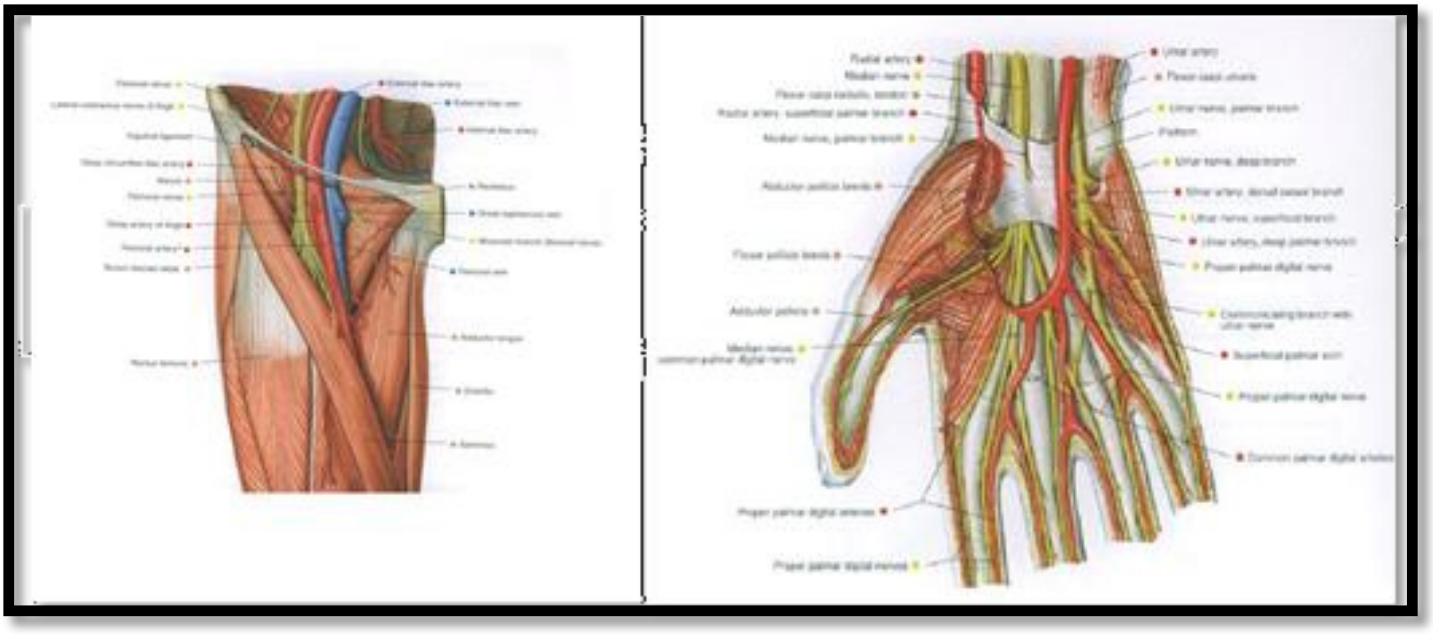


Figure 1: Inflation of Ballon Inside a Coronary Artery.



A B

Figure 2: The femoral artery, femoral vein and femoral nerve at the groin, B; The radial and the ulnar arteries at the wrist.

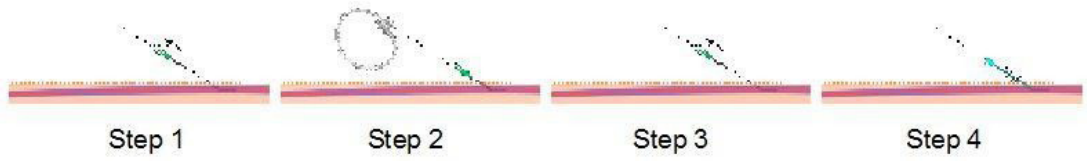


Figure 3: Steps of percutaneous technique for coronary angiography, Seldinger's method.

Methodology

This current cross-sectional study was conducted at Department of Cardiology AFIC & National Institute of Heart Diseases Rawalpindi. Duration to our study was to 1st November 2021 to 31st November 2022. Total 205 patients enrolled using Consecutive non probability sampling technique, this study patients included (Patient undergoing Percutaneous coronary intervention, Age 20 to 75 and Patients of either gender). Patients with known bleeding diathesis**.** Patient having chronic kidney disease, chronic liver disease. Base line platelets <100,000 units, abnormal coagulation profile. Patients on oral anticoagulants was excluded from study.

Patients fulfilling the inclusion criteria were recruited for the study after informed consent and explanation about risks and benefits of the procedure. Bleeding complications was determined in transradial or transfemoral access groups undergoing Percutanous Coronary Intervention. The data was gathered through a pre tested questionnaire after informed consent. Every patient was given an ID, Privacy of the patient was ensured. Post procedure patient was examined immediately for localized swelling, hematoma formation and hemoglobin were assessed (after 4 to 6 hours if bleeding is suspected and after 12 and24 hours as a routine practice. Statistical package for social sciences (SPSS form 21) was utilized to examine the assembled data. Mean and standard deviation was assessed for the quantitative variables like age and percentage, and for qualitative variables like gender and complications via femoral and radial artery routes. Frequency of major bleeding complications was estimated and compared by Chi square test between the groups. P-value ≤ 0.05 considered as significant. Effect modifiers like gender was used for stratification. Post stratification chi-square test was applied.

Results

Total 205 patients were included according to the inclusion criteria of the study. Descriptive statistics of age (years) of patient was also calculated in terms of mean and standard deviation. Mean age (years) in the study was 53.51 ± 13.97, as shown in Table 1.

Table 1: Descriptive statistics of Age (years).

	Number of Patients	Mean	Std. Deviation
Age (years)	205	53.51	13.97

Distribution of gender of patient was also calculated in terms of frequency and percentage of male and female patients. There were 146 (71.2) male and 59 (28.8) female patients who were included in the study according to the inclusion criteria, as shown in Table 2.

Table 2: Distribution of Gender.

	Number of Patients	Percentage
Male	146	71.2
Female	59	28.8
Total	205	100.0

The objective of the study is to determine frequency of bleeding complications of radial and femoral artery routes (major bleeding and localized formation) in patients undergoing percutaneous coronary intervention. Frequency and percentage of localized haematoma among radial and femoral artery was 02 (2.1) and 06 (5.6) respectively and retroperitonial haematoma among radial and femoral artery was 8 (8.2) and 17 (15.7) respectively, as shown Table 3.

Table 3: Comparison of Bleeding Complications among Radial & Femoral Artery.

	Artery		Total
	Radial	Femoral	
Localized Haematoma Bleeding	2	6	8
	2.1%	5.6%	3.9%
Retroperitonial complication after Haematoma procedure	8	17	25
	8.2%	15.7%	12.2%
Nil	87	85	172
	89.7%	78.7%	83.9%
Total	97	108	205

Frequency of major bleeding among radial and femoral artery was 06 (6.2) and 12 (11.1) respectively, as shown in Table 4.

Table 4: Comparison of Major Bleeding among Radial & Femoral Artery.

		Artery		Total	p-value
		Radial	Femoral		
Major bleeding	Yes	6	12	18	0.213
		6.2%	11.1%	8.8%	
	No	91	96	187	
		93.8%	88.9%	91.2%	
Total		97	108	205	

Effect modifier like age stratification was done and compared with frequency of bleeding complications of radial and femoral artery routes (major bleeding and localized formation) in patients undergoing percutaneous coronary intervention. Among patients with age 51 – 75 years, frequency and percentage of major bleeding among radial and femoral artery was 5 (7.4) and 14 (17.5) respectively, as shown in Table 5.

Table 5: Effect modifier like Age stratification with comparison of Major Bleeding among Radial & Femoral Artery.

Age group	Bleeding complication after procedure	Artery		Total	p-value
		Radial	Femoral		
20 - 50 years	Localized Haematoma	0	2	2	0.338
		0.0%	7.1%	3.5%	
	Major Bleeding	3	3	6	
		10.3%	10.7%	10.5%	
51 - 75 years	Localized Haematoma	2	4	6	0.136
		2.9%	5.0%	4.1%	
	Major Bleeding	5	14	19	
		7.4%	17.5%	12.8%	

Effect modifier like gender stratification was done and compared with frequency of bleeding complications of radial and femoral artery routes (major bleeding and localized formation) in patients undergoing percutaneous coronary intervention. Among male patients, frequency and percentage of major bleeding among radial and femoral artery was 3 (3.9) and 10 (14.3) respectively, as shown in Table 6.

Table 6: Effect modifier like Gender stratification with comparison of Major Bleeding among Radial & Femoral Artery.

Gender	Bleeding complication after procedure	Artery		Total	p-value
		Radial	Femoral		
Male	Localized Haematoma	1	4	5	0.026
		1.3%	5.7%	3.4%	
	Major Bleeding	3	10	13	
		3.9%	14.3%	8.9%	
Female	Localized Haematoma	1	2	3	0.886
		4.8%	5.3%	5.1%	
	Major Bleeding	5	7	12	
		23.8%	18.4	20.3%	

Discussion

Transfemoral and transradial techniques are safe, feasible and comparable techniques for cardiac catheterization, angiography and intervention. However, each of these two techniques has own applications and limitations. Although TF approach is dominant approach worldwide, TR approach is going to be the technique of choice for coronary angiography and percutaneous coronary intervention in the near future. TR approach reduces hospital stay, procedural cost and vascular complications and increases patients comfort and satisfaction. However, this approach needs more experience and greater learning curve compare to TF approach. In another word, TF approach is the easier and more operator-friendly technique for catheterization and angiography; but with substantial access site complications. On the other hand, TR approach is safer and more patient-friendly technique for catheterization and angiography but it needs more experience and higher learning curve.

The radial artery is a superficial artery that is readily compressible compared with the femoral artery, which is in a much deeper location and with a harder to achieve homeostasis. Accordingly, performing PCI via the radial artery is currently the most effective way to reduce access site bleeding. In the Radial Vs. femoral access for coronary intervention (RIVAL) trial, investigators randomized 7032 patients with acute coronary syndrome (ACS) who were undergoing invasive evaluation with coronary angiography [7]. The primary outcome was a composite of death, myocardial infarction, stroke or non-coronary artery bypass graft-related major bleeding at 30 days. More than half in patients randomized to radial access significantly reduced the hazard of bleeding. At 30 days, 3% in the femoral group had large haematoma and 0.6% had pseudoaneurysm requiring closure vs 1.2% with haematoma and 0.2% with pseudoaneurysm in the radial group 4 Performing radial access during ACS may also lead to improved clinical outcomes. Although the primary outcome of RIVAL was not significantly different in the treatment groups, evidence of a benefit for patients with ST segment elevation myocardial infarction (STEMI) has emerged. Among the 1958 patients with STEMI enrolled in the study, the rate of primary outcome was 3.1% in the radial group vs 5.2% in the femoral group and a 40% lower hazard of outcome was seen [8]. Despite these data, the adoption continues to be very low in many interventional centers.

The transradial approach for coronary procedures has gained progressive acceptance since its first introduction by Campeau in 1989 [9] for diagnostic coronary angiography and its improvement by Kiemeneij and Laarman for percutaneous transluminal coronary angioplasty (PTCA) and stenting. Subsequently, a widespread diffusion of coronary procedures via the radial artery took place in America, Asia and Europe [10].

Indeed, transradial access has been shown by some authors to have several advantages over transfemoral approach. The radial artery is easily compressible; thus, bleeding is controllable and hemorrhagic complications are significantly reduced. Moreover, no major nerves or veins are located near the artery, minimizing the risk of injury of these structures. Finally, postprocedural bed rest is not required, permitting immediate ambulation, more comfort, and early discharge. This last advantage has shown to improve quality of life for patients [11] and to reduce the costs of hospitalization. Despite this large amount of benefits, the transradial approach is more demanding than transfemoral access and requires a longer learning curve for the operator [12]. Furthermore, it does not give the possibility to use other devices such as a temporary pacemaker or intra-aortic balloon pump and to perform coronary interventions requiring 8-F catheters. Moreover, it is not always feasible, because some patients may have an anomalous palmar arch that does not provide sufficient blood supply to the hand in case of thrombotic or traumatic occlusion of the radial artery. Indeed, several authors have advocated, before the procedure, the mandatory assessment of adequacy of collateral blood flow from the ulnar artery by means of the Allen test [13], even if some authorities have recently reported no ischemic complications from radial catheterization, irrespective of any evaluation of blood supply to the hand. Finally, entry site failure is not a remote possibility, often because of anatomic variation and tortuosity of the radial artery [14].

Conversely, the femoral approach is still considered by many as the standard technique because of its optimal catheter control,

uncommon thrombotic complications, and immediate access to large-diameter devices. Nonetheless, such advantages are partially offset by bleeding complications, often mandating long bed rest, and the frequent occurrence of peripheral arterial disease, which limit transfemoral cardiac catheterization. The choice of vascular access site is thus in many centers more a matter of tradition, opinion, and expertise than an evidence- based decision [15]. Several randomized trials have been undertaken to compare the transradial and transfemoral approach, but the majority of them carefully selected a small number of homogeneous patients, were underpowered to detect differences in major adverse events, and yielded somewhat conflicting and inconclusive results.

In our study, the mean age (years) in the study was 53.51±13.97. Whereas a study conducted by included patients with the mean age of 61.8±6.6 years [16,17]. There were 71.2% male and 28.8% female patients who were included in the study. Another study [18] included 74% male and 26% female patients as per the inclusion criteria.

Frequency and percentage of localized haematoma among radial and femoral artery was 2.1% and 5.6% respectively and retroperitoneal haematoma among radial and femoral artery was 8.2% and 15.7% respectively. A study [4] showed the same results as our study i.e. in femoral access, retroperitoneal hematoma formation occurs in 3% of patients, while localized hematoma formulates in 1.2 % of patients undergoing PCI through radial route [19-22].

Frequency of major bleeding among radial and femoral artery was 6.2% and 11.1% respectively. Whereas in a study reported in American Journal of Cardiology in 2016, bleeding complications were 1.5% in transradial verses 4.8% in transfemoral artery group [23-26].

Conclusion

The study concluded that common bleeding complications were observed more in femoral artery route then radial artery route. Future studies must be conduct at multiple setups to know the proportion of bleeding complication either in radial or femoral artery route, so that to suggest a uniform protocol for the management of patients undergoing percutaneous coronary intervention (PCI).

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