# Comparison of Vascular Complications in Patients with Percutaneous Coronary Intervention by Trans-radial and Trans-femoral Approach

ABM Riaz Kawsar<sup>1</sup>, Mir Jamal Uddin<sup>2</sup>, Abdul Momen<sup>3</sup>, Tariq Ahmed Chowdhury<sup>4</sup>, Kajal Kumar Karmoker<sup>3</sup>, Samir Kumar Kundu<sup>3</sup>, Md. Monsurul Hoque<sup>3</sup>, Sharadindu Shekhar Roy<sup>5</sup>, Anup Kumar Howlader<sup>1</sup>, Mohammad Abdul Matin<sup>6</sup>

#### Abstract:

Background and Objective: Trans-radial approach of coronary catheterization has been increasingly used as an alternative to transfemoral approach due to less vascular complications, earlier ambulation and improved patient comfort. The aim of the study was to compare procedural and post procedural vascular complications in patients with percutaneous coronary intervention by trans-radial and transfemoral approach.

Methods: This observational comparative study was conducted in the National Institute of Cardiovascular Diseases between June 2015 to May 2016. A total of 180 patients were categorized into two groups according to the approach of the percutaneous coronary intervention (PCI). Group I comprising 90 patients who underwent trans-radial PCI and group II consists of 90 patients who underwent transfemoral PCI. Patients with an abnormal Allen's test, acute coronary syndrome, history of coronary artery bypass surgery, chronic renal insufficiency or older age (>75 years) were excluded.

Results: Patient demographics were the same in both groups. The mean procedural time in min (37.44±5.13 vs 34.14±4.42, p=0.004) and fluoroscopy time in min

(21.62±4.11 vs 17.55±2.78, p=0.02) were more in TR-PCI group but the mean haemostasis time in min (7.58±1.11 vs 15.59±3.33, p=0.005) and ambulation time in hour (0.00±0.00 vs 15.59±3.33, p=<0.001) were more in TF-PCI group. Significant arterial spasm following puncture (6.7% vs 0%, p=0.01) were found in trans-radial group but access site bleeding during procedure (2.2% vs 8.9%, p=0.04) were more in TF-PCI group. After the procedure major hematoma (0% vs 4.4%, p=0.04), minor hematoma (5.7% vs 14.4%, p=0.04) and ecchymosis (4.4% vs 13.3%) were significant in TF-PCI group but vessel occlusion (5.7% vs 0%, p=0.02) were significant in TR-PCI group. The mean hospital stays, day (1.64±0.42 vs 2.54±0.62) were more in TF-PCI group.

Conclusion: TR-PCI is safe in respect of procedural and post procedural vascular complications. Trans-radial procedure leads to improved quality of life after the procedure and thus gives much comfort to the patient. It also shortened mean duration of hospital stay. So, trans-radial approach is an attractive alternative to conventional transfemoral approach.

Key Words: Vascular complications, TR-PCI, TF-PCI.

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- 2. Professor, Department of Cardiology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh.
- 3. Associate Professor, Department of Cardiology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh.
- 4. Assistant Professor, Department of Cardiology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh.
- 5. Junior Consultant, Department of Cardiology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh.

<sup>1.</sup> Assistant Registrar, Department of Cardiology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh.

<sup>6.</sup> Junior Consultant, Cardiology, Upazilla Health Complex, Parshuram, Feni, Bangladesh.

Address of Correspondence: Dr. A.B.M. Riaz Kawsar, Department of Cardiology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh. Email: riazkawsar75@gmail.com

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## Introduction:

Coronary artery disease (CAD) is a major cause of mortality globally and this health problem is reaching pandemic in both developed, as well as in developing countries<sup>1</sup>. Percutaneous coronary intervention (PCI) is the standard treatment for ischemic heart disease and the use of PCI in appropriate patients reduces morbidity and mortality across the spectrum of risk<sup>2</sup>. Considerable evidence suggests that post-PCI bleeding is associated with an adverse prognosis<sup>3</sup>. Clinical trials evaluating new pharmacological strategies have focused on reducing this risk<sup>4</sup>; however, absolute reductions in bleeding risk have been modest across most studies.

Coronary interventions have been traditionally performed using the femoral approach for arterial access since its inception by Gruntzig<sup>5</sup> in 1977 to till date due to the fact that its size makes arterial cannulation and catheter manipulation easy. Despite these advantages, femoral access has several limitations. The femoral artery is relatively deep, especially in obese patients, and its proximity to the femoral vein and nerve is a potential source of iatrogenic injury. For this reason, transfemoral PCI is associated with bleeding complication rates of up to 10% in the elective setting<sup>6</sup>. Especially under conditions of aggressive anticoagulation and antiplatelet treatment, vascular bleeding complications at the femoral puncture site can result in increased morbidity and duration of hospitalization<sup>7</sup>. Trans-radial approach represents another way to reduce vascular & bleeding complications that make it an attractive alternative to brachial or femoral approaches<sup>8</sup>.

The radial artery is easily compressible; thus, bleeding is controllable and haemorrhagic complications are significantly reduced and improved clinical outcomes compared with trans-femoral approach in both young and elderly patients<sup>9</sup>.

The trans-radial PCI is associated with a lower risk of access site bleeding and hematoma, early patient ambulation, shorter length of hospital stays, and lower hospital costs. Moreover, no major veins or nerves are located near the artery, minimizing risk of injury to these structures. Finally, post procedure bed rest is not required, permitting immediate ambulation, more comfort and early discharge which improve quality of life of patients and reduced hospitalization cost<sup>10</sup>.

The trans-radial PCI may be routinely attempted, with some exceptions and is to be preferred in those patients at high risk of local vascular complications (such as the elderly, the obese, patients with aorta iliac diseases or those receiving anti-thrombotic and anti-platelet drugs). To date, many studies have confirmed the findings of the early pioneers of this technique. Today, 10 years after the first trans-radial PCI, it has found its place among the more conventional catheterization routes. The technique has spread all over the world and its popularity is increasing steadily. Therefore, the rationale for the trans-radial PCI is the intention to reduce access site bleeding complications, earlier ambulation, and improved patient comfort<sup>11</sup>.

## Methods:

A total of 180 patients were studied in this comparative study in the Department of Cardiology, National Institute of Cardiovascular Diseases (NICVD), Dhaka from June 2015 to May 2016who underwent elective PCI. The patients were divided into two groups according to the approach of the PCI. The group-I consisted of 90 patients who underwent trans-radial approach and the group- II consisted of 90 patients who underwent trans-femoral approach. Absence of radial artery pulse, Absence of functional collaterals between the radial and the ulnar artery - judged by Modified Allen's Test, Patient with Acute Coronary Syndrome (ACS), Prior coronary artery bypass surgery (CABG), peripheral vascular disease (e.g. Raynaud's phenomenon.), severe co morbidity (CKD, CVD, COPD) were excluded from the trans-radial PCI group.

Baseline clinical characteristics such as age, sex, occupation and risk factors including smoking, hypertension, diabetes mellitus and dyslipidemia were noted. Baseline investigations like RBS, serum creatinine, serum lipid profile, coagulation profile and screening blood tests for PCI were carried out for each of the patients. Procedural and post procedural vascular complications were compared in both groups

Statistical analysis was performed by using SPSS (Statistical Package for Social Science) statistical software (Version 19, SPSS Inc., Chicago, Illinos, USA). Data were expressed in percentage, frequencies and means and standard deviation. Continuous variables were compared through the Student's t-test and for the categorical variables the chi-square test was done. P value of less than 0.05 was considered as significant.

## **Results:**

The mean age was found 50.18±9.35years in Group I and 49.94±8.17 years in Group II. The mean age difference was insignificant (p=0.86) between two groups. Male patients were predominant in both groups. The Study compares the common risk factors for coronary artery diseases between two groups. Smoking was found 60 (66.7%) in the group I and 57 (63.3%) patients in the group II). Hypertension was found 55 (66.1%) and 56 (62.2%) in the group I and group II respectively. Diabetes mellitus was found 27 (30%) and 30 (33.3%) in the group I and group II respectively. Dyslipidemia was found 62 (68.9%) in the group I and 58 (64.4%) in the group II. Family history of CAD had found 28 (31.1%) and 25 (27.8%) in group I and group II respectively. Mean pulse rate was found 78.3±5.6/min in group I and 80.6±7.8/ min in group II. The mean systolic blood pressure was 126.6±16.6 mmHg in group I and 129.3±16.6 mmHg in group II. The mean diastolic blood pressure was 79.0±8.8 mmHg in group I and 79.5±9.2 mmHg in group II. All baseline characteristics were statistically insignificant in both groups.

Mean bleeding time was  $3.42\pm0.33$  min in group I and  $3.56\pm0.30$  min in group II. The mean of clotting time was  $6.48\pm0.6$  min and  $6.78\pm0.5$  min in group I and group II respectively and both were statistically insignificant difference.

The patients with chronic stable angina were 41 (45.6%) and 38 (42.2%), NSTEMI were 12 (13.3%) and 10 (11.1%) and STEMI were 37 (41.1%) and 42 (46.7%) in the group I and group II respectively. The differences between two groups were statistically identical (p>0.05) on the basis of clinical diagnosis (Fig.-1).

The mean procedural time was  $37.44\pm5.13$  min in group I and  $34.14\pm4.52$  min in group II with statistically significant differences (p=0.004). The mean fluoroscopy time was  $21.62\pm4.11$  min and  $17.55\pm2.78$  min in the group I and group II respectively with the statistically significant differences (p=0.02). The mean haemostasis

time was 7.58±1.11 min and 15.59±3.33 min in group I and group II respectively with the statistically significant differences (p=0.005).

The ambulation time was  $0.00\pm0.00$  hour in group I and  $15.84\pm4.89$  hour in group II with the statistically significant differences (p=<0.001) (Table-I).

Among the total procedural complications, the number of the patients noticed arterial spasm following puncture was 6 (6.7%) in the group I and none in group II with the statistically significant difference (p=0.01). Considering access site bleeding 2 (2.2%) and 8 (8.9%) study subjects experienced that in the group I and group II respectively and the difference was statistically significant (p=0.04). The number of catheter non-engagement was 3 (3.3%) and none was observed in group II respectively with the statistically insignificant differences (p=0.08) (Table-II).

In the group I, 0 (0.0%) and 4 (4.4%) in the group II had major hematoma with statistically significant differences (p= 0.04). There was 5 (5.7%) and 13 (14.4%) minor hematoma in group I and group II with statistically significant differences (p=0.04). There was also ecchymosis in group I subjects 4 (4.4%) whereas 12 (13.3%) patients in group II with statistically significant differences (p=0.03). The vessel occlusion was 5 (5.7%) in group I and none in group II with statistically significant differences (p=0.02).

Artery-venous fistula and limb ischemia were not found in both groups (Table-III). The mean hospital stay for trans-radial approach was  $1.64\pm0.42$  days while in transfemoral approach it was  $2.54\pm0.62$  days with the statistically significant differences (p=0.01). (Table-IV).

Procedural Characteristics	Group I (n= 90)	Group II (n= 90)	pvalue
	Mean ± SD	Mean ± SD	
Procedural time (min)	37.44±5.13	34.14±4.52	0.004 <sup>s</sup>
Fluoroscopy time (min)	21.62±4.11	17.55±2.78	0.02 <sup>s</sup>
Haemostasis time (min)	7.58±1.11	15.59±3.33	0.005 <sup>s</sup>
Ambulation time (hr)	0.00±0.00	15.84±4.89	<0.001 <sup>s</sup>

Table I								
Comparison of procedura	l characteristics	of the	study	population	(n=180).			

Table-II

Comparison of	f procedural	complications	between	two	groups (n=180).
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Procedural complications	Group I (n = 90)		Group II (n = 90)		p value
	Number	%	Number	%	
Arterial spasm following puncture	6	6.7	0	0.0	0.01 <sup>s</sup>
Access site bleeding	2	2.2	8	8.9'	0.04 <sup>s</sup>
Catheter non-engagement	3	3.3	0	0.0	0.08 <sup>ns</sup>

Post- procedural complications	Group I (n	= 90)	Group II (n = 90)		p value
	Number	%	Number	%	
Major hematoma	0	0.0	4	4.4	0.04 <sup>s</sup>
Minor hematoma	5	5.7	13	14.4'	0.04 <sup>s</sup>
Ecchymosis	4	4.4	12	13.3	0.03 <sup>s</sup>
Vessel occlusion	5	5.7	0	0.0	0.02 <sup>s</sup>
Artery-venous fistula	0	0.0	0	0.0	
Limb ischemia	0	0.0	0	0.0	

 Table-III

 Comparison of post procedural complications between two groups (n=180).

 Table-IV

 Distribution of the study patients by duration of hospital stay after procedure (n=180).

Duration of hospital stay	Group I (r	Group I (n = 90)		n = 90)	p value
after procedure (days)	Number	%	Number	%	
< 2	50	55.6	0	0	
2 – 3	30	33.3	60	66.7	
> 3	10	11.1	30	33.3	
Mean ± SD	1.64±	1.64±0.42		0.62	0.01 <sup>s</sup>



Fig.-1: Clinical diagnosis of the study population.



**Fig.-2:** Post-procedural complications between two groups in percentage.

# Discussion:

This observational study was conducted in the department of cardiology of National Institute of Cardiovascular Diseases (NICVD), Dhaka during the

period of June 2015 to May 2016 to evaluate vascular complications of trans-radial percutaneous coronary intervention compared to the transfemoral percutaneous coronary intervention in CAD patients. A total of 180 patients with coronary artery disease (CAD) who were admitted for elective percutaneous coronary intervention (PCI), were studied. The patients were divided into two groups according to the approach of the percutaneous coronary intervention (PCI). In the group I patients underwent trans-radial percutaneous intervention and, in the group II, patients underwent transfemoral percutaneous coronary intervention. Each group was comprised of 90patients.

In our study, the mean age, sex and common risk factors for coronary artery disease were not significantly different between two groups. The clinical parameters like Pulse and BP and bio-chemical parameters like RBS, Creatinine, Lipid profile were observed almost identical in both groups of patients. Regarding coagulation profile and clinical diagnosis no significant difference were found between two groups.

We found that, the mean procedural time was more in trans-radial group (Group-I) than in trans-femoral group (Group-II) which was statistically significant. Brueck M. et al (2009)<sup>12</sup> described in their study of more mean procedural time in trans-radial PCI group than in trans-femoral PCI group. We also found that, Regarding the mean fluoroscopy time was more in trans-radial group (Group-I) than in trans-femoral group (Group-II) with statistically significant value. It resembling a study done by Ibebuogu UN et al (2012)<sup>13</sup> where total fluoroscopy time was longer in the trans-radial access group compared to the transfemoral access group.

In terms of the haemostasis, the mean time was less in trans-radial group (Group I) than the trans-femoral group (Group II) with statistically significant differences. The result is very much consistent with the mean haemostasis time found by Patwary et al (2009)<sup>14</sup> in their study.

Among the procedural complications, arterial spasm following puncture was found only in trans-radial PCI group with the statistically significant differences. Considering access site bleeding, it was less in transradial group than in trans femoral group which was statistically significant. There were no vascular complications in the trans-radial access group compared to the trans-femoral access group observed by lbebuogu UN et al (2012)<sup>13</sup> in their study. Dehghani P et al (2009)<sup>15</sup> showed in their study, access site bleeding, access site hematoma and radial artery spasm which were the predictors of failed trans-radial PCI. We also found a little number of cases who were shifted to trans-femoral approach due to failed catheter engagement through trans- radial approach. In our study, post procedural complications were more in trans-femoral PCI group (Group-II) than in trans-radial PCI group (Group-I) and the difference was statistically significant. Among them no major hematoma was found in trans-radial PCI group. Minor hematoma was also less in trans-radial group (Group-I) than in trans-femoral group (group-II). The difference was statistically significant. Ecchymosis was less in trans-radial group (Group-I) than in trans-femoral group (Group-II) with statistically significant difference. Finally, the vessels occlusion was found only in trans-radial PCI group (Group-I). Following transfemoral PCI patients would have to confine in the bed for at least 6 hours when they can't move the leg where as in case of trans-radial PCI patients can even walk just after the procedure. For first couple of hours this group patient was advised to raise and not to move their operated hand. For this reason, urinary retention and low back pain is common in transfemoral PCI. There was no artery venous fistula, pseudo aneurysm, limb ischemia, and nerve injury's observed. The mean hospital staying was more in transfemoral PCI group with statistically significant differences than in trans-radial PCI group. It resembles with the mean hospital stay observed by Triantafyllou K et al (2010)<sup>14</sup>.

## Conclusion:

This study was conducted to evaluate the vascular complications of trans-radial percutaneous coronary intervention compared to the transfemoral percutaneous coronary intervention in CAD patients. The present study concluded that TR-PCI is safe in respect of procedural and post procedural vascular complications. More importantly, trans-radial procedure leads to improved quality of life after the procedure and thus gives much comfort to the patient.

## **Study limitations:**

The study was done in a single center. The sampling method was non-randomized. Hemostasis was achieved by using manual pressure in most of the patients and the study and follow up period was short.

#### **Recommendations:**

The study recommends that vascular complications of trans-radial PCI was lower than the transfemoral PCI except in two aspects, arterial spasm following puncture and occlusion of radial artery was more than that of transfemoral PCI. Apart from these two aspects trans-radial PCI is safer as well as more convenient. However, the result of this study in context of Bangladesh needs further confirmation in a randomized large scale multicenter prospective cohort study.

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