Original Article

Safety and Efficacy of Trans-Radial Percutaneous Coronary Intervention – Experience in a Tertiary Level Hospital of Bangladesh

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Abstract:

Key words:
Percutaneous Coronary Intervention, Radial Artery, Femoral Artery, Safety.

Background: Like elsewhere, there is an ongoing paradigm shift of route of vascular access for percutaneous coronary intervention (PCI) from trans-femoral to trans-radial in Bangladesh. However, the efficacy, safety and cost effectiveness of TRI in Bangladesh have not been studied adequately. The present study was carried out to find the safety and efficacy of trans-radial PCI in a tertiary level hospital of Bangladesh.

Methods: The prospective observational study was conducted in the Department of Cardiology, Sir Salimullah Medical College & Mitford Hospital (SSMC & MH), Dhaka over a period of 1 year from January to December 2016. A total of 90 subjects were included in the study. Of them, 45 patients had PCI through trans-femoral approach (group 1) and 45 through trans-radial approach (group 2).

Results: The baseline characteristics were comparable except the gender distribution. Vascular access failure was more commonly encountered in trans-radial than in trans-femoral route (p = 0.0002). Angiographic success was comparable between the groups. Though not statistically significant, overall complications and per-procedural and post-procedural complications were more commonly encountered in trans-femoral than in trans-radial approach. In-stent thrombosis, arrhythmia and fever were insignificantly more common in trans-radial access whereas, puncture related complications, bleeding and death were more common in trans-femoral than the counterpart.

Conclusion: Compared to trans-femoral PCI, trans-radial PCI has reasonable safety and efficacy. However, patients should be selected for TR-PCI more carefully to avoid vascular access failure.

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Introduction:

Percutaneous coronary intervention (PCI) continues to serve as the cornerstone for the treatment of coronary artery disease (CAD), including acute coronary syndrome (ACS).[1] Coronary interventions have traditionally been performed using the femoral approach for arterial access since its inception by Gruentzig in 1977. However, vascular access by femoral approach is associated with significant complications including hematoma formation (retroperitoneal hematoma sometimes requiring blood transfusion), neuropathy, pseudo-aneurysm, and arterio-venous fistula, leading to increased morbidity, prolonged hospitalization and increased expenditure.[2] On the other hand, compared to the femoral artery, the radial artery is superficial and overlies the bony surface making it readily compressible. Not only that, the introducer sheath used during PCI can immediately be removed upon completion of the procedure. Since bleeding is associated with morbidity, mortality and costs,[3-5] it is logical that, by reducing bleeding and its complications, trans-radial approach reduces the major adverse

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cardiovascular events (MACE). However, despite growing body of evidence in favor of the trans-radial approach, data related to outcomes of trans-radial PCI (TR-PCI) in a 'real-world' all-comers setting are in fact limited. Also, smaller caliber of the radial artery as well as the greater anatomical variability of vascular course and distribution in the arm have been associated with a steep learning curve for TR-PCI resulting in an increase in procedural failure and a higher rate of cross-over to femoral route.[6]

Bangladesh is a developing country with a large population burden. CAD is prevalent here demanding state-of- the art management strategy, including PCI. It should be cost-effective, technically sound, reasonably efficacious and at the same time, unequivocally safe. TR-PCI is an attractive choice in this regard. Since its inception in Bangladesh few years back, TR-PCI is being practiced increasingly here as well. However, the efficacy and safety of this newer approach in our setting is not yet established and the data generated elsewhere may not be readily extrapolated to our population. So, the present study was carried out to determine the safety and efficacy of TR-PCI.

Methods:

This prospective observational study was conducted among 90 adult males and females who underwent elective PCI in the Department of Cardiology, Sir Salimullah Medical College & Mitford Hospital from January, 2016 to December, 2016. Patients undergoing elective PCI of native coronary artery who were haemodynamically stable without any significant comorbidity (chronic kidney disease (CKD), cerebrovascular disease (CVD), chronic obstructive pulmonary disease (COPD)) were considered for the study. The patients were divided into two groups on the basis of procedural approach during PCI, Group 1: 45 patients undergoing trans-femoral PCI (TF-PCI and Group 2: 45 patients undergoing TR-PCI. The safety and efficacy were compared between 2 groups. For evaluation of safety, variables studied were presence of haematoma, ecchymosis, arterio-venous fistula, and pseudoaneurysm, occlusion of the vessels and limb ischaemia for both TF-PCI and TR-PCI groups. Change of vascular access from radial to femoral, and vice versa, was also considered. For evaluation of efficacy, angiographic success was assessed by

TIMI flow and percentage of residual stenosis in both groups.

Data were analyzed by SPSS (Statistical Package for Social Sciences) version 22.0. Statistical analyses were done by using appropriate statistical tools like chi-square test, Student's 't' test where applicable. P values of less than 0.05 were considered as significant.

Ethical approval from Ethical Approval Committee of Sir Salimullah Medical College was obtained prior to the commencement of the study. Informed written consent was taken from the participants.

Results:

The present study included 45 cases in both groups. Most of the patients belonged to age groups 41-50 years and 51-60 years with mean ages of the former and the later groups being 55.04±10.49 years and 52.40±10 years respectively (p = 0.0956). Male female ratio of group 1 was 1.64: 1 and in group 2 was 4: 1. The mean BMI of both groups were 24.10±2.42 Kg/m^2 and 24.38±3.26 Kg/m^2, respectively. Hypertension, diabetes mellitus and smoking were the major risk factors in both groups. (Fig 1).
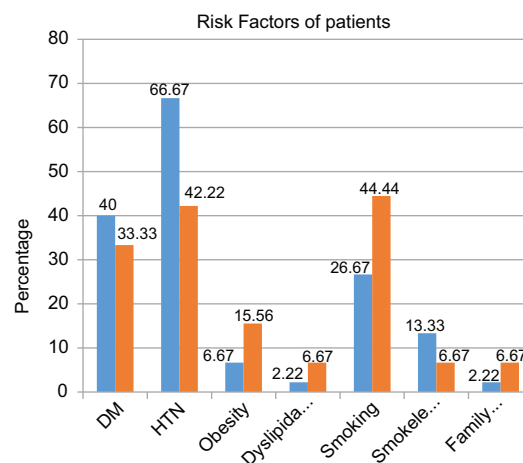

Fig.-1: *Distributions of study subjects by risk factors (N=90).*

Most of the patients of both groups had post-myocardial infarction (post-MI) status (28 vs. 27 respectively) and stable angina (11 vs. 13 respectively), and rest of the patients presented as unstable angina (6 vs. 5 respectively); however, no statistically significant difference was observed between the groups. In both groups, majority of

the patients were on clopidogrel (41 and 35 for group 1 and group 2, respectively) as a loading antiplatelet agent along with aspirin before PCI.

Most of the patients of both groups showed involvement of left anterior descending artery (45% vs.48.08%, respectively), right coronary artery (30% vs. 25%, respectively) and left circumflex artery (23.3% vs. 21.15%, respectively) as affected vessels. (Figure 2)
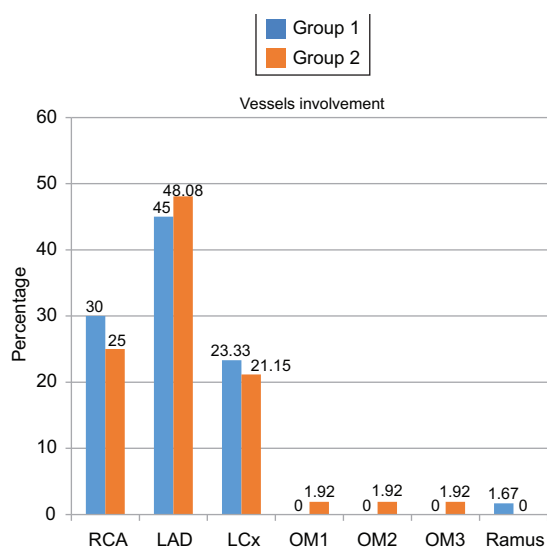

Fig.-2: *Distribution of study subjects according to vessels involvement (N=90).*

Group 1= trans-femoral; Group 2= trans-radial; RCA= right coronary artery; LAD= left anterior descending; LCx= left circumflex; OM= obtuse marginal; Ramus= ramus intermedius

The overall complications were commoner in group 1 than in group 2 (35.6% vs. 22.2%, respectively), however, the differences were not statistically significant (p = 0.097). (Table I).

Regarding changes of vascular access, radial-to-femoral was needed in 26.67% of group 1, but femoral-to-radial access was done for only 1 (2.22%) of the study subjects. (Table II)

For angiographic success during PCI, most of the patients of both groups had TIMI grade 3 blood flow (93.33% vs. 95.56% in group 1 and group 2, respectively), and there was no statistically significant difference (p = 0.64552). Regarding residual stenosis, 80% in group 1 and 88.89% in group 2 had <10% residual stenosis after PCI. However, there was no statistically significant difference between two groups (p =0.24604).

Stent thrombosis was the major complication during the procedure in group 2 which needed anticoagulation therapy with intravenous GP IIb/IIIa inhibitor. In group 1 cardiac arrest occurred in 1 patient which needed temporary pace-making. However, the difference in complication between the groups did not reach statistical significance. (Table IV)

Haematoma (4.44% in each group) and ecchymosis (2.22% in group 2, none in group 1) were the major puncture-related complications in both groups. However, the differences were not statistically significant. (Table V)

Regarding post-procedural complications, bleeding (8.89% and 4.44% in group 1 and group 2 respectively) and arrhythmia (2.22% in group 2, none in group 1) were the common post-procedural complications in both groups but bleeding were more frequently seen in group 1 than in group 2. Except for the occurrence of arrhythmia, complications and treatment of complications did not differ significantly. (Table VI).

Table-I.

Distribution of complications in study subjects (N=90).

Complications	No. of patients	Group 1n=45 (%)	Group 2n=45 (%)	p value
Yes	26	16 (35.6%)	10 (22.2%)	0.24
No	64	29 (64.4%)	35 (77.8%)	

Table-II

Comparison of change of vascular access in study subjects (N=90).

	Total no. of patients	Group 1n=45 (%)	Group 2n=45 (%)
No	77	33	44
Radial to femoral	12	12 (26.67)	00 (0)
Femoral to radial	1	0 (0)	1 (2.22)

Table-III
Comparison of angiographic success in the study subjects (N=90).

	Total no of patients	Group 1 n=45 (%)	Group 2 n=45 (%)	p value
3	85	42 (93.33)	43 (95.56)	0.64552
2	4	2 (4.44)	2 (4.44)	1.0
1	1	1 (2.22)	0	0.15854
0	0	0	0	0.0
Residual stenosis				
< 10%	76	36 (80)	40 (88.89)	0.24604
> 10%	14	09 (20)	05 (11.11)	0.24604

Table-IV
Comparison of per-procedural complications in study subjects (N=90).

Complications	Total no. of patients.	Group 1 n=45 (%)	Group 2 n=45 (%)	p value
Uneventful	85	43 (95.56)	42 (93.33)	0.88076
Stent thrombosis	04	01 (2.22)	03 (6.67)	0.30772
Cardiac arrest	01	01 (2.22)	00 (0)	0.15854

* z test was done to analyze the data and results were significant if p value ≤0.05

Table-V
Comparison of puncture-related complications in study subject (N=90).

Complications	Total no of patients	Group 1 n=45 (%)	Group 2 n=45 (%)	p value
Uneventful	85	43 (95.56)	42 (93.33)	0.88076
Haematoma	04	02 (4.44)	02 (4.44)	1.0
Ecchymosis	01	00 (0)	01 (2.22)	0.15854
Arteriovenous fistula	00	00	00	0
Pseudoaneurysm	00	00	00	0
Occlusion of vessel	00	00	00	0
Limb ischaemia	00	00	00	0

* z test was done to analyze the data and results were significant if p value ≥0.05

Table-VI
Post-procedural complications between the study groups (N=90).

	Total No. of patients	Group 1 n=45 (%)	Group 2 n=45 (%)	p value
Complications				
None	80	40 (88.89)	40 (88.89)	1.0
Bleeding	06	04 (8.89)	02 (4.44)	0.39532
Arrhythmias	02	00 (0)	02 (4.44)	0.0455
Fever	01	00 (0)	01 (2.22)	0.15854
Death	01	01 (2.22)	00	0.15854
Treatment of complication				
None	83	40 (90.91)	43 (95.56)	0.63836
Blood transfusion	05	04 (9.09)	01 (2.22)	0.05744
Treatment of arrhythmia	01	00	01 (2.22)	0.15854

* z test was done to analyze the data and results were significant if p value d" 0.05

Discussion:

Baseline demographic characteristics were almost similar in both groups without any statistically significant difference. The mean age of the study subjects was 55.04±10.49 years in group 1 and 52.40±10 years in group 2, and most of the patients belong to age group of 41- 50 years and 51- 60 years.

Majority of the patients were male in both groups. Male female ratio was 1.65: 1 and 4: 1 in group 1 and group-2, respectively. Male predominance was found by Haq MM et al.[7] and Mann T et al.[8] The mean height, weight and BMI were almost similar in both groups, and these parameters correlate with those of Brueck M et al.[9] Hypertension, diabetes mellitus and smoking were the major risk factors in both groups. Multiple risk factors were present in a single patient. Other studies showed the similar distribution of risk factors.[7,9,10] Regarding the clinical presentation, most of the patients presented as post-MI angina and stable angina. These findings correlate with those of the study by Abdelaal E et al.[11] However, unstable angina was the predominant presentation in another study.[8] No statistically significant differences were observed between the study groups regarding risk factors, clinical presentation, and use of antiplatelet drugs. In group 1 and group 2, LAD (45% vs. 48.08% respectively), RCA (30% vs. 25%, respectively) and LCx (23.33% vs. 21.15%, respectively) were the predominant vessels for PCI.

Changes in vascular access, mostly radial-to-femoral, were done in 13 patients. The main causes of vascular access failure were failure to cannulate the radial artery successfully, arterial spam and anatomical variation of the radial artery. These findings mimic those of some other studies.[8,9,11] Vascular access failure, to some extent, may be due to lack of sufficient experience in TRI in this institute.

TR-PCI has similar angiographic success with TF-PCI. Most of the patients in both groups had < 10% residual stenosis (80% vs. 88.89%) with final TIMI flow grade 3 (93.33% vs. 95.56%). Though residual stenosis (>10%) were more common in group 1 than in group 2 (20% vs. 11.11%), there was no statistically significant difference between them. These findings correlate with those of the study by Romagnoli E et al.[12]

Though not statistically significant, overall complications and per-procedural and post-procedural complications were more commonly encountered in trans-femoral than in trans-radial approach. Per-procedural complications were low in both groups without any statistically significant difference between them. In-stent thrombosis was the major complication observed during PCI procedure and use of intravenous GP IIb/IIIa inhibitors was higher in group 2 than in group 1. One patient of group 1 developed cardiac arrest during PCI procedure and temporary pace-maker was implanted. These findings correlate well with those of the study Yip HK et al.[10] on the other hand, puncture-site haematoma was equally seen in both groups (4.44%).

Regarding the post-procedural complications during hospital stay, no statistically significant differences were seen. One death occurred in group 1, whereas no death was found in group 2. Other study showed overall higher rates of post-procedural complications in trans-femoral route than in trans-radial.[10]

The study has got some important limitations. The sample size was small, and non-randomly selected. There were differences in some baseline characteristics like sex, risk factors, hardwires and type of stents used. Also, operator's choice regarding selection of PCI procedure and use of hardwires like guide-wires and stents were other limitations.

Conclusion:

The results indicate that, TR-PCI has similar angiographic success with TF-PCI. However, vascular access failure was more commonly encountered in trans-radial than in trans-femoral route. Though not statistically significant, overall complications and per-procedural and post-procedural complications were more commonly encountered in trans-femoral than in trans-radial approach. In-stent thrombosis, arrhythmia and fever were insignificantly more common in trans-radial access whereas, puncture related complications, bleeding and death were more common in trans-femoral than the counterpart. Larger, multicentric studies should be carried out to validate the findings of the present study. The patients should be selected for TR-PCI more carefully to avoid vascular access failure. Also, TR-PCI should be practiced more rigorously to deal with the flattened learning curve.

Conflict of Interest - None.

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