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Original Research Article

Comparison of puncture outcome between prolonged occlusion flow mediated dilatation method and conventional method during distal radial artery cannulation in coronary intervention

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ABSTRACT

Background: Distal transradial access is increasingly used for coronary angiography (CAG) and percutaneous coronary intervention (PCI), but radial artery cannulation can be technically demanding due to a steeper learning curve and smaller vessel caliber. Prolonged occlusion flow-mediated dilatation (PO-FMD) is a novel technique that may enhance distal radial artery (DRA) access by promoting vasodilatation. Aim was to compare the efficacy and vascular access-site complications of PO-FMD versus the conventional technique during distal transradial artery cannulation.
Methods: This cross-sectional analytic study was conducted at the department of cardiology, National Institute of Cardiovascular Diseases (NICVD), Dhaka, from March 2021 to February 2022. A total of 200 purposively selected patients with coronary artery disease (CAD) undergoing CAG with or without PCI via distal radial access were enrolled. Participants divided into 2 groups: Group I (PO-FMD, n=100) and II (conventional method, n=100). Efficacy outcomes included access time, procedural time, number of attempts, 1st-attempt success rate, and crossover rate. Vascular access-site complications such as hematoma, radial artery spasm, and radial artery occlusion were also assessed.
Results: Crossover to another access site was significantly lower in group I compared to group II (5% vs. 15%, p=0.030). Access time was shorter with PO-FMD (58.8±10.1 seconds vs. 78.9±7.9 seconds; p=0.006). Group I demonstrated fewer attempts and a higher first-attempt success rate (p=0.015 and p=0.021, respectively). Radial artery spasm and occlusion were significantly reduced in the PO-FMD group (p=0.048 and p=0.039). No significant differences were observed in hematoma formation or total procedural time.
Conclusions: PO-FMD-mediated radial artery dilatation appears to be a safer and more effective technique than the conventional method for DRA cannulation.

Keywords: Distal radial approach, Prolong occlusion flow mediated dilatation, Complication

INTRODUCTION

Cardiovascular disease (CVD) remains the leading cause of morbidity and mortality worldwide, affecting both developed and developing nations.[1] CAD, a major manifestation of CVD, can be diagnosed by CAG and treated through PCI.[2] Initially, cardiac catheterization was performed via the brachial cut-down technique until Seldinger introduced the percutaneous method of vascular access using the femoral and subclavian arteries, which became the standard approach for decades.[3] In 1989, Campeau first described the transradial approach (TRA)

for CAG,[4] and later[5] successfully performed coronary angioplasty through TRA, demonstrating its safety, feasibility, and advantages such as improved patient comfort and earlier discharge. The radial artery offers several anatomical and physiological benefits, including easy accessibility, superficial location, distance from major nerves and veins, and dual hand circulation via the ulnar artery. TRA provides early ambulation, shorter hospital stays, reduced costs, and fewer access-site complications compared to the femoral route.[6] Accordingly, the European Society of Cardiology (ESC) Guidelines[7] recommend the radial approach as the standard for CAG and PCI when technically feasible. Despite these benefits, vascular complications such as radial artery spasm (RAS), radial artery occlusion (RAO), pseudoaneurysm, arteriovenous fistula, and nerve injury may still occur.[8] Recently, the DRA approach has emerged as a safer alternative, offering a lower risk of RAS and RAO and faster hemostasis.[9,10] Successful transradial catheterization depends largely on the ability to achieve arterial access, which can be facilitated by prior radial artery dilation. Several methods, such as sublingual or subcutaneous nitrates, hand warming, hand exercises, and FMD, have been proposed to enhance radial artery caliber. Flow-mediated dilation is a physiological response induced by increased shear stress and nitric oxide (NO) release following transient ischemia, typically achieved by inflating and deflating a blood pressure cuff.[11] Although endothelial dysfunction may reduce NO-mediated vasodilation in atherosclerotic patients, prolonged occlusion can induce NO-independent dilation, providing more sustained vasodilatation.[12,13] A recent study demonstrated that the PO-FMD method significantly improves cannulation success (2.7% vs. 5.8%, p=0.01) and reduces the number of attempts (1 vs. 2, p<0.001) compared to the conventional approach.[14] Therefore, the present study aimed to compare the efficacy and vascular access site complications between the PO-FMD method and the conventional approach in DRA cannulation.

METHODS

This cross-sectional analytical study was conducted in the Department of Cardiology, NICVD, Dhaka, Bangladesh, from March 2021 to February 2022.

Study population and sampling

Patients admitted to the Department of Cardiology and undergoing coronary interventions (CAG/PCI) through the distal radial approach were included based on inclusion and exclusion criteria. Sampling was done by purposive method, and a total of 200 subjects were enrolled, with 100 patients in each group (PO-FMD and non-PO-FMD).

Sample size calculation

Using the formula for comparing two proportions (Hoque) and reference data from Doubell et al the minimum required sample size per group was calculated as n=124, assuming a transradial failure rate of 5.8% versus 2.7% at 95% confidence level (Z=1.96, E=0.05).[15,16] Total 200 subjects were taken for the study. 100 subjects were allocated in each group.

Inclusion criteria

Patients undergoing CAG or PCI through distal radial access were included.

Exclusion criteria

Patients requiring emergency PCI, hemodynamically unstable cases, previous distal radial intervention, thrombocytopenia, or CKD were excluded.

Study procedure

Eligible patients were randomized into two groups using a closed-envelope method. In the PO-FMD group, a blood pressure cuff was inflated to 50 mmHg above systolic pressure for 10 minutes before cannulation. In the non-PO-FMD group, the cuff was placed but not inflated. Operators were blinded to group allocation. Standard aseptic technique, 2 ml of 1% lidocaine, and the Seldinger method were used for cannulation. All patients received intra-arterial vasodilators (verapamil 2.5 mg, nitroglycerin 200 µg) and heparin. Procedural variables (attempts, time, success rate, complications) were recorded, and post-procedure radial flow was assessed by Doppler ultrasound.

Data analysis

Data were analyzed using SPSS v24.0. Quantitative variables were expressed as mean±SD and compared using Student's t-test; qualitative variables were compared using Chi-square or Z test. Multivariate regression analysis was performed. A p<0.05 was considered statistically significant.

Ethical considerations

The study protocol was approved by the ethical review committee of NICVD. Informed written consent was obtained from each participant or their relatives. Confidentiality was strictly maintained, and participants retained the right to withdraw at any time. Data were collected using a pre-approved data collection form.

RESULTS

The study was carried out at the department of Cardiology, NICVD, Dhaka, Bangladesh, from March 2021 to February 2022. Clinical characteristics, biochemical tests, vascular complications such as hematoma, radial artery spasm, radial artery occlusion and efficacy was measured in 200 patients.

Table 1 shows comparison of study group according to age distribution. Highest frequency was 41-50 years age, 36

and 48 in group I and group II, respectively and that is followed by 51-60 years age. Mean±SD of group I and group II was 52.10±8.3 years and 53.18±8.4 years, but this difference was not statistically significant (p=0.361).

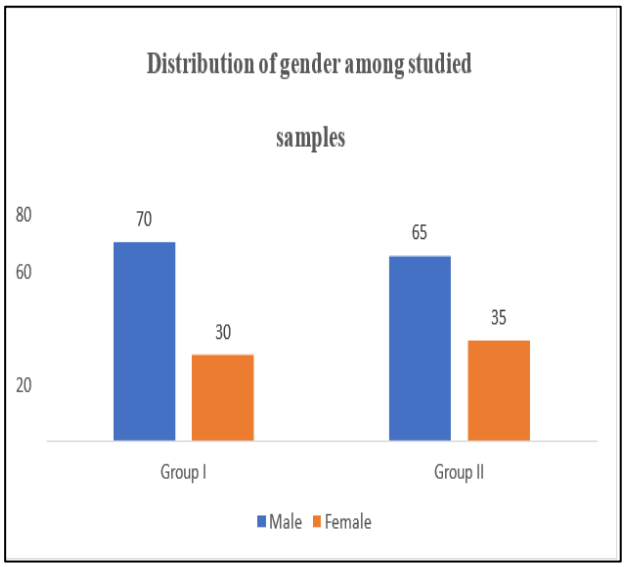

Figure 1: Distribution of gender among studied samples.

Among the 135 male patients, 70 belongs to group I and 65 to group II. In female group. 30 patients belonged to group I, whereas 35 to group II (p=0.450) (Figure 1).

Table 2 showed in group I 45 (45%) patients were hypertensive and in group II the number was 55 (55%) (p=0.157). For DM, not significant difference (p=0.465) existed between group I and group II (35% vs 40%). The 60 (60%) patients in group I and 55 (55.0 %) patients in group II were dyslipidaemic, and this difference was not statistically significant (p=0.474). Again, no significant difference was present in smoking among these two groups with p value 0.428. Overall, there was no significant difference present in traditional cardiovascular risk factors between these two groups.

Table 3 showed mean±SD of weight was 68.3±6.8 kg in studied samples, in group I it was 68.7±7.9 kg and in group II 67.5±5.1 kg, this difference was not statistically significant (p=0.06). Height (mean±SD) was 163.7±7.7 cm with 163.9±5.8 cm in group I and 163.4±9.1 cm in group II, again this difference was not significant (p=0.052). Non-significant difference (p=0.903) was noted in BMI value among group I and group II (25.5±1.8 vs 25.5±2.5). Overall, there was no significant difference was present in these variables.

The 75 (37.5%) patients underwent CAG±PCI for CCS, 40 (40%) patients in group I and 35 (35%) in group II. Similarly, distribution of other indications in group I and group II were not statistically significant (p=0.466) (Figure 2).

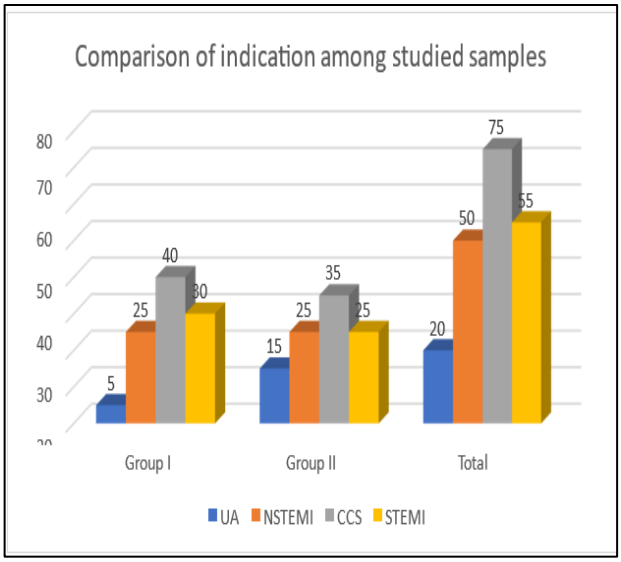

Figure 2: Comparison of indication among studied samples.

Total 15 (15%) patients needed cross-over to other site for cannulation in non-PO FMD group, whereas only 5(5%) patients needed to switch to other site in PO FMD group and this difference was statistically significant (p=0.030).Access time (mean±SD) was 68.3±13.6 sec with 58.8±10.1 sec in group I and 78.9±7.9 sec in in group II, this difference was significant (p=0.006). Significant difference (p=0.015) was noted in number of attempts among group I and group II (1.9±0.9 vs 3.6±1.6) (Table 4).

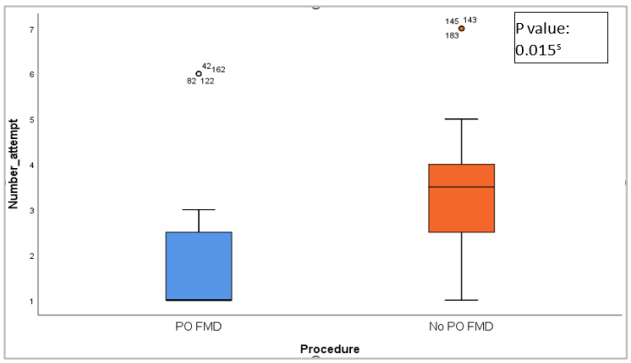

Figure 3: Number of radial artery puncture attempts in studied samples.

Figure 3 showed median number of attempts for radial artery puncture. In PO-FMD group median number of attempts was 1 and whereas in non-PO-FMD group it was 3.5.

Mean±SD of procedure time among patients underwent CAG in group I was 8.6±0.5 min. and in group II 8.8±0.9 min, and this difference was statistically non-significant (p=0.060). Again, difference in total procedure time in those underwent PCI was statistically non-significant (p=0.065) (Table 5).

Table 6 showed comparison of complication among study groups. Total 15 patients developed hematoma, 5 in group I and 10 in group II (p=0.060). Radial artery spasm and radial artery occlusion occurs in 24 and 15 patients respectively. Again, difference between group I and group II for these complications were statistically significant, p=0.048 and 0.039, respectively.

First attempt was successful in 45 (45%) patients in group I and 23 (23%) patients in group II and this difference was statistically significant (p=0.021) (Table 7). Table 8 shows multivariate logistic regression analysis showed male sex, age<60 years and PO-FMD method was protective factor for radial artery spasm with OR 0.459, 0.031 and 0.199 respectively.

Table 1: Comparison of the study groups according to their age.

Age (in years)	Total, (n=200)		Group I, (n=100)		Group-II, (n=100)		P value
	N	%	N	%	N	%	
≤40	16	8	10	10	6	6	0.361^{ns}
41-50	84	42	36	36	48	48	
51-60	67	33.5	40	40	27	27	
61-70	30	15	14	14	16	16	
>70	3	1.5	0	0	3	3	
Mean±SD	52.6±8.3		52.10±8.3		53.18±8.4		

*Group I-PO FMD group, group II-non-PO FMD group, independent sample t test, ns-non-significant.

Table 2: Comparison of the study groups according to their risk factors, (n=200).

Cardiac risk factor profiles	Total, (n=200)		Group I, (n=100)		Group II, (n=100)		P value
	N	%	N	%	N	%	
Hypertension	100	50	45	45	55	55	0.157^{ns}
Diabetes mellitus	75	37.5	35	35	40	40	0.465^{ns}
Dyslipidemia	115	57.5	60	60	55	55	0.474^{ns}
Smoking	55	27.5	30	30	25	25	0.428^{ns}

ns-non-significant.

Table 3: Comparison of weight, height and BMI between study samples.

Variables	Total, (n=200)	Group I, (n=100)	Group II, (n=100)	P value
Weight (Kg)	68.3±6.8	68.7±7.9	67.5±5.1	0.06^{ns}
Height (cm)	163.7±7.7	163.9±5.8	163.4±9.1	0.052^{ns}
BMI (kg/m^2)	25.5±2.2	25.5±1.8	25.5±2.5	0.903^{ns}

ns-non-significant.

Table 4: Comparison of crossover rate, access time and number of attempts among studied samples.

Variables	Group I (PO FMD), (n=100)	Group II (Non-PO FMD), (n=100)	Total, (n=200)	P value
Crossover required	5 (5%)	15 (15%)	20 (10%)	0.030^{s}
DRA successful	95 (95%)	85 (85%)	180 (90%)	
Conventional radial	3 (3%)	5 (5%)	8 (4%)	
Femoral	2 (2%)	10 (10%)	12 (6%)	
Access time (sec), mean±SD	58.8±10.1	78.9±7.9	68.3±13.6	0.006^{s}
Number of attempts, mean±SD	1.9±0.9	3.6±1.6	2.7±1.7	0.015^{s}

*Independent sample t-test applied for continuous variables, s=significant

Table 5: Comparison of procedure time among studied samples.

Variables	Group I, (n=100)	Group II, (n=100)	P value
CAG group	8.6±0.5	8.8±0.9	0.060^{ns}
PCI group	38.95±4.5	40.30±3.4	0.065^{ns}

*Group I-PO FMD group, Group II-Non-PO FMD group, independent sample t test, ns-non-significant.

Table 6: Comparison of complication among study samples.

Complications	Total, (n=200)		Group I, (n=100)		Group II, (n=100)		P value
	N	%	N	%	N	%	
Hematoma	15	7.5	5	5	10	10	0.060[ns]
Radial artery spasm	24	12	10	10	14	14	0.048[s]
Radial artery occlusion	15	7.5	4	4	11	11	0.039[s]

*s-significant, ns-not significant

Table 7: Comparison of successful first attempt among studied samples.

First attempt successful	Group I, (n=100) (%)	Group II, (n=100) (%)	Total (n=200) (%)	P value
Yes	45 (45)	23 (23)	68 (34)	0.021[s]
No	55 (55)	77 (77)	132 (66)	
Total	100 (100)	100 (100)	200 (100)	

*s-significant

Table 8: Multivariate logistic regression analysis of risk factors for radial artery spasm.

Risk factor	B	Std. error	OR	95% confidence interval for OR		P value
Age<60 (in years)	-0.780	0.318	0.459	0.246	0.854	0.014
Male	-3.473	0.728	0.031	0.007	0.129	0.001
Smoking	-0.401	0.767	0.669	0.149	3.009	0.601
HTN	-0.903	0.559	0.405	0.136	1.212	0.106
DM	0.187	0.655	1.206	0.334	4.352	0.775
Dyslipidaemia	-0.683	0.561	0.505	0.168	1.516	0.223
Indication	0.041	0.255	1.042	0.632	1.719	0.871
PO-FMD	-1.614	0.574	0.199	0.065	0.613	0.005

DISCUSSION

During this study period, 200 samples were collected and grouped into FMD group (n=100) and conventional technique group (n=100). The age distribution of the samples showed highest frequency (42%) was seen in 41-50 years age group followed by 51-60 years group. This finding was close to a Bangladeshi study where they reported highest frequency (41%) from 41-50 years age group.[17] On the contrary, (Shirin et al) found 37.5% of their study sample belonged to 51-60 years age group.[18] Mean age of our study samples were close to previous study in our population.[19] In Brazil, the mean age (57.2±11.1 years) was higher than ours.[20] This difference in age further proves the concept of earlier incidence of CAD in Bangladeshi people .[1]In this study, male female ratio was found to be 2:1, but previous studies showed much higher ratio, up to 11.5:1.[21] Our findings may reflect that women were more affected by CAD by now compared to recent past. This study showed prevalence of hypertension, DM, dyslipidaemia and smoking was present in 50%, 37.5%, 57.5% and 27.5% respectively. Prevalence of hypertension and DM of our study was comparable to the result Rafiquzzaman et al. But they reported smoking habit was present in 86% of their sample.[21] Our findings might indicate that smoking was reduced over the years or this reduction was reflection of relatively lower proportion of male patients in our study. The mean BMI of our studied sample was 25.5±2.2 kg/m^2. This value was well above the cut-off point for the Asian people. Obesity has significantly related with CAD in our population.[22] In this study, 37.5% patients had chronic coronary syndrome and 27.5% had STEMI.[23] Akanda et al reported that majority of Bangladeshi population had CAG due to acute coronary syndrome. In this study, 20 (10%) patients needed cross-over to other site for cannulation, 15 (15%) in non-PO FMD group and 5 (5%) in PO FMD group and this difference was statistically significant (p=0.030). Doubell et al reported cannulation failure rates of 2.7% in the PO-FMD group and 5.8% in the sham PO-FMD group (p=0.01), the overall rate was much lower than our study.[14] But in that study they cannulated traditional radial artery, not the DRA. In our center, a previous thesis reported cross over to other site in distal radial approach was 20%.[24] In radial artery access technique evaluation trial, cross over rate was found to be about 5% in conventional radial approach.[25] But, Koutouzis et al reported that in distal radial group cross over rate can be as high as 30%, whereas in traditional radial group, it can be as low as 2%.[10] That may explain why our cannulation failure rate was higher than that of (Doubell et al).[14] Number of attempts for successful puncture was significantly lower with PO FMD compared to counterpart (1.9±0.9 vs 3.6±1.6, p=0.015). Doubell et al reported significantly (p<0.001) lower puncture attempts in PO-FMD group (median value 1 vs 2).[14] Koutouzis et al reported that number of attempts was significantly higher in distal radial approach compared to traditional radial approach (6.8±6.2 vs 3.4±4.5, p<0.001).[10] So, our distal radial approach may be the reason why our attempts was higher than Doubell and his colleagues, but

use of FMD was significantly better than conventional approach. First attempt was successful in 45% patients in FMD group and 23% in non-PO FMD group (p=0.021). Our finding was similar to the result of Pancholy et al.[25] Access time (mean±SD) was 58.8±10.1 sec in group I and 78.9±7.9 sec in in group II, this difference was significant (p=0.006) in our study. Doubell et al reported median cannulation time was significantly (p<0.008) reduced with the use of PO- FMD method (61 sec vs 66 sec) (Doubell et al) similar to our study.[14] Although access time was lower, overall procedure time either for CAG or PCI was not significantly reduced (p=0.060 and 0.065, respectively) in our study. Doubell et al reported no difference in procedure time between PO-FMD group and non-PO-FMD group that is concurrent with our study.[14] Hematoma was present in 15 (7.5%) patients in our study samples, 5 in group I and 10 in group II and the difference was not statistically significant (p=0.060). Shadly in his MD thesis in our center reported hematoma in 10% of his study samples using distal radial approach, close to our study.[24] Among 24 (12%) patients with radial artery spasm in our study, PO-FMD group was significantly better than counterpart (10 vs 14, p=0.048). In their study, Doubell et al found radial artery spasm was reduced in PO-FMD group but failed to attain statistical significant (4.6% vs 4.3%, p=0.546). Similarly, in our study radial artery occlusion (RAO) rate was lower with use of PO-FMD group compare to non-PO-FMD group (4%vs 11%, p=0.039). Although researchers found RAO was reduced in PO FMD group, that was not statistically significant (5.7% vs 3.9%, p=0.200).[14] In his MD thesis in our center, Shadly reported RAO was 7.5% using distal radial approach, similar to our study.[24] We found that our efficacy and safety using PO-FMD method was concurrent to that described by previous researcher working on PO-FMD method (Doubell et al).[14] But the differences in result was explained by the difference in the site of puncture. Koutouzis et al reported significantly longer cannulation time and increased number of attempts with distal radial approach compared to traditional radial approach.[10] This may explain some inconsistency of our result with that of Doubell et al.[14]

Limitations

Ultrasound assessment of radial artery diameter before and after PO-FMD method could not be done. This is single center study, which does not represent the situation of whole country.

CONCLUSION

PO-FMD significantly reduced cross over rate and access time compared to conventional approach in DRA cannulation. This method also significantly increased the chances of successful first attempt of DRA cannulation. Complication rate such as hematoma formation, radial artery spasm and radial artery occlusion was also lower when PO-FMD method was used prior to cannulation.

Recommendations

PO-FMD can be introduced in DRA cannulation to improve efficacy and reduce vascular access site complications in radial intervention. A study with larger sample size involving multiple center and prospective design is recommended.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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