Original Research Article

https://doi.org/10.53339/aimdr.2025.11.3.9
E-ISSN: 2395-2822 | P-ISSN: 2395-2814

Comparison of vascular complications between Combo technique and conventional 6 Fr catheter in transradial percutaneous coronary intervention: A cross-sectional study in Bangladesh

Md. Mamunur Rahman[1], Mir Jamal Uddin[2], Abdul Momen[3], Tasnoma Siddiquee[4], Md. Ahasanul Haque Razib[1], Mohammad Ataullah[1], Mohammad Abdul Gaffar[5], Md. Afjal Hossain[6]

[1]Department of Cardiology, Mymensingh Medical College and Hospital, Mymensingh, Bangladesh, [2]Department of Cardiology, Bangladesh Specialized Hospital, Dhaka, Bangladesh, [3]Department of Cardiology, National Institute of Cardiovascular Disease and Hospital, Dhaka, Bangladesh, [4]Department of Anatomy, Mymemsingh Medical College, Mymensingh, Bangladesh, [5]Department of Cardiology, National Institute of Cardiovascular Disease and Hospital, Dhaka, Bangladesh, [6]Department of Cardiology, Sher-E-Bangla Medical College Hospital, Barisal, Bangladesh

Address for correspondence: Dr. Md. Mamunur Rahman, Indoor Medical Officer, Department of Cardiology, Mymensingh Medical College and Hospital, Mymensingh, Bangladesh. E-mail: mamun_m37@yahoo.com

Abstract

Introduction: Percutaneous coronary intervention (PCI) can be performed via radial or femoral access, with the radial route now preferred due to fewer complications and better outcomes. The recently introduced Combo technique, a modification of the mother-and-child method, aims to further reduce radial access-related complications. This study aimed to compare vascular complications during PCI in this newer Combo technique with a conventional 6 Fr guide catheter through a transradial approach.

Methods: This cross-sectional observational study was carried out in the Department of Cardiology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh, from July 2020 to June 2021. Study subjects were divided into two groups: Group I, transradial PCI using the Combo technique and Group II, transradial PCI using the conventional 6 Fr guide catheter technique, and in each group, 64 patients were included. Data were analyzed using Statistical Package for the Social Sciences Version 24.0.

Result: In this study of 128 patients undergoing PCI, the majority were aged 51–60 years, with a mean age of 52.60 ± 7.3 years in Group I and 51.89 ± 8.5 years in Group II ($P = 0.608$). Males predominated (89.8%), with an even gender distribution across the groups. Underlying diagnoses such as ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, and unstable angina were similarly distributed between the groups ($P = 0.857$). Complication rates were generally comparable, except for radial artery spasm, which was significantly more frequent in the conventional 6 Fr group (28.1%) than in the Combo technique group (12.5%) ($P = 0.047$).

Conclusion: PCI via the transradial approach is now preferred for its superior safety and faster recovery. This study highlights the Combo technique as a simple, cost-effective, and readily available alternative that significantly reduces radial artery spasm and shows a trend toward fewer hematomas compared to the conventional 6 Fr system.

Keywords: 6 Fr catheter, Combo technique, transradial percutaneous coronary intervention, vascular complications

Introduction

Cardiovascular diseases (CVDs) are the leading cause of death globally, accounting for 17.9 million deaths per year.[1] South Asians are prone to developing coronary artery disease (CAD). The most notable features of CAD in these populations are extreme prematurity and severity.[2] Bangladeshis are not exceptionally or unduly prone to develop CAD, which is often premature in onset, angiographically more severe, vere, and follows a rapidly progressive course.[3] In 1952, Seldinger first described the percutaneous method of vascular access most commonly used today, and since the 1980s, this has become a standard practice.[4] Arterial access via the femoral route allows larger diameter equipment for complex diagnostic and therapeutic techniques, and there is greater experience with both access and also the management of complications compared with other arterial access routes.[5] In 1989, Campeau first used the percutaneous transradial approach for coronary angiography; Kiemeneij *et al*. have done coronary angioplasty procedures via transradial approach (TRA). The radial artery is small in size compared to the femoral artery.[6,7] The radial artery has become the preferred choice for upper extremity arterial access due to its easy compressibility, distance from major veins and nerves, and companion blood flow through the ulnar artery to the palmar arch. The use of the radial artery for diagnostic and interventional procedures has been compared with the femoral and brachial approach in both randomized trials and observational studies and has consistently demonstrated statistically significant reductions in bleeding and access site complications.[8] Currently, the radial route is enjoying class IA recommendation for its own merits.[9] An updated meta-analysis including the MATRIX trial found a significant reduction in major bleeds, death, myocardial infarction or stroke, and all-cause mortality associated with radial as compared with femoral access.[10] The use of a conventional 6 Fr sheath results in a radial artery occlusion rate of 10.5%[11] and radial artery spasm of 22%. The rates of radial spasm have also been shown to be reduced through the incorporation of hydrophilic coatings on introducer sheaths.[12] The small size of the radial artery restricts sheath size and, hence, guides catheter size to 5 or 6 Fr in most patients, and when 6 Fr sheaths are used a significant rate of radial occlusion or stenosis rates is observed, limiting successive procedures.[13] To reduce the complications of a larger diameter of the catheter, Mamas *et al*. described a sheathless technique and performed 100 cases of percutaneous coronary intervention (PCI). Minor hematoma occurs in only 3% of the cases. Radial occlusion rate was 2% and radial artery spasm was 5%;[14] these complication rates were comparable with the 5 Fr conventional system.[13] Patel *et al*.[15] described the use of an innovative Combo technique (combination of virtual sheathless system and modified mother-and-child technique) in five successive cases of complex interventions using a 7 F guide catheter system through right atrium. Combo techniques help overcome the problems of radial and increase the success rate of radial access to reduce arm and forearm hematoma. The study aims to compare vascular complications during PCI in this newer Combo technique with a conventional 6 Fr guide catheter through a transradial approach.

Methods

This cross-sectional observational study was carried out in the Department of Cardiology, National Institute of Cardiovascular Diseases (NICVDs), Dhaka, Bangladesh, from July 2020 to June 2021. Based on the inclusion and exclusion criteria, patients with ischemic heart disease admitted to NICVD undergoing coronary angiogram (CAG) followed by *ad hoc* PCI or patients admitted for direct PCI (CAG done previously through transradial approach) were included in the study. The sample was collected by purposive sampling method. Study subjects were divided into two groups: Group I, transradial PCI using the Combo technique and Group II, transradial PCI using conventional 6 Fr guide catheter technique, and in each group, 64 patients were included. The study protocol was approved by the Ethical Review Committee of NICVD. Written informed consent

was taken from each patient or near relatives. Data were collected and compiled duly in a pre-designed data collection sheet for statistical analysis and interpretation. Data from the study were processed and analyzed both manually and using Statistical Package for the Social Sciences Version 24.0. Quantitative data were presented as mean and standard deviation, with comparisons performed using the Z-test and Student's *t*-test, as appropriate. Qualitative data were expressed as frequency and percentage, and comparisons between the groups were made using the Chi-square (χ^2) test. $P < 0.05$ was considered statistically significant.

Inclusion criteria

- Those patients undergoing coronary angiogram followed by *ad hoc* PCI or patients admitted for direct PCI were included in the study.

Exclusion criteria

- Primary PCI
- An absent radial pulse
- PCI using the femoral route from the very beginning
- Planned or present arteriovenous fistula for dialysis
- Patients with peripheral vascular disease.

Results

Table 1 shows the comparison of the study group according to age distribution. The highest frequency was 51–60 years, 29 and 23 in Group I and Group II, respectively, followed by 41–50 years. The mean ± SD of Group I and Group II was 52.60 ± 7.3 years and 51.89 ± 8.5 years, respectively, but this difference was not statistically significant ($P = 0.608$).

Table 2 shows that among the 115 male patients, 58 belonged to Group I and 57 to Group II. In the female group, 6 patients belonged to Group I, whereas 7 belonged to Group II.

Table 3 shows the comparison of the underlying diagnosis of the patients undergoing PCI in the studied groups, ST-elevation myocardial infarction occurred in almost half of the patients, in Group I 26 patients, and in Group II, 28 patients. Non-ST-elevation myocardial infarction comprised 24 patients in Group I and 21 patients in Group II, and there was no significant difference between the groups ($P = 0.857$).

Table 4 shows the comparison of complications among the study groups. Hematoma (minor) was present in 3 (4.7%) patients in Group I and 6 (9.4%) patients in Group II, and the difference was not statistically significant ($P = 0.492$). Radial artery spasm was present in 8 (12.5%) patients in Group I and 18 (28.1%) patients in Group II, and the difference was statistically significant ($P = 0.047$). Radial artery occlusion and persistent pain occurred in 9 (7%) and 17 (13.3%) patients, respectively. Again, the difference between Group I and Group II for these complications was not statistically significant, with $P = 1.00$ and 0.435, respectively.

Discussion

A total of 128 consecutive patients were included in the study. 40.6% of patients were in the age

Table 1: Comparison of the study groups according to their age (n=128)

Age (in years)	Group-I (n=64)		Group-II (n=64)		*P*-value
	n	Percentage	*n*	Percentage	
≤40	4	6.3	7	10.9	0.608^{ns}
41–50	21	32.8	24	37.5	
51–60	29	45.3	23	35.9	
61–70	10	15.6	10	15.6	
Mean±SD	52.60±7.3		51.89±8.5		

Group I: Combo technique group. Group II: Conventional 6 Fr group. Independent samples *t*-test. ns: Non-significant

group of 51–60 years, followed by 35.2% in the age group of 41–50 years. This pattern is consistent with the study conducted by Shirin *et al.*,[16] where the highest 37.5% belonged to 51–60 years and 32.5% to 41–50 years. On the contrary, Ahmed *et al*. found the highest frequency (41%) in the 41–50 years' age group. However, the mean age of our patients (52.25 ± 7.8 years) was similar to that of Ahmed *et al*.[17] In the European population, the mean age (60 ± 13 years) of the patients with ischemic heart disease was found to be higher, as studied by Kundi *et al*.[18] This age difference further proves the concept of earlier incidence of CAD in the Bangladeshi population.[3] In our study, 89.8% of the patients were male, which was consistent with a previous study done in our country.[19] In our study, local hematoma formation is higher in the conventional 6 Fr group (9.4%) compared to the Combo technique (4.7%). Although there is an increasing trend in the conventional group, the difference was not statistically significant ($P = 0.492$). This is probably due to the small sample size. Razor effect is a well-known phenomenon that occurs mainly during transradial angiography. Here, there is an injury to the arterial wall due to the sharp edge of the guide catheter during its advancement and manipulation, mainly through complex radial anatomy, i.e., radial artery spasm, small caliber radial artery, radial loops, and tortuous radial artery.[20] This effect plays a significant role in hematoma formation in the transradial approach. There is less chance of a razor effect with the Combo technique as a 5 Fr multipurpose catheter protruding through the 6 Fr guide catheter reduces the friction of the guide catheter with the arterial wall. That might explain the fewer hematoma formation with the Combo technique. Radial artery spasm was present in 19.5% of patients in our study. Previous studies reported that the prevalence of radial artery spasm was 2–24%.[21] Hence, the radial artery spasm rate in our study was similar to that described previously. In this study, the radial artery spasm was lower with the combo catheter than with the conventional 6 Fr catheter (12.5% vs. 28.1%), and the difference was statistically significant ($P = 0.047$). As the Combo technique reduces the razor effect, the spasm was lower during this technique. Radial artery occlusion (RAO) was present in a total of 9 (7%) patients in our study, and there was no statistical difference between Group I and Group II (6.3% vs. 7.8%, $P = 1.00$). Previously, a study in our center reported that the RAO rate was 9.6%, which is close to our result.[22] A total of 7 patients in Group I and 10 in Group II

Table 2: Distribution of patients by gender and study group (*n*=128)

Gender	Group I	Group II	Total
Male	58	57	115
Female	6	7	13
Total	64	64	128

Table 3: Comparison of underlying diagnosis of the studied groups (*n*=128)

Diagnosis	Group-I (*n*=64) *n* (%)	Group-II (*n*=64) *n* (%)	*P*-value
Unstable angina	14 (21.9)	15 (23.4)	0.857^{ns}
NSTEMI	24 (37.5)	21 (32.8)	
STEMI	26 (40.6)	28 (43.8)	

Group I: Combo technique group. Group II: Conventional 6 Fr group. Chi-square test. ns: Non-significant, STEMI: ST-elevation myocardial infarction, NSTEMI: Non-ST-elevation myocardial infarction

Table 4: Comparison of complications among the study groups (*n*=128)

Complications	Group-I (*n*=50)		Group-II (*n*=50)		*P*-value
	n	Percentage	*n*	Percentage	
Hematoma	3	4.7	6	9.4	^{b}0.492^{ns}
Radial artery spasm	8	12.5	18	28.1	^{a}0.047^{s}
Radial artery occlusion	4	6.3	5	7.8	^{b}1.00^{ns}
Persistent pain (up to 48 h)	7	10.9	10	15.6	^{a}0.435^{ns}

Group I: Combo technique group. Group II: Conventional 6 Fr group. ^{a}Chi-square test. ^{b}Fisher's exact. ns: Non-significant, s: Significant

reported some pain in the access site, but this was not statistically significant ($P = 0.435$). As this is a new comparative study, the data are lacking to compare all parameters with other studies. There was no radial artery perforation in both the groups. Even after 2 weeks of follow-ups, there was no pseudoaneurysm formation in any group.

Limitations of the study

The study has several limitations. First, the sample size was relatively small, which may affect the generalizability of the findings. Second, a non-randomized sampling method was used, introducing a potential risk of selection bias. Third, the COVID-19 pandemic adversely impacted patient admissions, which may have influenced the study population. In addition, as this was a single-center study, the results may not reflect the broader national context. Finally, the inability to perform fluoroscopy limited the scope of diagnostic evaluation.

Conclusion

PCI via the TRA is now preferred for its superior safety and faster recovery. This study highlights the Combo technique as a simple, cost-effective, and readily available alternative that significantly reduces radial artery spasm and shows a trend toward fewer hematomas compared to the conventional 6 Fr system. Despite being a single-center study with a limited sample size, the findings suggest that the Combo technique is a promising strategy to minimize vascular complications in transradial PCI, warranting further validation through larger multicenter trials.

Recommendation

Based on the findings, it is recommended that the Combo technique be routinely adopted for radial interventions to minimize vascular complications. As radial artery spasms emerged as the most common complication during PCI via radial access, deliberate preventive strategies such as thorough patient counseling, adequate sedation, and the use of spasmolytic agents should be employed. Finally, given the preliminary nature of this study, further multicenter research with a larger sample size is warranted to validate and expand upon these findings.

Funding

No funding sources.

Conflict of Interest

None declared.

References

1. Roth GA, Johnson C, Abajobir A, Abd-Allah F, Abera SF, Abyu G, *et al*. Global, regional, and national burden of cardiovascular diseases for 10 causes, 1990 to 2015. J Am Coll Cardiol 2017;70:1-25.
2. Enas EA, Senthilkumar A, Chennikkara H, Bjurlin MA. Prudent diet and preventive nutrition from pediatrics to geriatrics: Current knowledge and practical recommendations. Indian Heart J 2003;55:310-38.
3. Islam AK, Majumder AA. Coronary artery disease in Bangladesh: A review. Indian Heart J 2013;65:424-35.
4. Seldinger SI. Catheter replacement of the needle in percutaneous arteriography; A new technique. Acta Radiol (Stockh) 2008;49 Suppl 434:47-52.
5. Franchi E, Marino P, Biondi-Zoccai GG, De Luca G, Vassanelli C, Agostoni P. Transradial versus transfemoral approach for percutaneous coronary procedures. Curr Cardiol Rep 2009;11:391-7.
6. Kiemeneij F, Laarman GJ, Odekerken D, Slagboom T, Van Der Wieken R. A randomized comparison of percutaneous transluminal coronary angioplasty by the radial, brachial and femoral approaches: The access study. J Am Coll Cardiol 1997;29:1269-75.
7. Campeau L. Percutaneous radial artery approach for coronary angiography. Cathet Cardiovasc Diagn 1989;16:3-7.
8. Peterson ED, Dai D, DeLong ER, Brennan JM, Singh M, Rao SV, *et al*. Contemporary mortality risk prediction for percutaneous coronary intervention: Results from 588,398 procedures in the national cardiovascular data registry. J Am Coll Cardiol 2010;55:1923-32.
9. Roffi M, Patrono C, Collet JP, Mueller C, Valgimigli M, Andreotti F, *et al*. 2015 ESC guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. Pol Heart J (Kardiol Pol) 2015;73:1207-94.

10. Valgimigli M, Frigoli E, Leonardi S, Vranckx P, Rothenbühler M, Tebaldi M, *et al*. Radial versus femoral access and bivalirudin versus unfractionated heparin in invasively managed patients with acute coronary syndrome (MATRIX): Final 1-year results of a multicentre, randomised controlled trial. Lancet 2018;392:835-48.
11. Sanmartin M, Gomez M, Rumoroso JR, Sadaba M, Martinez M, Baz JA, *et al*. Interruption of blood flow during compression and radial artery occlusion after transradial catheterization. Catheter Cardiovasc Interv 2007;70:185-9.
12. Kiemeneij F, Vajifdar BU, Eccleshall SC, Laarman G, Slagboom T, Wieken RV. Evaluation of a spasmolytic cocktail to prevent radial artery spasm during coronary procedures. Catheter Cardiovasc Interv 2003;58:281-4.
13. Dahm JB, Vogelgesang D, Hummel A, Staudt A, Völzke H, Felix SB. A randomized trial of 5 vs. 6 French transradial percutaneous coronary interventions. Catheter Cardiovasc Interv 2002;57:172-6.
14. Mamas M, D'Souza S, Hendry C, Ali R, Iles-Smith H, Palmer K, *et al*. Use of the sheathless guide catheter during routine transradial percutaneous coronary intervention: A feasibility study. Catheter Cardiovasc Interv 2010;75:596-602.
15. Patel T, Shah S, Pancholy S. "Combo" technique for the use of 7F guide catheter system during transradial approach. Catheter Cardiovasc Interv 2015;86:1033-40.
16. Shirin M, Azad SA, Rahman M, Dina S, Karim E, Hossain A, *et al*. Detection of coronary artery diseases: Comparative study of multidetector computed tomography angiogram (64 slice scanner) and conventional angiogram. Cardiovasc J 2012;4:120-6.
17. Ahmed MI, Akhtaruzzaman KM, Rahman MA, Mahmod MS, Nahar S. Relationship between HDL-cholesterol and angiographic severity of coronary artery disease. Bangladesh Heart J 2018;33:32-8.
18. Kundi H, Kiziltunc EM, Cetin M, Cicekcioglu H, Cetin ZG, Cicek G, *et al*. Association of monocyte/HDL-C ratio with SYNTAX scores in patients with stable coronary artery disease. Herz 2016;41:523-9.
19. Sabah KM, Chowdhury AW, Khan HL, Hasan AH, Haque S, Ali S, *et al*. Body mass index and waist/height ratio for prediction of severity of coronary artery disease. BMC Res Notes 2014;7:246.
20. Garg N, Sahoo D, Goel PK. Pigtail assisted tracking of guide catheter for navigating the difficult radial: Overcoming the "razor effect". Indian Heart J 2016;68:355-60.
21. Bhat T, Teli S, Bhat H, Akhtar M, Meghani M, Lafferty J, *et al*. Access-site complications and their management during transradial cardiac catheterization. Expert Rev Cardiovasc Ther 2012;10:627-34.
22. Matin MA, Uddin MJ, Momen A, Aziz M, Reza AT, Cader FA, *et al*. Frequency and predictors of radial artery occlusion after coronary procedure through transradial approach: A vascular Doppler-guided study. Bangladesh Heart J 2019;34:111-7.