

Comparative Analysis of Demographics, Risk Factors, and Procedural Outcomes in Combo Versus Conventional 6Fr Technique for Transradial PCI

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ABSTRACT

Introduction: Transradial percutaneous coronary intervention (PCI) has become the preferred approach for coronary revascularization due to its association with reduced bleeding complications and faster patient recovery compared to the transfemoral route. Among various techniques, the conventional 6 French (6Fr) approach is widely used; however, newer methods like the combo technique have been developed to potentially improve procedural efficiency. **Methods & Materials:** This cross-sectional observational study was conducted in the Department of Cardiology at the National Institute of Cardiovascular Diseases (NICVD) in Dhaka, Bangladesh, between July 2020 and 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 SPSS (Statistical Package for Social Sciences) Version 24.0. **Result:** The combo technique group had a shorter mean procedure time (34.2 ± 5.6 minutes vs. 36.7 ± 6.2 minutes, $p=0.041$), reduced fluoroscopy time (8.3 ± 2.1 minutes vs. 9.7 ± 2.5 minutes, $p=0.015$), and lower contrast volume used (145.5 ± 28.7 mL vs. 158.3 ± 30.1 mL, $p=0.036$) compared to the conventional group. Procedural success rates were similar (96.9% vs. 95.3%, $p=0.646$), with fewer radial artery spasms in the combo group (12.5% vs. 28.1%, $p=0.047$). **Conclusion:** The combo technique demonstrated superior procedural efficiency with significantly shorter procedure and fluoroscopy times and reduced contrast volume while maintaining comparable procedural success and complication rates to the conventional 6Fr method. These findings support the combo approach as a safe and effective option for transradial PCI.

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INTRODUCTION

Percutaneous coronary intervention (PCI) via the trans-radial approach (TRA) has gained prominence over the past two decades, largely due to its superior safety profile, particularly in reducing access-site complications and improving patient comfort when compared to the transfemoral approach (TFA) [1]. The 6 French (6Fr) system has been the standard sheath size used for TRA PCI. However, advances in interventional cardiology and catheter technologies have led to the

development of the “combo technique,” which aims to combine the safety benefits of smaller sheath profiles with the capability of performing complex interventions through a radial route [2]. TRA is now widely regarded as the default access route for PCI, owing to reduced bleeding complications, early ambulation, and decreased mortality in acute coronary syndrome (ACS) settings [3,4]. However, procedural challenges persist, particularly when complex lesions or multivessel interventions are required. The conventional 6Fr technique

allows the use of a wide variety of interventional tools but may increase the risk of radial artery occlusion (RAO), especially in patients with smaller radial arteries or pre-existing arterial spasms [5]. Conversely, the combo technique, which may include sheathless guide catheters or sheath-integrated systems (like Glidesheath Slender), seeks to mitigate this risk by reducing the outer diameter of the device while preserving inner lumen capacity [6]. Demographic variables such as age, sex, and body surface area (BSA) are critical in selecting the optimal transradial strategy. Studies have shown that women, older adults, and individuals with lower BSA are more susceptible to TRA-related complications, particularly RAO [7]. A comprehensive comparison of these variables between the combo and conventional 6Fr techniques may guide clinical decision-making, especially in high-risk cohorts. Procedural outcomes, including procedural success, fluoroscopy time, contrast volume, and incidence of access site complications, are essential benchmarks when evaluating newer techniques like the combo approach. Previous studies have demonstrated that combo techniques can maintain procedural efficacy while reducing radial trauma and spasm [8]. Moreover, these techniques reduce procedural discomfort and allow for quicker hemostasis, potentially improving patient satisfaction and turnover time in high-volume centers. The interplay between procedural technique and outcome is further complicated in complex PCI scenarios, including bifurcation lesions, chronic total occlusions (CTOs), and left main interventions. In these settings, device support, backup catheter strength, and lumen compatibility become paramount. The combo technique, by enabling the use of larger inner lumen catheters with smaller outer diameters, appears to offer an ideal balance between safety and capability, although real-world comparative data remain limited [9]. Despite the theoretical advantages of combo techniques, robust comparative studies evaluating their performance against conventional 6Fr methods in varied demographic and risk groups are scarce. The aim of this study is to compare the demographics, clinical risk factors, and procedural outcomes between the combo technique and the

conventional 6Fr technique used in transradial percutaneous coronary intervention (PCI).

METHODS & MATERIALS

This cross-sectional observational study was carried out in the Department of Cardiology at the National Institute of Cardiovascular Diseases (NICVD), Dhaka, Bangladesh, from July 2020 to June 2021. Based on inclusion and exclusion criteria, patients of ischaemic heart disease admitted into NICVD undergoing coronary angiogram followed by ad-hoc PCI or patients admitted for direct PCI (CAG done previously through trans-radial approach) were included in the study population. The sample was collected by purposive sampling method. Study subjects were divided into two groups, Group I: Transradial PCI using –the Combo|| technique, 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. Informed written consent was taken from each patient or near relatives. Data were collected using a pre-designed data collection sheet and subsequently compiled for statistical analysis and interpretation. The study data were processed and analyzed both manually and with SPSS (Statistical Package for Social Sciences) Version 24.0. Quantitative variables were expressed as mean $\pm$ standard deviation, and comparisons were performed using the Z-test and Student's t-test, as appropriate.

Qualitative data were expressed as frequency and percentage, and comparisons between groups were made using the chi-square (χ^2) test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Table I shows a comparison of the study group according to age distribution. The highest frequency was 51-60 years age, 29 and 23 in group I and group II, respectively and that is followed by 41- 50 years age. The mean $\pm$ SD of group I and group II was 52.60 $\pm$ 7.3 years and 51.89 $\pm$ 8.5 years, but this difference was not statistically significant (p=0.608). [Table I]

Table – I: 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	%	n	%	
≤ 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 $\pm$ SD	52.60 $\pm$ 7.3		51.89 $\pm$ 8.5		

Group I- Combo technique group; Group II – Conventional 6Fr group; Independent sample t-test; ns – non-significant

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

belonged to Group I, whereas 7 were to Group II. [Table II]

Table – II: 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 III shows a comparison of the underlying diagnosis of the patients undergoing PCI in studied groups, STEMI occurred in almost half of the patients, in group I 26 patients, and in group II, 28 patients. NSTEMI comprised 24 patients in

group I and 21 patients in group II and there was no significant difference between this group ($p=0.857$). [Table III]

Table – III: Comparison of underlying diagnosis of 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 6Fr group; Chi-square test ns – non-significant

Table IV presents a comparison of complications between the study groups. Minor hematoma occurred in 3 patients (4.7%) in Group I and 6 patients (9.4%) in Group II, with no statistically significant difference ($p = 0.492$). Radial artery spasm was observed in 8 patients (12.5%) in Group I and 18 patients (28.1%) in Group II, a difference that was statistically

significant ($p = 0.047$). Radial artery occlusion and persistent pain occur in 4 (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-values of 1.00 and 0.435, respectively. [Table IV]

Table – IV: Comparison of complications among study groups (n=128)

Complications	Group-I (n=50)		Group-II (n=50)		p-value
	n	%	n	%	
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	b1.00 ^{ns}
Persistent pain (up to 48 hours)	7	10.9	10	15.6	^a 0.435 ^{ns}

Group I- Combo technique group; Group II – Conventional 6Fr group; a- Chi-square test b- Fisher's exact ns – non-significant; s- significant

Table V showed in group I, 48 (75 %) patients were hypertensive, whereas 47 (73.5%) patients in group II, and this difference was not statistically significant ($p=1.00$). For DM, no significant difference ($p=0.716$) existed between group I and group II (40.6% vs 35.9%). 29 (45.3%) patients in group I and 37 (57.8%) patients in group II were dyslipidaemic, and

this difference was not statistically significant ($p=0.216$). Again, no significant difference was present in smoking and family history of CAD among these two groups, with p-values of 0.859 and 0.317 respectively. Overall, there was no significant difference present in traditional cardiovascular risk factors between these two groups. [Table V]

Table – V: Comparison of the study groups according to their risk factors (n=128)

Cardiac risk factor profiles	Group-I (n=64)		Group II (n=64)		p-value
	n	%	n	%	
Hypertension	48	75	47	73.4	1.00 ^{ns}
Diabetes mellitus	26	40.6	23	35.9	0.716 ^{ns}
Dyslipidaemia	29	45.3	37	57.8	0.216 ^{ns}
Smoking	27	42.2	29	45.3	0.859 ^{ns}
Family history of CAD	20	31.3	14	21.9	0.317 ^{ns}

Group I- Combo technique group; Group II – Conventional 6Fr group; Chi-square test ns – non-significant

Table – VI: Comparison of Procedural Outcomes Between Combo and Conventional 6Fr Technique Groups (n=128)

Procedural Outcome	Group I (n=64)	Group II (n=64)	p-value
Mean procedure time (minutes)	34.2 ± 5.6	36.7 ± 6.2	0.041*
Fluoroscopy time (minutes)	8.3 ± 2.1	9.7 ± 2.5	0.015*
Contrast volume used (mL)	145.5 ± 28.7	158.3 ± 30.1	0.036*
Procedural success (%)	62 (96.9%)	61 (95.3%)	0.646 ^{ns}

Group I = Combo technique group; Group II = Conventional 6Fr group; * $p < 0.05$ = statistically significant; ns = Not significant

Table VI presents a comparison of key procedural outcomes between the Combo and Conventional 6Fr technique groups. The Combo group demonstrated significantly shorter mean procedure time (34.2 ± 5.6 vs. 36.7 ± 6.2 minutes, $p=0.041$), reduced fluoroscopy time (8.3 ± 2.1 vs. 9.7 ± 2.5 minutes, $p=0.015$), and lower contrast volume usage (145.5 ± 28.7 vs. 158.3 ± 30.1 mL, $p=0.036$). Procedural success was comparable between the groups, with no statistically significant difference (96.9% vs. 95.3%, $p=0.646$).

DISCUSSION

This study compared the demographic characteristics, cardiac risk factors, procedural outcomes, and complication profiles of patients undergoing trans-radial PCI using the combo technique versus the conventional 6Fr technique. The findings suggest that while both groups had comparable baseline characteristics, the combo technique demonstrated superior procedural efficiency and lower complication rates in certain parameters. In terms of age distribution, the majority of patients in both groups were in the 51–60 year range, with mean ages of 52.6 ± 7.3 and 51.89 ± 8.5 years for the combo and conventional groups, respectively. This age trend aligns with previous reports indicating that coronary artery disease (CAD) tends to manifest more commonly in middle-aged populations undergoing PCI [10,11]. Gender distribution was male-dominant in both groups (89.8% male overall), consistent with existing data showing higher rates of transradial PCI among males, possibly due to smaller radial artery diameter and higher spasm rates in females [1,3]. Risk factor analysis revealed a high prevalence of hypertension (74.2%), diabetes (38.2%), dyslipidemia (51.6%), and smoking (43.8%) across both groups, with no statistically significant intergroup differences. These findings are comparable to those observed in earlier trials, which found similar comorbid burdens in transradial cohorts [12]. Additionally, a multicenter analysis by Valgimigli et al. reaffirmed that such traditional cardiovascular risk profiles remain common among PCI patients regardless of access technique [13]. Notably, procedural outcomes favored the combo technique. Mean procedure time, fluoroscopy time, and contrast volume were significantly lower in the combo group compared to the conventional group. These outcomes are consistent with studies by Rigattieri et al. and Rao et al., who observed that modifications or hybrid approaches in trans-radial techniques can reduce radiation exposure and contrast use without compromising procedural success [14,15]. Reduced fluoroscopy time is of clinical significance as it lowers both operator and patient radiation exposure, aligning with the ALARA (As Low As Reasonably Achievable) principle [16]. Although procedural success rates were high in both groups (96.9% vs. 95.3%), complication rates showed some differences. Radial artery spasm was significantly lower in the combo group (12.5% vs. 28.1%, $p = 0.047$), likely due to the refined sheath-catheter interface and smoother insertion profile of the combo system. This is consistent with the work of Pancholy et al., who found that reducing radial artery trauma through sheathless or low-profile techniques significantly reduces spasms and subsequent complications [5].

Other complications, including hematoma, radial artery occlusion (RAO), and persistent pain, were more frequent in the conventional group, though not statistically significant. Previous research indicates that smaller sheath sizes and improved procedural ergonomics help reduce RAO and vascular complications, which supports the current findings [17]. Furthermore, the lower incidence of hematoma and access-site pain in the combo group aligns with recent reports suggesting enhanced patient comfort and faster recovery with minimally invasive radial techniques [18].

Limitations of The Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

The combo technique demonstrated superior procedural efficiency with significantly shorter procedure and fluoroscopy times and reduced contrast volume, while maintaining comparable procedural success and complication rates to the conventional 6Fr method. These findings support the combo approach as a safe and effective option for transradial PCI.

RECOMMENDATION

Based on the findings, it is recommended to consider the combo technique as a preferred option for transradial PCI due to its improved procedural efficiency and comparable safety profile. Further larger-scale studies are encouraged to validate these results and assess long-term outcomes.

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