

Factors influencing radial artery occlusion after transradial coronary intervention in the Indian population

ABSTRACT

Objective: Radial artery occlusion (RAO) is a common complication during transradial coronary intervention. Its incidence is variably reported in literature and its predictors are not completely understood. In this study, we aimed to define the incidence and factors influencing RAO in patients undergoing transradial coronary intervention.

Methods: This was a single-center prospective study (October 2018 to September 2019) that enrolled 1,754 patients who were evaluated for RAO 24 hours after transradial coronary intervention. Univariate as well as multivariate analyses were done to identify patient and procedure related factors predicting the occurrence of RAO.

Results: A total of 1,374 patients (78.3%) underwent angioplasty, whereas 380 (21.7%) underwent angiography alone. RAO was diagnosed in 11.97% patients. Lower glomerular filtration rate, multiple puncture attempts for radial artery access, larger sheath size, complex nature of interventional procedure, longer homeostasis time, and forearm hematoma formation were independent predictors for RAO.

Conclusion: RAO was not an uncommon complication in transradial coronary interventions, especially in the Indian population; and the knowledge of predictors may be helpful in its prevention.

Keywords: radial artery occlusion; transradial coronary intervention; coronary artery disease; percutaneous coronary intervention

INTRODUCTION

Transfemoral vascular access is the most common approach for both diagnostic as well as therapeutic coronary interventions; however, higher rate of vascular complications and bleeding have been reported especially in women and older patients than with radial access (1). Transradial approach (TRA) is now being increasingly used and is the preferred vascular access for cardiac interventions (2). TRA offers advantages such as minimal invasion, ease of performance of diagnostic and therapeutic coronary interventions, minimum patient discomfort, early ambulation, shorter hospital stay, and lower hospital costs (3-7). In addition, there are lower local site complications, morbidity, and mortality in patients who specifically present with acute coronary syndromes (6, 7). Radial artery occlusion (RAO) is one of the most frequent complications of TRA that affects a sizeable proportion of patients (8, 9). Post transradial coronary intervention (TCI), early RAO may occur because of radial artery spasm and thrombosis, which may be precipitated by combined effects of catheter-induced endothelial injury and decrease in blood flow after sheath and catheter insertion (8). The incidence of RAO varies in different studies ranging from 1% to 42%, and has been determined by the timing of evaluation and the method used for the diagnosis of RAO. Various patient-specific and procedure-related factors influence the occurrence and consequences of RAO (8-17). However, the predictors of RAO after TCI are not clearly defined. In this study, we determine the incidence and patient-specific and procedure-related predictors of RAO among patients undergoing TCI.



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ORIGINAL INVESTIGATION

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METHODS

This was a prospective study conducted at the King George's Medical University, India, between October 2018 to September 2019. Patients aged more than 18 years and who underwent coronary catheterization by radial artery route were enrolled in this study. Patients with prior radial intervention, high bleeding risk [glomerular filtration rate (GFR) <30 mL/minute/m², platelet count <70000 cells/mm³, use of anticoagulants with international normalization ratio (INR) >2.5], cardiogenic shock, hemodynamic instability, scleroderma, on hemodialysis, and with local site infection were excluded. Patients with failed radial access, that is, patients in whom the artery could not be punctured successfully, wire could not be crossed, or sheath could not be placed were also excluded. This was done to minimize the confounding effects of possible factors in radial versus femoral access, including varying levels of vascular and local tissue injury, doses of heparin, method and time of hemostasis, sheath size, and number of catheter exchanges (Fig. 1).

The study was conducted in compliance with the International Ethical Guidelines for Biomedical Research Involving Human Subjects, Good Clinical Practice Guidelines, the Declaration of Helsinki, and local laws. All the patients provided written informed consent. The study protocol was approved by the Institutional Ethics Committee (95th ECM 11B-Thesis/P51, 11/01 2016).

All the patients underwent a palpation examination of the radial artery, and the standard Barbeau test in the access arm (18). After successful sheath insertion, a bolus of combination of 2.5 mg verapamil and 200 µg nitroglycerin were given through the side-port of the sheath in all the patients. An initial dose of 5,000 IU unfractionated heparin bolus was given to all the patients. An adjunctive bolus of heparin was given during percutaneous coronary intervention to maintain activated clotting time range of 250–300 s. Sheath size and guiding catheter were chosen according to the operator's preference and lesion complexity. After completion of the procedure, the arterial sheath was removed, and hemostasis was achieved in all the patients with a radial compression device (TR band, Terumo, Inc) using the "patent hemostasis" protocol (12). Hemostasis time was measured from the time of removal of the introducer sheath to the

time when the TR band was removed, and hemostasis was achieved without evidence of puncture site bleeding. Every patient was assessed for RAO after 24 hours by radial artery palpation, followed by reverse Barbeau test (RBT), and finally confirmed by Doppler ultrasound examination. During RBT, a pulse oximeter with a display of plethysmographic waveform was placed on the thumb of the hand being examined (18). Ulnar artery was compressed, and the shape of the plethysmographic wave was carefully evaluated. All the patients with loss of waveform (type D) on RBT were subjected to color Doppler study to confirm the diagnosis of RAO. Color Doppler examinations were performed using GE Vivid E 95, 9 L, 3.6/7.2 MHz multi-frequency matrix linear vascular probe.

Local hematoma was graded according to the severity on the basis of the EARly Discharge after Transradial Stenting of Coronary Arteries Study (EASY) hematoma scale as grade I, <5 cm in diameter (nonsignificant); grade II, 5–10 cm diameter (mild); grade III, >10 cm but distal to the elbow (moderate); grade IV, extending above the elbow (severe); and grade V, anywhere with ischemic threat to the hand (compartment syndrome) (19).

All the patients underwent detailed clinical evaluation, and their biochemical and echocardiographic parameters were recorded. Procedural parameters recorded were number of attempts for radial artery access, sheath size, procedure

HIGHLIGHTS

- This study determined patient-specific and procedure-related predictors of radial artery occlusion (RAO) among patients undergoing transradial coronary intervention.
- After 24 hours of intervention, RAO was diagnosed in 11.97% patients through reverse Barbeau test which was confirmed on a color Doppler study.
- Procedural factors such as multiple radial artery punctures, larger sheath size, complex nature of interventional procedure, longer hemostasis time, and forearm hematoma formation were found to be significant predictors of RAO on univariate and multivariate analyses.

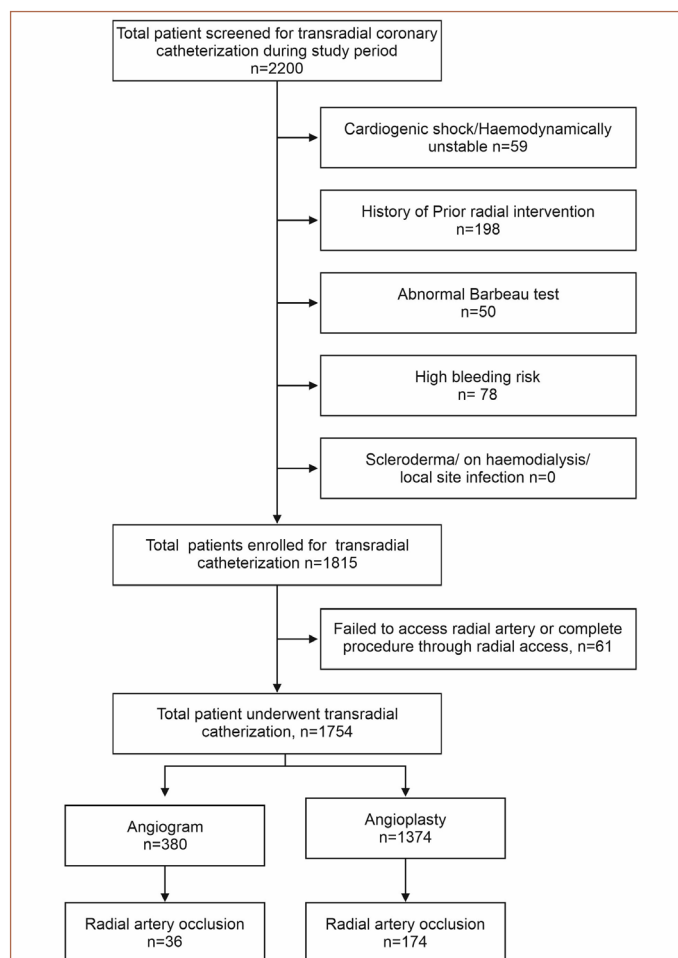


Figure 1. Flow chart of patient disposition

time, anticoagulation dose, antiplatelet therapy, diagnostic or therapeutic procedure, number of catheter exchanges, type of coronary lesion (chronic total occlusion, bifurcation lesion), contrast volume, post-procedure hemostasis time, and hematoma formation. Greater than 2 attempts at radial access was labelled as multiple attempts. Procedure time >60 minutes, >3 catheters exchanges, and chronic total and bifurcation coronary lesion interventions were included in complex procedure. Intensive antiplatelet therapy included use of ticagrelor or prasugrel and/or glycoprotein IIb/IIIa receptor antagonists. All the procedures were performed by interventional cardiologists (n=8), who had individual experience of at least >1000 radial interventions spanning across >3 years of experience in interventional procedures.

The primary endpoints were the incidence of RAO after 24 hours of procedure as defined by type D pattern on RBT and

absence of blood flow on color Doppler ultrasound examination. All the patients of RAO were followed up after 2 weeks of discharge, and repeat color Doppler ultrasound examination was performed for patency of radial artery.

Statistical analysis

Continuous variables were expressed as mean \pm standard deviation (SD). Categorical variables were expressed as frequency and percentages. Univariate analyses were performed to assess patient-specific and procedure-related predictors of RAO. Continuous variables were compared using the student's t-test, and categorical variables were compared using the chi-squared test or Fisher exact test as applicable. Bonferroni post-hoc test was performed to evaluate the effect of sheath size. Binary logistic regression analysis was performed to study the effect of patient specific and procedural factors, which had significant impact on RAO

Table 1. Demographics and baseline characteristics of patients undergoing transradial catheterization

Characteristic	n=1,754	RAO (n=210)	No RAO (n=1544)	P-value
Age (mean \pm SD, years)	56.31 \pm 10.58	57.3 \pm 11.3	56.2 \pm 10.5	0.167
Male, n (%)	1442 (82.2%)	172 (81.9%)	1270 (82.3%)	0.901
Body weight (mean \pm SD, kg)	64.38 \pm 9.00	63.81 \pm 8.82	64.45 \pm 9.03	0.335
Hypertension, n (%)	666 (38.0%)	80 (38.1%)	586 (38.0%)	0.968
Diabetes mellitus, n (%)	622 (35.5%)	82 (39.0%)	540 (35.0%)	0.247
Smoking, n (%)	570 (32.5%)	76 (36.2%)	494 (32.0%)	0.223
Hemoglobin (mean \pm SD, g/dL)	12.78 \pm 1.69	12.73 \pm 1.64	12.79 \pm 1.70	0.625
Serum Creatinine (mean \pm SD, mg/dL)	1.06 \pm 0.46	1.08 \pm 0.30	1.06 \pm 0.48	0.543
Glomerular filtration rate (mean \pm SD, mL/min)	73.99 \pm 24.51	70.11 \pm 23.32	74.51 \pm 24.63	0.015
Coronary artery disease, n (%)				
Acute coronary syndrome	702/978 (71.8%)	96/126 (76.2%)	606/852 (71.1%)	0.238
Stable coronary artery disease	276/978 (28.2%)	30/126 (23.8%)	246/852 (28.9%)	
Multiple puncture attempts, n (%)				
No	1091 (62.2%)	82 (39.1%)	1009 (65.3%)	<0.001
Yes	663 (37.8%)	128 (60.9%)	535 (34.7%)	
Sheath size, n (%)				
5F	378 (21.6%)	37 (17.6%)	341 (22.1%)	<0.001
6F	1367 (77.9%)	166 (79.1%)	1201 (77.8%)	
7F	9 (0.5%)	7 (3.3%)	2 (0.1%)	
Type of procedure, n (%)				
Angiography	380 (21.7%)	36 (17.1%)	344 (22.3%)	0.09
Angioplasty	1374 (78.3%)	174 (82.9%)	1200 (77.7%)	
Intensive antiplatelet treatment, n (%)				
No	1455 (83.0%)	167 (79.5%)	1288 (83.4%)	0.159
Yes	299 (17.0%)	43 (20.5%)	256 (16.6%)	
Heparin dose, n (%)				
5000 units	380 (21.7%)	36 (17.1%)	344 (22.3%)	0.09
>5000 units	1374 (78.3%)	174 (82.9%)	1200 (77.7%)	
Complex interventional procedure, n (%)				
No	1618 (92.2%)	165 (78.6%)	1453 (94.1%)	<0.001
Yes	136 (7.8%)	45 (21.4%)	91 (5.9%)	
Used contrast volume \geq100 mL, n (%)				
No	388 (22.1%)	36 (17.1%)	352 (22.8%)	0.064
Yes	1366 (77.9%)	174 (82.9%)	1192 (77.2%)	
Hemostasis time (mean \pm SD, minutes)	6.51 \pm 1.95	7.35 \pm 1.63	6.39 \pm 1.97	<0.001
Forearm hematoma	187 (10.7%)	57 (27.1%)	130 (8.4%)	<0.001

RAO - radial artery occlusion; SD - standard deviation

in the univariate analyses. All p values <0.05 were considered as statistically significant. Statistical analysis was performed using the Statistical Package for the Social Sciences, version 21.0 (SPSS, Inc., Chicago, IL, USA).

RESULTS

A total of 1,754 consecutive patients were included in the study (Fig. 1). The mean age of study participants was 56.31±10.58 years, and the majority (82.2%) were men. Demography and baseline characteristics are shown in Table 1. Mean hemostasis time was 390.6±117.4 minutes and was significantly higher for patients who underwent angioplasty when compared to those who underwent angiography (424.8±77.5 vs. 267.0±149.7 s; p<0.001). After 24 hours of TCI, RAO was diagnosed in 210 (11.97%) of patients on RBT examination which was confirmed on color Doppler. Of these, only 6 (2.86%) patients had a radial artery recanalization after 2 weeks of the procedure. Majority of the patients with RAO were asymptomatic, 47 (22.38%) patients reported local site pain. Forearm hematoma was reported in 187 (10.7%) patients. Maximum (n=62; 3.53%) had grade I hematoma followed by grade II (n=54; 3.08%), grade III (n=49; 2.83%), and

grade IV (n=22; 1.25%). None of the patients developed compartment syndrome (grade V hematoma). All the patients with hematoma were successfully managed conservatively with manual or device compression and with anti-inflammatory drugs according to grade and progression of hematoma.

Factors affecting RAO

Patient-related factors such as age, sex, body weight, diabetes mellitus, hypertension, smoking, hemoglobin level, and serum creatinine were not found to be associated with the development of RAO. However, GFR was significantly lower in patients who developed RAO than in patients with patent radial artery (Table 1).

Procedural factors like multiple radial artery punctures, larger sheath size, complex nature of interventional procedure, longer hemostasis time, and forearm hematoma formation were significantly more prevalent in patients with RAO on univariate analyses (Table 1). Other procedural factors such as volume of contrast (>100 mL), intensive antiplatelet therapy, angioplasty procedure, and >5000 units heparin use during the procedure did not significantly impact the development of RAO after TCI (Table 1). All the clinical and procedural predictors which had significant association with RAO on univariate analyses also had significant association on multivariate analysis (Table 2, Fig. 2).

DISCUSSION

In this study, RAO was seen in 12% patients who underwent TCI. Procedure-related factors, but not patient-specific factors, were independent predictors for the occurrence of RAO in the Indian population. To the best of our knowledge, it is the largest single-center study from this region, which includes real world population who were planned for TCI. Our study reinforced findings of earlier studies that the Indian population has a higher rate of post TCI radial artery occlusion than the western world, which may be attributable to smaller body surface area and radial artery diameter.

There are varying reports for the incidence rates of RAO in literature; incidences as low as 1% and as high as 43% have been reported in various studies (8-11). In a systematic review and meta-analysis of 66 studies (n=31,345), Rashid et al. (13) reported RAO in 7.8% patients within 24 hours of TCI. Higher incidence of RAO in our study may be explained by smaller diameter of the radial artery in the Indian population in comparison to their western counterparts, and assessment of RAO by RBT and confirmation by Doppler study, which excluded underestimation by radial artery palpation method (10, 14). Studies in the Indian population including those by Sinha et al. (15) and Garg et al. (10) have reported similar higher incidence of RAO of 17.4% and 15.2%, respectively.

Available evidence in literature is suggestive of various patient-specific and procedure-related predictors of RAO in patients who undergo TCI. Patient-specific factors like younger age (20-22), female sex (21-26), lower body weight (12, 27, 28), smoking (9, 29), hypertension (23), and diabetes (9, 10, 16, 25, 26) are reported to predict the occurrence of RAO. However, results are not consistent across studies. In our study, low GFR was the only patient-specific factor which independent-

Table 2. Binary logistic regression analysis for predictors of radial artery occlusion following transradial catheterization

Predictor	Odds ratio	95% CI		P-value
		Lower	Upper	
GFR <60 mL/min/1.73 m ²	1.504	1.085	2.083	0.014
Multiple puncture	2.733	2	3.736	<0.001
Sheath size				
6F vs 5F	0.137	0.021	0.887	0.037
7F vs 5F	0.369	0.029	4.649	0.441
Complex procedure	3.066	1.962	4.791	<0.001
Contrast volume ≥100 mL	4.981	0.763	32.521	0.093
Hemostasis time	1.004	1.002	1.006	<0.001
Forearm hematoma	2.595	1.751	3.846	<0.001

CI - confidence interval; GFR - glomerular filtration rate

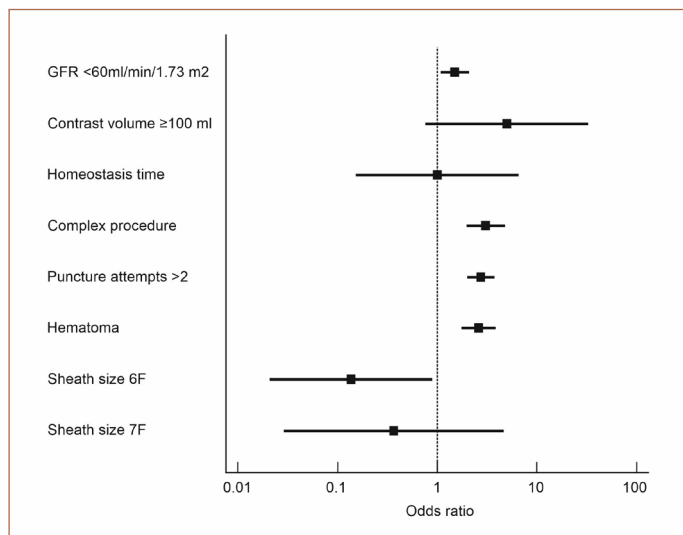


Figure 2. Predictors of radial artery occlusion following transradial catheterization

ly predicted the occurrence of RAO after TCI. Similar to our study, previous studies have reported renal dysfunction (24, 25) to be a predictor for the occurrence of RAO in patients who undergo TCI. Patients with impaired renal function are characterized by endothelial dysfunction and increased coagulation, especially FVIII activity, which leads to thrombotic occlusion (30). Systemic conditions like diabetes and hypertension were unpredictable in our study, which could be explained by the inclusion of hemodynamically stable patients. Moreover, the association of these factors could also be dependent on the duration of such illnesses, level of their control, and type of treatment being undertaken.

In our study, procedure-related factors predominantly predicted the occurrence of RAO after TCI. Multiple puncture attempts, use of larger sheath diameter (Supplement Table 1), complex nature of procedure, longer homeostasis time, and forearm hematoma formation were independent predictors for RAO. Similar to our study, multiple puncture attempts for radial artery access are reported to increase vascular injury and radial artery spasm, which leads to radial artery thrombosis (31, 32). Prior studies have also reported that the incidence of RAO progressively increased with sheath size, although results were not consistent in all the studies (3, 9, 10, 21, 22, 26, 31, 33, 34). Furthermore, Rashid et al. (13), in a meta-analysis, have evaluated the effect of sheath size among 19 studies, and the incidence of RAO ranged from nil to 19.5% according to used sheath size (0%, 2%, 11%, and 19.5%, respectively, for sheath size of 4F, 5F, 6F, and 7F, respectively). Complex coronary interventions are characterized by longer procedure time, multiple hardware exchanges, larger size sheath, and catheter use; all these factors lead to increase in endothelial injury and vascular stasis which may lead to RAO (28, 34, 35). Impact of chronic total occlusion and bifurcation coronary interventions in the category of complex procedure, were evaluated in our study for the first time. Minimal possible duration and magnitude of post procedure compression for hemostasis have been shown to be effective for prevention of RAO (36, 37). Similar to our study, other studies have reported a longer hemostasis time as an independent predictor of RAO (17, 38, 39). Post TCI hematoma formation has been shown to have a variable effect on RAO in prior studies, which may be owing to the small number of enrolled patients with hematoma (29, 35).

Adequate procedural anticoagulation and patent hemostasis are the most important reported strategies for prevention of RAO (12, 16, 40). Effect of procedural anticoagulation, specially heparin have been studied in multiple prior studies, and high levels of anticoagulation have been considered protective against RAO. However, results were not consistent across all the studies (13, 16, 41-43). In a meta-analysis of 112 studies assessing radial and/or ulnar artery occlusion rates (n=46,631), low-dose heparin was associated with a significantly higher RAO rate than with high-dose heparin (7.2%; 95% CI: 5.5–9.4 versus 4.3%; 95% CI: 3.5–5.3; p=0.003). Further, the rate of RAO was higher after diagnostic than with interventional coronary procedures. This could potentially be explained by the higher intensity of anticoagulation in the interventional procedures (42). Recently in a prospective, multicenter, ob-

servational cohort registry, Pacchioni et al. (44) reported a U-shaped relationship with activated clotting time value and RAO in 837 patients who underwent transradial coronary diagnostic angiography or interventions. The paradoxical rise in rates of RAO at increasing ACT was explained by mitigation of the protective effect of high anticoagulation level because of longer hemostasis time, more frequent occlusive hemostasis, and decrease in rate of successful patent hemostasis. Our study failed to demonstrate an association between RAO and the dose of heparin. This can be explained by the missing reports for total dose of heparin, rate of successful patent hemostasis, and ACT values.

To the best of our knowledge, we analyzed the largest patient population with post TCI forearm hematoma for its impact on RAO in our study. As in the study by Cuberto et al. (29), an increased rate of RAO in this study can possibly be explained by increased inflammatory response of local tissues and extravascular compression on radial artery by the hematoma. Other procedural factors like type of interventional procedure (diagnostic or therapeutic), periprocedural anticoagulation dose, contrast volume and use of different antiplatelets therapy did not show predictability for RAO in our study.

Study limitations

Our study had certain limitations inherent to the design of a single-center prospective observational study. Long-term follow-up was not done to assess resolution and occurrence of new cases. Preprocedural ultrasonographic examination was not performed for radial artery diameter, and post-procedural ultrasound was done only for patients with abnormal RBT. The precise duration of the procedure was not reported, and radial artery Doppler study was only done in patients who had findings suggestive of RAO on RBT. Operator experience has a significant impact on controlling the procedure-related factors for RAO.

CONCLUSION

Our study reported 12% incidence of RAO in patients who underwent TCI. Procedure-related factors dominantly influenced the incidence of RAO, whereas patient-related factors had minimal influence. Renal impairment should be taken into consideration when planning TCI to avoid the risk of RAO; and use of smaller sheaths, reduction of puncture attempts, and use of femoral access for complex interventions could also play a role in reducing the incidence of RAO. Further studies with a longer duration of follow-up are recommended to assess the long-term outcomes of RAO.

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Supplement Table 1. Bonferroni post-hoc test for multiple comparisons of sheath size and radial artery occlusion

Sheath size	RAO+	RAO-	P-value=0.05/6=0.0083
5F	37 (17.6%)	341 (22.1%)	0.134
6F	166 (79.1%)	1201 (77.8%)	0.689
7F	7 (3.3%)	2 (0.1%)	<0.001

RAO - radial artery occlusion