

Long-Term Radial Artery Patency Following Transradial Coronary Catheterization via a 7-Fr Sheath

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ABSTRACT: **Background:** Radial artery occlusion (RAO) may occur following transradial catheterization, precluding future use of the vessel for vascular access or as a coronary bypass graft. Recanalization of RAO may occur; however, long-term radial artery patency when revascularization is more likely to be required has not been investigated. Transradial catheterization is usually performed via 5-Fr or 6-Fr catheters. Insertion of 7-Fr sheaths into the radial artery enables complex coronary interventions but may increase the risk of RAO.

Objective: To assess the long-term radial artery patency following transradial catheterization via 7-Fr sheaths.

Methods: Antegrade radial artery blood flow was assessed by duplex ultrasound in 43 patients who had undergone transradial catheterization via a 7-Fr sheath.

Results: All patients had received intravenous unfractionated heparin with a mean activated clotting time (ACT) of 247 ± 56 seconds. Twenty-four patients (56%) had received a glycoprotein IIb/IIIa inhibitor and no vascular site complications had occurred. Mean time interval from catheterization to duplex ultrasound was 507 ± 317 days. Asymptomatic RAO was documented in 8 subjects (19%). Reduced body weight was the only significant univariate predictor of RAO (78 ± 11 vs. 89 ± 13 kg, $P = 0.031$). In a bivariate model using receiver operator characteristic (ROC) curves, the combination of lower weight and shorter ACT offered best prediction of RAO (area under the ROC curve 0.813).

Conclusions: Asymptomatic RAO was found at late follow-up in approximately 1 of 5 patients undergoing transradial catheterization via a 7-Fr sheath and was associated with lower body weight and shorter ACT.

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is usually asymptomatic due to preserved palmar perfusion via the ulnar artery and the interosseous vessels; however, it may preclude future use of the radial artery for vascular access or as a coronary bypass graft [4]. The frequency of RAO following TRA procedures varies according to the diagnostic method used to detect it and the time interval between the procedure and testing, since recanalization of the occluded radial artery may occur spontaneously or following anticoagulant therapy [5-7]. Long-term patency of the radial artery, at a time when the vessel may be required as an access site for repeat catheterization or as a coronary bypass graft, is clinically more important than short-term patency. Patency at late time points following TRA procedures, however, has not been investigated.

While transradial procedures are usually performed via 5-Fr or 6-Fr sheaths, insertion of larger-bore catheters may be required for complex coronary interventions such as treatment of bifurcations or thrombus aspiration [8]. It has been suggested that the size mismatch between a 7-Fr sheath and the relatively small diameter of the radial artery might traumatize the vessel wall and increase the likelihood of RAO [6,9-12]. The purpose of the present study was to document the long-term effect of insertion of 7-Fr sheaths on radial artery patency.

PATIENTS AND METHODS

Consecutive patients who had undergone TRA diagnostic coronary angiography or PCI via a 7-Fr sheath were identified from our prospective institutional catheterization laboratory database. Subjects were contacted and invited to a follow-up clinic where they completed a questionnaire relating to post-procedural vascular complications and underwent assessment of radial artery patency. Demographic and clinical variables were collected from the computerized database. The study protocol was approved by the institutional review board. Signed informed consent was obtained from each patient.

TRANSRADIAL PROCEDURE

In all patients dual palmar blood supply had been confirmed prior to the procedure with the Barbeau test in which a plethysmography signal was documented from a pulse oximeter placed on the patient's thumb during manual compression of the radial artery. Radial artery access was achieved following

Transradial access (TRA) for coronary catheterization and percutaneous coronary intervention (PCI) offers significant advantages compared to the transfemoral approach, namely decreased bleeding complications [1], increased patient comfort [2], earlier ambulation [3] and reduced costs [2]. Radial artery occlusion (RAO) is a complication of TRA procedures which

administration of local anesthesia with subcutaneous injection of 2% lidocaine. The radial artery was punctured with a 21 gauge needle followed by insertion of a 0.018" wire over which a 5-Fr 10 cm long sheath was introduced (Micropuncture Introducer Set, Cook Medical, USA). A 0.035" wire was then advanced to the brachial artery under fluoroscopy and a 7-Fr sheath (Radiofocus, Terumo, Japan) was inserted. All patients received an intra-arterial bolus of 5 mg verapamil and an intravenous bolus of 60 U/kg unfractionated heparin. Activated clotting time (ACT) was checked routinely. A glycoprotein IIb/IIIa inhibitor was administered selectively to patients who underwent PCI. At the end of the procedure the 7-Fr sheaths were removed immediately and radial artery hemostasis was achieved with a local compression device that was placed according to the manufacturer's instructions (TR Band, Terumo, Japan). The TR Band was applied with occlusive compression, slow removal of air until bleeding occurred, and then re-insufflation of 1 to 2 ml of air. Gradual decompression and complete release of the TR band were performed over 2–4 hours post-procedure.

STUDY ENDPOINT

The study endpoint was documentation of antegrade blood flow within the radial artery by duplex ultrasound (Sonos 5500 vascular probe 3-10 MHZ linear array transducer, Agilent Technologies, Palo Alto, CA, USA) by an experienced operator (S.A.).

STATISTICAL METHODS

Statistical analysis was performed using IBM SPSS 21 statistical software. Data were tested for normal distribution and presented as mean ± SD. Categorical variables were expressed as percentages and examined using chi-square or Fisher's exact test as appropriate. Continuous variables were examined with binary logistic regression. A bivariate model was constructed from the two most significant explanatory variables and discrimination of the individual and combined variables was examined using receiver operator characteristic (ROC) curves. All tests of significance were two-sided and a probability of < 0.05 was considered significant.

RESULTS

We identified 104 patients from our prospective catheterization laboratory database who had undergone transradial catheterization via a 7-Fr sheath at the Carmel Medical Center over a period of 4 years. Forty-three of these patients were available for follow-up. Demographic and clinical patient characteristics are detailed in Table 1. Mean age was 65 ± 10 years and 42 (98%) of the subjects were male. Procedural characteristics are detailed in Table 2. A 7-Fr sheath was used for facilitated thrombus aspiration in 26 patients (60%) with acute myocardial infarction and for facilitating complex bifurcation stenting in

Table 1. Demographic and clinical characteristics examined as predictors of radial artery occlusion

	Radial artery occlusion (N=8)	Patent radial artery (N=35)	P value
Age (years)	61 ± 6	64 ± 11	0.405
BMI	26 ± 3	29 ± 4	0.074
Weight (kg)	78 ± 11	89 ± 13	0.031
Height (cm)	172 ± 5	174 ± 8	0.317
Diabetes mellitus	3 (37)	13 (37)	0.985
Hypertension	5 (50)	27 (77)	0.123
Smoking history	5 (50)	19 (54)	0.826
Acute ST-elevation MI	7 (87)	19 (54)	0.098
Ejection fraction	52 ± 9	56 ± 9	0.387
Creatinine clearance (ml/min)	91 ± 21	96 ± 26	0.657
Hemoglobin (g/dl)	14 ± 1	15 ± 2	0.721
Platelet count (x1000/ml)	251 ± 40	201 ± 60	0.072
Cholesterol (mg/dl)	173 ± 36	165 ± 30	0.538
Time interval from TRA to duplex sonography (days)	789 ± 431	568 ± 277	0.075

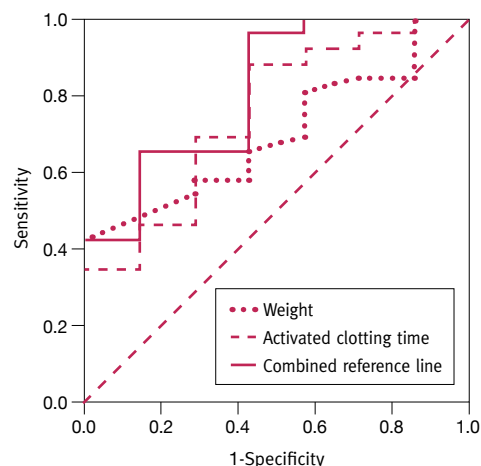
BMI = body mass index, MI = myocardial infarction, TRA = transradial access

Table 2. Procedural variables examined for prediction of radial artery occlusion

	Radial artery occlusion (N=8)	Patent radial artery (N=35)	P value
Percutaneous coronary intervention	6 (75)	26 (74)	0.967
Heparin dose (IU)	4375 ± 1250	4567 ± 1424	0.800
Activated clotting time (sec)	219 ± 43	263 ± 55	0.061
Glycoprotein IIb/IIIa inhibitor	6 (75)	18 (51)	0.226
Fluoroscopy time (sec)	12 ± 4	11 ± 6	0.720
Contrast volume (ml)	191 ± 40	153 ± 64	0.117

the remainder. In all cases the radial artery had not been used previously for vascular access. Mean ACT was 247 ± 56 seconds and 24 patients (56%) received a glycoprotein IIb/IIIa inhibitor. There were no periprocedural vascular site complications. Mean time interval from the procedure to follow-up examination was 507 ± 317 days. The radial artery was patent in 35 (81%). All 8 cases of RAO (19%) were asymptomatic. Lower body weight was the only nominally significant univariate predictor of radial artery occlusion (78 ± 11 vs. 89 ± 13 kg, P = 0.031) whereas a shorter ACT tended towards significance (219 ± 43 vs. 263 ± 55 seconds, P = 0.061). The area under the ROC curve (c statistic) was greater for the combined variable of body weight and ACT (0.813), indicating better discrimination of the combined variable for RAO than either variable alone (lower weight 0.698, lower ACT 0.753) [Figure 1].

Figure 1. Receiver operator characteristic curves of weight and activated clotting time and the combined variable for prediction of radial artery occlusion



DISCUSSION

We studied late patency of the radial artery in a cohort of patients who had undergone TRA catheterization via a 7-Fr sheath and found RAO in approximately 1 in 5 subjects, which was asymptomatic in all cases.

Radial artery occlusion may occur following TRA procedures and precludes future use of the vessel as an access site for percutaneous catheterization and intervention or as a surgical coronary bypass graft [4]. RAO is usually asymptomatic if dual palmar blood supply via the radial and ulnar arteries is confirmed before the procedure. Frequency of RAO depends on the diagnostic method used to detect it as well as the time interval between the TRA procedure and testing of radial artery patency. A palpable radial pulse does not rule out RAO since retrograde filling of an occluded vessel from the ulnar artery via the palmar vessels can occur [6]. Visualization of antegrade blood flow by duplex ultrasound is the definitive non-invasive test for demonstration of radial artery patency. Pathophysiology of RAO is believed to be due to a thrombotic process, and recanalization of RAO may occur spontaneously or following anticoagulant therapy. Sanmartin et al. [13] reported renewed patency at 1 week in approximately half the arteries found to be occluded immediately after removal of hemostatic compression [13]. Other studies reported renewed patency in approximately 50% of occluded arteries from 1 to 30 days post-procedure [5,7,14]. Long-term radial artery patency following TRA procedures may be more clinically important than short-term patency since it determines the suitability of the vessel for future vascular access or as a coronary bypass graft; however, radial artery patency at time intervals longer than 1 month post-procedure has not been studied.

Factors reported to increase the rate of RAO include application of occlusive post-procedural hemostatic compression [13,14], increased duration of hemostatic compression [7], and insufficient anticoagulation [15]. Larger sheath size may traumatize the wall of the radial artery and increase the likelihood of RAO [16]. In a non-randomized registry of patients undergoing TRA catheterization in whom radial artery patency was assessed 1 day post-procedure by duplex sonography, insertion of 6-Fr sheaths increased the occurrence of RAO from 14% to 30% compared to 5-Fr sheaths [12]. However, most of the subjects received a low dose of unfractionated heparin (2500 IU), and activated clotting time was not reported. Low molecular weight heparin, which was administered post-procedure to most of the patients with RAO, was associated with a recanalization rate of 56% two weeks later compared to 13% in RAO patients who did not receive anticoagulation. In a randomized trial of patients undergoing TRA catheterization in whom radial artery patency was assessed 1 month post-procedure, insertion of 6-Fr sheaths increased occurrence of RAO from 1.1% to 5.9% compared to 5-Fr sheaths [10]. However, the rate of RAO in this study may have been underestimated since ultrasound examination was reserved for patients without a palpable radial pulse, potentially missing cases in which an occluded radial artery was filled retrogradely via the palmar arch [6]. In a series of patients who underwent TRA procedures via 7-Fr or 8-Fr sheaths in whom angiographic evaluation of the radial artery anatomy was performed routinely prior to insertion of the large bore sheaths, RAO was reported in 10% [11]. However, RAO was diagnosed by physical examination without ancillary testing in the majority of subjects, the time interval from the TRA procedure to assessment of radial artery patency was not reported, and angiography of the radial artery may have prevented insertion of large bore in patients with unsuitable anatomy. Conversely, in the present study long-term patency of the radial artery following TRA via a 7-Fr sheath (averaging more than a year following the procedure) was assessed uniformly with duplex ultrasound.

LIMITATIONS

This single-center study was non-randomized, potentially leading to selection bias with exclusion of patients deemed clinically to have small radial arteries. Nonetheless, the study is unique due to the long-term follow-up and uniform assessment of radial artery patency by duplex ultrasound. In the present cohort the TR Band was applied with occlusive compression according to the manufacturer's instructions without emphasis on the technique of patent hemostasis which may have increased the rate of RAO [14]. The small sample size implies the need for larger confirmatory studies.

CONCLUSIONS

Asymptomatic radial artery occlusion was found at late follow-up in approximately 1 in 5 patients undergoing transradial

catheterization via a 7-Fr sheath and was associated with lower body weight and shorter ACT. The findings emphasize the need to maintain adequate anticoagulation during TRA procedures and suggest that femoral vascular access should be considered when there is need for insertion of large-bore sheaths in patients with low body weight.

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