Abstract

Background: Transradial coronary catheterization has already become popular in clinical practice. Radial artery occlusion (RAO) is an infrequent but discouraging complication of transradial access. Despite this complication is usually asymptomatic and clinically silent, it limits future transradial access. It seems that the presence of anterograde flow in the artery during hemostasis (patent hemostasis) plays a preventive role for arterial occlusion.

Objectives: The aim of this study was to compare conventional versus patent hemostasis after transradial coronary angiography regarding the access site complications especially RAO.

Methods: The present study was designed as a prospective randomized, parallel, open-label clinical trial which was conducted on consecutively adult patients scheduled to undergo a diagnostic or therapeutic transradial coronary procedure at Bu-Ali Sina and Mehregan Hospitals (Qazvin, Iran) based during 3 months' period between March 2021 and May 2021. The number 200 patients divided randomly into two groups, including conventional hemostasis group and patent hemostasis group. The incidence of RAO at discharge were evaluated in both groups as the primary endpoint, and we considered other access site complications as the secondary endpoints.

Results: The mean age of the patients was 61.60±10.45 (range 34-86) years, and gender distribution (male/female) of the patients was 119/76. The baseline characteristics were similar in the two study groups. RAO at discharge in patent hemostasis group with a frequency of two cases (2.02%) was significantly less than conventional hemostasis group with a frequency of nine cases (9.37%) (P= 0.02). Furthermore, demographic, clinical, and procedural variables were not found to be associated with RAO.

Conclusion: Our study clearly demonstrated that patent haemostasis is highly effective in reducing radial artery occlusion after Transradial coronary catheterization

Keywords: Coronary artery disease, Transradial angiography, Radial artery occlusion, Patent hemostasis

1. Background

Previously, the femoral artery was the main access routes for coronary angiography or angioplasty, and the greater number of coronary procedures were done by this way (1). It had gained widespread acceptance because of some advantages like a long history of use, coupled with technical ease, and the capacity for interventionists to apply larger catheters. However, transfemoral approach have some vascular complications which are inherent with this type of access. These include pseudoaneurysm, arteriovenous fistula, and significant bleeding, including retroperitoneal hematomas (2). In 1989, Campeau (3) initially described the radial artery approach for performing coronary angiography, and a few years later in 1993, the technique was proposed for percutaneous coronary intervention (PCI) and stent implantation by Kiemeneij and Laarman (4). Afterwards, transradial approach for coronary procedures gradually diffused supported by a growing body of evidence, and became the most favorable between interventional cardiologists (5-7). Indeed, in 2015, 80% of percutaneous coronary interventions were performed through the radial route in the UK (8).

The location of radial artery is more superficial than femoral artery that allows an easier localization and compression. Moreover, there isn't any major vein and nerve or damageable structures located near the radial artery at the wrist, so the chance of neurological or vascular damage is very low (9). As compared to the conventional femoral approach, the radial approach is associated lower puncture site complications and accelerates mobilization and ambulation of the patients post procedure and thereby significantly reducing the length of hospital stay, and consequently decreases costs (10, 11). On the contrary, there are potential disadvantages to the radial approach including vessel spasm is more common, and guide placement is more challenging and needs a longer learning curve for operators (12, 13). Nevertheless, the transradial approach has become the prior route for diagnostic and therapeutic coronary procedures in current guidelines (14, 15). In addition, a systematic review article that enrolled 31 studies (44 reports) including 27,071 and assessed the benefits and harms of the radial vs. femoral artery approaches during diagnostic coronary angiography and PCI demonstrates a lower risk of all-cause mortality and access site complications with transradial access (16).

Radial artery occlusion (RAO) is an infrequent but discouraging complication after TRA that occurs in about 1 to 10% of cases (17-19), and has been described as the "Achilles' heel" of the transradial approach. This complication is usually asymptomatic and clinically silent in the acute setting due to the rich network of collateral circulation (20). Pathophysiology of RAO is thrombus formation in the radial artery lumen. However, the radial artery recanalizes spontaneously in many patients, but it can cause hand ischemia and even amputation in some patients has been reported (21-23). Moreover, its occurrence makes it impossible to use the radial artery as an access site for repeat catheterization or as a free graft for patients undergoing myocardial revascularization (21) .

According to the previous studies, several factors play role in developing RAO. Among some of the procedure-related factors are incompatibility between the diameter of the introducer sheath and diameter of the radial artery, insufficient anticoagulation, prolonged cannulation times, complete vessel occlusion during postprocedural care, and recurring procedures (24-26). In addition, some factors like diabetes, low body weight, peripheral arterial disease, smoking, and small radial artery diameter are considered as patient- and disease- related risk factors of RAO (27, 28). On the other hand, the presence of anterograde flow in the artery during hemostasis (patent hemostasis), the reduction in compression time, and the use of hemostatic devices to compression of the puncture site of the radial artery are preventive factors for RAO (17, 29).

There are several methods which can used for hemostasis of the radial artery after sheath removal (30). These include manual pressure and a pressure bandage, or several types of compression devices have been used (including; Radistop, TR band, Tourniquet, etc), and proved effective and safe. Patent hemostasis is a strategy that consists of providing distal blood flow to the hand during arterial compression, and it seems that maintaining the patency of the radial artery can reduce the risk of RAO (18, 31). The TR Band (Terumo Inc., Tokyo, Japan) is now used in Iran to assist us to be sure that we are properly doing patent hemostasis after a transradial procedure. In regard to the important of choosing the best approach for hemostasis, our aim of this randomized trial was to compare conventional versus patent hemostasis after transradial coronary angiography regarding the access site complications.

2. Methods

2-1. Trial design

The present study was designed as a prospective randomized, parallel, open-label clinical trial which was conducted to compare the complications of two hemostasis methods (conventional and patent) after transradial angiography. We recruited consecutively patients scheduled to undergo diagnostic or therapeutic interventional cardiology procedures through the radial artery approach at Bu-Ali Sina and Mehregan Hospitals (Qazvin, Iran) based on below eligible criteria during 3 months' period between March 2021 and May 2021.

2.2. Participants

Adult patients scheduled to undergo a diagnostic or therapeutic transradial coronary procedure were enrolled into the study. We excluded patients with coagulation disorders as well as hand anatomic disorders, and those who had a D pattern on Barbeau's test (loss of tracing without reestablishment of the curve on the oximeter screen). Moreover, in the case of failure in angiography or changes in angiography technique for any reason, and tendency to leave the study for any reason were excluded from the study.

2.3. Ethical issues

The study protocol was approved by the institutional review board (IRB) of Qazvin University of Medical Sciences and the approval of the Ethics Committee was achieved before the study was commenced. All the participants gave their informed written consent. Moreover, the study protocol was registered at Iranian registry of clinical trials (www.IRCT.IR) under the registration number of IRCT20210305050585N1.

2.4. Intervention

Before the catheterization, Barbeau's test was done to ensure the function of collateral arteries. The catheterization was done using French gauge sheath size 6 sheath and guidewire trauma on right radial artery and 200 µ nitroglycerin, and 70 units/kg heparin (maximum 7000 units) were injected through the sheath, and then angiography was performed using 6F catheter.

At the end of the procedure, the introducer sheaths was immediately removed. The sheath was pulled out 4–5 cm and a TR band was fasten around the wrist. The TR band was inflated with 13 ml of air after which the sheath was completely pulled out, so that blood flow of the radial artery was completely stopped. After that, the patients were randomized into two groups, and a pulse oximeter sensor was placed over the index finger in the both groups.

In the patients of the first group (conventional hemostasis method), air pressure of TR band was gradually deflated to start blood oozing from the puncture site, then 2 cc of air was added to the previous amount (for example, by reducing 3 cc of air began to bleed that means bleeding is occurred in 10 cc of air, and after adding 2 cc of air, TR band was kept in 12 cc of air). After that, we manually compressed the ulnar artery from above of TR band to check the presence or absence of the pulse waveform on the pulse oximetry monitor. In the second group (patent hemostasis method), we manually compressed the ulnar artery from above of TR band until the pulse waveform disappears on the pulse oximetry monitor. Then, air pressure of TR band was gradually deflated till plethysmographic signal returned on the pulse oximeter (confirming radial artery patency), and air pressure of TR band was kept constant at that level of air pressure. After 2 hours of compression, the TR cuff was deflated gradually (2 ml every 30 minutes) in both groups until the band came off and no active bleeding was detected. After complete removal of the TR band, the puncture site was covered with a light dressing including bandage, gauze, and tape, and then Barbeau's test was performed to look for any immediate occlusion.

2.5. Outcomes

Demographic and clinical data including age, gender, body mass index (BMI), and details on patients' medical history were obtained by a date gathering form. Procedural data including number of catheters, kind of procedures (diagnostic or therapeutic), procedure duration, total time for TR band removal were also recorded. The primary outcome was the incidence of RAO at discharge. In addition, we considered other access site complications at discharge including hematoma, bleeding, and feeling numbness as secondary outcomes. The complications were assessed at discharge by using a checklist. Radial artery patency was assessed using Barbeau's test. If it was suspected to RAO, the patients underwent Doppler ultrasonography for confirming RAO.

2.6. Randomization

Randomization was done using a randomization table based on the registration number of the patients (on the order of referral).

2.7. Statistical analyses

All statistical analyses were performed using the SPSS software (SPSS Inc. Version 22.0. Chicago, Illinois, USA). The sample size was calculated as 90 patients in each group using sample size formula for comparing and taking into account the 95% confidence level, 80% statistical power, prevalence of TRA complications which approximately estimated as 18%, and the least significant difference between the two methods of hemostasis that was considered equal to 2.0. To compensate for possible missing patients and those who would possibly exit the study, we enrolled 100 patients in each group. Values were expressed as mean ± standard deviation (SD) for the quantitative variables and percentages for the categorical variables. The distribution of variables was analyzed with Kolmogorov-Smirnov test. Student t test was used for normally distributed data and Mann–Whitney U test was used for non-normally distributed data. Chi-square test was used for categorical values. Moreover, bivariate correlation was done to determine the role of demographic and clinical variables on the incidence of RAO. A p value <0.05 was considered significant. A two-sided P value <0.05 was considered statistically significantly.

3. Results

Out of the 200 consecutive hospitalized patients were assessed for eligibility, two did not meet the inclusion criteria due to a previous ipsilateral transradial procedure. Thus, the final number of patients being randomized into two study groups was 198. The procedure failed in three patients in conventional hemostasis group, and finally we enrolled 96 patients in the conventional hemostasis group and 99 patients in the patent hemostasis group (Figure 1).

The mean age of the patients was 61.60±10.45 (range 34-86) years, and gender distribution (male/female) of the patients was 119/76. PCI prevalence was 33.8% (66 patients) and the other 129 patients received only coronary angiography. The demographic and clinical features of both groups are summarized in Table 4-1. No significant differences were observed between two study groups in regards to age, gender, body mass index (BMI), number of catheters during procedure, procedure duration, hemostatic compression time, prevalence of PCI, and risk factors such as history of smoking, diabetes, hypertension, lipid disorders ($P > 0.05$).

RAO at discharge in conventional hemostasis group with a frequency of nine cases (9.37%) was significantly more than patent hemostasis group with a frequency of two cases (2.02%) ($P = 0.02$). However, the frequency distribution of other access site complications such as bleeding in the first hour of TR band removing and hematoma formation at discharge in conventional hemostasis group were 4 (4.16%) and thirteen cases (13.54%) and in patent hemostasis group were 4 (4.04%) and eleven cases (11.11%), respectively, which the occurrence of these complications had no significant difference between the two groups ($P > 0.05$). All the bleeding episodes were very mild oozing without required transfusions, and all the hematomas were small (<1 cm). Moreover, feeling numbness was experienced by three patients (3.12%) in conventional hemostasis group, and it was in 1 patients (1.01%) in patent hemostasis group, and was not significantly different between the two groups ($P=0.29$). Table 2 represents comparing the access site complications of the patients between two study groups.

A separate analysis was performed on patients by dividing the population into those who developed RAO versus those who did not. This was done to evaluate the role of demographic and clinical factors and procedural variables on the incidence of RAO. Bivariate analysis was done on all variables for the entire population. The results showed that patient's age, BMI, procedure duration, and total time for TR band removal didn’t have a significant role on the incidence of RAO ($P > 0.05$). Moreover, no statistically significant difference was found in the distribution of gender, PCI, number of catheters, hypertension, diabetes mellitus, dyslipidemia, and smoking. These findings are shown in Table 3.

In another analysis, we compared the rate of access site complications in conventional group between the patients with or without waveform on the pulse oximetry after ulnar compression. Of 96 patients with conventional hemostasis, 42 (43.75%) had waveform on the pulse oximetry after ulnar compression. Overall, there aren't any significant difference between two groups regarding access site complications. Although the incidence of RAO in those who had waveform after ulnar compression was lower than those without waveform, but the different wasn't statically significant [3 (7.14%) vs. 6 (11.11%); P=0.51]. Table 4 represents comparing the rate of access site complications between the groups.

4. Discussion

In recent years, the radial artery approach has become the standard mode of access for cardiac catheterization in many countries (14, 15). The advantages of TRA have been mentioned in several studies. These advantages include less bleeding, lower puncture site complications, early ambulation, higher patient satisfaction, reducing the costs and length of hospital stay, and easy access for the cases with myocardial infarction and aortic aneurysm (10, 11). However, RAO remains the silent protagonist in radial approach, restricting subsequent use of the radial artery for future procedures (32). Among the several strategies used to prevent RAO, recent data suggest that patent hemostasis, shorter compression time, and higher dose of heparin independently appear to reduce RAO (18).

In the present study we compared conventional and patent hemostasis of the radial artery after transradial coronary angiography regarding access site complications. At discharge, the incidence of RAO was 2.02% in patent hemostasis group against 9.37% in conventional group, so the RAO rate in patent hemostasis was significantly lower than it in conventional hemostasis. This finding is consistent with previous studies. In a trial conducted by Pancholy et al. 436 patients undergoing TRA, and randomized into 2 groups of hemostasis (conventional and patent) (33). Their results demonstrated that lower rate of RAO after transradial operation in patent hemostasis group. Finally they concluded that patent hemostasis is highly effective in reducing RAO. In another study, Roghani and collogues evaluated the efficacy of hemostasis with patency in avoiding RAO after transradial catheterization (34). They involved 60 patients in each group, and found that the incidence of RAO was considerably lower in patent groups (3.3%) compared with traditional group (13.3%). Furthermore, we found that no significant differences were observed regarding hematoma, bleeding, or numbness rates between the two study groups. Our data indicated that

11.11% of patients developed hematoma, 1.01% developed numbness, and 4.04% have bleeding with patent hemostasis method. This finding was along with the results from previous studies (34, 35).

Regarding to our assessment for other predictors of RAO, none of the demographic, clinical, and procedure variables were related to occlusion. Therefore, patent hemostasis was independently associated with lower incidence of RAO at discharge, with adjustment for possible confounding variables relative to RAO incidence. This was in contrast with the results from the previous mentioned trial. Age and hypertension had a significant role on RAO incidence in a trial conducted by Roghani et al (34). In another trial, Desai and colleagues observed that only age, and the radial artery diameter are the predictors of RAO (35).

Up to now no study has investigated the presence of waveform on the pulse oximetry after ulnar compression in conventional hemostasis while the TR band had been inflated. This study revealed that pulse oximetry did not show any curve after ulnar artery compression in less than 50% of the patients in conventional group, so there is no patency in more than 50% patients in conventional method. As a new finding, our results demonstrated that the rate of RAO in those who had waveform after ulnar compression was lower than those without waveform the pulse oximetry after ulnar compression; however the different wasn't statically significant. It may be due to a rich network of collateral circulation of the radial artery which can a vital role in prevention of radial artery occlusion.

There were a number limiting factors diminishing the impact of results, of which the open-label design, and a small proportion of PCI among the study patients. In addition, the only serious concern raised in this trial was that we didn't have no a 30-day follow-up for reassessment the patients regarding RAO. However, early occlusion was more frequent than late occlusion in previous studies. We suggest that future trials with a 30-day follow-up using Doppler ultrasonography are required to assess late occlusion.

Conclusion

In conclusion, this study suggests that patent hemostasis after TRA is more safe than conventional hemostasis with respect to access site complications especially RAO, without compromising hemostatic efficacy.

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Table 1. Baseline characteristics in two study groups

Variables	Conventional hemostasis (n=96)	Patent hemostasis (n=99)	P value
Demographics			
Age (years)	60.39±10.43	62.79±10.39	0.12
Gender (male/female)	58/38	61/38	0.86
BMI (kg/m^2)	27.37±4.51	28.06±4.08	0.27
Procedural data			
Number of catheters			0.36
1	49 (51.04%)	57 (57.57%)	
2 or 3	47 (48.95%)	42 (42.42%)	
Procedure duration (min)	28.57±21.36	28.87±21.22	0.92
Hemostatic compression time (min)	157.11±31.98	159.25±34.69	0.65
PCI (n, %)	34 (35.41%)	32 (32.32%)	0.64
Risk factors			
Hypertension (n, %)	72 (75%)	73 (73.73%)	0.84
Diabetes mellitus (n, %)	35 (36.45%)	49 (49.49%)	0.06
Dyslipidemia (n, %)	49 (51.04%)	45 (45.45%)	0.43
Cigarette smoking (n, %)	30 (31.25%)	25 (25.25%	0.35

BMI: body mass index; **PCI:** percutaneous coronary intervention.
*Values are mean ± standard deviation, or n (%).

Table 2. Comparing the access site complications of the patients between two study groups

Variables	Conventional hemostasis (n=96)	Patent hemostasis (n=99)	P value
Hematoma	13 (13.54%)	11 (11.11%)	0.58
Bleeding	4 (4.16%)	4 (4.04%)	0.95
Feeling numbness	3 (3.12%)	1 (1.01%)	0.29
Radial artery occlusion	9 (9.37%)	2 (2.02%)	<u>0.02</u>

Table 3. Results of Bivariate comparison of patients with or without Radial Artery Occlusion

Variables	Occluded Radial artery (n=11)	Non-occluded Radial artery (n=184)	P value
Age (years)	59.67±9.63	61.67±10.52	0.56
BMI (kg/m^2)	26.05±4.25	27.82±4.29	0.18
Gender (female)	7 (63.63%)	68 (36.95%)	0.08
Number of catheters			0.06
1	9 (81.81%)	96 (52.17%)	
2 or 3	2 (18.18%)	87 (47.28%)	
Procedure duration (min)	22.72±15.22	29.21±21.54	0.32
Hemostatic compression time (min)	158.18±19.41	158.17±33.99	0.99
PCI (n, %)	2 (18.18%)	64 (34.78%)	0.25
Hypertension (n, %)	8 (72.72%)	137 (74.45%)	0.87
Diabetes mellitus (n, %)	6 (54.54%)	78 (42.39%)	0.44
Dyslipidemia (n, %)	6 (54.54%)	88 (47.82%)	0.66
Cigarette smoking (n, %)	5 (45.45%)	50 (27.17%)	0.19

BMI: body mass index; **PCI:** percutaneous coronary intervention.
*Values are mean ± standard deviation, or n (%).

Table 4. Comparing the rate of access site complications between the patients with and without waveform on the pulse oximetry after ulnar compression

Variables	**Waveform on the pulse oximetry** (n=42)	**Flat on the pulse oximetry** (n=54)	**P value**
Hematoma	8 (19.04%)	5 (9.25%)	0.16
Bleeding	1 (2.38%)	3 (5.55%)	0.44
Feeling numbness	2 (4.76%)	1 (1.85%)	0.41
Radial artery occlusion	3 (7.14%)	6 (11.11%)	0.51