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Original Article

Conventional vs Patent Hemostasis of the Radial Artery After Transradial Coronary Angiography: A Randomized Clinical Trial

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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. Anterograde flow in the artery during hemostasis (patent hemostasis) may prevent arterial occlusion. This study aimed to compare conventional vs patent hemostasis after transradial coronary angiography regarding access site complications, especially RAO.

Methods: A prospective randomized, parallel, open-label clinical trial 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) during a 3-month period between March 2021 and May 2021. Two hundred patients were divided randomly into conventional hemostasis and patent hemostasis groups. The incidence of RAO at discharge was evaluated in both groups as the primary endpoint, and other access site complications were considered the secondary endpoints.

Results: The mean age of the patients was 61.60 ± 10.45 (range = 34-86) years, and the sex distribution (male/female) of the patients was 119/76. The baseline characteristics were similar in the 2 study groups. RAO at discharge was significantly less frequent in the patent hemostasis group (2 patients [2.02%]) than in the conventional hemostasis group (9 patients [9.37%]) (P = 0.02). Furthermore, demographic, clinical, and procedural variables were not associated with RAO.

Conclusions: Our study clearly demonstrated that patent hemostasis was highly effective in reducing RAO after transradial coronary catheterization. ***(Iranian Heart Journal 2024; 25(1): 56-65)***

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

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In 1989, Campeau [1] described the radial artery approach for performing coronary angiography. A few years later, in 1993, the technique was proposed for percutaneous coronary intervention (PCI) and stent implantation by Kiemeneij and Laarman. [2] Afterward, the transradial approach for coronary procedures was supported by a growing body of evidence and became the most favorable among interventional cardiologists. [3-5]

Compared with the conventional femoral approach, the radial approach is associated with low puncture site complications and accelerated mobilization and ambulation of patients postprocedurally, significantly reducing the length of hospital stay and costs. [6, 7] On the other hand, potential disadvantages to the radial approach include vessel spasms and challenging guide placement, necessitating a longer learning curve for operators. [8, 9] Nevertheless, the transradial approach has become the prior route for diagnostic and therapeutic coronary procedures in the current guidelines. [10, 11]

Radial artery occlusion (RAO) is an infrequent but discouraging complication after TRA that occurs in about 1-10% of cases [12-14] 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. [15] The pathophysiology of RAO is thrombus formation in the radial artery lumen. The radial artery recanalizes spontaneously in many patients, but it can cause hand ischemia and even amputation. [16-18] 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. [16]

Previous studies have shown that several factors contribute to RAO development. Among procedure-related factors are incompatibility between the diameter of the introducer sheath and the diameter of the radial artery, insufficient anticoagulation, prolonged cannulation times, complete vessel occlusion during postprocedural care, and recurring procedures. [19-21] In addition, factors such as diabetes, low body weight, peripheral arterial disease, smoking, and small radial artery diameters are considered patient- and disease-related risk factors of RAO. [22, 23] On the other hand, the presence of anterograde flow in the artery during hemostasis (patent hemostasis), the reduction in the compression time, and the use of hemostatic devices to compress the puncture site of the radial artery are preventive factors for RAO. [12, 24]

Several methods can be used effectively for the hemostasis of the radial artery after sheath removal, [25] including manual pressure, pressure bandages, and compression devices (eg, the RadiStop, the TR Band, and tourniquets). Patent hemostasis is a strategy that provides distal blood flow to the hand during arterial compression, and maintaining the patency of the radial artery might reduce the risk of RAO. [13, 26] Still, controversy persists regarding how to apply patent hemostasis and the role of the presence of waveform on pulse oximetry. The TR Band (Terumo Inc, Tokyo, Japan) helps ascertain successful patent hemostasis following a transradial procedure. Given the significance of choosing the best approach for hemostasis, the aim of the present randomized trial was to compare conventional vs patent hemostasis after transradial coronary angiography vis-à-vis the access site complications and to determine the role of the presence or absence of waveform on pulse oximetry in the incidence of access site complications.

METHODS

Trial Design

The present study was designed as a prospective randomized, parallel, open-label

clinical trial to compare the complications of 2 hemostasis methods, namely conventional and patent, after transradial angiography. Patients scheduled to undergo diagnostic or therapeutic interventional cardiology procedures through the radial artery approach at Bu-Ali Sina and Mehregan hospitals (Qazvin, Iran) were recruited consecutively based on the study's eligibility criteria during a 3-month period between March 2021 and May 2021.

Participants

Adult patients scheduled to undergo a diagnostic or therapeutic transradial coronary procedure were enrolled in the study. Exclusion criteria were coagulation disorders, anatomic disorders of the hand, and a D pattern on the Barbeau test (loss of tracing without the reestablishment of the curve on the oximeter screen). Moreover, failure in angiography, changes in the angiography technique for any reason, and the decision to leave the study for any reason were the other exclusion criteria.

Ethical Considerations

The study protocol was approved by the institutional review board of Qazvin University of Medical Sciences, and the approval of the Ethics Committee was obtained before the study commencement. All the participants gave their informed written consent. Additionally, the study protocol was registered at the Iranian Registry of Clinical Trials (www.IRCT.IR) (registration number: IRCT20210305050585N1).

Intervention

Before catheterization, the Barbeau test was done to ensure the function of the collateral arteries. Catheterization was performed using 6-Fr gauge sheaths. In addition, 200 μ of nitroglycerin and 70 U/kg of heparin (maximum 7000 units) were injected through the sheath, and then angiography was performed using 6-Fr catheters.

At the end of the procedure, the introducer sheaths were immediately removed. The TR Band was fastened around the wrist after pulling out the sheath 4-5cm. The TR Band was inflated with 13 mL of air, and the sheath was completely withdrawn so that blood flow of the radial artery was completely stopped. Afterward, the patients were randomized into 2 groups, and a pulse oximeter sensor was placed over the index finger in both groups.

In the conventional hemostasis method, the air pressure of the TR Band was gradually deflated to start blood oozing from the puncture site. Subsequently, 2 mL of air was added to the previous amount. Next, the ulnar artery was manually compressed from above the TR Band to check the presence or absence of the pulse waveform on the pulse oximetry monitor. In the patent hemostasis method, the ulnar artery was manually compressed from above the TR Band until the pulse waveform disappeared on the pulse oximetry monitor. In the next stage, the air pressure of the TR Band was gradually deflated until plethysmographic signals returned on the pulse oximeter (confirming radial artery patency). The air pressure of the 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. Following the complete removal of the TR Band, the puncture site was covered with light dressing, including bandage, gauze, and tape, and then the Barbeau test was performed to look for any immediate occlusion.

Outcomes

The study population's demographic characteristics and clinical data including age, sex, body mass index (BMI), and detailed medical history were obtained with

a data-gathering form. Procedural data, composed of the number of catheters, the type of procedure (diagnostic or therapeutic), the duration of the procedure, and the total time for TR Band removal were also recorded. The primary outcome was the incidence of RAO at discharge. In addition, other access site complications at discharge, including hematomas, bleeding, and numbness, were considered secondary outcomes. Complications were assessed at discharge by using a checklist. Radial artery patency was assessed via the Barbeau test. If RAO was suspected, the patient underwent Doppler ultrasonography for confirmation.

Randomization

Randomization was done using a computer-based random digit generator based on the registration number of the patients. This method ensured that the allocation of the patients to the 2 treatment groups was unbiased and fair. The computer algorithm employed in the current study generated a random sequence of numbers based on the unique registration number assigned to each patient. The method ensured that each patient had an equal chance of being assigned to any group, and the allocation was truly random and unbiased. To implement this method, we first obtained the registration numbers of all patients who met the inclusion criteria for the study. These numbers were then entered into the computer program, which generated a random sequence of numbers using the random digit generator. The patients were subsequently allocated to the treatment groups based on this sequence of numbers. The use of patient registration numbers for randomization helped to maintain patient confidentiality and privacy. The use of a unique identifier, such as a registration number, ensured that the patients' personal information was kept separate from the randomization process, minimizing the risk of data breaches or privacy violations.

Statistical Analysis

All the 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 via sample size formula for comparing and considering a 95% confidence level, an 80% statistical power, a prevalence rate of transradial access complications estimated as 18%, and the least significant difference between the 2 methods of hemostasis considered to be 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 quantitative variables and percentages for categorical variables. The distribution of variables was analyzed with the Kolmogorov-Smirnov test. The Student *t* test was used for normally distributed data and the Mann–Whitney *U* test for non-normally distributed data. The χ^2 test was employed for categorical values. Moreover, bivariate correlation was done to determine the role of demographic characteristics and clinical variables in the incidence of RAO. A 2-sided *P* value of less than 0.05 was considered statistically significantly.

RESULTS

Of the 200 consecutive hospitalized patients assessed for eligibility, 2 cases did not meet the inclusion criteria due to a previous ipsilateral transradial procedure. Thus, the final number of patients randomized into 2 study groups was 198. The procedure failed in 3 patients in the conventional hemostasis group. Ultimately, 96 patients were enrolled in the conventional hemostasis group and 99 patients in the patent hemostasis group (Fig. 1).

The mean age of the study population was 61.60 ± 10.45 (range = 34-86) years, and the sex distribution (male/female) of the patients was 119/76. The PCI prevalence rate was

33.8% (66 patients), and the other 129 patients received only coronary angiography. The demographic characteristics and clinical features of both groups are summarized in Tables 1-4. No significant differences were observed between the 2 study groups in regard to age, sex, BMI, the number of catheters during the procedure, procedure duration, hemostatic compression time, PCI prevalence, and risk factors such as a history of smoking, diabetes, hypertension, lipid disorders ($P > 0.05$).

RAO at discharge was significantly more frequent in the conventional hemostasis group (9 patients [9.37%]) than in the patent hemostasis group (2 patients [2.02%]) ($P = 0.02$). However, the frequency distribution rates of other access site complications, such as bleeding in the first hour of the TR Band removal and hematoma formation at discharge, were 4 (4.16%) and 13 (13.54%) cases in the conventional hemostasis group and 4 (4.04%) and 11 (11.11%) cases in the patent hemostasis group, respectively. The occurrence of these complications had no significant differences between the 2 groups ($P > 0.05$). All the bleeding episodes were very mild oozing not requiring transfusions, and all the hematomas were small (< 1 cm). Feeling numbness was experienced by 3 patients (3.12%) in the conventional hemostasis group and 1 patient (1.01%) in the patent hemostasis group, which was not significantly different between the groups ($P = 0.29$). Table 2 compares access site complications between the 2 study groups.

A separate analysis was performed on the patients by dividing the population into those who developed RAO by those who did not. The analysis was done to evaluate the role of demographic characteristics, clinical factors, and procedural variables in the incidence of RAO. Bivariate analysis was conducted on all the variables for the entire population. The results showed that age, BMI, procedure duration, and total time for the TR Band removal did not significantly affect the incidence of RAO ($P > 0.05$). Furthermore, no statistically significant differences existed in the distribution of sex, PCI, the number of catheters, hypertension, diabetes mellitus, dyslipidemia, and smoking (Table 3).

In another analysis, we compared the rate of access site complications in the conventional group between patients with or without waveform on pulse oximetry after ulnar compression. Of 96 patients with conventional hemostasis, 42 (43.75%) had waveform on pulse oximetry following ulnar compression. Overall, no significant differences existed between the 2 subgroups regarding access site complications. Although the incidence of RAO in patients with waveform after ulnar compression was lower than that in those without waveform, the difference was nonsignificant (3 [7.14%] vs 6 [11.11%]; $P = 0.51$). Table 4 compares the rate of access site complications between the groups.

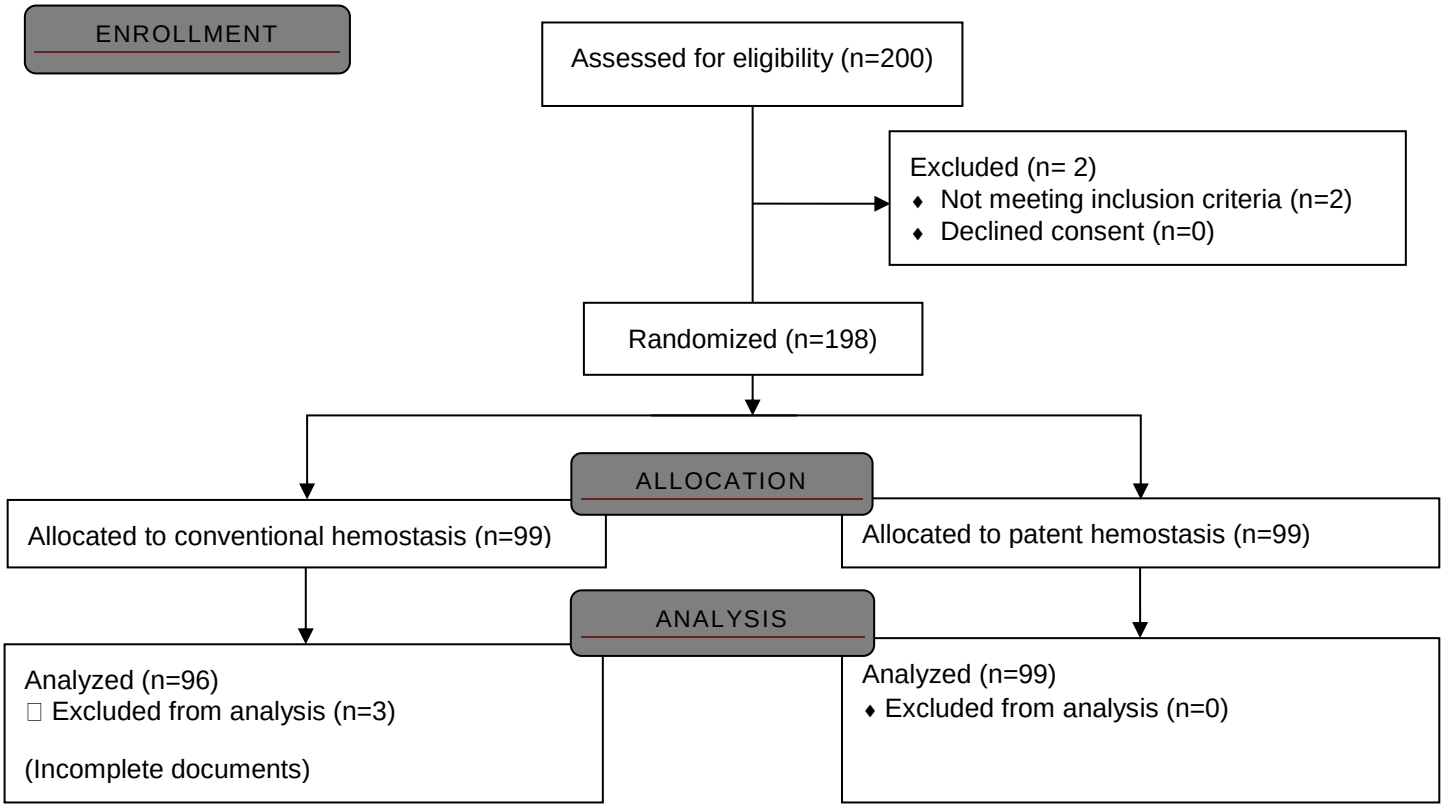

Figure 1: The CONSORT 2010 flow diagram for the present randomized clinical trial compares complications between the 2 hemostasis methods (conventional and patent) after transradial angiography.

Table 1: Baseline Characteristics of the Study Groups

Variable	Conventional Hemostasis (n=96)	Patent Hemostasis (n=99)	*P* value
Demographics			
Age (y)	60.39±10.43	62.79±10.39	0.12
Sex (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: Comparison of Access Site Complications Between the Study Groups

Variable	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%)	0.02

Table 3: Results of the Bivariate Comparison of Patients With or Without Radial Artery Occlusion

Variable	Occluded Radial artery (n=11)	Non-occluded Radial artery (n=184)	*P* value
Age (y)	59.67±9.63	61.67±10.52	0.56
BMI (kg/m^2)	26.05±4.25	27.82±4.29	0.18
Sex (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: Comparison of the Rate of Access Site Complications Between Patients With and Without Waveform on Pulse Oximetry After Ulnar Compression

Variable	Waveform on Pulse Oximetry (n=42)	Flat on 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

DISCUSSION

In recent years, the radial artery approach has become the standard mode of access for cardiac catheterization in many countries. [10, 11] The advantages of transradial access have been mentioned in several studies. These advantages include less bleeding, fewer puncture site complications, earlier ambulation, higher patient satisfaction, lower costs and lengths of hospitalization, and easier access for patients with myocardial infarction and aortic aneurysm. [6, 7] Still, RAO remains the silent protagonist in the radial approach, restricting the use of the radial artery for future procedures. [27] Among the several strategies used to prevent RAO, recent data suggest that patent hemostasis, shorter compression duration, and higher doses of heparin independently appear to reduce RAO. [13]

In the present study, we compared conventional vs patent hemostasis of the radial artery after transradial coronary angiography regarding access site complications. At discharge, the incidence of RAO was 2.02% in the patent hemostasis

group compared with 9.37% in the conventional group. Consequently, the RAO rate in patent hemostasis was significantly lower than that in conventional hemostasis. Our finding is consistent with previous studies. Pancholy et al [28] randomized 436 patients undergoing transradial access into 2 hemostasis groups (conventional and patent) and reported a lower rate of RAO following the transradial operation in the patent hemostasis group. Pancholy and colleagues concluded that patent hemostasis was highly effective in reducing RAO.

Roghani et al [29] evaluated the efficacy of hemostasis with patency in avoiding RAO after transradial catheterization by examining 60 patients in each group. The authors found that the incidence of RAO was considerably lower in the patent group (3.3%) than in the traditional group (13.3%). We found no significant differences regarding hematoma, bleeding, and numbness rates between the 2 study groups. Our data indicated that 11.11% of the study population developed hematomas, 1.01% experienced numbness, and 4.04% had bleeding with the patent hemostasis method. This finding chimes in with the results from previous studies. [29, 30] Regarding our assessment for other predictors of RAO, none of the demographic characteristics, clinical factors, and procedural variables was related to occlusion. Therefore, patent hemostasis was independently associated with a lower incidence rate of RAO at discharge, with adjustments for possible confounding variables relative to RAO incidence. This finding disagrees with the results from the aforementioned trial.

Age and hypertension had a significant role in RAO incidence in a trial conducted by Roghani et al. [29] In another trial, Desai et al [30] observed that only age and the radial artery diameter were the predictors of RAO.

Thus far, no study has investigated the presence of waveform on pulse oximetry following ulnar compression in conventional hemostasis while the TR Band has been inflated. Our findings revealed that pulse oximetry showed no curves after ulnar artery compression in fewer than 50% of the patients in the conventional group. Accordingly, there was no patency in more than 50% of our patients in the conventional method. As a new finding, our results demonstrated that the RAO rate in patients with waveform after ulnar compression was lower than that in those without waveform on pulse oximetry following ulnar compression; however, the difference was not statistically significant. The finding may be due to a rich network of the collateral circulation of the radial artery, which can be crucial to RAO prevention.

The results of the present study have some limitations, the most salient of which are the open-label design and the low number of PCI procedures in the studied patients. That we did not have a 30-day follow-up to reassess the study population in terms of RAO is a notable weakness. However, it is worthy of note that 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 assess late occlusion.

CONCLUSIONS

The findings of the present study suggest that patent hemostasis after TRA is safer than conventional hemostasis concerning access site complications, especially RAO, without compromising hemostatic efficacy.

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