Original Article

Compare Complication of Classic versus Patent Hemostasis in Transradial Coronary Angiography

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Abstract

Background: Coronary artery disease (CAD) is multifactorial disease, in which thrombotic occlusion and calcification occur usually. New strategies have been made for diagnosis and treatment of CAD, such as transradial catheterization. Hemostasis could be done in two approaches: traditional and patent. Our aim is to find the best approach with lowest complication. **Materials and Methods:** In a comparative study, 120 patients were recruited and divided randomly into two subgroups, including traditional group (60 patients; 24 females, 36 males; mean age: 64.35 ± 10.56 years) and patent group (60 patients; 28 females, 32 males; mean age: 60.15 ± 8.92 years). All demographic data including age, gender, body mass index, and CAD-related risk factors (smoking, diabetes, hypertension) and technical data including the number of catheters, procedure duration, and hemostatic compression time and clinical outcomes (radial artery occlusion [RAO], hematoma, bleeding) were collected. Data were analyzed by SPSS version 16. **Results:** Our findings revealed that the incidence of RAO was significantly lower in patent groups compared with traditional group (P = 0.041). Furthermore, the difference incidence of RAO was higher in early occlusion compare with late one (P = 0.041). Moreover, there were significant relationship between some factors in patients of traditional group with occlusion (gender [P = 0.038], age [P = 0.031], diabetes mellitus [P = 0.043], hemostatic compression time [P = 0.036]) as well as in patent group (age [P = 0.009], hypertension [P = 0.035]). **Conclusion:** Our findings showed that RAO, especially type early is significantly lower in patent method compared classic method; and patent hemostasis is the safest method and good alternative for classical method.

Keywords: *Coronary artery disease, patent hemostasis, radial artery occlusion, traditional hemostasis, transradial catheterization*

Introduction

Coronary artery disease (CAD) is multifactorial disease, in which thrombotic occlusion and calcification are usually appearing.[1] Scientists found that atherosclerosis in coronary leads to myocardial infraction which consequently results in coronary sclerotic state.[2-4] Previous studies stated that beneficial treatment method for this complication would be bed rest[5] and electrocardiography was introduced as a diagnosed approach.[6] Lifestyle was the most important risk factors in the development of coronary heart disease which leads to elevation in blood pressure and cholesterol level, consequently cause ischemic heart and myocardial infraction diseases.[7] Catheterization and angiography were used for defining the exact cardiac hemodynamics and prevent the coronary restenosis.[8,9]

Today, based on valuable previous studies,[10] new strategies have been made for diagnosis and treatment of CAD, such as transradial catheterization. Transradial coronary intervention (TRI) was first introduced in 1993[11] and became worldwide acceptable and popular method for CAD, due to its lower puncture site problems and more satisfied method than transfemoral coronary intervention method.[12-14] Furthermore, many studies have reported that TRI is feasible for those who have acute myocardial infraction (AMI).[15] One of the few problems of transradial angiography (TRA) method is radial artery occlusion (RAO), in which rare ischemia has been reported.[16,17]

One of the arteries using in angiography is radial artery which is recommended method in some cases, such as obese people and those with peripheral vascular disease.[14] Transradial approach has different

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advantages and disadvantages. Beneficial aspects can be achieved in patients with increased international normalized ratio, reducing the time and earlier discharge of patients' hemostasis, applicable in obese patients and those who have peripheral vascular problems. Among the disadvantages of this method, the more difficulty of operation and longer duration of exposure to radiation are the most considerable points.[18] The main side effects of transradial approach are hematoma, pseudoaneurysm, bleeding, spasm, and RAO.[19] RAO is the major complication after TRA that an incidence between 2% and 18% has been reported among literature.[20,21] Pathophysiology of RAO is thrombosis in the radial artery, which can cause ischemia of the fingers and even amputation in some cases.[22] Moreover, it leads to difficulty in coronary angiography at the same previous site and causes to hemodialysis fistula and/or revascularization surgery impairment for the disorder.[22] Risk factors of RAO are including not using of anticoagulant, sturdy banding of radial artery for long time, smoking, being smaller radial artery compared with sheet, and recurring procedures.[23] Regarding to the important role of choosing the best approach with which patients have the least complication, our aim to evaluate both conventional and transradial methods in regard to the beneficial advantages.

Materials and Methods

This study is a comparative with target population of all patients undergoing TRA referred to Noor hospital and Shahid Chamran Heart Education Center in 2015–2016. The sample size was calculated as sixty 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%,[5] and the least significant difference between the two methods of hemostasis that was considered equal to 2.0.

Our subjects were selected randomly based on the acceptable criteria among the candidates of coronary angiography of Noor Hospital and Shahid Chamran Heart Education Center in 2015–2016. Inclusion criteria were not having hemorrhagic diseases as well as hand anatomic disorders and filling the consent to participate in the study. On the other hand, in the case of failure in angiography for various reasons, lack of information about complications after coronary angiography or changes in angiography technique for any reason subjects were excluded from the study. All the patients should have a good normal Allen's test and radial pulse of the right hand. Furthermore, the study was approved by Isfahan University of Medical Sciences Ethical Committee with the code of 395272.

6F sheath and guidewire trauma were used for all patients, and then, it was injected 200 μ nitroglycerin, 2.5 mg verapamil, and 5000 μ heparin through the sheath and angiography was performed using 6F catheter.

After angiography, TR band was fasten and TR cuff was blowing with 15 cc of air, so that the radial artery blood flow was completely stopped, and then immediately, air pressure of TR band was deflated to start bleeding from the puncture site (for example, by reducing 5 cc of air began to bleed that means bleeding is occurred in 10 cc of air).

Patients were randomly divided into two different groups, so that they were matched in terms of sex, age, hypertension, and the other confounding risk factors.

In the first group or traditional hemostasis method, 2 cc of air was added to the previous amount (for example, in the above situation, it was kept in 12 cc). Within 30–60 min, TR band pressure was gradually reduced and the band was removed.

In the second group or patent hemostasis method, with the same maximum of air pressure and a little bit of blood leakage (in the above example 10 cc), patient was placed under supervision. In this method, the distal flow was done throughout the patient's wrist TR band was established.

In both groups, pulse oximetry has been simultaneously connected to the patients' index finger.

In Group I, if the ulnar artery was compressed, pulse oximetry shows a flat line and would not show oxygen saturation.

In Group II, if the ulnar artery was compressed, pulse oximetry would show higher than 90% of oxygen saturation due to radial arterial blood flow.

After removing the sheet, patients were under the direct supervision all the time until TR band removing and if it was necessary, open hemostasis method would change to classic method.

Before discharging, both groups were examined about hand pulse, hand color, hematoma, bleeding, and pulse oximetry (if the ulnar artery was compressed) and complications were recorded.

If it was suspected to RAO that usually caused by radial artery thrombosis (e.g., drop in O_2 saturation, weak or no pulse, cold or pale hands), patients underwent Doppler ultrasonography.

Since some complications such as RAO may be delayed a few days after, all the patients were reexamined about hematoma, pulse rate, and pulse oximetry with ulnar artery pressure in the next week and if they were suspected to RAO, Doppler ultrasonography was done.

Data were analyzed by SPSS (version 20) (SPSS Inc., Chicago, Illinois, USA) software using Fisher's exact test, Chi-square, *t*-test, and logistic regression with significance level of 0.05.

Results

In the present study, Group I (traditional hemostasis) including 24 (40%) female and 36 (60%) male with a mean

age of 64.35 ± 10.56 years and Group II (patent hemostasis) including 28 (46.67%) female and 32 (53.33%) males with the mean age of 60.15 ± 8.92 years. According to Table 1, the two groups were matched in terms of age, sex, body mass index, and risk factors such as history of smoking, diabetes, hypertension, number of catheters during procedure, and time of compression with TR band ($P > 0.05$).

RAO in Group I with a frequency of eight cases (13.33%) was considerably more significant than Group II with a frequency of two cases (3.33%) ($P = 0.041$), so that the distribution of early RAO (before discharge) in Group I rather than Group II was more ($P = 0.42$). However, the frequency of delayed RAO (a week after angiography) had no significant difference between the two groups ($P = 0.599$) [Table 1 and Figure 1].

In addition, the frequency distribution of other complications such as hematoma before and 1 week after discharge, and bleeding in the first hour of TR band removing in Group I was 5 (8.33%) and two cases (3.33%) and in Group II was 8 (13.33%) and four cases (6.67%), respectively, which the occurrence of these complications had no significant difference between the two groups ($P > 0.05$) [Table 1].

The results of evaluating the role of demographic and clinical factors and angiography conditions on the incidence of RAO in each of the two groups showed that patient's age had a significant role on the incidence of RAO ($P < 0.05$). Furthermore, in Group I from the patients with occlusion 5 ones (62.5%) and from the patients nonocclusion 14 ones (24.1%) were female ($P = 0.038$). From the patients with occlusion 50% and from nonocclusion only 15.4% had diabetes ($P = 0.043$). In addition, the mean duration of TR band compression in patients with occlusion was 60.00 ± 10.69 min which was significantly more than the group nonocclusion with the mean of 51.55 ± 10.45 min ($P = 0.036$). Hypertension had a significant role in the incidence of occlusion in Group II ($P = 0.035$); so that the both patients with occlusion had high blood pressure [Tables 2 and 3].

Finally, logistic regression analysis to identify factors affecting the incidence of complications (at least one of the RAO, hematoma or bleeding) showed that in the Group I, factors such as diabetes (β = 3.40), hypertension (β = 3.29), duration of procedures (β = 0.31), and duration of TR band compression (β = 0.14) had a significant role in the incidence of complications. In Group II, only two factors of age with impact factor of 0.14 and hypertension with impact factor of 2.22 had a significant role on complications' incidence [Table 4].

Discussion

Despite transradial approach is acceptable method for coronary angiography, RAO is the most disadvantage

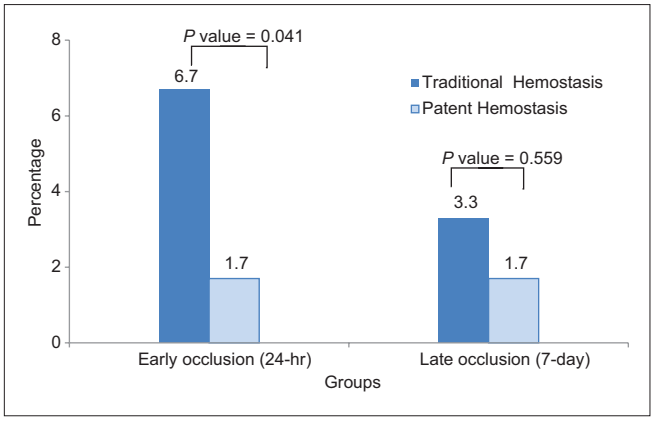

Figure 1: Patent hemostasis leads to a significant decrease in the incidence of radial artery occlusion at 24-h and 7-day follow-up

Table 1: Demographic and procedural data in two study groups

Variables	Traditional hemostasis (n=60)	Patent hemostasis (n=60)	P
Demographics			
Sex (female)	24 (40)	28 (46.67)	0.647
Age (year)	64.35±10.56	60.15±8.92	0.058
BMI (kg/m^2)	25.11±3.95	24.65±3.44	0.590
Risk factors			
Cigarette smoking	25 (41.67)	18 (30)	0.253
Hypertension	22 (36.67)	28 (46.67)	0.355
Diabetes mellitus	12 (20)	10 (16.67)	0.814
Number of catheters			
1	50 (83.33)	53 (88.33)	0.602
2 or 3	10 (16.67)	7 (11.67)	
Procedure duration (min)	17.81±7.62	17.88±6.01	0.967
Hemostatic compression time (min)	53.38±12.31	55.88±17.24	0.470
Outcomes			
Radial artery occlusion	8 (13.33)	2 (3.33)	0.041*
Hematoma	5 (8.33)	8 (13.33)	0.558
Bleeding	2 (3.33)	4 (6.67)	0.679

Data shown n (%) or mean±SD. *Level significant was <0.05. SD: Standard deviation, BMI: Body mass index

Table 2: Comparison factors affecting on patients with or without radial artery occlusion in traditional hemostasis group

Factors	Nonocclusion (*n*=52)	Occlusion (*n*=8)	OR (95% CI)	*P*
Gender (female)	14/52 (24.1)	5/8 (62.5)	5.24 (1.11-10.74)	0.038*
Age (year)	62.69±10.82	70.38±7.25	1.09 (1.01-1.29)	0.031*
BMI (kg/m^2)	25.59±4.06	23.38±3.38	0.84 (0.66-1.08)	0.141
Cigarette smoking	27/52 (51.9)	3/8 (37.5)	0.56 (0.12-2.57)	0.706
Hypertension	22/52 (42.3)	6/8 (75)	4.09 (0.75-20.22)	0.130
Diabetes mellitus	8/52 (15.4)	4/8 (50)	5.50 (1.14-6.63)	0.043*
Number of catheters				
1	41/52 (78.8)	6/8 (75)	0.81 (0.14-4.55)	0.991
2 or 3	11/52 (21.2)	2/8 (25)		
Procedure duration (min)	17.17±7.35	20.13±8.65	1.05 (0.95-1.16)	0.399
Hemostatic compression time (min)	51.55±10.45	60.00±10.69	1.06 (1.01-1.13)	0.036*

*Level significant was <0.05. BMI: Body mass index, OR: Odds ratio, CI: Confidence interval

Table 3: Comparison factors affecting on patients with or without radial artery occlusion in patent hemostasis group

Factors	Nonocclusion (*n*=58)	Occlusion (*n*=2)	OR (95% CI)	*P*
Gender (female)	28/58 (48.3)	1/2 (50)	1.17 (0.07-9.67)	0.915
Age (year)	58.66±9.82	68.50±2.12	2.14 (1.94-2.40)	0.009*
BMI (kg/m^2)	24.58±3.51	26.00±1.41	1.13 (0.75-1.69)	0.576
Cigarette smoking	21/58 (36.2)	1/2 (50)	1.76 (0.11-9.65)	0.708
Hypertension	17/58 (29.3)	2/2 (100)	-	0.035*
Diabetes mellitus	14/58 (24.1)	1/2 (50)	3.14 (0.18-5.59)	0.441
Number of catheters				
1	47/58 (81.1)	2/2 (100)	-	0.496
2 or 3	11/58 (18.9)	0 (0)		
Procedure duration (min)	17.76±6.08	20.00±5.66	1.06 (0.85-1.31)	0.615
Hemostatic compression time (min)	55.39±17.22	65.00±21.21	1.03 (0.95-1.12)	0.450

*Level significant was <0.05. BMI: Body mass index, OR: Odds ratio, CI: Confidence interval

Table 4: Risk factors affecting the prevalence outcomes in each of two groups

Variables	β±SE	OR (95% CI)	*P*	Observed power
Group I: Classic hemostasis				
Diabetes mellitus	3.40±1.54	29.87 (1.45-36.23)	0.028*	0.586
Hypertension	3.29±1.63	26.87 (1.09-39.25)	0.044*	0.519
Procedure duration (min)	0.31±0.12	1.36 (1.08-1.72)	0.009*	0.928
Hemostatic compression time (min)	0.14±0.07	1.14 (1.01-1.30)	0.040*	0.532
Group II: Patent hemostasis				
Age, year	0.14±0.06	1.15 (1.02-1.29)	0.019*	0.588
Hypertension	2.22±1.22	9.18 (0.84-39.98)	0.041*	0.868

*Level significant was <0.05. Used of regression logistics for estimated prevalence outcomes with adjusted sex, age, BMI, cigarette smoking, hypertension, diabetes mellitus, procedure duration, hemostatic compression time in each groups. BMI: Body mass index, OR: Odds ratio, CI: Confidence interval, SE: Standard error

of this method. Early occlusion was more frequent than late occlusion although for patent hemostasis, our result showed that there was not any change in incidence of RAO whether in early or late occlusion. Previous studies stated that RAO is rare occurrence. RAO can be reduced by lower profile equipment and hydrophilic introducers, in spite of the fact that heterogeneous candidates can increase the RAO prevalence.[16] We found that early occlusion incidence was higher in traditional hemostasis than in patent group. The prevalence of RAO in traditional group was eight; six patients had early RAO and two cases had late RAO. Doppler sonography was done for all of them and thrombus was confirmed. In patent hemostasis group, there were two patients who had RAO and they also had thrombus. Sanmartin *et al*. found the higher prevalence of RAO after transradial operation. They followed up the patients using plethysmographic method and observed that only about 10% faced with RAO.[24] In the study done by Choussat *et al*. reported that transradial approach would be an efficient method for the patients with AMI.[19]

Having spasm or thrombose formation was thought to be the most important symptoms for pathophysiology of RAO.[16] Previous study tried to perform a new technique which can reassess radial artery after RAO. They could manage thrombus soon after radial artery.[25] RAO after transradial access causes local trauma which happens in smaller radial arteries, consequently leads to formation of occlusive thrombus and all these processes cause to occlusion development.[16]

Regarding to our assessment for traditional hemostasis group, gender was one of the significant factors which was related to occlusion (P = 0.038). Furthermore, age had an association with occlusion; in other words, with the increasing of age, the risk of occlusion was considerably raised up (P = 0.031). Moreover, the patients with diabetes mellitus were more likely to occlusion occurrence (P = 0.043). What was more, patients with longer hemostatic compression were more likely to have occlusion (P = 0.036). In agreement with our results, Pancholy *et al*. found that age and gender were significantly correlated with occlusion; however, opposed us, they did not detect any significant relationship between diabetes mellitus and procedure time and occlusion incidence. Similar to our findings, they also demonstrated that careful prevention of radial artery flow at the time of compression can decrease RAO after transradial catheterization.[16] Sanmartin *et al*. in their clinical investigation showed that prevention of radial artery flow can noticeably help reduce RAO during transradial approach.[24]

In patent hemostasis group, age was also had a significant effect on occlusion rate (P = 0.009). Meanwhile, hypertension was existed in all patients with occlusion. We believe that TRA should be avoided in patients with hypertension. Our assessment demonstrated that RAO was observed more in women which might be due to having smaller radial artery than sheet. On the other hand, after final evaluation, we found that all risk factors which make effect on traditional hemostasis was not appear in patent group which means that patent hemostasis could be a beneficial approach which can be constituted with the previous conventional method.[20]

These findings showed the patent of transradial strategy compared with traditional method due to its safety and convenience and less complications. In agreement with us, many studies prove this claim that it is time to change the conventional method.[15,18,23] It should be noted that despite of having many advantages of transradial in comparison with femoral method, still this approach needs more modify to eliminate all risk factors and less aggressive in operation. We believe more study in larger scale should be performed to find the best procedure with lowest complication. Screening meticulously of equipment profile and as well as interventional procedure and heparinization when safe, control the patency, choosing the best site for intervention to have shortest compression duration and using of hemostatic devices to reduce systolic blood in local site would be ideal suggestions for ensuring this method can be done in the best and lowest complication circumstances.

Conclusion

Our findings showed that RAO, especially type early, was significantly lower in patent method compared with classic approach; and patent hemostasis is the safest strategy and good alternative for classical technique.

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Conflicts of interest

There are no conflicts of interest.

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