Observational Study

Medicine®

OPEN

Radial artery occlusion with a kaolin-filled pad after transradial cardiac catheterization

Chun-Yen Chiang, MD[a,b], Weng-Ting Chang, MD[a], Chung-Han Ho, PhD[c,d], Chon-Seng Hong, MD[a], Jhih-Yuan Shih, MD[a], Wen-Shiann Wu, MD[a], Zhih-Cherng Chen, MD[a], Ming-Ting Chou, MD[a,e,*]

Abstract

Radial artery occlusion (RAO) occurs in 2% to 18% of patients after transradial access (TRA) cardiac catheterization. Using a kaolin-filled pad (QuikClot) reduces compression time during TRA and might reduce RAO. We examined the RAO risk with the kaolin-filled pad after TRA cardiac catheterization.

This was a prospective cross-sectional study of 260 patients who underwent TRA cardiac catheterization in a cardiac ward of a Medical Center from 2012 to 2016. Patients were randomly assigned to 1 of 2 groups: the case group (n = 130) was postoperatively treated with a kaolin-filled pad, and the control group (n = 130) was treated with conventional hemostasis. Color duplex ultrasound was used to evaluate the 24-hour and 1-month postoperative radial artery flow velocity, diameter, patency, and RAO risk.

RAO risk was not significantly different between the case and control groups after 24 hours (4.6% vs 5.4%, $P = .776$) or after 1 month (5.4% vs 6.1%, $P = .789$), regardless of whether it was a first TRA cardiac catheterization (after 24 hours [$P = .153$] or after 1month [$P = .617$], respectively) or a repeated TRA cardiac catheterization (after 24 hours [$P = .754$] or after 1month [$P = .753$], respectively).

Using a kaolin-filled pad after TRA cardiac catheterization did not significantly reduce RAO risk compared with conventional hemostasis.

Abbreviations: ACS = acute coronary syndrome, ACT = activated clotting time, BMI = body mass index, BP = blood pressure, BW = body weight, CI = confidence interval, DBP = diastolic blood pressure, DM = diabetes mellitus, HL = hyperlipidemia, HTN = hypertension, MHz = megahertz, MI = myocardial infarction, OR = odds ratio, PCI = percutaneous coronary intervention, RAO = radial artery occlusion, SBP = systolic blood pressure, SD = standard deviation, TRA = transradial access.

Keywords: kaolin-filled pad, radial artery occlusion, transradial access

Editor: Stefano Omboni.

Funding: The study was supported by grant CMFHR10467 from Chi-Mei Medical Center.

Patient consent: Obtained.

Ethical s approval: The study was approved by the Institutional Review Board of Chi-Mei Medical Center (IRB No: 10110-012 and IRB No: 10407-003).

Provenance and peer review: Not commissioned: externally peer reviewed.

Data sharing statement: No additional data available.

The authors have no conflicts of interest to disclose.

[a] Division of Cardiology, Department of Internal Medicine, Chi-Mei Medical Center, Yong-Kang District, [b] Department of Optometry, Chung Hwa University of Medical Technology, Rende District, [c] Department of Medical Research, Chi-Mei Medical Center, Yong-Kang District, [d] Department of Hospital and Health Care Administration, [e] Department of Recreation and Healthcare Management, Chia Nan University of Pharmacy and Science, Rende District, Tainan City, Taiwan.

[*] Correspondence: Ming-Ting Chou, 901 Zhonghua Road, Yong-Kang District, Tainan City 71044, Taiwan (e-mail: choumingtingt@yahoo.com.tw).

Medicine (2018) 97:46(e13134)

Received: 6 June 2018 / Accepted: 12 October 2018

http://dx.doi.org/10.1097/MD.0000000000013134

Strengths and limitations of this study

1. This study was a prospective cross-sectional clinical trial to compare the risks of radial artery occlusion (RAO) in patients treated with kaolin-filled pads and conventional hemostasis after transradial access (TRA) cardiac catheterization.
2. We examined the risks of first-time and repeated-TRA.
3. Detailed personal information was collected, which allowed us to adjust for the major risk factors of radial artery occlusion after cardiac catheterization.
4. The major limitation in our study is the compression time required for hemostasis was not precisely estimated.

1. Introduction

Transradial cardiac catheterization is being used more frequently for percutaneous angiography and intervention. Percutaneous angiography cases are treated using transradial access (TRA) because it reduces access-site bleeding, increases patient comfort, and improves recovery compared with transfemoral access.[1,2] TRA is limited by

radial artery occlusion (RAO), a frequently asymptomatic complication that occurs in 2% to 18% of TRA procedures.[3]

RAO eliminates subsequent TRA because it is likely related to the size of the sheath and even more likely related to the ratio of the arterial diameter to the sheath.[4] Repeated cannulation predisposes a patient to have a higher rate of RAO.[5]

Increasing the heparin dose[6] and achieving post-procedure patent hemostasis reduces RAO.[7] Shorter durations of hemostatic compression after TRA are associated with a lower incidence of RAO.[8] The QuikClot interventional bandage (Z-Medica LLC, Wallingford, CT) is a novel hemostatic device that consists of a procoagulant (kaolin)-filled hydrophilic nonwoven pad. It is applied topically as an adjunct to manual compression and is indicated for locally managing and controlling surface bleeding from vascular access sites,[9] and for reducing compression time during TRA. The aim of this prospective cross-sectional study was to compare the effect on RAO of short-term compression with a kaolin-filled pad and longer term compression with conventional sterile gauze after TRA cardiac catheterization.

2. Methods

Two methods of compression—kaolin-filled pad hemostasis and conventional sterile gauze hemostasis—were used after TRA cardiac catheterization. We used duplex echocardiography to evaluate the 24-hour and the 1-month radial artery flow velocity, artery diameter, and patency of RAO. All patients were randomly assigned to 1 of 2 groups: the case group (treated with a kaolin-filled pad) and the control group (treated with conventional hemostasis). All patients provided written informed consent. The study was approved by the Chi-Mei Medical Center Institutional Review Board (IRB No: 10110-012 and IRB No: 10407-003). Minimal sample size was calculated before starting the study. The primary outcome was the RAO rate 24 hours and 1 month after TRA cardiac catheterization. RAO was confirmed by an absence of antegrade flow measured using high-resolution vascular ultrasound.

2.1. Transradial access

Initially we used a modified Allen's test over the left hand to check the patient's arterial competency (blood flow). If the result was normal, we used left-side TRA. If it was abnormal, we used right-side TRA. After sterile preparation and local anesthesia (2% xylocaine), we punctured the left-side radial artery using a 4.0-cm 20G angiographic needle (Angiographic Advance Needle; Merit Medical Systems, South Jordan, UT) and inserted a 10-cm 6 Fr introducer sheath (Radifocus Introducer II; Terumo Interventional Systems, Tokyo, Japan) into the left radial artery lumen using a 0.025-inch 45-cm mini guidewire. All patients were given 200 μg of nitroglycerin, 2.5 mg of verapamil, and 3000 units of unfractionated heparin through the introducer sheath. The diagnostic catheterizations in the study were done using 6 Fr Judkins left 3.5 and right 4.0 diagnostic catheters (Boston Scientific International, Marlborough, MA). The radial artery occlusion was checked using high-resolution vascular ultrasound (iE33 duplex echo; Philips Ultrasound, Bothell, WA) 24 hours and 1 month after TRA cardiac catheterization. Demographic and procedural data were recorded.

2.2. Hemostasis

After TRA cardiac catheterization, the patients in the case group were treated with a QuikClot kaolin-filled interventional hemostatic compression pad applied directly on the skin with a folded gauze over the pad. The entire dressing was wrapped with adhesive tape for 15 minutes, after which the compression was removed, and then an adhesive bandage (Tegaderm; 3M Co., St. Paul, MN) secured the QuikClot pad. In the control group, patients were given a traditional 4-inch × 4-inch elastic gauze bandage wrapped around the puncture, and then 2 layers of 3M Coban Self-Adherent Wrap. After 3 hours of continuous compression at the puncture site, the bandage was gradually relieved. The patients were then monitored for at least 30 minutes. If bleeding reoccurred, the bandage was reapplied, and the procedure was repeated.

2.3. Ultrasound examinations for RAO

RAO was confirmed if, after the sheath was removed, color Doppler ultrasound with an L11–3 probe featuring a 3- to 11-MHz multifrequency vascular probe showed no radial artery blood flow. All patients underwent ultrasound examinations of their radial artery patency to evaluate their RAO (both 24 hours and then 1 month after the introducer sheath had been removed). The occlusion rate of RAO was used to check the possible level of RAO patency in our study.

2.4. Data collection and statistical analysis

The primary aim of the present study was to compare kaolin-filled QuikClot pad hemostasis with conventional hemostasis. All data—age, gender, and heparin dose—were prospectively collected and entered in the study.

Analyses were done on an intention-to-treat basis with patients assigned to their original groups. The categorical variables are presented as frequency and percentages, and Pearson's χ^2 test was used to estimate the difference between the 2 methods of hemostasis. Continuous variables are reported as mean ± standard deviation (SD), and the difference between the 2 groups was evaluated using Student's t test. A logistic regression analysis was used to estimate the association between the predictors and RAO both 24 hours and 1 month after cardiac catheterization. Significance was set at $P < .05$ (2-tailed). SAS 9.4 for Windows (SAS Institute, Cary, NC) was used for all analyses. A univariate logistic regression analysis was also done.

3. Results

We enrolled 260 patients (204 men and 56 women; mean age: 62.6 years) in the study. There were no significant baseline demographic or clinical differences between the case and control groups (Table 1). All patients underwent radial artery duplex color Doppler ultrasound examinations 24 hours after TRA coronary catheterization. In the 1-month follow-up, however, 13 patients in the case group and 11 patients in the control group did not.

3.1. Incidence of RAO after TRA cardiac catheterization

Six patients (4.6%) in the case group and 7 patients (5.4%) in the control group (both in first-time and in repeated TRA patients, had RAO in the 24-hour follow-up (Table 2), but the incidence of RAO was not significantly different ($P = .776$) between the 2 groups, nor was there a significant difference in the incidence of RAO between first-time and repeated-TRA patients after 24 hours in the 2 groups.

Seven patients (5.4%) in the case group and 8 patients (6.1%) in the control group (both first-time and repeated-TRA patients) had RAO in the 1-month follow-up (Table 2), but the incidence of

Table 1

Baseline characteristics of patients.

Variable	Cases (n = 130)	Controls (n = 130)	P
Age, years	63.4 ± 10.6	61.9 ± 13.0	.3000
Male	98 (75.97)	106 (81.5)	.2732
Diabetes mellitus (Yes)	57 (43.9)	46 (35.4)	.1631
Hypertension (Yes)	82 (63.1)	95 (73.1)	.0837
Dyslipidemia (Yes)	85 (65.4)	78 (60.0)	.3694
MI history (Yes)	33 (25.4)	26 (20.0)	.3000
ACS (Yes)	13 (10.0)	9 (6.92)	.3727
Height, cm	163.4 ± 7.7	164.6 ± 7.7	.2466
Body weight, kg	69.3 ± 10.9	71.6 ± 13.0	.1289
BMI	25.9 ± 3.3	26.4 ± 4.4	.3022
Systolic BP, mm/Hg	136.8 ± 18.2	138.4 ± 20.9	.5061
Diastolic BP, mm/Hg	76.6 ± 11.8	78.4 ± 12.7	.2410
Surgery duration, minutes	35.2 ± 25.8	40.5 ± 27.2	.1106
PCI (Yes)	78 (60.5)	86 (67.7)	.2267
ACT, seconds	272.6 ± 74.9	262.4 ± 60.4	.2295
Heparin dose (unit)	7369.2 ± 3270.5	7650.0 ± 3174.3	.4831
Radial artery size			
24 hours post-TRA cardiac catheterization	0.29 ± 0.06	0.30 ± 0.14	.4490
1 month post-TRA cardiac catheterization	0.27 ± 0.07	0.30 ± 0.27	.1837
Radial artery side (left)	125 (96.2)	127 (97.69)	.4726

All values are mean ± standard deviation or n (%).
cases = QuikClot hemostasis, controls = conventional hemostasis, ACT = activated clotting time, BMI = body mass index, BP = blood pressure, MI = myocardial infarction, PCI = percutaneous coronary intervention, TRA = transradial access.

RAO was not significantly different ($P = .789$) between the groups. In addition, there was no difference of the incidence of RAO between first-time and repeated-TRA patients after 1 month in the 2 groups. A univariate analysis of RAO-related factors showed that none were associated with RAO 24 hours or 1 month (Tables 3 and 4) after TRA cardiac catheterization.

4. Discussion

In this prospective cross-sectional study, we found that kaolin-filled QuikClot pads with a short compression time did not significantly reduce the incidence of RAO, and that the heparin dose and radial artery size were not correlated with RAO. One study[10] reported that QuikClot pads reduced RAO after TRA, but the study had few patients and evaluated RAO in only one 24-hour follow-up. We hypothesized that patients with repeated-TRA cardiac catheterization procedures would have a higher risk of RAO than would patients with first-time TRA procedures. We found that the ratio of RAO in repeated-TRA patients in both groups was not significantly higher than that for first-TRA patients. Studies with larger samples are needed to confirm this finding.

The incidence rate of RAO in our study was low (< 7%) in both patient groups. The Leipzig Prospective Vascular Ultrasound Registry[11] used high-resolution color Doppler ultrasound, as did we, to evaluate the incidence of RAO, and found it to be as high as 30.5% using 6-F introducer-sheath TRA. This implies that routine clinical radial pulse checks and other methods might be inaccurate and insufficiently sensitive to detect all RAO. In our center, patients who undergo cardiac catheterization are centralized in a special ward for observation and further care. Our well-trained nursing staff closely follow

Table 2

Radial artery occlusion (RAO) incidence after first- and after repeated-TRA cardiac catheterization.

RAO incidence after TRA	Cases (n = 130)	Controls (n = 130)	P
After 24 hours	6/130 (4.6)	7/130 (5.4)	.7760
For first-TRA patients	0/50 (0.0)	2/50 (4.0)	.1531
For repeated-TRA patients	6/80 (7.5)	5/80 (6.3)	.7547
After 1 month	7/130 (5.4)	8/130 (6.1)	.7899
For first-TRA patients	1/50 (2.0)	3/50 (6.0)	.6173
For repeated-TRA patients	6/80 (7.5)	5/80 (6.3)	.7539

All values are n (%).
Note: $P = 0.081$ for RAO incidence between first TRA and repeated TRA in patients using kaolin-filled pad hemostasis device after 24 hours, $P = .249$ for RAO incidence between first TRA and repeated TRA in patient using kaolin-filled pad hemostasis device after 1 month, $P = .707$ for RAO incidence between first TRA and repeated TRA in patients using conventional hemostasis device after 24 hours, $P = 1.000$ for RAO incidence between first TRA and repeated TRA in patients using conventional hemostasis device after 1 month.
RAO = radial artery occlusion, TRA = transradial access.

Table 3

Univariate analysis of RAO in all patients 24 hours after TRA cardiac catheterization.

Variable	OR	95% CI	P
RAO	0.66	(0.16–2.77)	.5703
Age	0.99	(0.92–1.07)	.8204
Sex	0.37	(0.05–2.63)	.3208
Height	1.03	(0.91–1.17)	.6212
BW	1.07	(0.98–1.16)	.1178
SBP	1.02	(0.98–1.06)	.4433
DBP	0.97	(0.91–1.04)	.3675
DM (Yes/No)	1.84	(0.43–7.81)	.4094
HTN (Yes/No)	0.28	(0.06–1.38)	.1170
HL (Yes/No)	1.21	(0.25–5.78)	.8095
MI (Yes/No)	0.25	(0.02–3.38)	.2973
Surgery duration	0.97	(0.9–1.04)	.4100
ACT	1.01	(0.99–1.03)	.3407
Heparin dose	1.00	(1.00–1.00)	.1649

ACT = activated clotting time, BW = body weight, CI = confidence interval, DBP = diastolic blood pressure, DM = diabetes mellitus, HTN = hypertension, HL = hyperlipidemia, MI = myocardial infarction, OR = odds ratio, RAO = radial artery occlusion, SBP = systolic blood pressure, TRA = transradial access.

Table 4

Univariate analysis of radial artery occlusion after 1 month for all patients.

Variable	OR	95% CI	P
RAO	0.87	(0.25–3.07)	.8241
Age	0.95	(0.88–1.01)	.1112
Sex	2.51	(0.43–14.51)	.3049
Height	0.92	(0.83–1.02)	.1171
BW	1.05	(0.98–1.12)	.1552
SBP	1.01	(0.98–1.05)	.5297
DBP	0.97	(0.92–1.02)	.2568
DM (Yes/No)	2.01	(0.59–6.91)	.2679
HTN (Yes/No)	0.35	(0.1–1.27)	.1115
HL (Yes/No)	0.65	(0.19–2.26)	.4938
MI (Yes/No)	1.15	(0.23–5.79)	.8688
Surgery duration	1.00	(0.95–1.04)	.8861
ACT	1.01	(0.99–1.02)	.4308
Heparin dose	1.00	(1.00–1.00)	.0646

ACT = activated clotting time, BW = body weight, CI = confidence interval, DM = diabetes mellitus, DBP = diastolic blood pressure, HTN = hypertension, HL = hyperlipidemia, MI = myocardial infarction, OR = odds ratio, RAO = radial artery occlusion, SBP = systolic blood pressure.

each patient's condition. Usually a nurse loosens the bandage early if there are no signs of bleeding; this also increases the patient's comfort. In our study, the total duration of compression was not precisely measured, but medical records indicated that, in the case group, hemostasis usually occurred in less than 10 minutes but in 4 to 6 hours in the control group. We found that compression time did not affect the result of RAO between the kaolin-pad compression and conventional compression. In contrast, Pancholy and Patel[12] reported that short-duration compression was associated with a lower incidence of early and chronic RAO, as did Politi et al[15]: 15 minutes versus 2 hours. Anticoagulation medication also appears to have a significant preventive effect on the occurrence of RAO.[8] The anticoagulant effect of 70 U/kg of systemically administered unfractionated heparin is expected to last for approximately 4 hours[13] This might be why occlusive compression for intervals less than 4 hours have a higher probability of recanalization than does compression for more than 4 hours.

Patency when applying hemostatic compression has the most significant preventive effect against RAO. If radial artery flow is maintained during hemostatic compression, a longer duration of compression is well tolerated with no higher risk of RAO. Others[14,15] have also reported that relieving compression early and concurrently maintaining patent hemostasis after TRA reduced the incidence rate of RAO.

4.1. Limitations

Our study has some limitations. The number of patients in the case and control groups might be insufficient to show a conclusive difference between these 2 hemostasis methods. The decision to relieve QuikClot pad compression and conventional hemostasis compression was determined by our nursing staff based on their observations and experience, but there was no precise record of the timing.

5. Conclusion

Using a kaolin-filled pad with a short compression time post-TRA in cardiac catheterization did not effectively reduce the RAO incidence rate compared with conventional hemostasis in patients who underwent a first TRA or repeated TRAs.

Acknowledgments

We are indebted to the participants of the present study for their persistent outstanding support and to our colleagues for their valuable assistance.

Author contributions

Conceived and designed the clinical trial: MTC and CYC. Performed the clinical trial: CYC, WTC, CSH, JYS, WSW, ZCC, and MTC. Analyzed the data: CHH. Wrote the manuscript: CYC and MTC. The work has not been previously published and is not under consideration elsewhere for publication in part or in whole.

Conceptualization: Chun-Yen Chiang.
Project administration: Chun-Yen Chiang.
Writing – original draft: Chun-Yen Chiang.
Data curation: Weng-Ting Chang, Chon-Seng Hong, Jhih-Yuan Shih, Wen-Shiann Wu, Zhih-Cherng Chen.
Resources: Weng-Ting Chang, Zhih-Cherng Chen.
Formal analysis: Chung-Han Ho.
Methodology: Chung-Han Ho, Ming-Ting Chou.
Supervision: Zhih-Cherng Chen.
Validation: Ming-Ting Chou.
Writing – review & editing: Ming-Ting Chou.
Chung-Han Ho: 0000-0001-5925-8477.
Chung-Han Ho orcid: 0000-0001-5925-8477.

References

[1] Jolly SS, Amlani S, Hamon M, et al. Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: a systematic review and meta-analysis of randomized trials. Am Heart J 2009;157:132–40.
[2] Jolly SS, Yusuf S, Cairns J, et al. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial. Lancet 2011;377:1409–20.
[3] Kanei Y, Kwan T, Nakra NC, et al. Transradial cardiac catheterization: a review of access site complications. Catheter Cardiovasc Interv 2011;78: 840–6.
[4] Saito S, Ikei H, Hosokawa G, et al. Influence of the ratio between radial artery inner diameter and sheath outer diameter on radial artery flow after transradial coronary intervention. Catheter Cardiovasc Interv 1999;46:173–8.
[5] Sanmartin M, Gomez M, Rumoroso JR, et al. Interruption of blood flow during compression and radial artery occlusion after transradial catheterization. Catheter Cardiovasc Interv 2007;70:185–9.
[6] Spaulding C, Lefevre T, Funck F, et al. Left radial approach for coronary angiography: results of a prospective study. Cathet Cardiovasc Diagn 1996;39:365–70.
[7] Pancholy S, Coppola J, Patel T, et al. Prevention of radial artery occlusion-patent hemostasis evaluation trial (PROPHET study): a randomized comparison of traditional versus patency documented hemostasis after transradial catheterization. Catheter Cardiovasc Interv 2008;72:335–40.
[8] Pancholy SB. Comparison of the effect of intra-arterial versus intravenous heparin on radial artery occlusion after transradial catheterization. Am J Cardiol 2009;104:1083–5.
[9] Choi EY, Ko YG, Kim JB, et al. Hemostatic efficacy of hydrophilic wound dressing after transradial catheterization. J Invasive Cardiol 2005;17:459–62.
[10] Cox ED, Schreiber MA, McManus J, et al. New hemostatic agents in the combat setting. Transfusion 2009;49(suppl 5):248s–55s.
[11] Uhlemann M, Mobius-Winkler S, Mende M, et al. The Leipzig prospective vascular ultrasound registry in radial artery catheterization: impact of sheath size on vascular complications. JACC Cardiovasc Interv 2012;5:36–43.
[12] Pancholy SB, Patel TM. Effect of duration of hemostatic compression on radial artery occlusion after transradial access. Catheter Cardiovasc Interv 2012;79:78–81.
[13] Hirsh J, Raschke R. Heparin and low-molecular-weight heparin: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Chest 2004;126(3 suppl):188s–203s.
[14] Edris A, Gordin J, Sallam T, et al. Facilitated patent haemostasis after transradial catheterisation to reduce radial artery occlusion. Euro-Intervention 2015;11:765–71.
[15] Politi L, Aprile A, Paganelli C, et al. Randomized clinical trial on short-time compression with Kaolin-filled pad: a new strategy to avoid early bleeding and subacute radial artery occlusion after percutaneous coronary intervention. J Interv Cardiol 2011;24:65–72.