Influence of Puncture Site on Radial Artery Occlusion After Transradial Coronary Intervention

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Abstract

Background: The risk of radial artery occlusion (RAO) needs particular attention in transradial intervention (TRI). Therefore, reducing vascular occlusion has an important clinical significance. The aim of this study was to determine the appropriate puncture site during TRI through comparing the occurrence of RAO between the different puncture sites to reduce the occurrence of RAO after TRI.

Methods: We prospectively assessed the occurrence of RAO in 606 consecutive patients undergoing TRI. Artery occlusion was evaluated with Doppler ultrasound in 2 days and 1 year after the intervention. Risk factors for RAO were evaluated using a multivariate model analysis.

Results: Of the 606 patients, the RAO occurred in 56 patients. Compared with TRI at 2–5 cm away from the radius styloid process, the odds ratio (OR) for occlusion risk at 0 cm and 1 cm were 9.65 (P = 0.033) and 8.90 (P = 0.040), respectively. The RAO occurred in the ratio of the arterial diameter to the sheath diameter ≤1 (OR = 2.45, P = 0.004).

Conclusion: Distal puncture sites (0–1 cm away from the radius styloid process) can lead to a higher rate of RAO.

Trial Registration: ClinicalTrials.gov, NCT01979627, https://clinicaltrials.gov/ct2/show/NCT01979627?term = NCT01979627 and rank = 1.

Key words: Percutaneous Coronary Intervention; Puncture Site; Radial Artery; Risk Factors

INTRODUCTION

Transradial intervention (TRI) is widely used for percutaneous coronary intervention (PCI) due to lower risk of bleeding and complications. It also facilitates rapid patient mobilization after TRI.\(^1\,^2\) However, complications, such as potential radial artery occlusion (RAO), could limit the use of forearm arteries as an access site for coronary interventions during postoperative re-examination. Despite pretreatment with heparinization, RAO occurs in 5–12% of patients after TRI.\(^1\,^2\,^3\,^4\) The risk of RAO needs particular attention.\(^5\,^6\) Therefore, reducing vascular occlusion has an important clinical significance.

So far, several approaches are proposed to reduce the risk of RAO that include anticoagulation, immediate postprocedural sheath removal, and a small sheath/radial artery (RA) ratio.\(^6\,^7\,^8\) Nevertheless, puncture site at RA may play an important role in RAO prevention. Interventional cardiologists usually choose the site 0–5 cm away from the radius styloid process as their puncture site. Whether this is the best puncture site during TRI remains unclear. Thus, we designed the present prospective study to determine the best puncture site to reduce occlusion risk during TRI.

METHODS

Patient selection

From November 2013 to November 2014, 669 consecutive patients admitted at our institution undergoing percutaneous coronary diagnostic or interventional procedures with an attempt to use the transradial approach as a first access were prospectively enrolled in the present registry. The inclusion criterium was adult patients (≥18 years) who were admitted for transradial catheterization. The exclusion criteria were patients on femoral access, arterial circulatory disease, pathological Allen tests, decompensated heart failure, chronic renal failure, puncture access crossover, and those who had a prior TRI. A preoperative forearm artery ultrasound was

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performed in all patients. The Allen and reverse Allen tests were routinely used with a cutoff time of <10 s. Before the procedure, a ruler was used to measure the length from the radius styloid process to 2 cm below the cubital fossa. RA lengths from the radius styloid process to the bifurcation of the brachial artery were measured by computer-based quantitative coronary analysis when performing a forearm angiography. The study was approved by the local Institutional Review Board. The study was conducted in accordance with the guidelines of the Declaration of Helsinki.

Procedure
The right forearm artery was the first choice for access. A dedicated 6F arterial puncture kit (with plastic cannula and hydrophilic 0.025-inch guidewire) and long (16 cm) hydrophilic sheath (Terumo Corporation, Tokyo, Japan) were used for RA catheterization. The overlying skin of RA was infiltrated with 2% lidocaine. RA was punctured with a 20G needle using the Seldinger technique. A small incision was made with a No. 11 surgical blade. The stylet was removed and a 0.025-inch guidewire and a 16 cm long 6Fr sheath were inserted. After sheath replacement, a solution of 3000 U unfractionated heparin and 200 µg nitroglycerin was administered into the side port of the sheath for coronary angiography (CAG). At the beginning of PCI, a weight-adjusted dose of unfractionated heparin (100 U/kg) was administrated through the sheath catheter to maintain an activated clotting time between 250 s and 350 s. CAG was performed with a 4Fr or 5Fr catheter, and PCI was performed with a 6Fr catheter. All patients without contraindications underwent percutaneous coronary procedures with double anti-platelet therapy (aspirin and clopidogrel). The arterial sheath was always removed after the completion of CAG or PCI. In all patients, a folded bandage consisting of three adhesive elastic bands for compression hemostasis. The overlying skin of RA was infiltrated with 2% lidocaine. RA was punctured with a 20G needle using the Seldinger technique. A small incision was made with a No. 11 surgical blade. The stylet was removed and a 0.025-inch guidewire and a 16 cm long 6Fr sheath were inserted. After sheath replacement, a solution of 3000 U unfractionated heparin and 200 µg nitroglycerin was administered into the side port of the sheath for coronary angiography (CAG). At the beginning of PCI, a weight-adjusted dose of unfractionated heparin (100 U/kg) was administrated through the sheath catheter to maintain an activated clotting time between 250 s and 350 s. CAG was performed with a 4Fr or 5Fr catheter, and PCI was performed with a 6Fr catheter. All patients without contraindications underwent percutaneous coronary procedures with double anti-platelet therapy (aspirin and clopidogrel). The arterial sheath was always removed after the completion of CAG or PCI. In all patients, a folded bandage consisting of three gauze layers was applied to the access site and wrapped with three adhesive elastic bands for compression hemostasis. The bandage was kept on for 6 h, but was loosened every 2 h.[11]

During the application of folded bandage, the monitoring of plethysmography and oximetry pulse was performed to assess RA patency palm circulation status. The signal of plethysmography and oximetry pulse was observed using fingertip oxygen saturation. When the compression pressure was moderate, there was no significant decrease.[12,13]

Vascular complication definitions
RAO was defined as the absence of a flow signal on Doppler ultrasound examination. Local bleeding was defined as insignificant subcutaneous bleeding or hematoma formation around the puncture site. All patients were assessed forearm artery by Doppler ultrasound in two days after TRI. RAO was also evaluated in one year after the coronary intervention.

Statistical analysis
The Statistical Package for Social Sciences (SPSS) for Windows, version 13.0 (SPSS, Chicago, IL, USA) and MedCalc Software (version 12.2.1.0, MedCalc Software, Mariakerke, Belgium) were used for statistical analyses. The Chi-square test was used to compare categorical data, and the results were expressed as numbers and percentages. Continuous variables were expressed as the mean ± standard deviation (SD) for normally distributed variables and as the median (25th to 75th percentiles) for nonnormally distributed variables. P = 0.05 was considered statistically significant. Logistic regression (LR) was then used to predict the probability of RAO. First, the unadjusted odds ratio (OR) value of the RAO for various patient characteristics included sex, body mass index (BMI), smoking, hypertension, diabetes, dyslipidemia, puncture site, spasms, and diameter/sheath ratio. The independent categorical variables were coded as follows: diameter/sheath (the ratio of the arterial diameter to the sheath; 0 stands for diameter/sheath >1 and 1 stands for diameter/sheath ≤1); puncture site (the distance from the radius styloid process to puncture site; 0 stands for 5 cm, 1 stands for 4 cm, 2 stands for 3 cm, 3 stands for 2 cm, 4 stands for 1 cm, and 5 stands for 0 cm). A final multivariate model was then assigned that included all factors related to the occurrence of the RAO in the univariate analyses. Multivariate analysis, a binary LR of backward LR method (with the value of the P-entry [0.05] and P-exit [0.10]), was performed to identify the predictive variables of RAO.

RESULTS
Population characteristics
During the study period, 669 patients underwent TRI at our institution. Twenty-four of them did not meet the inclusion criteria and were excluded. Thirty-one patients crossed over to other artery after failed TRI. Of the 614 patients, 8 were excluded from the final analysis because of a lack of clinical follow-up data (n = 6) and death (n = 2). The remaining 606 patients who used RA as the first approach were enrolled in the study [Figure 1]. Baseline demographic and clinical history characteristics were overall matched [Table 1]. The average length from the styloid process to 2 cm below the cubital fossa was 19.5 ± 2.1 cm, which was similar to the average length of RA (19.0 ± 2.2 cm). There was no significant difference among the age, gender, BMI, coronary artery disease risk factors, medicine use, procedural time, and spasms between groups. The distribution of RA access puncture site using frequency were expressed as numbers and percentages. Continuous variables

Figure 1: Study flow chart. TRI: Transradial intervention.
by Doppler ultrasound preoperatively [Figure 3]. The diameters of the RA at 0–5 cm (at 1 cm increments) from the radius styloid process were 2.78 ± 0.25 mm, 2.86 ± 0.30 mm, 2.86 ± 0.32 mm, 2.88 ± 0.31 mm, 2.81 ± 0.29 mm, and 2.86 ± 0.31 mm, respectively. The depths of the RA at 0–5 cm (at 1 cm increments) from the radius styloid process were 2.50 ± 0.23 mm, 2.69 ± 0.22 mm, 2.72 ± 0.31 mm, 2.72 ± 0.31 mm, 2.82 ± 0.36 mm, and 4.16 ± 0.40 mm, respectively.

The primary outcome
Fifty-six out of 606 patients suffered from RAO during the one year follow-up period. Sixteen of 67 patients with a puncture site located at 0 cm from the radius styloid process suffered RAO (P = 0.002), and fourteen of 62 patients suffered RAO at the 1 cm (P = 0.001). There was no difference between groups with regard to hemorrhage risk [Table 1].

The multivariate analysis
The unadjusted OR of the RAO for 606 patient characteristics was assessed in Figure 4. The RAO rate was significantly increased between the groups when the ratio of the arterial diameter to the sheath was ≤1 (41.1% vs. 23.6%, P = 0.04). There was a significant increase in the occurrence of RAO at puncture site 0 and 1 cm away from the radius styloid process (P = 0.002 and P = 0.001, respectively). However, the rate of RAO was significantly less with radial access at 4 cm from the radius styloid process (P = 0.001). A final multivariate LR analysis of RAO outcome is shown in Figure 5. When we used the puncture site at 0 cm (OR = 9.65, 95% confidential interval [CI]: 1.20–77.50; P = 0.033) and 1 cm (OR = 8.90, 95% CI: 1.10–72.40; P = 0.040), the rate of RAO was higher. The higher occurrence of RAO occurred in the ratio of the arterial diameter to the sheath ≤1 (OR = 2.45, 95% CI: 1.30–4.51; P = 0.004).

Discussion
Although the TRI is considered a safe and effective option for coronary artery intervention, RAO is an important complication of TRI. Despite the fact that RAO tends to be asymptomatic, it limits the option of using RA as an access site in the future.[14] Therefore, reducing vascular occlusion has an important clinical significance. This study aimed at comparing the risk of RAO through TRI up to one year. Our

Table 1: Baseline and procedural data

| Variables                        | All        | RAO (+)  | RAO (−)  | P       |
|----------------------------------|------------|----------|----------|---------|
| Age (years)                      | 63.5 ± 5.7 | 62.1 ± 5.6| 64.5 ± 6.1| 0.16    |
| Men, n (%)                       | 382 (63.0) | 35 (62.5)| 347 (63.1)| 0.97    |
| BMI (kg/m²)                      | 27.1 ± 2.5 | 26.9 ± 2.2| 27.2 ± 3.1| 0.49    |
| Smoking, n (%)                   | 194 (32.0) | 20 (35.7)| 174 (31.6)| 0.66    |
| Hypertension, n (%)              | 295 (48.7) | 23 (41.1)| 272 (49.5)| 0.47    |
| Diabetes, n (%)                  | 157 (25.9) | 14 (25.0)| 143 (26.0)| 0.90    |
| Dyslipidemia, n (%)              | 226 (37.3) | 18 (32.1)| 208 (37.8)| 0.51    |
| Aspirin, n (%)                   | 595 (98.2) | 54 (96.4)| 541 (98.4)| 0.61    |
| Statin, n (%)                    | 590 (97.4) | 55 (98.2)| 535 (96.9)| 0.89    |
| Clopidogrel, n (%)               | 598 (98.7) | 55 (98.2)| 543 (98.7)| 0.77    |
| Unfractionated heparin (U/kg)    | 72.0 ± 6.9 | 73.0 ± 7.0| 72.0 ± 7.1| 0.32    |
| Three vessel disease, n (%)      | 58 (9.6)   | 6 (10.7) | 52 (9.5) | 0.95    |
| Asymmetry of sheath size, n (%)  | 153 (25.2) | 23 (41.1)| 130 (23.6)| 0.04    |
| Length (cm)                      | 19.0 ± 2.2 | 18.9 ± 2.1| 19.2 ± 2.5| 0.13    |
| Bleeding, n (%)                  | 5 (0.8)    | 1 (1.8)   | 4 (0.7)   | 0.41    |
| Procedure time (min)             | 22.9 ± 5.5 | 23.4 ± 5.6| 22.6 ± 6.3| 0.36    |

Results are mean ± SD or n (%). RAO: Radial artery occlusion; BMI: Body mass index; Length: The distance from the radius styloid process to bifurcation of the brachial artery; SD: Standard deviation.

Figure 2: Frequency of TRI puncture site use distribution of frequency in radial access puncture site use during TRI by 606 puncture sites. TRI: Transradial intervention.

Figure 3: (a) Distribution of the radial artery diameter. (b) Distribution of the radial artery depth. The diameter and depth at 0–5 cm from the styloid process were measured by Doppler ultrasound preoperatively.
Figure 4: Forest plot of RAO by risk factors. Puncture site: Defined as the distance from the radius styloid process to the puncture site; Diameter/sheath: The ratio of the arterial diameter to the sheath. RAO: Radial artery occlusion; OR: Odds ratio; CI: Confidence interval; BMI: Body mass index.

Figure 5: Predictors of the radial artery occlusion by multivariate analysis. Puncture site: Defined as the distance from the radial styloid process to puncture site; Diameter/sheath: The ratio of the arterial diameter to the sheath. OR: Odds ratio; CI: Confidence interval.

data showed that the diameter of the RA from the distal to proximal puncture site was similar, although the depth of the RA increased from distal to proximal puncture site. This did not lead to an increase in bleeding complications. There was a statistically and clinically significant reduction in the incidence of RAO in the patients whose puncture site was >2 cm (from the radius styloid process) compared to those puncture sites that were within 0–1 cm.

This appears to be a relationship exists between the length of the radial sheath and the length of the forearm. The average length from the radius styloid process to 2 cm below the cubital fossa was similar to the average length of RA. However, the length of the 6Fr radial sheath was only 16 cm, shorter than the length of the RAs. If the puncture sites were closer to the distal end of the artery, the length of the proximal RA with no sheath protection would increase. Thrombus formation is a direct pathophysiological consequence of RAO.\textsuperscript{[15,16]} Finding thrombi in the proximal artery may be due to using a short sheath, and thus is one disadvantage of its use. Using optical coherence tomography (OCT), Yonetsu \textit{et al.}\textsuperscript{[17]} found that more than half of the intimal tears were observed at the proximal end of the sheath and close to the RA ostium, possibly because the protective sheath itself may cause intimal tears.

In addition, medial dissections also occur in the proximal RA. The proximal medial dissections are likely to be caused by advancing or withdrawing of catheters through the proximal RA where there was no sheath protection. The more catheters used, the higher the risk of occlusion. The interruption of blood flow tended to occur in the proximal artery was probably caused by occlusive thrombus formation. The thrombus formation in the distal of RA in a small proportion of patients was probably caused by the sheath implanted or repeated puncture. The intimal and medial thickening after transradial coronary interventions
which was observed through OCT was also noted by Yonetsu et al.[17] Furthermore, the risk of medial dissections caused by sheath insertion may increase if the diameter/sheath ratio is ≤1.[18] Our results suggest that the risk of occlusion may be reduced by moving the puncture site proximally or by increasing the length of the sheath according to the forearm length of each patient.[19]

There were some limitations in this study. This was a nondouble-blind trial between patients undergoing coronary procedures. We cannot exclude patients whose RA diameter was smaller than radial sheath that could have affected the results. In cardiology center of China, we routinely use heparin 3000 U for CAG rather than 5000 U, this may have affected the RAO results.[20] The procedures were performed by four operators, which may also have resulted in some bias. The application of compressive bandage may not allow patent hemostasis depending on pressure adjusted.

In conclusion, this study demonstrated that distal puncture sites (0–1 cm away from the radius styloid process) can result in higher occurrence of RAO. This was probably due to the longer distance of no sheath protection that increased with more distal puncture sites. Therefore, the risk of RAO after TRI could be reduced by adopting more proximal puncture sites and usage of longer sheaths.

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**Conflicts of interest**
There are no conflicts of interest.

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