BMC Medicine

RESEARCH

Open Access

Distal radial access to prevent radial artery occlusion for STEMI patients (RAPID III): a randomized controlled trial

Zixuan Li[1†], Yujie Wang[3†], Jiahui Song[1†], Senhu Wang[2], Yuntao Wang[4], Yongxia Wu[1], Haotian Wang[2], Zijing Liu[1], Rui Yan[1], Guangyao Zhai[1*] and Jincheng Guo[1*]

Abstract

Background Compared with conventional transradial access (TRA), distal radial access (DRA) is rarely used for percutaneous coronary intervention (PCI) in patients with ST-elevation myocardial infarction (STEMI) and may be beneficial to prevent radial artery occlusion (RAO). We aimed to evaluate the incidence of RAO between DRA and TRA 24 h after primary PCI in patients with STEMI.

Methods This is a single-center, open-label, prospective, randomized controlled trial conducted at Beijing Luhe Hospital, China, between January 2022 and July 2023. Five hundred and twenty patients (mean age: 61.3 ± 13.0 years; 81% male) with STEMI were randomly assigned to the DRA ($n = 260$) or TRA ($n = 260$) group. Primary PCI was performed using the radial artery access assigned study group. The primary endpoint was the rate of RAO assessed using Doppler ultrasound 24 h after primary PCI. Secondary outcomes included time taken for sheath insertion, access success rate, hemostasis time, fluoroscopy time, radiation dosage, and access-related complications.

Results The incidence of RAO was significantly lower in the DRA group than that in the TRA group (1.9% vs. 8.5%, $P = 0.001$). Access was successful in 94.6% of patients, and the crossover rate was 5.4% in both groups. The median time taken for sheath insertion was significantly longer (133 s vs. 114 s, $P = 0.009$), whereas the mean hemostasis time was shorter (209 ± 71 min vs. 372 ± 70 min, $P < 0.001$) in the DRA group. The incidence of modified Early Discharge After Transradial Stenting of Coronary Arteries (mEASY) ≥ II hematoma was lower in the DRA group (0.8% vs. 3.5%, $P = 0.033$). However, there was no significant difference in fluoroscopy time, radiation dosage, or access-related complications.

Conclusions In patients with STEMI undergoing primary PCI, compared with TRA, DRA prevented RAO 24 h postoperatively and was associated with shorter hemostasis time and a lower incidence of mEASY ≥ II hematoma.

Trial registration Clinical Trials.gov Identifier: NCT05461781.

Keywords Distal radial access, ST-segment elevation myocardial infarction, Percutaneous coronary intervention, Radial artery occlusion

†Zixuan Li, Yujie Wang and Jiahui Song contributed equally to this work and are first co-authors.

*Correspondence:
Guangyao Zhai
Drzhaiguangyao@163.com
Jincheng Guo
guojcmd@126.com
Full list of author information is available at the end of the article

Background

The radial artery is the preferred access route for patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) [1]. However, radial artery occlusion (RAO) remains a common complication, with incidence rates of 1–33% [2]. Maintaining radial artery patency is crucial for patients with STEMI, especially those with multivessel disease requiring staged PCI, and serves as a donor for bypass grafts and creating arteriovenous fistulas for hemodialysis. Strategies to reduce RAO include reducing catheter or sheath size, providing adequate procedural anticoagulation, having a patent hemostasis protocol, minimizing pressure, and shortening hemostasis time [3].

Previous studies have indicated that the incidence of RAO was significantly lower after distal radial access (DRA) than after conventional transradial access (TRA) [4, 5]. However, these studies excluded patients with STEMI, limiting the data on RAO reduction during primary PCI via DRA. Thus, the effectiveness of DRA for patients with STEMI undergoing primary PCI, which requires prompt action and great skill to access the distal radial artery, is unclear; therefore, we designed a randomized controlled trial (RCT) to compare primary PCI through DRA and TRA in those patients.

Methods

Study design and participants

The RAPID III study is an open-label, single-center, prospective, RCT conducted at Beijing Luhe Hospital, China, between January 2022 and July 2023. Participants aged ≥ 18 years, diagnosed with STEMI, admitted within 12 h of symptom onset, and having palpable pulses on both radial artery access sites (DRA and TRA) were eligible. The inclusion and exclusion criteria were detailed in Additional file 1: Table S1 [6]. Patients were randomly assigned to two groups (DRA or TRA) in a 1:1 ratio with a block size of 4 using Strata software (Version 17.0, Strata Decision Technology, Chicago, IL, USA). The randomization results were sealed in opaque envelopes, which were opened by a trainee before the arterial puncture to reveal the patient's group assignment and proceed with the corresponding intervention.

The study was approved by the Beijing Luhe hospital Institutional Review Board, adhered to the Declaration of Helsinki, was registered on ClinicalTrials.gov as "Distal Radial Access for Primary PCI in STEMI Patients to Prevent RAO [RAPID III]" (NCT05461781), and complies with the Consolidated Standards of Reporting Trials guidelines for RCTs. Written informed consent was obtained from all participants.

Coronary intervention protocol

Before primary PCI, all patients received a pretreatment loading dose of 300 mg aspirin and a P2Y12 inhibitor (600 mg clopidogrel or 180 mg ticagrelor). The right access site was our study's preferred choice for the DRA and TRA groups.

Before coronary angiography, the operator assessed the eligibility of patients scheduled for catheterization. Participants were randomly assigned to the DRA or TRA group for primary PCI if clinically indicated. The decision to use unfractionated heparin or bivalirudin, glycoprotein IIb/IIIa inhibitors, and the individual PCI strategy was at the operators' discretion. Notably, all access procedures were performed by three high-volume interventional cardiologists who had at least 5 years of experience with TRA and had performed at least 150 PCI procedures via DRA.

Puncture and hemostasis procedure

In the TRA group, 2% lidocaine was used as a local anesthetic. The arterial puncture was performed 2 cm proximal to the styloid process with a 20-gauge needle using the through-and-through technique. After inserting a 16-cm 6F Radifocus® Introducer II hydrophilic sheath (Terumo Corp., Tokyo, Japan), a "cocktail" comprising 200 μg nitroglycerin, 2.5 mg verapamil, and 100 IU/kg unfractionated heparin was administered through the sheath's side port. The heparin dosage was adjusted based on the activated clotting time (ACT).

In the DRA group, the puncture site was located at the anatomical snuffbox. The same transradial kit was used or TRA. After a successful puncture, the needle was removed, and a hydrophilic, straight plastic 0.025″ mini guidewire of the sheath was inserted through the venipuncture catheter. If the mini guidewire encountered resistance, a 0.014″ guidewire with the tip hand-shaped at 30° was used; once successful, the venipuncture catheter was advanced further, and the 0.025″ guidewire was reinserted. The remaining steps of the procedure were conducted following the TRA method.

Hemostasis protocol

After the procedure, the sheath was immediately removed. Hemostasis was achieved using an Airpower (Shenzhen, China) compression device for 2–3 h in the DRA group and 4–6 h in the TRA group. The hemostatic time was recorded from the device application until removal. Trained nurses checked the compression site hourly. If the puncture site was bleeding or swollen with a slight hematoma, compression was continued for 30–60 min. Access time, calculated in minutes, started when the puncture needle made contact with the skin

and ended once the guidewire passed through the puncture needle into the artery [7]. All patients were evaluated for radial artery patency within 24 h after the procedure using Doppler ultrasound.

Study endpoints

The primary endpoint in the two groups was RAO at 24 h after primary PCI was assessed by an independent investigator, who was not involved in the procedure. RAO was determined by the absence of a duplex ultrasound anterograde flow signal distal to the RA access site, using a portable ultrasound machine with a 7.5MH frequency probe.

The secondary endpoints included successful sheath insertion, time required for sheath insertion, fluoroscopy time, radiation dosage, contrast volume, hemostasis time, and other access-related complications such as arterial-venous fistula formation, arterial dissection/perforation, pseudoaneurysm, and local hematoma. These were routinely recorded for all patients during the hospital stay. Puncture site bleeding was defined using the modified Early Discharge After Transradial Stenting of Coronary Arteries (mEASY) study criteria [5]. The endpoints definitions were available in Additional file 1: Table S2 [7].

Statistical analysis

This study was designed as a superiority trial, with the incidence rate of RAO 24 h post-intervention as the primary outcome measure. Sample size calculations were based on previous reports on the difference between DRA and TRA [4, 5]. Specifically, the incidence of RAO at 24 h post-intervention was set at 8% and 1% for the TRA and DRA groups, respectively [4]. The DRA and TRA groups were randomly divided in a 1:1 ratio to achieve a 90% power and 0.05 significance level. Using PASS software (version 16.0.1, NCSS Kaysville, UT, USA), the calculated sample size was 244 cases per group. Accounting for a dropout rate of 5%, the final sample size was set at 512 cases (256 cases per group).

All statistical analyses were performed based on the intention-to-treat (ITT) principle, including randomization of all patients and treatment according to the allocated access, regardless of whether they crossed over to another access site or did not undergo PCI. The per-protocol (PP) population excluded patients who were not suitable for the study protocol or/and were lost to follow-up. The primary endpoint was analyzed using ITT and PP analysis. The secondary endpoints were analyzed using the ITT approach.

Categorical variables are presented as numbers and percentages, and continuous variables as mean ± standard deviation or median (interquartile range). Continuous variables were compared using Student's *t*-tests or the Mann–Whitney *U* test, and categorical variables were compared using the chi-square or Fisher's exact test as appropriate. To identify the predictors of RAO and forearm hematoma, multivariate analysis was performed using binary logistic regression. All variables with $P<0.1$ in the univariable analysis were included in the multivariable model.

All statistical analyses were performed using IBM SPSS Statistics 24.0 (Chicago, IL, USA). Statistical significance was set at $P<0.05$.

Results

Patient characteristics

Between January 2022 and July 2023, 520 patients who met the inclusion criteria were assigned to the DRA or TRA group. Patient recruitment details are provided in Fig. 1. The ITT population comprised 520 patients, randomized to the DRA ($n=260$) or TRA ($n=260$) groups. The PP population ($n=239$ per group) excluded the patients whose access site changed or were lost followed-up (data of patients without ultrasound follow-up is available in Additional file 1: Table S3).

There were no significant differences ($P>0.05$) in baseline traits between the groups other than ejection fraction and the number of patients taking β-blockers (Table 1). The mean age of all patients was 61.3 years, 81% were male, 24.8% had diabetes mellitus, and 57.3% had hypertension. Notably, 12.1% of the patients had a history of myocardial infarction and 12.9% had previously undergone TRA. Most patients (99.6%) had received antiplatelet medications and 3.3% were on oral anticoagulants.

Procedural characteristics

Table 2 presents the procedural characteristics. Right-side access was initially selected in most patients in both groups (100% vs. 98.8%, $P=0.249$), and similar proportions of patients underwent primary PCI in both groups (98.1% vs. 99.6%, $P=0.10$). The success rates of primary PCI were high in both groups, with Thrombolysis in Myocardial Infarction (TIMI) grade-3 flow rates of 96.5% and 94.6%, $P>0.05$. The groups showed no significant differences in culprit vessels and intravascular-guided imaging, and their ACTs were similar (mean: 319 s vs. 318 s; $P=0.687$).

The DRA group had more puncture attempts, but the difference was not statistically significant ($P=0.079$). To achieve successful sheath insertion, a 0.014" guidewire was used more frequently in the DRA group than in the TRA group (8.5% vs. 1.2%, $P<0.001$). The overall rate of vascular approach crossover was 5.4% and similar in both groups. Crossover occurred in 14 patients randomized to the DRA group: 11 crossed over to the same-side TRA, two to femoral arteries, and one to the brachial artery.

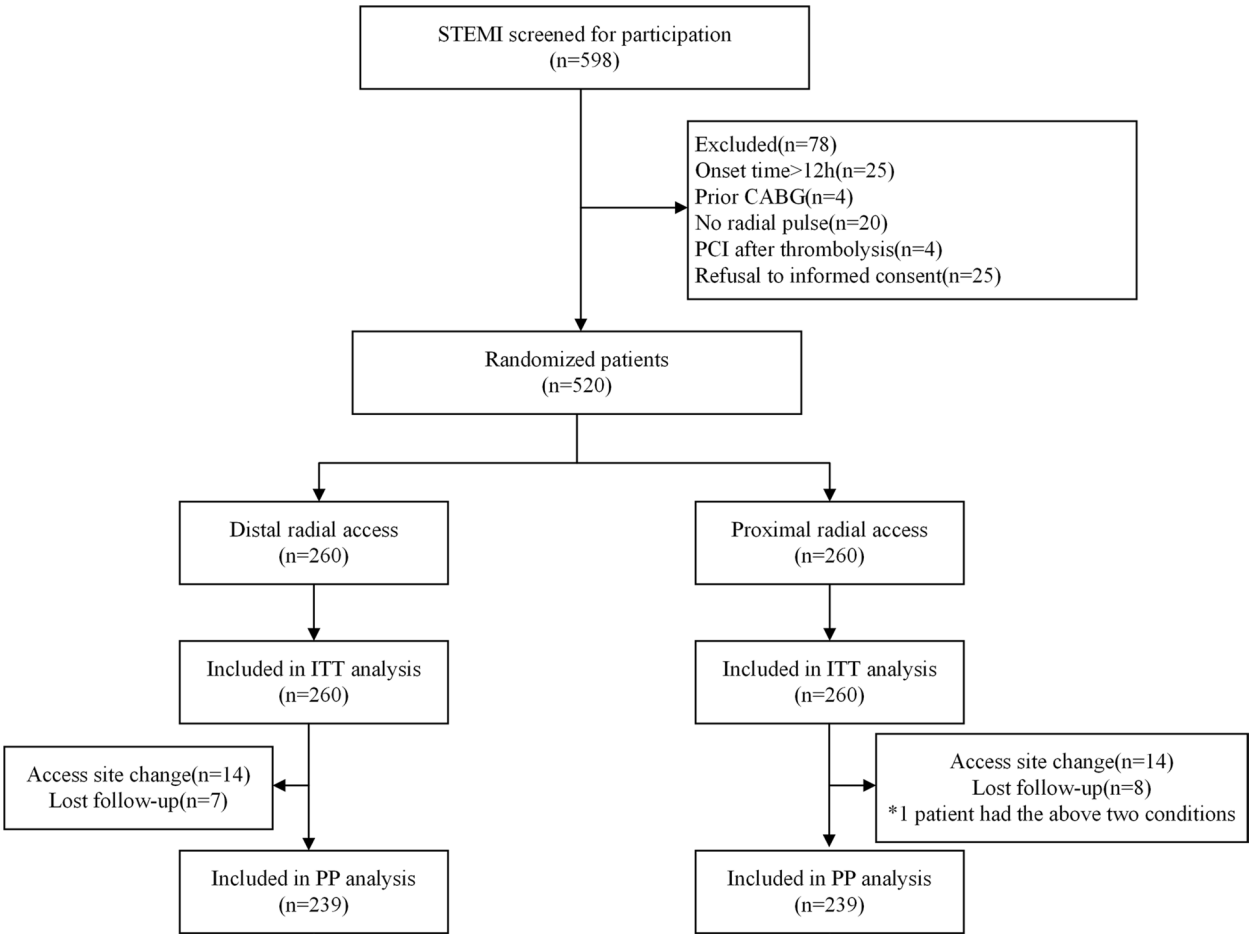

Fig. 1 Flowchart depicting patient selection. This flow chart illustrates the selection and randomization of STEMI patients for the study, comparing distal radial access (DRA) and proximal radial access (PRA). Out of 598 screened patients, 520 were randomized equally into DRA ($n=260$) and PRA ($n=260$) groups. The diagram details exclusions due to various criteria (e.g., onset time > 12 h, prior CABG), and follow-up data, showing the inclusion in intention-to-treat (ITT) and per-protocol (PP) analyses leading to inclusion of 239 patients in each group. CABG, coronary artery bypass graft; ITT, intention-to-treat; PCI, percutaneous coronary intervention; PP, per-protocol; PRA, proximal radial access; STEMI, ST-segment elevation myocardial infarction

However, in the TRA group, 14 patients crossed over: nine to DRA, four to femoral artery access, and one to brachial artery access. The reasons for the crossover are provided in Table 3.

Doppler evaluation and primary endpoint

When evaluating RAO 24 h after the procedure, Doppler follow-up was available within 24 h for 253 (97.3%) and 252 (96.9%) patients in the DRA and TRA groups, respectively. ITT analysis revealed RAO in 1.9% and 8.5% of patients in the DRA and TRA groups, respectively ($P=0.001$). Primary endpoint analysis in the PP population yielded consistent results: RAO rates were 1.7% and 8.4% for the DRA and TRA groups, respectively ($P=0.001$) (Fig. 2). Multivariate logistic regression analysis identified TRA (OR: 5.872; 95% CI: 1.971 to 17.499; $P=0.001$), bivalirudin use (OR: 2.811; 95% CI: 1.214 to 6.507; $P=0.016$), and the RA/sheath diameter ratio (OR: 0.034; 95% CI: 0.002 to 0.487; $P=0.013$) as independent predictors of RAO at 24 h (Additional file 2: Table S1–2).

Secondary outcomes and access-related complications

Successful sheath insertion was observed in 94.6% of patients in the DRA and TRA groups. Furthermore, access time was significantly longer in the DRA group than in the TRA group (133 s vs. 114 s, $P=0.009$). However, there was no difference in puncture time, and door-to-balloon (DTB) time between the two groups. Also, no significant differences were observed in mean fluoroscopy time or radiation dosage. However, hemostasis time was significantly shorter in the DRA than in the TRA group (209 ± 71 min vs. 372 ± 69.6, $P<0.001$) (Fig.3).

Table 1 Comparison of baseline data between the two patient groups

Variable	DRA ($n=260$)	TRA ($n=260$)	*P*-value
Age, years	61.3 ± 12.9	61.1 ± 13.1	0.861
Male	214 (82.3)	207 (79.6)	0.434
Height, cm	167.8 ± 7.4	167.8 ± 7.4	0.920
Weight, kg	73.5 ± 10.7	73.6 ± 12.8	0.910
BMI, kg/m^2	26.0 ± 3.2	26.0 ± 3.9	0.885
Risk factors for CHD, *n* (%)			
Hypertension	139 (53.5)	159 (61.2)	0.076
Diabetes	69 (26.5)	60 (23.1)	0.361
Hyperlipidemia	77 (29.6)	78 (30.0)	0.924
Smoking	147 (56.5)	138 (53.1)	0.428
Family history of CHD	56 (21.5)	57 (21.9)	0.915
Past medical history			
Previous angiography	36 (13.8)	37 (14.2)	0.900
Previous myocardial infarction	30 (11.5)	33 (12.7)	0.687
Peripheral vascular disease	12 (4.6)	12 (4.6)	1.000
Stroke	26 (10.0)	25 (9.7)	0.894
Previous TRA	33 (12.7)	34 (13.1)	0.896
Vital signs on admission			
Systolic BP, mmHg	120.6 ± 20.4	117.8 ± 20.7	0.128
Diastolic BP, mmHg	80.3 ± 16.4	78.3 ± 17.5	0.182
Heart rate, beats/min	76.0 ± 17.1	76.0 ± 18.9	0.966
Clinical presentation			
Anterior STEMI	122 (46.9)	126 (48.5)	0.725
Inferior STEMI	138 (53.1)	134 (51.5)	
Atrial fibrillation	16 (6.2)	18 (6.9)	0.723
Killip classification, *n* (%)			0.489
I–II	247 (95.0)	247 (95.0)	
III	4 (1.5)	1 (0.4)	
IV	9 (3.5)	12 (4.6)	
Ejection fraction, %	62.5 ± 9.7	60.8 ± 9.7	0.047*
Laboratory tests			
White blood cell count, × 10^9/L	10.0 ± 3.1	10.2 ± 3.0	0.409
Creatinine, μmol/L	83.6 ± 64.3	81.9 ± 30.1	0.707
LDL, mmol/L	2.9 ± 0.8	3.0 ± 0.9	0.078
C-reactive protein, mg/L	9.1 ± 14.9	11.6 ± 24.2	0.171
Glucose, mmol/L	9.5 ± 3.5	10.0 ± 4.5	0.178
Lactate, mmol/L	2.6 ± 6.4	2.4 ± 1.6	0.652
Hemoglobin A1c, %	6.5 ± 1.3	6.6 ± 1.5	0.405
Medications			
Aspirin	258 (99.2)	260 (100)	0.499
Clopidogrel	58 (22.3)	60 (23.1)	0.834
Ticagrelor	199 (76.5)	200 (76.9)	1.000
ACEI/ARB	170 (65.4)	176 (67.7)	0.577
Beta-blockers	146 (56.2)	171 (65.8)	0.025
Statins	253 (97.3)	251 (96.5)	0.612
Oral anticoagulants	12 (4.6)	5 (1.9)	0.084

Values are presented as *n* (%) or mean ± standard deviation

ACEI Angiotensin-converting enzyme inhibitor, *ARB* Angiotensin receptor blocker, *BMI* Body mass index, *BP* Blood pressure, *CHD* Coronary heart disease, *LDL* Low-density lipoprotein cholesterol, *STEMI* ST-segment elevation myocardial infarction, *TRA* Transradial access, *DRA* Distal radial access

Vascular complications occurred in 16.5% and 19.6% of patients in the DRA and TRA groups, respectively ($P=0.362$). The incidence of severe hematoma (mEASY ≥ II) was significantly lower in the DRA group than in the TRA group (0.8% vs. 3.5%, $P=0.033$) (Fig.3), and no patient required surgical treatment. Multivariate logistic regression analysis revealed that weight (OR: 0.968; 95% CI: 0.942 to 0.993; $P=0.014$), multiple puncture attempts (OR: 1.455; 95% CI: 1.082 to 1.956; $P=0.013$), and TRA (OR: 1.906; 95% CI: 1.010 to 3.597; $P=0.047$) were independent predictors for hematoma formation (Additional file 2:Table S3). Furthermore, the incidence of hematomas, spasms, finger numbness, and pseudoaneurysm did not differ between the two groups (Table 4).

Discussion

This single-center, open-label RCT compared the efficacy and safety between DRA and TRA in patients undergoing primary PCI for STEMI. The major findings were that DRA significantly reduced RAO and hemostasis time compared with TRA. DRA was also associated with a lower incidence of mEASY ≥ II hematoma but led to a marked increase in the time required for sheath insertion. However, this increase did not result in a longer DTB time, and the longer sheath insertion time was not clinically relevant.

RAO benefits from DRA

Data from registries [8, 9], RCTs [4, 5, 10–13], and meta-analyses [14, 15] indicate a significantly low incidence of RAO associated with DRA. For instance, the multicenter Korean Prospective Registry reported a low RAO rate of 0.8% at a 1-month follow-up [9]. Furthermore, a meta-analysis involving 6208 patients across 14 RCTs comparing DRA with TRA found a significant reduction in RAO rates, both in-hospital (1.4% vs. 5.3%, $P<0.001$) and during follow-up (1–60 days follow-up, 1.6% vs. 5.2%, $P<0.001$) in patients, when DRA was used [11, 14]. A substantial reduction in RAO rates, ranging from 0.7%-3.7% for DRA compared with 3.3%—9.0% for TRA, was also observed in the six original RCTs published as full papers with RAO as the primary endpoint [4, 11–13, 16, 17]. Consistent with these findings, our results demonstrated a significant decrease in early RAO rates with DRA compared with TRA (1.9% vs. 8.5%, $P<0.01$, based on ITT analysis). However, the large-scale DISCO RADIAL trial revealed no significant difference in RAO between DRA and TRA (0.31% vs. 0.91%, $P=0.29$) [15]. This can be explained by the fact that the RAO rate in the

Table 2 Comparison of procedural characteristics between the two patient groups

Variable	DRA (*n* = 260)	TRA (*n* = 260)	*p*-value
Loading dose, *n* (%)			
Aspirin 300 mg + clopidogrel 600 mg	23 (8.8)	34 (13.1)	0.123
Aspirin 300 mg + ticagrelor 180 mg	237 (91.2)	226 (86.9)	
Anticoagulants			
Bivalirudin	74 (28.5)	69 (26.5)	0.623
Heparin	186 (71.5)	191 (73.5)	
GP IIb/IIIa inhibitor			
Tirofiban	12 (4.6)	20 (7.7)	0.144
6F sheath used	260(100)	260(100)	
Target vessel, *n* (%)			0.648
Left anterior descending	123 (47.3)	123 (47.3)	
Left circumflex	19 (7.3)	24 (9.2)	
Right coronary artery	117 (45.0)	113 (43.5)	
Left main	1 (0.4)	0(0.0)	
Angiographic results, *n* (%)			
Single vessel disease	79 (30.4)	63 (24.2)	0.115
Multivessel disease	181 (69.6)	197 (75.8)	
Interventional strategies, *n* (%)			
Stent implantation	193 (74.2)	193 (74.2)	1.000
Drug balloon dilatation	44 (16.9)	45 (17.3)	0.907
Door-to-balloon time, min	69 (57–88)	66 (56–82)	0.242
Catheter lab door-to-balloon time, min	23 (20–28)	22 (19–26)	0.093
Procedure time, min	50 (37–64)	51 (38–66)	0.616
IABP	2 (0.8)	5 (1.9)	0.450
Simultaneous treatment of non-culprit vessel	10 (3.8)	18 (6.9)	0.120
Total number of catheters	1.2 ± 0.5	1.2 ± 0.5	0.807
Number of guide wires	1.1 ± 0.3	1.1 ± 0.3	0.722
Intravascular imaging, *n* (%)			
OCT/IVUS	123 (47.3)	111 (42.7)	0.290
Preoperative TIMI flow, *n* (%)			
0/1	224 (86.2)	220 (84.6)	0.774
2	30 (11.5)	35 (13.5)	
3	6 (2.3)	5 (1.9)	
Postoperative TIMI flow, *n* (%)			
0/1	4 (1.5)	1 (0.4)	0.067
2	5 (1.9)	13 (5.0)	
3	251 (96.5)	246 (94.6)	
Contrast agent dose, mL	130 (110–210)	150 (110–210)	0.538
Activated clotting time, s	319 (272–399)	318 (272–384)	0.687
Length of hospital stay, days	6 (5–7)	6 (5–7)	0.689

Values are presented as *n* (%), median (interquartile range), or mean ± standard deviation

IABP Intra-aortic balloon pump, *IVUS* Intravenous ultrasound, *OCT* Optical coherence tomography imaging, *TIMI* Thrombolysis in myocardial infarction, *TRA* Transradial access, *DRA* Distal radial access

control group was much lower than expected. As a result, the calculated study population was too low, and the study was underpowered to demonstrate any significant difference.

Risk factors influencing RAO

Notably, various factors account for the observed discrepancies in RAO rates. First, the timing of RAO assessments: 24 h [4], at discharge [17], 30 days [4], 60 days [5], 90 days [12], and 3 months [13]. The optimal RAO

Table 3 Access site crossover between the two patient groups

Variable	DRA ($n=260$)	TRA ($n=260$)	*P*-value
Distal radial artery diameter, mm	2.26 ± 0.45	2.21 ± 0.34	0.107
0.014″ guidewire assist	22 (8.5)	3 (1.2)	< 0.001
Access crossover rate	14 (5.4)	14 (5.4)	1.000
Same-side TRA	11 (4.2)	0 (0.0)	
Same-side DRA	0 (0.0)	9 (3.5)	
Femoral access	2 (0.8)	4 (1.5)	
Brachial access	1 (0.4)	1 (0.4)	
Causes of crossover			
Puncture failure	4 (1.5)	7 (2.7)	0.361
Wire failure	8 (3.1)	5 (1.9)	0.399
Sheath wire only	7 (2.7)	4 (1.5)	
Assist 0.014-inch guidewire	1 (0.4)	1 (0.4)	
Vessel tortuosity	2 (0.8)	1 (0.4)	0.561
Need good support	0 (0.0)	1 (0.4)	0.317

Values are presented as *n* (%) or mean ± standard deviation

DRA Distal radial access, *TRA* Transradial access

assessment time remains unknown [18]. Previous studies demonstrated that the RAO rate decreases over time after the first day and is attributed to the radial artery's spontaneous recanalization [2, 19]. Radial arteries that are initially patent, typically remain patent [2, 18, 20]. Our study focused on early RAO within 24 h post-procedure, when we observed a higher incidence rate than at other times.

Second, most RCTs have excluded STEMI patients due to the need for immediate coronary reperfusion during primary PCI and the potential delays caused by longer puncture time with DRA [4, 5, 11–13, 16]. However, despite limitations such as small sample sizes and lack of randomization, small observational studies have shown the efficacy of DRA in primary PCI with lower RAO rates [21, 22]. A small-scale RCT comprising patients with STEMI found that DRA had a significantly lower RAO incidence at discharge when compared with TRA (2.0% vs. 9.0%, $P=0.030$) [17]. Thus, our study confirms differences in RAO rates 24 h post-procedure between DRA and TRA in patients receiving primary PCI.

Third, the sheath size outer diameter is associated with RAO [23]. Various studies have used different sheath sizes, as follows: a 6F Slender sheath (2.46 mm) in 99.5%

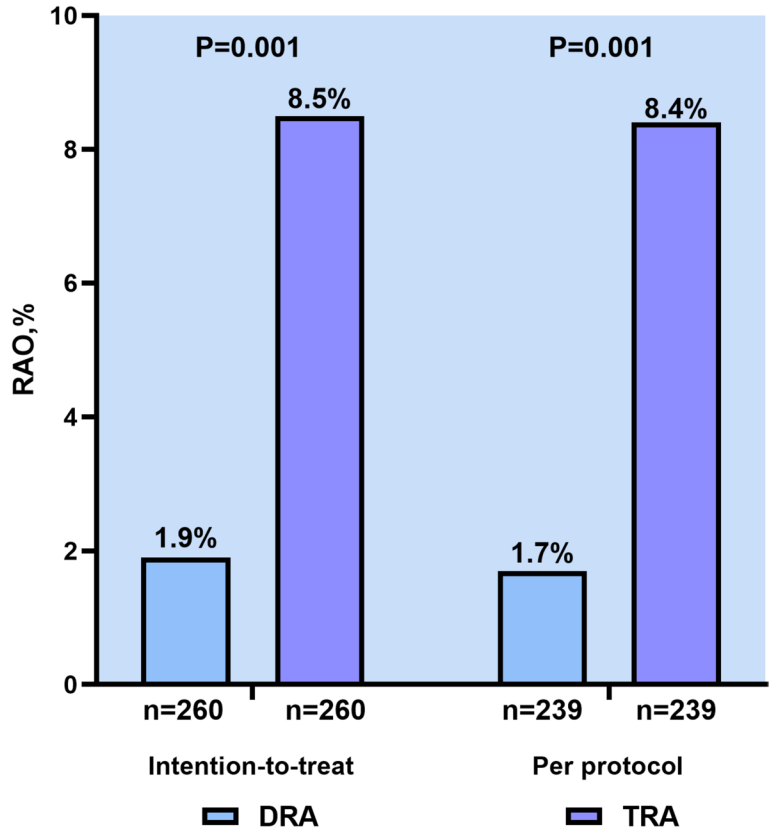

Fig. 2 Primary endpoint. The distal radial access (DRA) strategy for primary percutaneous coronary intervention (PCI) reduces radial artery occlusion (RAO) as the primary endpoint

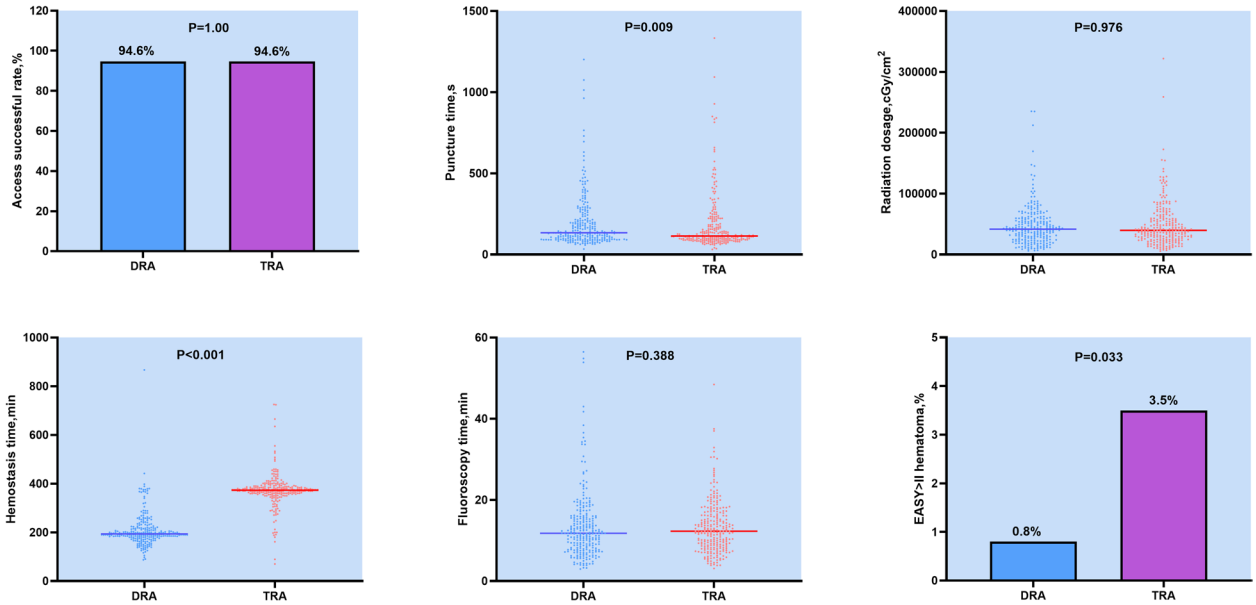

Fig. 3 Secondary endpoint. Secondary endpoint comparison showed that DRA had a shorter hemostasis time and a lower incidence of mEASY ≥ II hematoma but had a longer puncture time. There was no impact on access success rate, radiation dosage, and fluoroscopic time. mEASY, modified Early Discharge After Transradial Stenting of Coronary Arteries; STEMI, ST-segment elevation myocardial infarction

Table 4 Comparison of study endpoints between the two patient groups

Variable	DRA ($n=260$)	TRA ($n=260$)	*P*-value
Forearm radial artery occlusion	5 (1.9)	22 (8.5)	0.001
Access successful rate	246 (94.6)	246 (94.6)	1.000
Sheath insertion time, s	133 (97–213)	114 (92–184)	0.009
Fluoroscopy time, min	11.7 (8.1–15.7)	12.2 (8.6–16.4)	0.388
DAP, cGy/cm^2	78,762 (54,775–103,977)	77,296 (55,077–106,069)	0.704
AK, mGy	1214 (867–1613)	1162 (845–1597)	0.594
Hemostasis time, min	209 ± 71	372 ± 69.6	< 0.0001
Complications, *n* (%)			
Hematoma	20 (7.7)	32 (12.3)	0.079
Local hematoma	18 (6.9)	23 (8.8)	0.416
Hematoma (mEASY ≥ II)	2 (0.8)	9 (3.5)	0.033
Spasm	19 (7.3)	16 (6.2)	0.600
Finger numbness	4 (1.5)	3 (1.2)	1.000
Pseudoaneurysm	0	1 (0.4)	1.000
Arteriovenous fistula	0	0	-

Values are presented as *n* (%), mean ± standard deviation, or median (interquartile range)

AK Air kerma, *DAP* Dose area product, *DRA* Distal radial access, *TRA* Transradial access, *mEASY* modified Early Discharge After Transradial Stenting of Coronary Arteries

of DISCO RADIAL cases [16], and a standard 6F sheath (2.63 mm) in 90.8% of DAPRAO cases [4], 99.5% of CONDITION cases [13], and 98.8% of cases in our study. The ANGIE trial [5] used a 5F sheath in 62.7% and a 6F sheath in 36.8% of cases, while The Litaunent study [11] used a 5F sheath in 16.4% and a 6F sheath in 76.9% of cases.

Fourth, patent hemostasis is crucial for preventing RAO [24], although its application varies across studies. It was used in 94.4% of DISCO RADIAL cases [16], 100% of DAPRAO cases, and 100% of cases in our trial [4]. However, it was not used in the ANGIE [5] or CONDITION [13] trials.

Fifth, longer hemostasis time independently predicts RAO [25]. Optimal hemostasis duration for TRA varies from 20 min to 10 h [13, 26, 27], and is influenced by sheath size [25], procedure type [20], and hemostatic method [28]. In various RCTs, PCI rates were low, ranging from 22.5% to 50.8% [5]. In our study, PCI was performed on 98.8% of patients via TRA. Post-DRA, the optimal compression time varies across studies, ranging from 85 to 155 min [11, 12, 16]. Roh et al. [29] recommended 3 h compression hemostasis post-DRA based on the results of a multicenter study. In our study, the compression time was 209 min, which is similar to that observed in previous reports [12, 16].

Finally, anticoagulation levels significantly affect RAO rates [30]. One study demonstrated that heparin doses of > 50 IU/kg reduced RAO risk by 80% [31]. Typically, patients receive 5000 IU of intra-arterial heparin during sheath insertion, with additional doses during interventions [4, 12, 16]. In our study, heparin (100 IU/kg) was used for all patients after sheath insertion. The average ACT was 320 s, higher than the 250 s reported in the DISCO study [15]. This difference may be related to longer hemostasis times. In our study, several potential predictors of RAO were identified, and the independent predictors of RAO were TRA, bivalirudin use, and the RA/sheath diameter ratio. Except for bivalirudin use, the other two variables are consistent with findings from meta-analyses and RCT trials [4, 14, 32].

Learning curve

There is a smaller diameter and more tortuous angulation with DRA than with TRA, resulting in a steeper learning curve, as evidenced by more puncture attempts, longer insertion times, and lower success rates [12], and contributing to a significantly higher crossover rate for DRA (4.5–21.8%) than for TRA (0.71–5.5%) [3, 7, 10, 14].Typically, proficiency in DRA requires 100–200 cases [9, 33], compared to 30–100 cases for TRA [34–36]. Our results demonstrated longer access time for DRA, aligning with previous findings [5, 12, 14, 16], but no significant difference in crossover rates, likely due to the extensive experience of our interventional cardiologist, having performed at least 150 transradial procedures in the preceding year.

Notably, the use of a 0.014″ guidewire was more common in DRA than in TRA (8.5% vs. 1.2%, $P < 0.001$), highlighting the need for dedicated sheaths. A specialized tapered hydrophilic sheath design, combined with a hydrophilic 30° J-tip or adjustable-tip miniwire, and a finer tip size (e.g., 0.014″), would help better navigate the challenging anatomy of the distal radial artery, improving wire advancement and DRA success.

Procedure time and dose area product (DAP)

Meta-analyses and several RCTs showed similar procedure times for DRA and TRA [4, 11–13, 16], but the ANGIE trial showed a longer procedure time for DRA (14 min vs. 11 min; $P < 0.001$) [5]. Radiation exposure results have been equivocal, with no significant difference in air kerma [12, 13, 16], fluoroscopic time [4, 5, 13, 16], or DAP [11] between DRA and TRA across studies. However, Tsigkas et al. [5] reported higher DAP with DRA. Our results showed no significant differences between DRA and TRA in radiation dose, contrast volume, or procedure time.

Access-related complications

In this study, we observed no significant difference in local hematoma rates and other complications, including finger numbness, pseudoaneurysms, and spasms between the DRA and TRA groups, consistent with the findings of previous studies [4, 13, 37]. Previous reports have shown that the incidence of forearm hematoma, according to the mEASY classification, ranges from 6.34 to 10% [9, 38] with mEASY ≥ II occurring in 0.08% to 6.0% cases [5, 9, 38]. In our study, the incidence of forearm hematoma was 10%, with mEASY ≥ II hematomas being observed in 2.1%, which is consistent with previously reported data. However, mEASY ≥ II hematomas were significantly more frequent in the TRA group than in the DAR group (3.5% vs. 0.8%, $P = 0.033$), consistent with the meta-analysis of Ferrante [14]. Predictors of hematoma in our study included low weight, multiple puncture attempts, and transradial access, which align with findings from previous studies [38].

Clinical implications of DRA in patients with STEMI

Unlike earlier RCTs that excluded patients with STEMI, this study focuses on those patients undergoing primary PCI through DRA. Our results showed a significant reduction in RAO rates 24 h post-procedure without impacting the procedure time. This finding supports the effectiveness of DRA as an access site for primary PCI, enhancing patient outcomes by minimizing vascular complications without compromising procedural efficiency.

Study limitations

Our study highlights DRA's benefits in preventing RAO post-PCI but has limitations. First, the single-center design may limit generalizability. Second, the open-label nature could introduce bias, although the objective measures of RAO and hemostasis time likely mitigate this concern. Although ultrasound-guided puncture can improve puncture success rates, it was not used in this study. We

hope that future studies will evaluate the potential value of ultrasound guidance in emergency interventions.

Conclusions

This prospective RCT study demonstrated that DRA is superior to TRA in preventing RAO in patients with STEMI.

Abbreviations

DRA	Distal radial access
ITT	Intention-to-treat
mEASY	Modified Early Discharge After Transradial Stenting of Coronary Arteries
PCI	Percutaneous coronary intervention
PP	Per-protocol
RAO	Radial artery occlusion
RCT	Randomized controlled study
STEMI	ST-segment elevation myocardial infarction
TRA	Conventional transradial access

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12916-025-04005-1.

Additional file 1: Tables S1-S3. Table S1- Inclusion and Exclusion criteria. Table S2- Endpoint definitions. Table S3- Patients without ultrasound follow-up.

Additional file 2: Predictors of RAO and Hematoma. Table S1- Univariate analysis of Potential risk factors for RAO. Table S2- Predictors of RAO. Table S3- Predictors of hematoma formation.. Table S4- Predictors of hematoma (mEASY≥II).

Acknowledgements

None.

Authors' contributions

JCG conceptualized and designed the study. ZXL acquired, analyzed, and interpreted the data. ZXL, YJW, and JCG drafted the manuscript. JCG and GYZ made critical reviews for intellectual content on the manuscript. ZXL and YJW performed statistical analysis, and funding was acquired by JCG. ZXL, YJW, JHS, SHW, YTW, YXW, HHW, ZJL, and RY offered administrative, technical, or material support. All authors read and approved the final manuscript.

Funding

Dr. Jincheng Guo received support from the Capital's Funds for Health Improvement and Research (Grant No. 2022–2-7086).

Data Availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study was approved by the ethics committees of Beijing Luhe Hospital, Capital Medical University (the ethics approval number 2021-LHKY-122–02) and is in accordance with the declaration of Helsinki. Informed consent was obtained from all subjects.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

[1]Division of Cardiology, Beijing Luhe Hospital, Capital Medical University, Beijing 101149, China. [2]Division of Emergency, Beijing Luhe Hospital, Capital Medical University, Beijing 101149, China. [3]Department of Nephrology, Yan'an People's Hospital, Yan'an 716000, China. [4]Division of Cardiology, Danjiangkou First Hospital, Hubei Province, Danjiangkou 442700, China.

Received: 9 October 2024 Accepted: 13 March 2025
Published online: 24 March 2025

References

1. Neumann FJ, Sousa-Uva M, Ahlsson A, Alfonso F, Banning AP, Benedetto U, et al. 2018 ESC/EACTS Guidelines on myocardial revascularization. Kardiol Pol. 2018;76(12):1585–664. https://doi.org/10.5603/KP.2018.0228.
2. Rashid M, Kwok CS, Pancholy S, Chugh S, Kedev SA, Bernat I et al. Radial Artery Occlusion After Transradial Interventions: A Systematic Review and Meta-Analysis. J Am Heart Assoc 2016;5(1).https://doi.org/10.1161/JAHA.115.002686
3. Tsigkas G, Apostolos A, Davlouros P. Less Is More, But Not Always: Distal Transradial Access for Radial Artery Occlusion Prevention. JACC Cardiovasc Interv. 2022;15(12):1202–4. https://doi.org/10.1016/j.jcin.2022.05.001.
4. Eid-Lidt G, Rivera Rodríguez A, Jimenez Castellanos J, Farjat Pasos JI, Estrada López KE, Gaspar J. Distal Radial Artery Approach to Prevent Radial Artery Occlusion Trial. JACC Cardiovasc Interv. 2021;14(4):378–85. https://doi.org/10.1016/j.jcin.2020.10.013.
5. Tsigkas G, Papageorgiou A, Moulias A, Kalogeropoulos AP, Papageorgopoulou C, Apostolos A, Papanikolaou A, Vasilagkos G, Davlouros P. Distal or Traditional Transradial Access Site for Coronary Procedures: A Single-Center. Randomized Study JACC Cardiovasc Interv. 2022;15(1):22–32. https://doi.org/10.1016/j.jcin.2021.09.037.
6. Thygesen K, Alpert JS, Jaffe AS, Chaitman BR, Bax JJ, Morrow DA, et al. Fourth universal definition of myocardial infarction (2018). Eur Heart J. 2019;40(3):237–69. https://doi.org/10.1093/eurheartj/ehy462.
7. Sgueglia GA, Lee BK, Cho BR, Babunashvili A, Lee JB, Lee JW, Schenke K, Lee SY, Harb S. Distal Radial Access: Consensus Report of the First Korea-Europe Transradial Intervention Meeting. JACC Cardiovasc Interv. 2021;14(8):892–906. https://doi.org/10.1016/j.jcin.2021.02.033.
8. Oliveira MD, Navarro EC, Caixeta A. Distal transradial access for coronary procedures: a prospective cohort of 3,683 all-comers patients from the DISTRACTION registry. Cardiovasc Diagn Ther. 2022;12(2):208–219.https://doi.org/10.21037/cdt-21-542
9. Lee JW, Kim Y, Lee BK, Yoo SY, Lee SY, Kim CJ, et al. Distal Radial Access for Coronary Procedures in a Large Prospective Multicenter Registry: The KODRA Trial. JACC Cardiovasc Interv. 2024;17(3):329–40. https://doi.org/10.1016/j.jcin.2023.11.021.
10. Valgimigli M, Landi A. Distal Transradial Access for Coronary Procedures: Old Certainties, Novel Challenges, and Future Horizons. JACC Cardiovasc Interv. 2022;15(1):33–8. https://doi.org/10.1016/j.jcin.2021.10.032.
11. Acar E, Izci S, Donmez I, Yilmaz MF, Ozgul N, Kayabasi O et al. The Left Distal transradial access site could give a safe alternate site for transradial coronary intervention (The Litaunent Study). Angiology 2023:33197231183226.https://doi.org/10.1177/00033197231183226
12. Korotkikh A, Babunashvili A, Kaledin A, Akhramovich R, Derkach V, Portnov R, Kartashov D, Kazantsev A. Distal Radiation Access as an Alternative to Conventional Radial Access for Coronary Angiography and Percutaneous Coronary Interventions (According to TENDERA Trial). Curr Probl Cardiol. 2023;48(4):101546. https://doi.org/10.1016/j.cpcardiol.2022.101546.
13. Chen T, Li L, Li F, Lu W, Shi G, Li W, et al. Comparison of long-term radial artery occlusion via distal vs. conventional transradial access (CONDITION): a randomized controlled trial. BMC Med 2024, 22(1):62.https://doi.org/10.1186/s12916-024-03281-7
14. Ferrante G, Condello F, Rao SV, Maurina M, Jolly S, Stefanini GG, et al. Distal vs Conventional Radial Access for Coronary Angiography and/or Intervention: A Meta-Analysis of Randomized Trials. JACC Cardiovasc Interv. 2022;15(22):2297–311. https://doi.org/10.1016/j.jcin.2022.09.006.
15. Feghaly J, Chen K, Blanco A, Pineda AM. Distal versus conventional radial artery access for coronary catheterization: A systematic review and

meta-analysis. Catheter Cardiovasc Interv. 2023;101(4):722–36. https://doi.org/10.1002/ccd.30602.
16. Aminian A, Sgueglia GA, Wiemer M, Kefer J, Gasparini GL, Ruzsa Z, et al. Distal Versus Conventional Radial Access for Coronary Angiography and Intervention: The DISCO RADIAL Trial. JACC Cardiovasc Interv. 2022;15(12):1191–201. https://doi.org/10.1016/j.jcin.2022.04.032.
17. Wang Y, Liu Z, Wu Y, Li Z, Wang Y, Wang S, et al. Early prevention of radial artery occlusion via distal transradial access for primary percutaneous coronary intervention. Front Cardiovasc Med. 2022;9:1071575. https://doi.org/10.3389/fcvm.2022.1071575.
18. Lavi S, Cheema A, Yadegari A, Israeli Z, Levi Y, Wall S et al. Randomized Trial of Compression Duration After Transradial Cardiac Catheterization and Intervention. J Am Heart Assoc. 2017;6(2).https://doi.org/10.1161/JAHA.116.005029
19. Pancholy SB, Bernat I, Bertrand OF, Patel TM. Prevention of Radial Artery Occlusion After Transradial Catheterization: The PROPHET-II Randomized Trial. JACC Cardiovasc Interv. 2016;9(19):1992–9. https://doi.org/10.1016/j.jcin.2016.07.020.
20. Mason PJ, Shah B, Tamis-Holland JE, Bittl JA, Cohen MG, Safirstein J, et al. An Update on Radial Artery Access and Best Practices for Transradial Coronary Angiography and Intervention in Acute Coronary Syndrome: A Scientific Statement From the American Heart Association. Circ Cardiovasc Interv. 2018;11(9):e000035. https://doi.org/10.1161/HCV.0000000000000035.
21. Kim Y, Lee JW, Lee SY, Bae JW, Lee SJ, Jeong MH, Lee SH, Ahn Y. Feasibility of primary percutaneous coronary intervention via the distal radial approach in patients with ST-elevation myocardial infarction. Korean J Intern Med. 2021;36(Suppl 1):S53–61. https://doi.org/10.3904/kjim.2019.420.
22. Lee OH, Kim Y, Son NH, Roh JW, Im E, Cho DK, Choi D. Comparison of Distal Radial, Proximal Radial, and Femoral Access in Patients with ST-Elevation Myocardial Infarction. J Clin Med. 2021;10(15).https://doi.org/10.3390/jcm10153438
23. Aminian A, Saito S, Takahashi A, Bernat I, Jobe RL, Kajiya T, et al. Comparison of a new slender 6 Fr sheath with a standard 5 Fr sheath for transradial coronary angiography and intervention: RAP and BEAT (Radial Artery Patency and Bleeding, Efficacy, Adverse evenT), a randomised multicentre trial. EuroIntervention. 2017;13(5):e549–56. https://doi.org/10.4244/EIJ-D-16-00816.
24. Eid-Lidt G, Reyes-Carrera J, Farjat-Pasos JI, Saenz AL, Bravo CA, Rangel SN, et al. Prevention of Radial Artery Occlusion of 3 Hemostatic Methods in Transradial Intervention for Coronary Angiography. JACC Cardiovasc Interv. 2022;15(10):1022–9. https://doi.org/10.1016/j.jcin.2022.03.011.
25. Aminian A, Saito S, Takahashi A, Bernat I, Jobe RL, Kajiya T, et al. Impact of sheath size and hemostasis time on radial artery patency after transradial coronary angiography and intervention in Japanese and non-Japanese patients: A substudy from RAP and BEAT (Radial Artery Patency and Bleeding, Efficacy, Adverse evenT) randomized multicenter trial. Catheter Cardiovasc Interv. 2018;92(5):844–51. https://doi.org/10.1002/ccd.27526.
26. Li W, Wang J, Liang X, Wang Q, Chen T, Song Y, et al. Comparison of the feasibility and safety between distal transradial access and conventional transradial access in patients with acute chest pain: a single-center cohort study using propensity score matching. BMC Geriatr. 2023;23(1):348. https://doi.org/10.1186/s12877-023-04058-y.
27. Maqsood MH, Pancholy S, Tuozzo KA, Moskowitz N, Rao SV, Bangalore S. Optimal Hemostatic Band Duration After Transradial Angiography or Intervention: Insights From a Mixed Treatment Comparison Meta-Analysis of Randomized Trials. Circ Cardiovasc Interv. 2023;16(2):e012781. https://doi.org/10.1161/CIRCINTERVENTIONS.122.012781.
28. Petroglou D, Didagelos M, Chalikias G, Tziakas D, Tsigkas G, Hahalis G, et al. Manual Versus Mechanical Compression of the Radial Artery After Transradial Coronary Angiography: The MEMORY Multicenter Randomized Trial. JACC Cardiovasc Interv. 2018;11(11):1050–8. https://doi.org/10.1016/j.jcin.2018.03.042.
29. Roh JW, Kim Y, Takahata M, Shiono Y, Kim HY, Jeong MH, Akasaka T. Optimal hemostasis duration for percutaneous coronary intervention via the snuffbox approach: A prospective, multi-center, observational study (HEMOBOX). Int J Cardiol. 2021;338:79–82. https://doi.org/10.1016/j.ijcard.2021.06.035.
30. Pacchioni A, Ferro J, Pesarini G, Mantovani R, Mugnolo A, Bellamoli M, et al. The Activated Clotting Time Paradox: Relationship Between Activated Clotting Time and Occlusion of the Radial Artery When Used as Vascular Access for Percutaneous Coronary Procedures. Circ Cardiovasc Interv. 2019;12(9):e008045. https://doi.org/10.1161/CIRCINTERVENTIONS.119.008045.
31. Hahalis GN, Leopoulou M, Tsigkas G, Xanthopoulou I, Patsilinakos S, Patsourakos NG, et al. Multicenter Randomized Evaluation of High Versus Standard Heparin Dose on Incident Radial Arterial Occlusion After Transradial Coronary Angiography: The SPIRIT OF ARTEMIS Study. JACC Cardiovasc Interv. 2018;11(22):2241–50. https://doi.org/10.1016/j.jcin.2018.08.009.
32. Babunashvili AM, Pancholy S, Zulkarnaev AB, Kaledin AL, Kochanov IN, Korotkih AV, Kartashov DS, Babunashvili MA. Traditional Versus Distal Radial Access for Coronary Diagnostic and Revascularization Procedures: Final Results of the TENDERA Multicenter. Randomized Controlled Study Catheter Cardiovasc Interv. 2024. https://doi.org/10.1002/ccd.31271.
33. Roh JW, Kim Y, Lee OH, Im E, Cho DK, Choi D, Jeong MH. The learning curve of the distal radial access for coronary intervention. Sci Rep. 2021;11(1):13217. https://doi.org/10.1038/s41598-021-92742-7.
34. Hess CN, Peterson ED, Neely ML, Dai D, Hillegass WB, Krucoff MW, et al. The learning curve for transradial percutaneous coronary intervention among operators in the United States: a study from the National Cardiovascular Data Registry. Circulation. 2014;129(22):2277–86. https://doi.org/10.1161/circulationaha.113.006356.
35. Hamon M, Pristipino C, Di Mario C, Nolan J, Ludwig J, Tubaro M, et al. Consensus document on the radial approach in percutaneous cardiovascular interventions: position paper by the European Association of Percutaneous Cardiovascular Interventions and Working Groups on Acute Cardiac Care** and Thrombosis of the European Society of Cardiology. EuroIntervention. 2013;8(11):1242–51. https://doi.org/10.4244/EIJV8I11A192.
36. Huded CP, Youmans QR, Sweis RN, Ricciardi MJ, Flaherty JD. The impact of operator experience during institutional adoption of trans-radial cardiac catheterization. Catheter Cardiovasc Interv. 2017;89(5):860–5. https://doi.org/10.1002/ccd.26657.
37. Sgueglia GA, Hassan A, Harb S, Ford TJ, Koliastasis L, Milkas A, et al. International Hand Function Study Following Distal Radial Access: The RATATOUILLE Study. JACC Cardiovasc Interv. 2022;15(12):1205–15. https://doi.org/10.1016/j.jcin.2022.04.023.
38. Garg N, Umamaheswar KL, Kapoor A, Tewari S, Khanna R, Kumar S, Goel PK. Incidence and predictors of forearm hematoma during the transradial approach for percutaneous coronary interventions. Indian Heart J. 2019;71(2):136–42. https://doi.org/10.1016/j.ihj.2019.04.014.

Publisher's Note