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Feasibility of percutaneous coronary intervention using a 7-French thin-walled sheath via the distal radial access

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We evaluated the feasibility and safety of the 7-Fr hydrophilic coated thin-walled sheath for distal radial access (DRA) - percutaneous coronary intervention (PCI). We prospectively collected data from 100 patients who underwent PCI via DRA with a 7-Fr hydrophilic thin-walled sheath at a single center in Korea between August 2021 and April 2024. Co-primary outcomes were PCI success rate and access site complications assessed by vascular ultrasound during hospitalization and at 1-month follow up. The mean age of study population was 65.9 years, and all patients presented acute coronary syndrome. DRA-PCI was successful in all patients. Of the 43 patients evaluated forearm radial artery with intravascular imaging after PCI, there were 2 cases of thrombus and 1 intimal dissection. Access site complications included 2 small hematomas and 1 hand edema. Vascular ultrasound performed the day after PCI showed no forearm radial artery occlusion (RAO) but 2 distal RAO cases without serious complications. At 1 month follow-up, 2 consistent and 1 new case of distal RAO were observed without hand dysfunction. The SEVEN-BOX trial showed that DRA using a 7-Fr hydrophilic coated thin-walled sheath could be a feasible and safe option for complex PCI.

Clinical trial registration: https://www.clinicaltrials.gov. Unique identifier: NCT05006027.

Keywords Distal radial access, Percutaneous coronary intervention, Radial artery

The transradial access (TRA) has become the standard access site for percutaneous coronary interventions (PCI) due to its lower rate of vascular complications compared to transfemoral access (TFA)[1]. TRA is particularly advantageous in reducing access site-related bleeding and has demonstrated superiority in reducing overall mortality in complex coronary procedures[2,3]. Despite these benefits, TRA carries a risk of forearm complications, including radial artery occlusion (RAO), particularly when larger guiding catheters are required for complex procedures[4]. Forearm RAO has been reported to occur in up to 1–33% of cases and limits the use of the radial artery for future additional coronary interventions[5].

The distal radial access (DRA), first described by A.M. Babunashvili in 2003[6], provides an alternative access route for coronary interventions that could significantly reduce the risk of forearm RAO[7]. By puncturing the artery close to the anatomical snuffbox, the DRA technique minimizes damage to the forearm radial artery, facilitates repeat access and reduces the risk of forearm RAO[8,9]. However, due to the tortuosity and small diameter of the DRA, it requires a learning curve and is still not widely used in daily practice, especially for complex PCI[10].

The increasing complexity of PCI, such as the treatment of chronic total occlusions, true bifurcation lesions, acute coronary syndromes (ACS) with adverse hemodynamics, and heavily calcified vessels, sometimes requires the use of large-bore guiding catheters, over 7-Fr sheath system. Traditionally, TFA has been preferred for these procedures due to the anatomically smaller diameter of the radial artery with the risk of access site complications[1]. However, advances in 7-Fr thin-walled sheath technology, which has a similar outer diameter to the conventional forearm 6-Fr radial sheath, have expanded the use of radial access to more complex procedures in recent years[11]. The DRA has recently emerged as an alternative access site for complex PCI, demonstrating

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feasibility even in complex procedures such as bifurcation PCI without major complications[12]. Despite the potential benefits of DRA, data on the usage of using a 7-Fr sheath via DRA are sparse. Therefore, the aim of this study was to evaluate the feasibility and safety of the 7-Fr hydrophilic coated thin-walled sheath for DRA-PCI.

Methods

Study population and design

The SEVEN-BOX (Feasibility of Percutaneous Coronary Intervention Using 7-Fr Thin-Walled Sheath Via the Distal Radial Access; NCT05006027) trial was a prospective, observational registry. The study was conducted at Yongin Severance Hospital by three interventional cardiologists with extensive DRA experience, defined as operators who performed at least 50% of all DRA-PCI procedures among whole PCI cases. Operators excluded the patients who were unsuitable for a large-bore sheath, such as those with weak distal radial artery pulsation prior to coronary angiography. During the study period, between August 2021 and April 2024, 100 patients were enrolled who underwent DRA-PCI using a 7-Fr hydrophilic coated thin-walled sheath (Fig. 1). This study protocol was approved by the Institutional Review Board of Yongin Severance Hospital (approval number: 9-2021-0031). Written informed consent was obtained from all participants before participating in this study. The study protocol was registered in the trial was registered at ClinicalTrial.gov (NCT05006027) and adhered to the ethical guidelines of the Declaration of Helsinki. The funding sources did not participate in the design or conduct of the study, analysis or interpretation of the data, or the decision to submit the manuscript for publication.

Procedures

All patients used the 7-Fr Prelude IDeal™ sheath kit (Merit Medical, South Jordan, USA), which includes 0.018" hair wire, 21G open needle and a 7-Fr hydrophilic coated thin-walled sheath with an outer diameter of 2.77 mm, similar to the forearm 6-Fr radial sheath (2.62–2.73 mm)[11,13]. After injecting 1 cc of lidocaine around the anatomical snuffbox, the open needle for Seldinger technique was performed. We mainly used an open needle and allowed the use of a two-piece needle when necessary. The use of ultrasound guidance for puncture, first sheath size, left or right-side DRA were left to the operator's choice. Direct 7-Fr sheath insertion

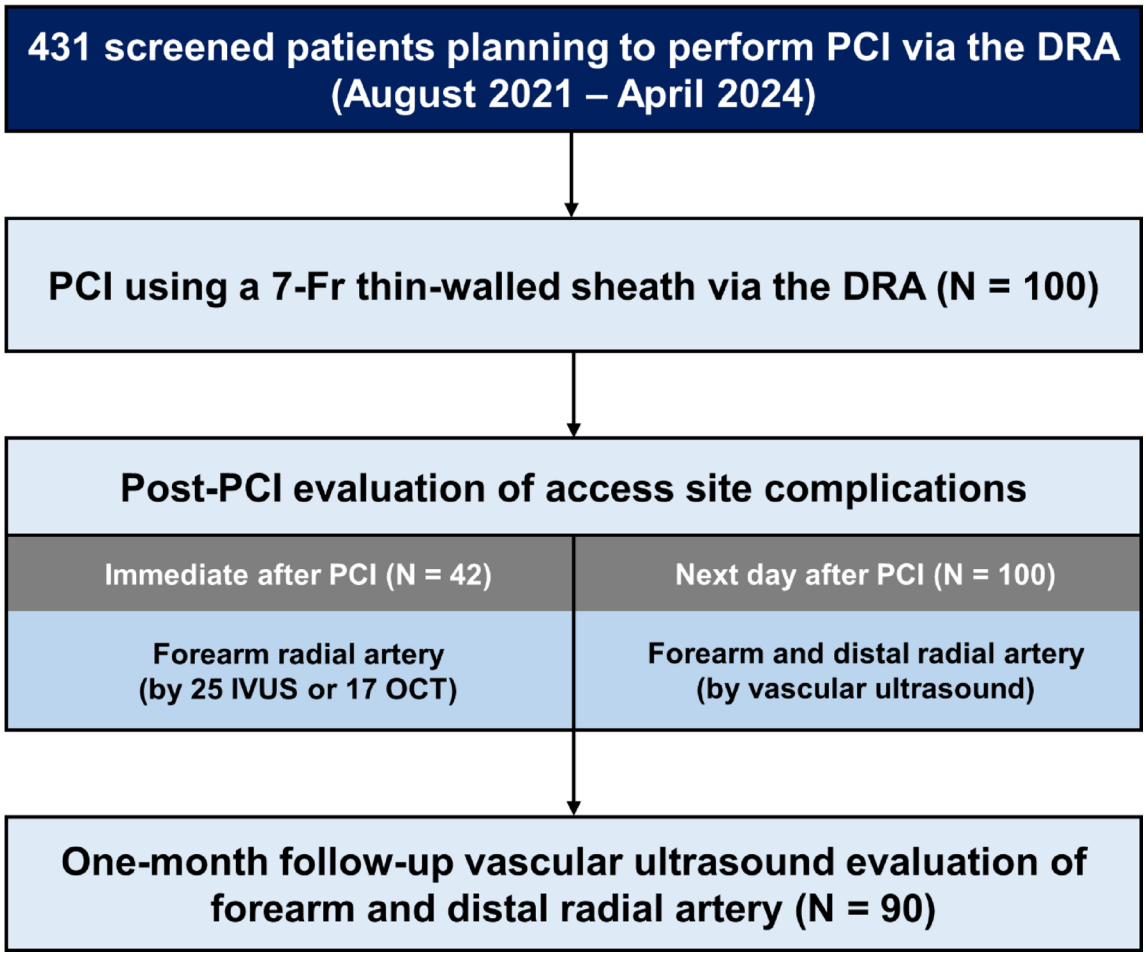

Fig. 1. Study flow. *PCI* percutaneous coronary intervention; *DRA* distal radial access, *IVUS* intravascular ultrasound, *OCT* optical coherence tomography.

was preferred when complex PCI requiring a large guiding catheter was certainly anticipated. Stepwise upgrade from a 4-Fr, 5-Fr and 6-Fr sheath to a 7-Fr sheath was used in cases where initial diagnostic angiography was performed before deciding on the need for a larger guiding catheter. Finally, the operator switched to a 7-Fr hydrophilic coated thin-walled sheath inserted into the distal radial artery for PCI. Anticoagulation was achieved with an initial bolus of 5,000 IU unfractionated heparin, and activated clotting time was maintained between 250–300 seconds. Lesions were treated with standard PCI techniques, including balloon angioplasty and stent implantation. Intravascular imaging, including optical coherence tomography (OCT) or intravascular ultrasound (IVUS), was used to guide stent implantation at the discretion of the operator.

Hemostasis

After all procedures were completed, hemostasis was achieved by applying a 3-way elastic bandage wrapping technique with sterile 4 × 4 gauze and self-adhesive bandage (Coban™, 3 M Health Care, St. Paul, Minnesota) for 5 h (Supplementary Fig. 1). Adequate hemostasis was assessed and finally confirmed by the operator; If hemostasis was not achieved after 5 h, we performed hemostasis using bandage compression for an additional 1 h as in the previous study protocol[14].

Endpoints, definitions, data collection, and statistics

Co-primary outcomes were procedural success rate and access site complications after PCI. Procedural success was defined as successful completion of PCI without major periprocedural complications including acute closure, dissection of at least type B, perforation, intraprocedural stent thrombosis. Access site complications included access site hematoma, distal or forearm RAO, arteriovenous fistula, pseudoaneurysm, hand edema, and numbness. To assess radial artery patency and complications, vascular ultrasound was conducted during hospitalization and within 1-month of follow up after index PCI. Moreover, forearm radial artery was assessed by IVUS or OCT as possible after intravascular image-guided PCI (Fig. 1). Based on a previous study, the tip of a thin walled 7-Fr introducer sheath was pulled out and placed at the dorsal tubercle of the radius; this was defined as the distal margin of the forearm RA area[15]. A 0.014 guide wire was placed in the radial artery and the IVUS or OCT catheter was pullback after injection of nitroglycerin 200 μm via sheath to prevent radial artery spasm (Fig. 2). During the OCT pullback, 5 cc of contrast media was manually injected via the radial sheath. With respect to the quantitative assessment, the regions within 50 mm of the forearm radial artery at 1 mm intervals were assessed on the IVUS/OCT images. The image frame with arterial spasm was excluded for analysis. OCT and IVUS confirmed vessel damage, including intimal dissection, which was defined as a discontinuity of the luminal surface limited to the intimal layer. Media or adventitial dissection was also defined as a discontinuity of the luminal surface that later extended into the medial or adventitial space. The presence of thrombus was also assessed; a thrombus was defined as high backscatter enhancement within the lumen of the artery on the OCT or IVUS images. Chronic kidney disease was defined as eGFR < 60 mL/min/1.73 mm^2 or less.

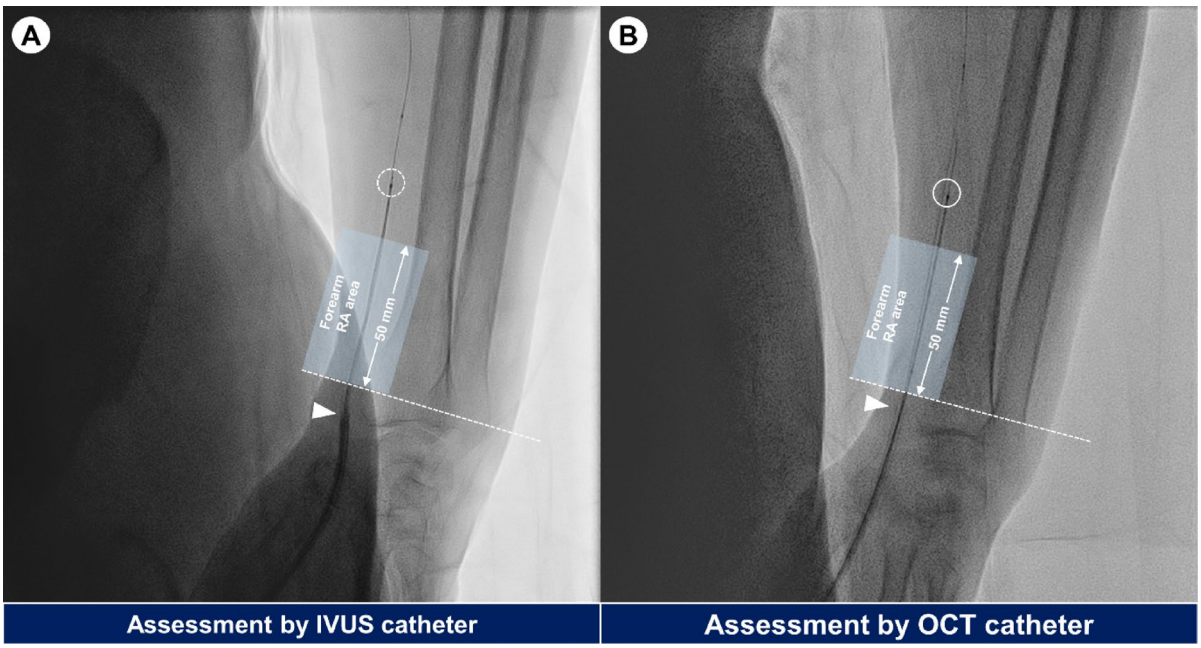

Fig. 2. Assessment of the forearm radial artery using intravascular imaging catheter. IVUS catheter pullback (**A**) (White dotted circle: IVUS lens) and OCT catheter pullback (**B**) (White circle: OCT lens) through forearm radial artery (arrowheads: distal tip of 7-Fr thin-walled sheath; white line with dots: distal margin of the forearm radial artery). *IVUS* intravascular ultrasound, *OCT* optical coherence tomography, *RA* radial artery.

All data are expressed as mean ± standard deviation (SD) or median (IQR) for continuous variables and number of patients (%) for categorical variables. All statistical analyses were performed using R software (version 4.3.0; R Foundation for Statistical Computing, Vienna, Austria).

Results

Baseline clinical characteristics

In the 100 patients enrolled, the mean age of the study population was 65.9 ± 10.6 years, and 91% of patients were male. The mean body mass index was 25.9 ± 3.9 kg/m^2. Cardiovascular risk factors were presented, including hypertension (71%), diabetes mellitus (50%), and chronic kidney disease (7%). All patients were presented with acute coronary syndrome, including 32 patients with STEMI. Potent $P2Y_{12}$ inhibitors, including ticagrelor and prasugrel, were used in 25% of patients and glycoprotein IIb/IIIa inhibitors in 16 cases (Table 1).

Procedural characteristics and hemostasis

The median DRA puncture time was 60 s (Q1-Q3: 44.0–94.5 s). Left DRA was performed in 97% of cases and ultrasound guidance was used in 38% of cases. A 5-Fr sheath was initially used in 54% of patients and then changed to a 7-Fr thin-walled sheath after PCI was decided, and a 7-Fr thin-wall sheath was initially chosen in 15% of the study population. The procedural success rate was 100% with a mean total procedure time of 68.7 ± 28.1 min. Complex PCI, which included PCI for unprotected left main disease, multivessel PCI, bifurcation PCI with two stents, PCI for chronic total occlusion, or PCI for in-stent restenosis or stent thrombosis, was performed in 51% of the study population. Intravascular image-guided PCI was performed in 81 patients, with OCT in 30 and IVUS in 51. Hemostasis achieved with 3-way elastic bandaging had a mean time of 302.7 ± 43.0 min, and 3 patients required additional hemostasis (Table 2).

Access-site and procedural complications

Two patients (2%) developed access site hematomas classified as grade 2 (2–5 cm) according to the modified EASY criteria. These hematomas were minor and did not require surgical intervention. Other complications were also assessed by ultrasound prior to discharge in all 100 study participants, and 2 cases of distal RAO without forearm RAO were confirmed during hospitalization. One-month follow up ultrasound was obtained in 90 patients and confirmed a total of 3 patients with distal RAO, 2 patients had persistent distal radial artery occlusion, which was already present at the initial post-procedural ultrasound and remained unchanged at the one-month follow-up and 1 additional patient with delayed distal RAO. However, no forearm RAO, arteriovenous fistula or pseudoaneurysm was observed on ultrasound either during hospitalization or one month follow up, and none of the patients complained of numbness (Table 3). Regarding radial artery diameter assessed by ultrasound, the mean diameter of distal and forearm radial artery was 2.5 ± 0.4 mm and 3.1 ± 0.4 mm before discharge, and 2.3 ± 0.4 mm and 3.0 ± 0.6 mm at one month follow up, respectively (Supplementary Table 1).

Assessment of the forearm radial artery using IVUS or OCT

If the patient's clinical condition allowed for an evaluation of the radial artery in the forearm with an intravascular imaging catheter, IVUS or OCT evaluation of the forearm radial artery was performed in 42 patients including 25 patients with IVUS and 17 patients with OCT immediately after IVUS- or OCT-guided PCI. The total number of cross sections analyzed for the 42 study subjects was 1,595, including 680 OCT and 915 IVUS images. The mean diameter of the forearm radial artery was 3.2 ± 0.5 mm, while the median diameter was observed to be 3.1 mm (IQR: 2.8–3.5 mm). Three cases of acute injury, including 2 cases of intraluminal thrombus and 1 case of intimal dissection, were observed in the forearm radial artery immediately after PCI (Table 4, Supplementary Fig. 2). However, no medial or adventitial dissection was observed. None of the 3 patients had forearm RAO, and 1 patient with an intraluminal thrombus had a distal RAO detected on vascular ultrasound the following day.

Discussion

This study showed the feasibility and safety of DRA-PCI using a 7-Fr hydrophilic coated thin-walled sheath with a 100% procedural success rate and few minor access site complications. There were 2 patients with minor hematomas, and 3 cases of distal RAO without hand dysfunction were observed at 1 month follow-up; however, no forearm RAO occurred during hospitalization and at 1 month follow-up.

Several studies have shown that TRA is associated with a significant reduction in clinically relevant bleeding and vascular complications compared to TFA, without compromising procedural success[2,3,16]. With an ageing population, the complexity of PCI is increasing and large-bore sheaths over 7-Fr are sometimes required[17,18], a number of studies have been conducted which compare TRA and TFA in large bore over 7-Fr sheaths and the results of these studies consistently demonstrate that access site bleeding or serious bleeding complications are significantly reduced in the TRA group[19–21]. However, when TRA approached, it has been reported that the risk of forearm complications, including forearm RAO, is higher when a large sheath is used on a small diameter of radial artery[1,3,5]. There is also an increasing number of patients who are not suitable for TFA because of peripheral artery disease or a high bleeding risk. In addition, in cases of chronic kidney disease or end-stage renal disease, the radial artery must be preserved for the creation of arteriovenous fistula, so TRA also may not be suitable[22]. Consequently, DRA may be an alternative for patients for whom TFA or TRA is not a good option, particularly those requiring the preservation of the forearm radial artery for future interventions or dialysis access, but there is limited data on the use of a large diameter sheath over 7-Fr due to concerns about small diameter of DRA.

The previously published observational study of DRA confirmed the safety, comfort and feasibility of the procedure. No major complications requiring surgery were found, and no forearm RAO was observed in 70

Characteristic	Value
Demographics	
Age, years	65.9 ± 10.6
Male	91 (91.0)
Height, cm	167.0 ± 6.5
Weight, kg	72.3 ± 12.8
Body mass index, kg/m^2	25.9 ± 3.9
Cardiovascular risk factors	
Current smoking	33 (33.0)
Hypertension	71 (71.0)
Diabetes mellitus	50 (50.0)
Dyslipidemia	94 (94.0)
Chronic kidney disease (eGFR < 60 mL/min/1.73 m^2)	7 (7.0)
End stage renal disease (Hemodialysis state)	1 (1.0)
Atrial fibrillation	2 (2.0)
Previous myocardial infarction	5 (5.0)
Previous percutaneous coronary intervention	11 (11.0)
Previous cerebrovascular accident	11 (11.0)
Vital signs from catheterization lab	
Systolic blood pressure, mmHg	145.5 ± 29.5
Diastolic blood pressure, mmHg	77.0 ± 13.9
Heart rate, beat/min	74.9 ± 13.4
Laboratory findings	
Hemoglobin, g/dL	14.1 ± 2.2
Platelet, 10^3/mm^3	232.7 ± 66.1
eGFR, mL/min/ 1.73m^2	84.5 ± 18.3
Total cholesterol, ml/dL	163.6 ± 51.5
Triglyceride, ml/dL	150.1 ± 94.9
HDL-cholesterol, ml/dL	44.2 ± 11.0
LDL-cholesterol, ml/dL	103.4 ± 45.5
Clinical diagnosis	
Unstable angina	19 (19.0)
NSTEMI	49 (49.0)
STEMI	32 (32.0)
Left ventricular ejection fraction, %	51.8 ± 10.7
Periprocedural antithrombotic treatment	
Aspirin	99 (99.0)
$P2Y_{12}$ receptor inhibitor	100 (100.0)
Clopidogrel	75 (75.0)
Ticagrelor	24 (24.0)
Prasugrel	1 (1.0)
Glycoprotein IIb/IIIa inhibitors	16 (16.0)
Oral anticoagulant	1 (1.0)

Table 1. Clinical characteristics of the study population ($N = 100$). Data are presented as the mean ± SD or number (%). *eGFR* estimated glomerular filtration rate, *HDL* high density lipoprotein, *LDL* low density lipoprotein, *NSTEMI*, non-ST-segment elevation myocardial infarction, *STEMI* ST-segment elevation myocardial infarction.

patients who underwent left DRA coronary angiography[23]. Other randomized studies also support the lower incidence of complications including distal and forearm RAO compared TRA, making it a favorable approach to maintaining radial artery patency[9,24]. In recent years, several meta-analyses have also reported that DRA has a clear advantage over RAO[25,26]. To date, all studies reporting on the use of 7-Fr slender sehath via DRA have been small observational studies. One study treated 41 CTO patients with left DRA and reported no major complications and a distal RAO rate of 4.3% at 1 month[27], and another study in 102 complex PCI patients reported a procedural success rate of 97.2% with a 2.2% RAO and 3.3% distal RAO at 1 month[28]. Interestingly, the incidence of forearm RAO in our study did not occur with few distal RAO, a finding consistent with previous large real-world studies showing that DRA is definitely associated with a lower risk of forearm or distal RAO[7]. The absence of forearm RAO could be explained by several factors. DRA does not cause direct injury to the forearm

Characteristic	Value
Distal radial access details	
Initial puncture time, sec	
Mean ± SD	88.9 ± 78.5
Median (IQR)	60.0 (44.0-94.5)
Puncture frequency	1.1 ± 0.3
Left DRA	97 (97.0)
Ultrasound-guided puncture	38 (38.0)
Initial introducer sheath size	
4-Fr	2 (2.0)
5-Fr	54 (54.0)
6-Fr	29 (29.0)
7-Fr	15 (15.0)
Lesion characteristics	
Treated lesion (*N* = 133)	
Left main coronary artery	13 (9.8)
Left anterior descending artery	63 (47.4)
Left circumflex artery	30 (22.6)
Right coronary artery	26 (19.5)
Ramus intermediate artery	1 (0.8)
ACC/AHA B2/C lesion	85 (85.0)
Procedural characteristics	
Procedural success rate	100 (100)
Total procedure time, min	68.7 ± 28.1
Total contrast volume, mL	293.5 ± 101.4
Stent implantation	87 (87.0)
Complex PCI*	51 (51.0)
Unprotected left main disease	13 (13.0)
Multivessel PCI	31 (31.0)
Bifurcation PCI with two stents	6 (6.0)
Chronic total occlusion	14 (14.0)
PCI for in-stent restenosis or stent thrombosis	5 (5.0)
Intravascular imaging-guided PCI	
Optical coherence tomography	30 (30.0)
Intravascular ultrasound	51 (51.0)
Guiding catheter for PCI	
Left guiding catheter (*N* = 88)	
Judkins left type	32 (36.4)
EBU type	56 (63.6)
Right guiding catheter (*N* = 27)	
Judkins right type	23 (85.2)
Amplatz type	4 (14.8)
Continued	

Characteristic	Value
Hemostasis by 3-way elastic bandage wrapping	
Final ACT	274.0 ± 50.6
Initial hemostasis duration, min	302.7 ± 43.0
Recompression	3 (3.0)
Total hemostasis duration, min	310.9 ± 90.3

Table 2. Procedural characteristics of the study population ($N = 100$). Data are presented as the mean ± SD, median or number (%). *ACC* American College of Cardiology, *ACT* activated clotting time, *AHA* American Heart Association, *DRA* distal radial access, *EBU* extra backup, *IQR* inter quartile range, *PCI* percutaneous coronary intervention, *SD* standard deviation. *Complex PCI included PCI for unprotected left main disease, multivessel PCI, bifurcation PCI with two stents, PCI for chronic total occlusion, or PCI for in-stent restenosis or stent thrombosis.

Characteristic	Value
Access site hematoma degree (modified EASY criteria)	
Ia (Hand limited)	2 (2.0)
Grade 1 (< 2 cm)	0 (0.0)
Grade 2 (2–5 cm)	2 (2.0)
Grade 3 (> 5 cm)	0 (0.0)
Grade 4 (Hand swelling)	0 (0.0)
Ib (Wrist < 5 cm)	0 (0.0)
II (Wrist < 10 cm)	0 (0.0)
III (Forearm)	0 (0.0)
IV (Upper arm)	0 (0.0)
Other access site complications	
Before discharge (median [IQR], day)	1.0 (1.0–2.0)
Evaluation by vascular ultrasound	100 (100.0)
Distal radial artery occlusion	2 (2.0)
Forearm radial artery occlusion	0 (0.0)
Arteriovenous fistula	0 (0.0)
Pseudoaneurysm	0 (0.0)
Hand edema	1 (0.0)
Numbness	0 (0.0)
1-month follow-up (median [IQR], day)	30.0 (25.0–37.0)
Evaluation by vascular ultrasound	90 (90.0)
Distal radial artery occlusion	3 (3.0)
Forearm radial artery occlusion	0 (0.0)
Arteriovenous fistula	0 (0.0)
Pseudoaneurysm	0 (0.0)
Hand edema	0 (0.0)
Numbness	0 (0.0)

Table 3. Distal radial access site complications. Values are presented as number (%). *EASY* Early Discharge After Transradial Stenting of Coronary Arteries Study, *IQR* interquartile ranges, *PSV* peak systolic velocity.

radial artery from the introducer sheath. A previous retrospective study reported no major vascular injury other than intraluminal thrombus on forearm radial OCT after DRA-PCI using conventional 6-Fr sheaths[15]. In addition, hemostasis for the puncture site in DRA avoids compression of the forearm radial artery to prevent forearm RAO. The size of the sheath is also known to have a significant impact on RAO in the forearm[29]. In this study, a thin-walled 7-Fr sheath with a comparable outer diameter to conventional 6-Fr was used, and in particular one with a hydrophilic coating, which is known to reduce vasospasm and vascular injury[30]. The use of a thin-walled sheath with a hydrophilic coating might have contributed to the observation of only one case of intimal dissection without major vessel injury on OCT and IVUS of the forearm radial artery immediately after PCI. Furthermore, in the present study, a smaller sheath was initially inserted, gradually transitioning to a 7-Fr sheath with a 2.77 mm outer diameter in 85% of cases. This transition was considered by the safety of the large bore sheath DRA approach which had a distal radial artery diameter of approximately 2.33 mm as examined in prior studies[13]. This modification may have contributed to the observed minor complications.

Parameters	Value
Intravascular Imaging evaluation	42
Number of total analysed cross sections, frame	1,595
Average number of analysed cross sections, frame	38.0 ± 13.9
Optical coherence tomography evaluation	17
Number of total analysed cross sections, frame	680
Average number of analysed cross sections, frame	40.0 ± 15.3
Intravascular ultrasound evaluation	25
Number of total analysed cross sections, frame	915
Average number of analysed cross sections, frame	36.6 ± 13.1
Mean diameter of forearm radial artery diameter	3.2 ± 0.5
Median diameter of forearm radial artery diameter	3.1 (2.8–3.5)
Acute injury of forearm radial artery immediately after the PCI	3
Intraluminal thrombus	2
Intimal dissection	1
Media or adventitia dissection	0

Table 4. Forearm radial artery assessment using intravascular imaging modalities immediately following percutaneous coronary intervention. Values are presented as number (%).

In terms of distal RAO without hand dysfunction, DRA offers advantages over TRA by exploiting anatomical and physiological advantages[31,32]. DRA involves puncture at distal sites, such as the anatomical snuffbox or first intermetacarpal space, where the radial artery has already branched. These branches support collateral blood flow, reducing the risk of complications such as forearm RAO, which can lead to hand ischemia, pain or loss of function. DRA can preserve the patency of the forearm radial artery and does not cause major hand dysfunction, ensuring robust blood flow to the hand even if occlusion occurs at the DRA puncture site[8]. In addition, our study found minimal access site hematoma without serious complications, confirmed by vascular ultrasound. Therefore, our results showed that DRA using a 7-Fr hydrophilic coated thin-walled sheath could be an alternative access route to TRA or TFA in terms of safety for complex PCI.

Furthermore, successful PCI was achieved in all 100 patients in our study, including 51% of complex PCIs. Previously, another study showed that the success rate of PCI by DRA using a 5-Fr or 6-Fr conventional radial sheath was 99.2% in 252 study patients[14]. Recently, a large, prospective, multicenter registry of DRA showed a PCI success rate of 98.8% in 1,606 cases[7]. A higher success rate in our research expected that it would be a possible option to increase the success rate when performing complex PCI in cases where TRA or TFA are not suitable.

This study has several limitations. First, as a single-center, prospective, observational study with a relatively small sample size and three highly experienced DRA operators, the generalizability of the results may be limited. Second, as the study was conducted by selecting only patients who needed a 7-Fr sheath due to complex PCI, it inevitably took a long time of 3 years. Third, our study did not include a TRA or TFA group as a control. Fourth, our study cohort was predominantly male (91%), a common selection bias in radial access studies, as men tend to have strong pulsations with larger distal radial artery diameters than women, who often have smaller DRA diameters and a potentially higher baseline risk of access site complications such as RAO and may have different outcomes. Fifth, although the DRA was generally smaller in diameter, vascular ultrasound was not used in all patients to assess the DRA diameter prior to insertion of the 7-Fr sheath. Also, ultrasound was not performed in 10 patients at the 1-month follow-up, so there is a possibility of underestimating distal and forearm RAO. Further large-scale, multicenter, randomized trials are needed to confirm the feasibility of a 7-Fr thin-walled sheath during DRA-PCI.

The SEVEN-BOX trial showed that DRA with a 7-Fr hydrophilic coated thin-wall sheath is a feasible and safe option for PCI with a high procedural success rate and minimal access site complications, including two minor hematomas and three distal RAO without hand dysfunction and no forearm RAO. The results of our study suggest that DRA could be considered as an alternative safe access route for complex PCI requiring a large-bore guiding catheter when a 7-Fr thin-walled sheath is available.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Research concept and design: JWR, OHL, YCK. Data collection: JWR, OHL, YCK, SJH, EI, DKC. Data analysis and interpretation: SJH. Drafting of the paper: JWR, OHL, YCK. Critical revision of the paper: JWR, OHL, YCK, EI, DKC. Final approval of the completed paper: JWR, OHL, YCK, SJH, EI, DKC.

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Declarations

Competing interests
The authors declare no competing interests.

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