

Original Research



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Feasibility of Distal Radial Access in the Use of a Large-Bore Sheath for Percutaneous Coronary Intervention: Real-World Evidence From the Nationwide Cohort

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AUTHOR'S SUMMARY

In patients undergoing percutaneous coronary intervention (PCI) via distal radial access,
the use of a 7 Fr sheath did not lead to a higher incidence of access-site complications
compared with smaller sheaths. However, crossover to another access site occurred more
frequently with a 7 Fr sheath use than with smaller sheaths. These findings suggest that, with

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Trial Registration

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Conflict of Interest

The authors have no financial conflicts of interest.

appropriate patient selection, the distal radial artery can serve as a feasible and safe access route for PCI requiring large-bore sheaths.

ABSTRACT

Background and Objectives: Despite the established benefits of distal radial access (DRA) in reducing access-site complications compared to conventional radial access, evidence regarding the feasibility of using large-bore sheaths via DRA remains limited. This study aimed to evaluate the feasibility of using a 7 Fr sheath via DRA in patients who underwent percutaneous coronary intervention (PCI).

Methods: Among 4,977 patients enrolled in the Korean Prospective Registry for Evaluating the Safety and Efficacy of Distal Radial Approach registry, a total of 1,599 patients who underwent PCI were selected. Patients were classified according to the use of a 7 Fr sheath. The primary endpoint was overall access-site complication before discharge and at 1-month follow-up.

Results: Of 1,599 patients, 115 patients underwent PCI via DRA using a 7 Fr sheath. There was no significant difference in overall access-site complications between the 7 Fr sheath group and the smaller sheaths group (12.2% vs. 9.5%, adjusted odds ratio [OR], 1.66; 95% confidence interval [CI], 0.88–2.92; $p=0.111$). However, patients in the 7 Fr sheath group had a significantly higher rate of access-site crossover compared to the smaller sheath group (10.4% vs. 1.4%, adjusted OR, 7.87; 95% CI, 3.58–16.52; $p<0.001$).

Conclusions: In patients undergoing PCI via DRA, the use of a 7 Fr sheath did not significantly increase access-site complications compared to smaller sheath. These findings suggest that DRA can be considered as a feasible and safe route for a 7 Fr sheath, provided that it is coupled with meticulous patient selection and pre-procedural vascular assessment.

Trial Registration: ClinicalTrials.gov Identifier: [NCT04080700](https://clinicaltrials.gov/ct2/show/study/NCT04080700)

Keywords: Distal radial access; Percutaneous coronary intervention; A 7 Fr sheath; Access-site complications

INTRODUCTION

Located within the anatomical snuffbox or on the dorsum of the hand, distal radial artery—characterized by its smaller caliber and ease of compression—provides unique anatomical and physiological advantages.¹⁾ Recently, coronary intervention via distal radial access (DRA) has shown the benefit of fewer bleeding events at access site and a lower radial artery occlusion in clinical trials.²⁻⁴⁾ Therefore, DRA has been considered as a promising alternative to conventional radial access for percutaneous coronary intervention (PCI).²⁻⁴⁾

In contemporary practice of PCI, a significant proportion of patients have complex coronary artery lesions and the proportion of complex and high-risk PCI has been steadily increasing.⁵⁾ Larger sheaths are often required in complex PCI procedures, including bifurcation stenting, heavily calcified lesions, and chronic total occlusions, to ensure adequate back-up support and device compatibility, thereby enhancing procedural success.^{6,7)} As the demand for complex coronary interventions continues to increase, the relatively small diameter of the distal radial artery has raised concerns about potential risks when using larger sheaths, such as increased

Data Sharing Statement

The data generated in this study is available from the corresponding authors upon reasonable request.

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incidence of vascular spasm, bleeding, or long-term arterial complications. However, evidence regarding the feasibility and safety of using large bore sheaths remains limited.

Therefore, we sought to evaluate the feasibility and safety of a 7 Fr sheath usage through DRA using the nationwide, multicenter, prospective the Korean Prospective Registry for Evaluating the Safety and Efficacy of Distal Radial Approach (KODRA) registry.

METHODS

Study protocol and patient selection

The KODRA was a prospective, multicenter registry which enrolled patients aged 20 years and over who underwent coronary angiography with a palpable distal radial artery at 14 cardiovascular centers in Korea from September 2019 to September 2021. The detailed study protocol of the KODRA registry was previously described.⁸⁾ The protocol of the KODRA registry was approved by the Institutional Review Board (IRB) of Chungbuk National University Hospital (IRB No. 2019-10-018) and each participating center. All patients provided written informed consent. The registry protocol was conducted in accordance with the latest version of the Declaration of Helsinki.

Among a total of 4,977 patients enrolled in the KODRA registry, we selected patients who underwent PCI via DRA. Patients were excluded without 1-month follow-up data and sheath size information (**Figure 1**). As a result, 1,599 patients were included for the current analysis and

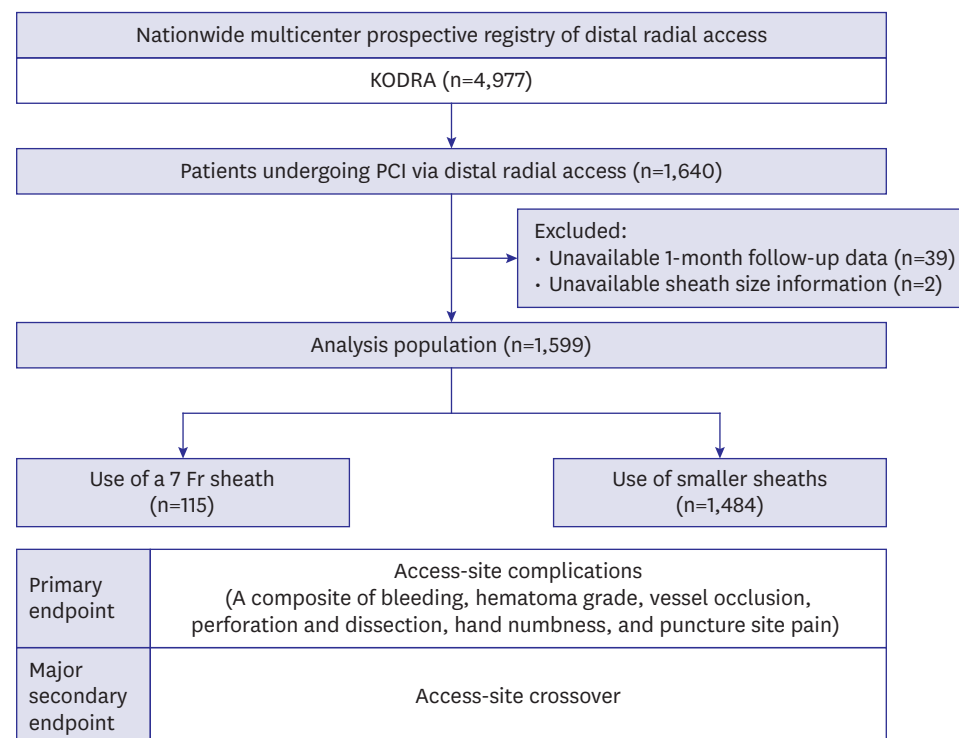


Figure 1. Study flow.

The study population was derived from the nationwide, multicenter, prospective KODRA registry. KODRA = Korean Prospective Registry for Evaluating the Safety and Efficacy of Distal Radial Approach; PCI = percutaneous coronary intervention.

classified according to use of a 7 Fr sheath. Specifically, patients using a standard 7 Fr sheath were assigned to the 7 Fr sheath group, while those using 5 or 6 Fr sheaths, or sheathless 6.5 Fr guiding catheter, were assigned into the smaller sheaths group. All patients in whom DRA were attempted with the intention of using a 7 Fr sheath were included in the 7 Fr group, regardless of whether the sheath was successfully inserted or a crossover was required.

Study procedures

DRA was achieved either through the anatomical snuffbox or the dorsal aspect of the hand, using either a 20-gauge venipuncture catheter needle or a 21-gauge open steel needle, following the administration of subcutaneous lidocaine for local anesthesia.⁸⁾ A mini-guidewire was then advanced into the artery, followed by the placement of an introducer sheath.⁸⁾ Decision regarding treatment strategies, including the choice of specific interventional devices and sheath type, the use of medication such as antiplatelet agents, and peri-procedural unfractionated heparin, and intervention techniques were left to the operator's discretion. Operators were advised to apply appropriate hemostatic methods including adhesive tape, elastic banding, compression devices, or manual compression and minimize compression duration to achieve effective hemostasis.

Study endpoints and definitions

The primary endpoint was overall access-site complication including bleeding, hematoma grade, vessel occlusion, perforation and dissection, hand numbness, and puncture site pain—assessed systematically both before hospital discharge and at the 1-month follow-up visit. The secondary endpoints included the individual components of primary endpoint, DRA-related bleeding, access-site crossover, and major complication defined as a composite of major hematoma and radial artery injury including occlusion, perforation, and dissection.

Access site hematoma was assessed using a modified version of the Early Discharge After Transradial Stenting of Coronary Arteries Study (EASY) classification.³⁾ Based on modified EASY classification hand hematomas (type 1a) is categorized into four grades based on their extent from the puncture site: grade 1 (<2 cm), grade 2 (2–5 cm), grade 3 (>5 cm), and grade 4 (hand swelling). Above the hand level, the classification begins with type 1b (wrist hematoma <5 cm), progressing to type II (wrist hematoma <10 cm), type III (hematoma extending to forearm), and type IV (hematoma reaching upper arm). DRA-related bleeding was defined as any hematoma at the DRA access site. Radial artery occlusion was defined as absence of the pulse of the radial or distal radial artery by palpation or the antegrade flow signal by doppler ultrasonography. Detailed definitions of endpoints are described in **Supplementary Table 1**.

Statistical analysis

Categorical variables are presented as frequencies with percentages, and continuous variables were expressed as mean $\pm$ standard deviation or median (interquartile range) according to their distribution, checked by Kolmogorov-Smirnov test. To examine the significance of differences in baseline characteristics among groups, we used the χ^2 test for categorical variables and Student's t-test or Mann-Whitney U test for continuous variables according to their distribution. Firth's logistic regression was used to analyze the odds ratio (OR) with a 95% confidence interval (CI) for each endpoint.⁹⁾ Comparison of OR between the groups was estimated using the Wald test. The multivariable adjustment analysis was performed to reduce the effect of bias caused by potential confounders. Covariables in the multivariable model were selected if significantly different between the two groups or clinically relevant. Adjusted variables were age, sex, presented with acute coronary syndrome, peripheral arterial disease, chronic kidney

disease, previous myocardial infarction, previous stroke, diabetes mellitus, current smoking, and use of potent P2Y₁₂ inhibitor, and oral anticoagulants.

All probability values were 2-sided, and p values <0.05 were considered statistically significant. Statistical analyses were performed using R version 4.4.2 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Baseline clinical and procedural characteristics

Baseline clinical and procedural characteristics are summarized in **Tables 1 and 2**.

Among a total of 1,599 patients (mean age, 66.6±11.8 years; 401 females [25.1%]), 114 (7.1%) patients received coronary intervention via DRA using a 7 Fr sheath and 1,484 (92.9%) patients received coronary intervention via DRA using smaller sheaths (5 or 6 Fr sheath, or sheathless 6.5 Fr guiding catheter). There were no significant differences in age and sex between the two groups. A greater proportion of patients in the 7 Fr sheath group had diabetes mellitus and dyslipidemia than in the smaller sheaths group.

A 7 Fr sheath insertion via DRA was more frequently performed by operators with extensive DRA experience (≥500 cases). During the procedure, patients in the 7 Fr sheath group had better distal radial pulses and received more spasmolytics compared with patients in smaller sheaths group. A 7 Fr sheath was more used for complex coronary lesions such as chronic total occlusion and multivessel lesions. In the 7 Fr sheath group, both procedure time and hemostasis time were longer, and more contrast was used during procedure than the smaller sheaths group.

Clinical outcomes according to use of a 7 Fr sheath

Comparisons of clinical outcomes between the two groups are presented in **Table 3**. Overall access-site complications occurred in 14 of 115 patients in the 7 Fr sheath group and 141 of 1,484 patients in the smaller sheaths group. Most of access-site complications were associated with DRA related bleeding in both groups. There was no significant difference in the risk of overall access-site complications (12.2% vs. 9.5%, adjusted OR, 1.66; 95% CI, 0.88–2.92; p=0.111) and DRA-related bleeding (5.2% vs. 6.2%, adjusted OR, 1.05; 95% CI, 0.42–2.25; p=0.905). Regarding clinically important events, the rate of major complications was comparable between the 7 Fr sheath group and the smaller sheaths group (4.3% vs. 3.2%, adjusted OR, 2.29; 95% CI, 0.80–5.48; p=0.114). However, hand numbness around the puncture site at 1-month follow-up was more frequently occurred in patients receiving coronary intervention via DRA using a 7 Fr sheath (3.5% vs. 0.9%, adjusted OR, 4.38; 95% CI, 1.29–12.44; p=0.021).

In terms of access-site crossover during procedure, 10.4% of patients in the 7 Fr sheath group required access-site crossover, whereas access-site crossover was only observed in 1.4% of patients in the smaller sheaths group (adjusted OR, 7.87; 95% CI, 3.58–16.52; p<0.001) (**Table 4**). Most of the patients were crossed over to the femoral artery, and the small diameter of distal radial artery was the most common cause of crossover (**Table 4**).

In the exploratory subgroup analysis, the association between use of a 7 Fr sheath and the primary endpoint showed a consistent trend without significant interaction across various

Table 1. Baseline characteristics according to the use of a 7 Fr sheath

Characteristics	Total (n=1,599)	7 Fr sheath (n=115)	Smaller sheaths (n=1,484)	p value
Demographics				
Age (years)	66.6±11.8	66.5±11.0	66.6±11.9	0.953
Female	401 (25.1)	25 (21.7)	376 (25.3)	0.456
Height (cm)	163.5±9.0	164.8±9.0	163.4±9.0	0.113
Weight (kg)	67.0±11.8	68.3±11.3	66.9±11.9	0.225
Body mass index (kg/m ²)	24.9±3.4	25.0±3.2	24.9±3.4	0.729
Acute coronary syndrome	1,164 (72.8)	85 (73.9)	1,079 (72.7)	0.864
Unstable angina	607 (38.0)	39 (33.9)	568 (38.3)	
Non-ST-segment elevation MI	374 (23.4)	38 (33.0)	336 (22.6)	
ST-segment elevation MI	183 (11.4)	8 (7.0)	175 (11.8)	
Hemodynamic data				
Systolic blood pressure (mmHg)	133.1±21.6	127.1±19.0	133.6±21.7	0.002
Diastolic blood pressure (mmHg)	78.3±13.0	75.9±11.4	78.4±13.1	0.039
Heart rate (beats/min)	75.2±14.9	73.0±13.0	75.4±15.0	0.063
Medical history				
Hypertension	1,024 (64.0)	68 (59.1)	956 (64.4)	0.299
Diabetes mellitus	641 (40.1)	62 (53.9)	579 (39.0)	0.002
Dyslipidemia	933 (58.3)	100 (87.0)	833 (56.1)	<0.001
Peripheral arterial disease	33 (2.1)	5 (4.3)	28 (1.9)	0.148
Chronic kidney disease	133 (8.3)	10 (8.7)	123 (8.3)	0.999
Current smoking	356 (22.3)	21 (18.3)	335 (22.6)	0.340
Previous MI	170 (10.6)	10 (8.7)	160 (10.8)	0.588
Previous PCI	336 (21.0)	22 (19.1)	314 (21.2)	0.692
Previous CABG	11 (0.7)	1 (0.9)	10 (0.7)	0.999
Previous stroke	137 (8.6)	7 (6.1)	130 (8.8)	0.416
Atrial fibrillation	74 (4.6)	6 (5.2)	68 (4.6)	0.935
LVEF (%)	56.5±10.5	54.7±11.2	56.6±10.4	0.102
Laboratory data				
Hemoglobin (g/dL)	13.7±2.1	13.7±2.3	13.7±2.1	0.918
Cr (mg/dL)	1.1±1.3	0.9±0.6	1.2±1.4	0.002
eGFR (mL/min/1.73 m ²)	77.6±25.2	78.1±17.7	77.6±25.7	0.771
Glycated hemoglobin (%)	6.6±1.5	6.8±1.3	6.5±1.5	0.193
Total cholesterol (mg/dL)	161.2±48.4	163.3±57.7	161.0±47.7	0.679
Triglyceride (mg/dL)	144.8±109.3	160.9±105.0	143.5±109.6	0.106
HDL-cholesterol (mg/dL)	44.3±11.9	43.6±12.0	44.4±11.9	0.484
LDL-cholesterol (mg/dL)	97.6±41.9	103.7±46.9	97.1±41.4	0.113
hs-CRP (mg/L)	1.1±4.6	1.2±5.5	1.1±4.5	0.772
Discharge medication				
Aspirin	1,560 (97.6)	113 (98.3)	1,447 (97.5)	0.848
P2Y ₁₂ inhibitors	1,565 (97.9)	111 (96.5)	1,454 (98.0)	0.479
Potent P2Y ₁₂ inhibitors	542 (34.5)	41 (36.9)	501 (34.3)	0.641
Clopidogrel	1,023 (65.0)	70 (63.1)	953 (65.2)	0.727
Ticagrelor	492 (31.3)	35 (31.5)	457 (31.3)	0.999
Prasugrel	50 (3.2)	6 (5.4)	44 (3.0)	0.268
Oral anticoagulants	59 (3.7)	4 (3.5)	55 (3.7)	0.999

Categorical variables are presented as frequencies with percentages, and continuous variables were expressed as mean ± standard deviation.

CABG = coronary artery bypass grafting; Cr = creatinine; eGFR = estimated glomerular filtration rate; HDL = high density lipoprotein; hs-CRP = high sensitivity C-reactive protein; LDL = low density lipoprotein; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention.

subgroups (**Figure 2**). Specifically, even in procedures performed by operators with less than 500 cases or in patients with weak distal radial pulses, the use of a 7 Fr sheath was not associated with a statistically significant increase in overall access-site complications compared to smaller sheaths.

Table 2. Procedural characteristics according to the use of a 7 Fr sheath

Characteristics	Total (n=1,599)	7 Fr sheath (n=115)	Smaller sheaths (n=1,484)	p value
Puncture experience of DRA				<0.001
<100 cases	356 (22.3)	17 (14.8)	339 (22.8)	
100–499 cases	408 (25.5)	2 (1.7)	406 (27.4)	
≥500 cases	835 (52.5)	96 (83.5)	739 (49.8)	
Snuff box puncture	216 (13.5)	9 (7.8)	207 (13.9)	0.087
Pulsation				<0.001
Good	605 (37.8)	96 (83.5)	509 (34.3)	
Weak	994 (62.2)	19 (16.5)	975 (65.7)	
Sono-guided puncture	111 (6.9)	5 (4.3)	106 (7.1)	0.344
Puncture time (seconds)	93.3±113.7	92.5±83.6	93.3±115.8	0.916
Route for PCI				<0.001
Left distal radial artery	1,010 (63.2)	93 (80.9)	917 (61.8)	
Right distal radial artery	564 (35.3)	11 (9.6)	553 (37.3)	
Left radial artery	1 (0.1)	0 (0.0)	1 (0.1)	
Right radial artery	1 (0.1)	0 (0.0)	1 (0.1)	
Femoral artery	23 (1.4)	11 (9.6)	12 (0.8)	
Use of spasmolytics	1,225 (76.6)	109 (94.8)	1,116 (75.2)	<0.001
Sheath length during PCI (cm)	10.8±3.4	10.9±2.0	10.8±3.5	0.538
Culprit lesion				0.481
Left main coronary artery	42 (2.7)	6 (5.3)	36 (2.4)	
Left anterior descending artery	859 (54.2)	60 (53.1)	799 (54.3)	
Left circumflex artery	231 (14.6)	17 (15.0)	214 (14.5)	
Right coronary artery	439 (27.7)	29 (25.7)	410 (27.9)	
Ramus intermedius artery	13 (0.8)	1 (0.9)	12 (0.8)	
Treatment of culprit lesion				0.665
Stent	1,447 (91.6)	107 (94.7)	1,340 (91.4)	
Balloon	129 (8.2)	6 (5.3)	123 (8.4)	
Thrombus aspiration	2 (0.1)	0 (0.0)	2 (0.1)	
Rota-ablation	1 (0.1)	0 (0.0)	1 (0.1)	
Number of stents	1.1±0.6	1.3±0.7	1.1±0.6	0.013
Diameters of stents (mm)	3.1±0.6	3.1±0.5	3.1±0.6	0.455
Length of stents (mm)	32.8±18.2	36.6±20.7	32.5±18.0	0.041
Complex PCI				
Multivessel	400 (25.3)	37 (32.7)	363 (24.7)	0.074
Bifurcation	279 (17.6)	21 (18.6)	258 (17.5)	0.878
Chronic total occlusion	84 (5.3)	15 (13.3)	69 (4.7)	<0.001
In-stent restenosis	120 (7.6)	3 (2.7)	117 (8.0)	0.062
Use of intravascular imaging device	721 (45.5)	66 (58.4)	655 (44.5)	0.006
Use of thrombus aspiration	115 (7.3)	8 (7.1)	107 (7.3)	0.999
Unfractionated heparin	1,587 (99.2)	115 (100.0)	1,472 (99.2)	0.684
Low molecular weight heparin	40 (2.5)	0 (0.0)	40 (2.7)	0.141
Hemostasis methods				<0.001
Gauze compression	915 (57.2)	9 (7.8)	906 (61.1)	
Sticky bandage	663 (41.5)	106 (92.2)	557 (37.5)	
Manual compression	8 (0.5)	0 (0.0)	8 (0.5)	
Device	13 (0.8)	0 (0.0)	13 (0.9)	
Total time of hemostasis (minutes)	242.6±191.5	303.6±266.1	237.8±183.8	0.010
Total time of CAG (minutes)	9.4±7.4	15.6±8.1	8.9±7.2	<0.001
Total time of PCI (minutes)	38.3±29.1	54.0±42.8	37.1±27.4	<0.001
Total procedure time (minutes)	47.4±30.8	68.7±42.8	45.8±29.0	<0.001
Total fluoroscopic time (minutes)	19.2±15.6	28.2±18.4	18.5±15.2	<0.001
Fluoroscopic radiation dose (Gy cm ²)	141.0±163.0	121.6±156.2	142.5±163.5	0.186
Contrast volume (mL)	206.2±92.1	272.0±100.1	201.1±89.5	<0.001

Categorical variables are presented as frequencies with percentages, and continuous variables were expressed as mean ± standard deviation. CAG = coronary angiography; DRA = distal radial access; PCI = percutaneous coronary intervention.

Table 3. Clinical outcomes according to the use of a 7 Fr sheath

Clinical outcomes	Total (n=1,599)	7 Fr sheath (n=115)	Smaller sheaths (n=1,484)	Unadjusted OR (95% CI)	Adjusted OR* (95% CI)	p value
Overall access-site complications	155 (9.7)	14 (12.2)	141 (9.5)	1.32 (0.71–2.30)	1.66 (0.88–2.92)	0.111
Major complications†	53 (3.3)	5 (4.3)	48 (3.2)	1.36 (0.46–3.18)	2.29 (0.80–5.48)	0.114
DRA related bleeding	98 (6.1)	6 (5.2)	92 (6.2)	0.83 (0.32–1.79)	1.05 (0.42–2.25)	0.905
Hematoma grade						
Minor hematoma						
Size <2 cm	43 (2.7)	2 (1.7)	41 (2.8)			
Size ≥2 and <5 cm	18 (1.1)	1 (0.9)	17 (1.1)			
Size ≥5 cm	8 (0.5)	0 (0.0)	8 (0.5)			
Major hematoma						
Hand swelling	26 (1.6)	3 (2.6)	23 (1.5)			
Wrist swelling (<5 cm)	3 (0.2)	0 (0.0)	3 (0.2)			
Wrist swelling (<10 cm)	1 (0.1)	0 (0.0)	1 (0.1)			
Forearm swelling	5 (0.3)	0 (0.0)	5 (0.3)			
Other access site complications						
Before discharge						
Radial artery occlusion	7 (0.4)	1 (0.9)	6 (0.4)	2.16 (0.11–12.80)	3.04 (0.23–19.65)	0.337
Hand edema	57 (3.6)	5 (4.3)	52 (3.5)	1.25 (0.43–2.91)	1.62 (0.58–3.72)	0.323
Numbness	11 (0.7)	1 (0.9)	10 (0.7)	1.29 (0.07–6.84)	1.46 (0.15–6.56)	0.688
Perforation	3 (0.2)	0 (0.0)	3 (0.2)	NA	NA	NA
Dissection	4 (0.3)	0 (0.0)	4 (0.3)	NA	NA	NA
1-month follow-up						
Radial artery occlusion	7 (0.4)	1 (0.9)	6 (0.4)	2.16 (0.11–12.80)	3.04 (0.23–19.65)	0.337
Tenderness	4 (0.3)	0 (0.0)	4 (0.3)	NA	NA	NA
Hand edema	9 (0.6)	2 (1.7)	7 (0.5)	3.73 (0.55–15.66)	4.55 (0.85–17.14)	0.072
Numbness	17 (1.1)	4 (3.5)	13 (0.9)	4.08 (1.13–11.74)	4.38 (1.29–12.44)	0.021
Hand dysfunction	3 (0.2)	1 (0.9)	2 (0.1)	6.50 (0.30–68.35)	7.08 (0.70–46.20)	0.087

CI = confidence interval; DRA = distal radial access; NA = not applicable; OR = odds ratio.

*Adjusted for variables of age, sex, presented with acute coronary syndrome, peripheral arterial disease, chronic kidney disease, previous myocardial infarction, previous stroke, diabetes mellitus, current smoking, and use of potent P2Y₁₂ inhibitor, and oral anticoagulants.

†Major complications were a composite of major hematoma and radial artery injury including occlusion, perforation and dissection.

Table 4. Access crossover according to the use of a 7 Fr sheath

Procedural outcomes	Total (n=1,599)	7 Fr sheath (n=115)	Smaller sheaths (n=1,484)	Unadjusted OR (95% CI)	Adjusted OR* (95% CI)	p value
Access crossover	33 (2.1)	12 (10.4)	21 (1.4)	8.12 (3.78–16.72)	7.87 (3.58–16.52)	<0.001
Final crossover route						
Same-side radial artery	0 (0.0)	0 (0.0)	0 (0.0)			
Opposite-side distal radial artery	8 (0.5)	1 (0.9)	7 (0.5)			
Opposite-side radial artery	2 (0.1)	0 (0.0)	2 (0.1)			
Femoral artery	23 (1.4)	11 (9.6)	12 (0.8)			
Reason for crossover						
Vessel tortuosity	8 (0.5)	1 (0.9)	7 (0.5)			
Vasospasm	3 (0.2)	1 (0.9)	2 (0.1)			
Vessel occlusion	5 (0.3)	1 (0.9)	4 (0.3)			
Small vessel	14 (0.9)	7 (6.1)	7 (0.5)			
Other	3 (0.2)	2 (1.7)	1 (0.1)			

CI = confidence interval; NA = not applicable; OR = odds ratio.

*Adjusted for variables of age, sex, presented with acute coronary syndrome, peripheral arterial disease, chronic kidney disease, previous myocardial infarction, previous stroke, diabetes mellitus, current smoking, and use of potent P2Y₁₂ inhibitor, and oral anticoagulants.

DISCUSSION

The current study evaluated the feasibility and safety of using a 7 Fr sheath via DRA for PCI using nationwide, multicenter, and prospective the KODRA registry. Main findings were as follows. First, there was no significant difference in overall access-site complications or DRA-related bleeding between the 7 Fr sheath group and the smaller sheaths group. Second,

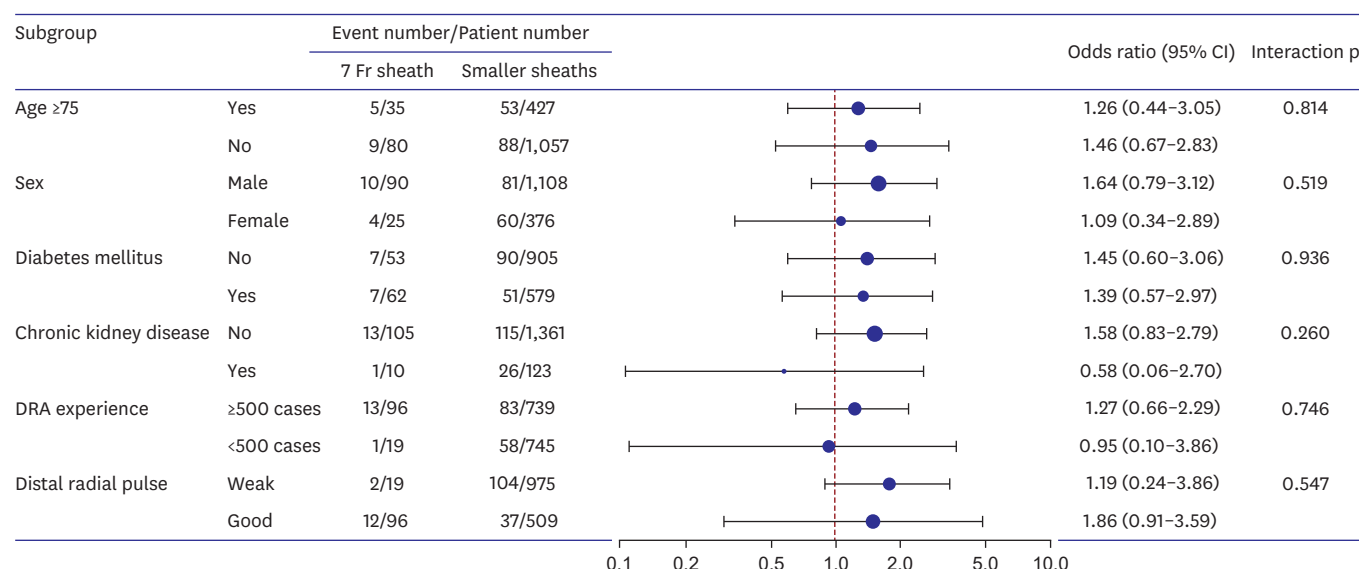


Figure 2. Subgroup analysis regarding primary endpoint.

The risks of overall access-site complications associated with a 7 Fr sheath versus smaller sheaths are presented across various clinical and procedural subgroups. CI = confidence interval; DRA = distal radial access; OR = odds ratio.

the use of a 7Fr sheath via DRA was associated with a significantly higher rate of access-site crossover compared to smaller sheaths.

As complex and high-risk PCI has become more prevalent, larger sheaths are often required to increase back-up support and facilitate delivery of interventional devices.⁵⁾⁷⁾¹⁰⁾ Traditionally, femoral access has been the preferred approach for complex PCI due to its ability to accommodate large-bore sheaths.¹¹⁾ However, recent clinical trials have demonstrated the clinical benefits of radial access in reducing access-site bleeding and vascular complications without affecting procedural success for patients undergoing complex PCI.¹²⁻¹⁴⁾ Furthermore, DRA has gained attention due to its potential to lower the incidence of radial artery occlusion and access-site bleeding compared to conventional radial access.²⁻⁴⁾ Despite established clinical benefit of DRA, there is a lack of prospective data about the safety and efficacy of using large-bore sheaths through distal radial artery and concerns remain regarding the feasibility of large-bore sheath insertion via DRA due to the smaller caliber and anatomical differences of the distal radial artery.

Given the lack of robust evidence supporting the use of large-bore sheaths via DRA in patients undergoing PCI, the current study evaluated the largest number of patients who underwent PCI using a 7 Fr sheath via DRA. Our study demonstrated that the use of a 7 Fr sheath via DRA did not lead to a significant increase in overall access-site complications compared with the use of smaller sheaths. These findings contrast with earlier literature on transradial coronary intervention, such as the study by Dahm et al. in 2002, which reported that large-bore devices (6 Fr vs. 5 Fr guiding catheter) were associated with increased vascular complications, including radial artery occlusion.¹⁵⁾ However, several contemporary advancements differentiate our results. Modern sheath designs featuring thin-walled, hydrophilic-coated technology have significantly reduced arterial friction. Moreover, the anatomical configuration of the distal radial artery offers a distinct physiological response compared to the conventional radial approach. Research by Sgueglia et al. using doppler ultrasound suggests that antegrade blood flow in the forearm radial artery is maintained

even during simulated distal radial artery occlusion.¹⁶⁾ Similarly, a propensity score matching analysis by Pacchioni et al.¹⁷⁾ demonstrated the clinical advantages of the distal approach, showing that it consistently leads to better-preserved arterial flow and more efficient hemostasis, thereby reducing the likelihood of radial artery occlusion compared to the standard transradial approach.

The comparable incidence of overall access-site complications between the two groups remained consistent across various subgroups, without significant interaction. Notably, complication rate did not appear significantly higher than that of the smaller sheaths group, even among operators with low-volume DRA experience (<500 cases) or in patients with weaker distal radial pulses. While these findings clinical reassurance regarding the feasibility of 7 Fr DRA across various settings, we observed that a 7 Fr sheath insertion via DRA was more frequently performed at institutions with high-volume DRA experience (≥ 500 cases), and patients in the 7 Fr sheath group had a higher quality of distal radial pulse. Both the quality of the distal radial pulse and extensive experience with DRA may be an important factor for the successful insertion of a 7 Fr sheath via DRA.

However, the significantly higher rate of hand numbness at 1-month in the 7 Fr sheath group was observed. The longer total procedure time and hemostasis time in the 7 Fr sheath group compared with smaller sheaths group and larger diameter itself may have resulted in prolonged pressure on adjacent nerves, contributing to the observed numbness. Furthermore, significant increase in access-site crossover was observed in the 7 Fr sheath group. These findings suggest that while large-bore sheaths can be used in distal radial artery, their insertion through DRA is technically more challenging. Considering that access-site crossover is associated with prolonged procedure duration, increased contrast volume, and higher radiation exposure, meticulous pre-procedural vascular assessment and careful patient selection are paramount to enhancing the success rate of large-bore sheath insertion through DRA. Future randomized clinical trials for PCI via DRA using large-bore sheath are required to validate and clarify the current observations.

There are several limitations that should be considered. First, this study has an inherent limitation regarding its observational nature with registry data. However, a large sample size was analyzed in this study, and confounding factors were adjusted to minimize the bias from different baseline characteristics. Second, the study did not include a control group using traditional radial access, making it difficult to directly compare the feasibility of a 7 Fr sheath via DRA versus traditional radial access. Third, the study population consisted of East Asian patients, which may limit generalizability of these findings to other patient populations. Fourth, as this study was not specifically designed to evaluate 7 Fr sheath usage, data regarding the patient phenotypes most suitable for large-bore sheath via DRA were not systematically collected. Consequently, future research focusing on identifying ideal candidates is warranted to refine patient selection criteria for 7 Fr DRA.

In patients undergoing PCI via DRA, the use of a 7 Fr sheath did not result in a significant increase in access-site complications compared with the use of smaller sheaths. However, a significantly higher rate of access-site crossover was observed in the 7 Fr sheath group. These findings suggest that distal radial artery can be considered a feasible and safe route for a 7 Fr sheath, provided that it is coupled with meticulous patient selection and pre-procedural vascular assessment.

SUPPLEMENTARY MATERIAL

Supplementary Table 1

Study definitions of endpoints

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