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Impact of obesity on palpation-guided distal radial access for coronary procedures: subgroup analysis of the multicenter, prospective KODRA registry

Ji Woong Roh[1*], Seok-Jae Heo[2*], Oh-Hyun Lee[1], Eui Im[1], Deok-Kyu Cho[1], Jun-Won Lee[3], Bong-Ki Lee[4], Sang-Yong Yoo[5], Sang Yeub Lee[6], Chan Joon Kim[7], Han-Young Jin[8], Jin Sup Park[9], Jung Ho Heo[10], Do Hoi Kim[11], Jin Bae Lee[12], Dong-Kie Kim[13], Jun Ho Bae[14], Sung-Yun Lee[15], Seung-Hwan Lee[16], Yongcheol Kim[1]

[1]Division of Cardiology, Department of Internal Medicine, Yonsei University College of Medicine and Cardiovascular Center, Yongin Severance Hospital, Yongin, South Korea
[2]Division of Biostatistics, Department of Biomedical Systems Informatics, Yonsei University College of Medicine, Seoul, South Korea
[3]Division of Cardiology, Department of Internal Medicine, Wonju Severance Christian Hospital, Yonsei University Wonju College of Medicine, Wonju, South Korea
[4]Division of Cardiology, Department of Internal Medicine, Kangwon National University Hospital, Kangwon National University School of Medicine, Chuncheon, South Korea
[5]Division of Cardiology, Department of Internal Medicine, Good Morning Hospital, Pyeongtaek, South Korea
[6]Division of Cardiology, Chung-Ang University College of Medicine, Chung-Ang University Gwangmyeong Hospital, Gwangmyeong, South Korea
[7]Division of Cardiology, Department of Internal Medicine, Uijeongbu St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Uijeongbu, South Korea
[8]Division of Cardiology, Department of Internal Medicine, Busan Paik Hospital, Inje University College of Medicine, Busan, South Korea
[9]Division of Cardiology, Department of Internal Medicine, Pusan National University Hospital, Busan, South Korea
[10]Division of Cardiology, Department of Internal Medicine, Kosin University Gospel Hospital, Kosin University College of Medicine, Busan, South Korea
[11]Division of Cardiology, Department of Internal Medicine, Soonchunhyang University Hospital Gumi, Gumi, South Korea
[12]Division of Cardiology, Department of Internal Medicine, Daegu Catholic University Medical Center, Daegu, South Korea
[13]Division of Cardiology, Department of Internal Medicine, Haeundae Paik Hospital, Inje University College of Medicine, Busan, South Korea
[14]Division of Cardiology, Department of Internal Medicine, SM Christianity Hospital, Pohang, South Korea
[15]Division of Cardiology, Department of Internal Medicine, Seoul Medical Center, Seoul, South Korea
[16]Division of Cardiology, Department of Internal Medicine, Konkuk University Chungju Hospital, Chungju, South Korea

Address for correspondence: Yongcheol Kim, tel: +823151898967, e-mail: yongcheol@yuhs.ac or Oh-Hyun Lee, tel: +82 3151898786, e-mail: decenthyun@yuhs.ac; Cardiovascular Center, Yongin Severance Hospital, 363 Dongbaekjukjeon-daero, Giheung-gu, Yongin-si, Gyeonggi-do, 16995, South Korea
*These authors contributed equally to this work.

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ABSTRACT

Background: *There is limited data on the impact of body mass index (BMI) on distal radial access (DRA). Using a large-scale prospective registry, the influence of obesity on DRA outcomes was evaluated, including cannulation and complications.*

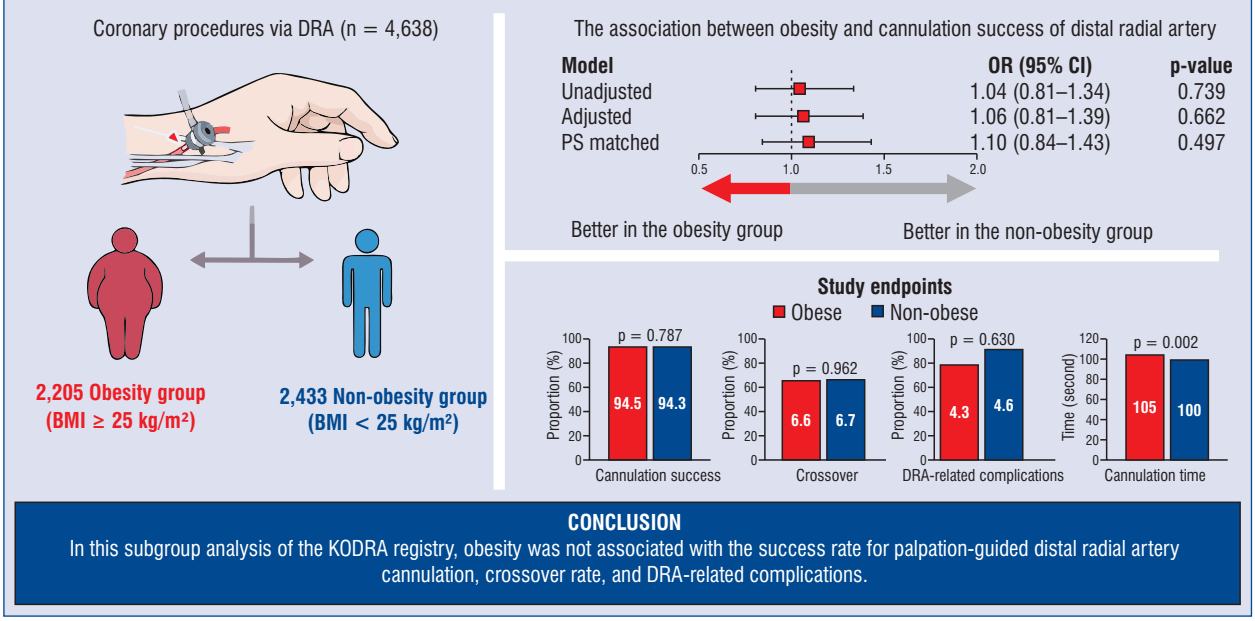
Methods: *Using data from the prospective, multicenter KODRA (Korean Prospective Registry for Evaluating the Safety and Efficacy of Distal Radial Approach) registry data, 4,638 patients who planned palpation-guided distal radial artery puncture were enrolled into two groups, both with body mass index (BMI) information available: obese (n = 2,205; BMI ≥ 25 kg/m^2) and non-obese (n = 2,433). The primary endpoint was the success rate of distal radial artery cannulation. Secondary endpoints included cannulation time, crossover rate, and DRA-related complications.*

Results: *The mean age was 66.6 ± 11.7 years and 67.2% were men. No significant difference existed in the success rate of distal radial artery cannulation between the two groups (94.5% in the obese group vs. 94.3% in the non-obese group, p = 0.787). This tendency in cannulation success rate was consistently observed in multiple sensitivity analyses, including multivariable and propensity score-matched analyses. Crossover rate (6.6% vs. 6.7%, p = 0.962) and DRA-related complications (4.3% vs. 4.6%, p = 0.630) were not significantly different between groups. However, cannulation time was significantly longer in the obese group compared to the non-obese group [105 (101–109) sec vs. 100 (97–103) sec, p = 0.046].*

Conclusions: *In this subgroup analysis of the KODRA registry, obesity was not associated with the success rate for palpation-guided distal radial artery cannulation, crossover rate, and DRA-related complications.*

Keywords: radial artery, obesity, coronary angiography, percutaneous coronary intervention

Graphic abstract. Impact of obesity on palpation-guided distal radial access for coronary procedures: subgroup analysis of the multicenter, prospective KODRA registry



BMI — body mass index; CI — confidence interval; DRA — distal radial access; OR — odds ratio; PS — propensity-score

Introduction

Current clinical guidelines recommend transradial access (TRA) as the standard vascular access for patients with ischemic heart disease undergoing percutaneous coronary intervention (PCI), including those presenting with acute coronary syndrome, because it reduces the incidence of bleeding, access site complications, and mortality compared to femoral access [1, 2]. Recently, several randomized trials and meta-analyses revealed that distal radial access (DRA) is associated with a significantly lower risk of radial artery occlusion (RAO) and puncture site hematoma formation compared to TRA [3–6]. However, DRA has a lower success rate, longer cannulation time, and a higher number of puncture attempts than conventional TRA, reflecting the presence of a learning curve for the former.

Elucidating the factors that influence DRA outcomes — many of which reflect this learning curve — has the potential to inform patient selection and improve procedural efficiency. In this context, several retrospective studies have attempted to identify predictors of DRA failure, but the results have been heterogeneous [7, 8]. In particular, limited evidence exists on how obesity affects the outcomes indicating the learning curve, namely the DRA success rate, cannulation time, and crossover rate. The KODRA (Korean Prospective Registry for Evaluating the Safety and Efficacy of Distal Radial Approach) registry is a large-scale, multicenter, prospective study that demonstrated the feasibility of DRA for coronary procedures in real-world clinical practice [9]. The present study evaluated the influence of obesity on DRA outcomes using this large-scale prospective registry.

Methods

Study design and population

Data from the KODRA registry was analyzed, which included patients from 14 hospitals across South Korea from September 2019 to September 2021. Details of the study protocol have been published previously [9]. The selection overview of the study population is shown in Figure 1. Among the 4,977 patients enrolled in the KODRA registry, patients with planned ultrasound-guided DRA puncture and those lacking body mass index (BMI) data were excluded. In the final analysis, a total of 4,638 patients were included and categorized into two groups: obese (BMI $\geq$ 25 kg/m^2) and non-obese (BMI < 25 kg/m^2). The study protocols were approved by the ethics committees of Yongin Severance Hospital (IRB No. 9-2020-0027) and other participating hospitals, following the principles of the revised Declaration of Helsinki. All patients provided written informed consent. This study was registered at ClinicalTrials.gov (NCT04080700).

Study endpoints and definitions

The primary endpoint was the success rate for distal radial artery cannulation, defined as the successful placement of an introducer sheath following guidewire insertion through the puncture needle. Secondary endpoints included access site crossover rate; DRA-related complications before discharge including DRA-related hematoma, distal and forearm RAO, numbness, and dissection or perforation of forearm radial artery; and cannulation time. Distal radial access related hematoma was assessed using the modified EASY (Early Discharge After Trans-radial Stenting of Coronary Arteries Study) classification, as follows [4]: Grade Ia hematoma was defined as limited to the hand and was further categorized into 4 grades at the DRA puncture site (hematoma: < 2 cm, 2–5 cm, > 5 cm, and hand swelling); Grade Ib and II hematomas were defined as limited to the wrist (Ib: wrist < 5 cm, II: wrist < 10 cm); Grade III and IV were defined as hematoma extending to the forearm and upper arm, respectively. Total hemostasis time was defined as the duration from compression initiation to the complete removal of compressive materials. Cannulation time was defined as the total time from lidocaine injection to successful insertion of the introducer sheath. Finally, access site crossover was defined as the failure to access the initial route of the distal radial artery, causing a switch to another route.

Statistical analysis

Continuous variables are presented as mean ± standard deviation or median (interquartile range) and were analyzed using the independent two sample t-test or the Wilcoxon rank-sum test between obese and non-obese groups, depending on the normality assumption. The normality assumption of the continuous variables was assessed using the Shapiro–Wilk test and graphical method, such as histogram and quantile-quantile plot. Categorical variables are expressed as percentages or rate and were analyzed using the chi-squared or the Fisher exact test as appropriate. Univariate and multivariable logistic regression analyses were performed to evaluate the effect of obesity on puncture success; covariates of multivariable logistic regression included age, sex, BMI, hypertension, diabetes

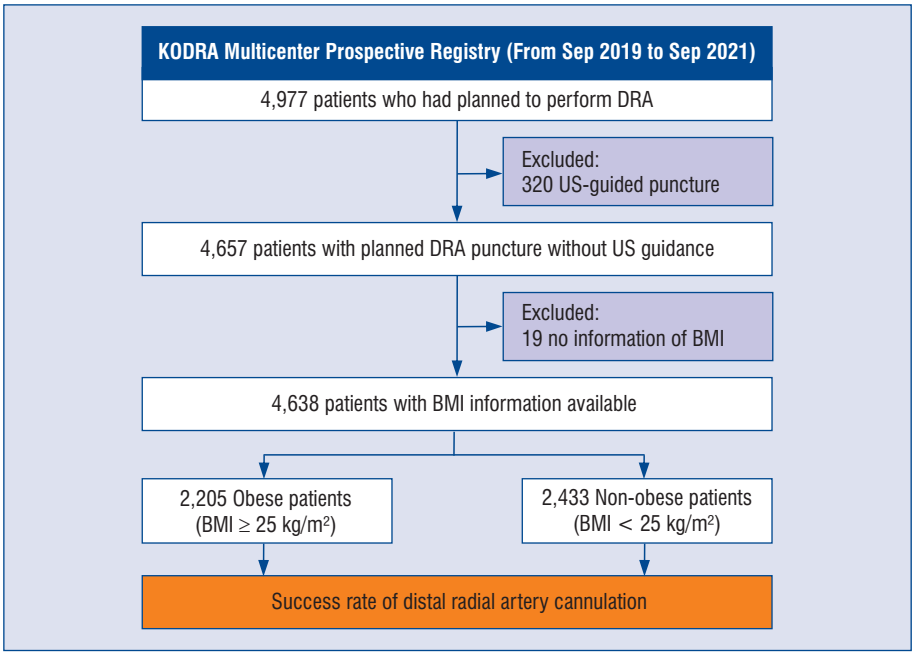


Figure 1. Study flow chart. BMI — body mass index; DRA — distal radial access; KODRA — The Korean Prospective Registry for Evaluating the Safety and Efficacy of Distal Radial Approach; US — ultrasound

mellitus, dyslipidemia, acute coronary syndrome, DRA experience, and weak pulsation. As a sensitivity analysis, propensity-score (PS) matching according to BMI groups with the same covariates was implemented. The odds ratios (OR) with 95% confidence intervals (CI) were calculated from the logistic regression models. For cannulation time, univariate and multivariable quantile regression analyses were conducted, and the same approach was applied to the PS-matched data to estimate the adjusted median difference with 95% CIs. The significance level was set at $p < 0.05$. All statistical analyses were performed with R software (version 4.3.0; R Foundation for Statistical Computing, Vienna, Austria).

Results

Baseline and procedural characteristics

The mean age was 66.6 ± 11.7 years, and 67.2% (3,115 men and 1,523 women) of the 4,638 patients enrolled were men. Of the 4,638 patients, 2,205 were obese and 2,433 were non-obese. The baseline and procedural characteristics of the patients are shown in Table 1. Mean BMI in the obese and non-obese group was 27.8 ± 2.5 kg/m^2 and 22.4 ± 2.0 kg/m^2, respectively ($p < 0.001$). The obese group was younger and had a higher prevalence of comorbidities such as hypertension, diabetes, and dyslipidemia. In terms of DRA, the most common puncture site in both groups was located in the anatomical snuffbox, and the success rate of coronary angiography was 100% in both groups. No significant differences were found in left DRA use, total procedure time, contrast volume, or hemostasis time. The success rate of DRA-PCI was 98.9% (741/749) and 98.4% (854/868) in the obese and non-obese groups, respectively.

Outcomes analysis

In terms of success rate for distal radial artery cannulation, no significant difference existed in either group (94.5% in obese group vs. 94.3% in non-obese group, $p = 0.787$) (Fig. 2A). In the sensitivity analysis using multivariable logistic regression and PS-matched analyses, obesity was not significantly associated with the cannulation success rate for DRA (Fig. 3). In addition, the restricted cubic spline curve demonstrated no significant association between BMI and cannulation success ($p = 0.295$) (Fig. 4). Moreover, crossover rates were also similar between the two groups (6.6% vs. 6.7%, $p = 0.962$) (Fig. 2B). The most common cause of crossover in both groups was puncture failure (Supplementary Table 1). Cannulation time was significantly longer in the obese group than that in the non-obese group [105 (101–109) sec vs. 100 (97–103) sec, $p = 0.046$] (Fig. 2C). This tendency in cannulation time was consistently observed in multiple sensitivity analyses (Supplementary Table 2).

Table 1. Baseline and procedural characteristics

	Obese (n = 2,205)	Non-obese (n = 2,433)	p value
Body mass index, kg/m^2	27.8 ± 2.5	22.4 ± 2.0	< 0.001
Age, years	64.8 ± 11.8	68.2 ± 11.7	< 0.001
Male	1,485 (67.3)	1,630 (67.0)	0.823
Height, cm	162.3 ± 9.7	162.5 ± 9.0	0.553
Weight, kg	73.6 ± 10.9	59.4 ± 8.8	< 0.001
Hypertension	1,537 (69.7)	1,415 (58.2)	< 0.001
Diabetes mellitus	869 (39.4)	841 (34.6)	< 0.001
Dyslipidemia	1,401 (63.5)	1,298 (53.3)	< 0.001
Chronic kidney disease, ≥ stage 3	149 (6.8)	186 (7.6)	0.267
Prior myocardial infarction	244 (11.1)	263 (10.8)	0.817
Prior PCI	526 (23.9)	551 (22.6)	0.348
Acute coronary syndrome	833 (37.8)	894 (36.7)	0.486
DRA experience (≥ 100 cases)	1,819 (82.5)	1,988 (81.7)	0.511
Weak pulse	330 (15.0)	411 (16.9)	0.080
Puncture site			0.922
Anatomical snuffbox	1,851 (83.9)	2,046 (84.1)	
Dorsum of the hand	354 (16.1)	387 (15.9)	
Left distal radial approach	1,252 (56.8)	1,335 (54.9)	0.201
Success rate of CAG	2,187 (100.0)	2,418 (100.0)	
Total procedure time, min	13 (6–32)	13 (6–32)	0.860
Contrast volume, ml	100 (60–150)	100 (60–150)	0.664
Hemostasis time, min	180 (120–180)	180 (120–180)	0.137
Hemostasis method			0.377
Adhesive tape fixation	1,122 (50.9%)	1,276 (52.4%)	
Elastic bandage wrapping	1,057 (47.9%)	1,122 (46.1%)	
Others (compression device or manual compression)	26 (1.2%)	35 (1.4%)	
Additional hemostasis	75 (3.4%)	97 (4.0%)	0.329
Hemostasis total time, min	180 (120-180)	180 (120-180)	0.169
PCI	749 (34.0)	868 (35.7)	0.235
Success rate of PCI	741 (98.9)	854 (98.4)	0.625

Data are presented as the mean ± SD, median (interquartile range), or number (%); CAG — coronary angiography; DRA — distal radial access; PCI — percutaneous coronary intervention

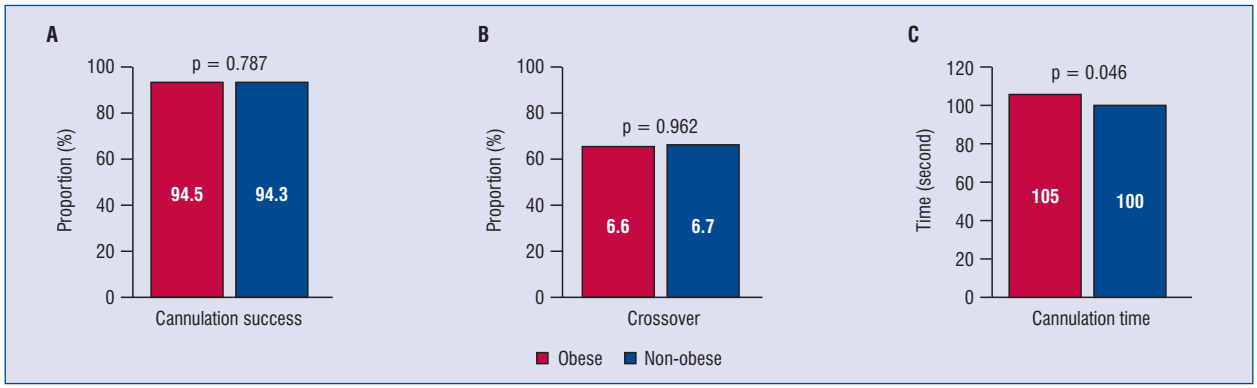


Figure 2. Success rate of distal radial artery cannulation (**A**), rate of crossover (**B**), and distal radial artery cannulation time (**C**)

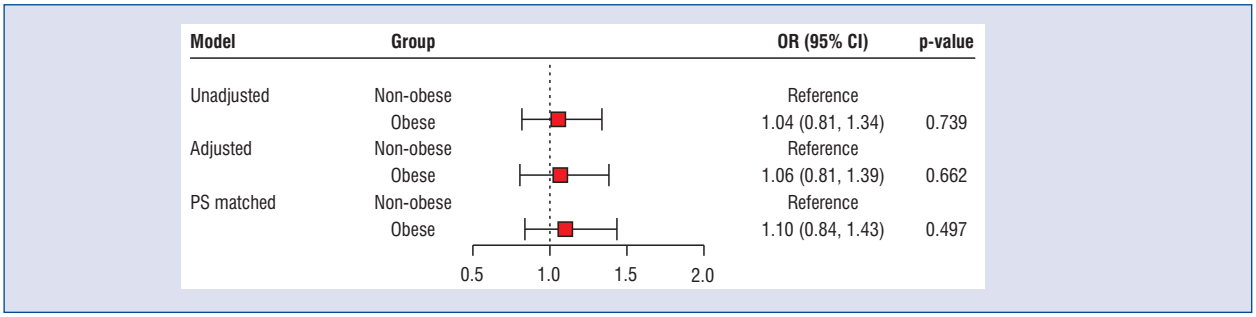


Figure 3. Forest plot of odds ratio for the association between obesity and cannulation success of distal radial artery. Multivariable logistic regression was performed with covariates including age, sex, BMI, hypertension, diabetes mellitus, dyslipidemia, acute coronary syndrome, DRA experience, and weak pulsation. Propensity score matching was performed according to BMI groups with the same covariates. BMI — body mass index; DRA — distal radial access; OR — odds ratio; PS — propensity score

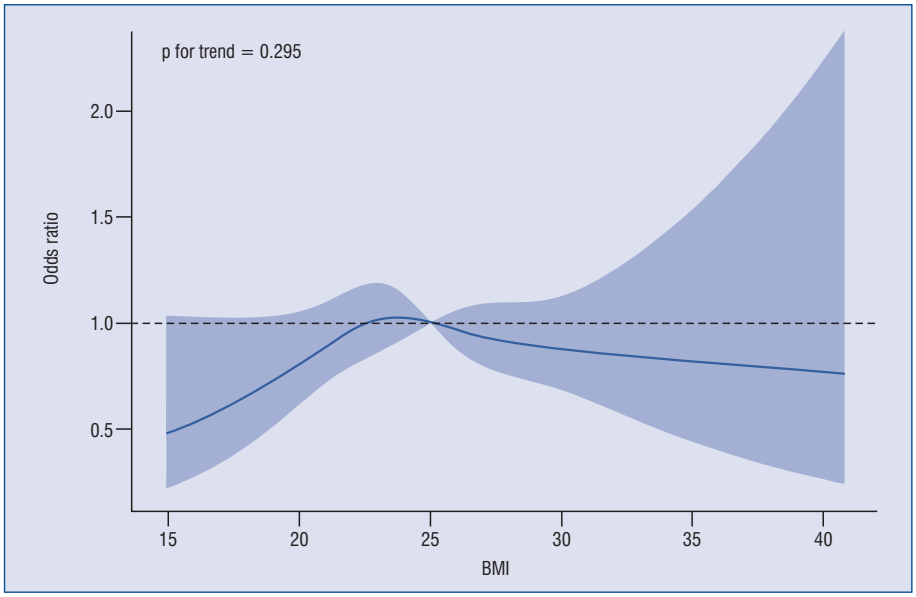


Figure 4. Cannulation success of distal radial artery according to BMI. BMI — body mass index

Access site related complications are shown in Table 2. No significant differences existed in DRA-related complications between the two groups (4.3% vs. 4.6%, p = 0.630). The incidence of distal and forearm RAO by palpation at the time of discharge was < 0.5% in both groups, indicating no significant difference between the two groups.

Discussion

In the current subgroup analysis of the large-scale, multicenter, prospective KODRA registry, the success rate of palpation-guided distal radial artery cannulation and access site complications according to the presence or absence of obesity was evaluated. The results showed that obesity was not associated with the success rate for distal radial artery cannulation, which was consistently observed in sensitivity analyses using multivariable logistic regression and PS-matched analyses. In addition, no significant differences existed between the groups in terms of DRA-related complications. The cannulation time in the obese group was statistically significant, being longer than that in the non-obese group, but only by 5 to 7 seconds before and after adjustment.

DRA is more technically challenging than TRA because the distal radial artery has a smaller diameter and more tortuous angulation than the forearm radial artery [10]. A single-center randomized trial comparing DRA and TRA, the DAPRAO (Distal Radial Approach to Prevent Radial Artery Occlusion) trial, showed that the crossover rate and the number of puncture attempts were significantly

Table 2. Access site related complications

	Obese (n = 2,205)	Non-obese (n = 2,433)	p-value
DRA-related complications	95 (4.3)	113 (4.6)	0.630
DRA-related hematoma (modified EASY classification)			
Ia	65 (2.9)	89 (3.7)	0.205
< 2cm	37 (1.7)	47 (1.9)	0.591
2–5 cm	15 (0.7)	12 (0.5)	0.520
> 5 cm	3 (0.1)	4 (0.2)	> 0.999
Hand swelling	10 (0.5)	26 (1.1)	0.027
Ib (wrist < 5 cm)	2 (0.1)	4 (0.2)	0.773
II* (wrist < 10 cm)	1 (0.0)	0 (0.0)	0.961
III* (forearm)	0 (0.0)	1 (1.0)	> 0.999
IV (upper arm)	0 (0.0)	0 (0.0)	
Other DRA-related complications before discharge			
RAO by palpation			
Distal RAO	9 (0.4)	6 (0.2)	0.478
Forearm RAO	5 (0.2)	3 (0.1)	0.622
Numbness	8 (0.4)	8 (0.3)	> 0.999
Perforation	5 (0.2)	2 (0.1)	0.375
Dissection	6 (0.3)	3 (0.1)	0.415

Data are presented as number (%); *Hematoma happened because of the self-removal of compressive materials by the patients; BARC — Bleeding Academic Research Consortium; DRA — distal radial access; EASY — early discharge after transradial stenting of coronary arteries study; RAO — radial artery occlusion

higher in the DRA group than in the TRA group [3]. Another single-center randomized trial, the ANGIE (Anatomic Snuffbox for Coronary Angiography and Interventional Procedures) trial, also revealed that the DRA group had a significantly lower success rate of cannulation, longer puncture time, and more puncture attempts compared with the TRA group [4]. A meta-analysis of 14 randomized trials enrolling 6,208 patients demonstrated that DRA was associated with a higher crossover rate, more puncture attempts, and a longer puncture time compared with TRA [5]. This data supports the existence of a learning curve for DRA, which is a newer vascular access method following TRA.

For untrained operators to overcome the learning curve of DRA, the appropriate patients are vital. Therefore, several studies have investigated the predictors of DRA failure. Data from a single experienced operator showed that female sex and systolic blood pressure < 120 mmHg were factors associated with failed DRA [7]. Retrospective single-center data revealed that low body weight was a predictor of DRA failure and ultrasound guidance was associated with a high DRA success rate [8]. More recently, the KODRA registry demonstrated weak pulse and less experienced operators in DRA (< 100 cases) as predictors of puncture failure [9]. However, the impact of BMI on DRA failure has not been clearly established in these studies. In addition, the impact of BMI on the crossover rate and puncture time, which are other indicative factors of the learning curve, has not been investigated either. In the present study, it was found that the success rate of distal radial artery cannulation was not significantly different between the obese and non-obese groups before and after sensitivity analysis using multivariable and PS-matched analyses. The crossover rate was also similar in both the groups. Regarding the distal radial artery cannulation time, it was statistically longer in the obese group than in the non-obese group before and after adjustment. This may be explained by the fact that increased adipose tissue in patients with obesity may attenuate the tactile sensation of arterial pulsation, making distal radial artery cannulation by palpation guidance more technically demanding despite unchanged intraluminal pressure of distal radial artery [11]. However, since the diameter of the arteries of patients with obesity is relatively large, if the puncture needle is successfully positioned in the arterial lumen, there is a high probability of successful cannulation [12].

In the present study, difficulties in palpating arterial pulses and the large distal radial artery diameter in patients with obesity may have contributed to longer cannulation times in the obese group, although no difference existed in cannulation and crossover rates between the groups. However, a delay of only 5–7 seconds in achieving arterial access is clinically insignificant and unlikely to impact patient outcomes, total procedure time, radiation exposure, or catheterization laboratory throughput.

Regarding DRA-related complications, the present study showed no significant differences in DRA-related complications in both groups. In addition, most of the DRA-related complications had limited cases of DRA-related hematoma. In both groups, the rate of distal and proximal RAO was very rare (< 0.5 % in a total study population of 4,638). Numerous studies have demonstrated that DRA is a safe alternative access route for coronary procedures [13–16]. Furthermore, DRA could be feasible option without significant safety concerns in patients with ST-segment elevation myocardial infarction, hemodialysis status, or high bleeding risk [17–19]. Transradial access is associated with lower bleeding complication across all BMI categories, from non-obese (BMI < 25) to morbidly obese (BMI ≥ 40) [20]. Although DRA with TRA or the femoral approach was not compared, the results of this study support that DRA is a safe approach for all patients regardless of obesity.

The limitations of this study should be considered. First, this subgroup analysis was conducted within a prospective KODRA registry. Therefore, the baseline characteristics between the obese and non-obese groups were different, because the KODRA registry was not originally designed to compare obesity and non-obesity. Although sensitivity analyses including multivariable logistic regression and PS-matched analyses were conducted to adjust for the measured confounding factors of different baseline characteristics, unmeasured factors could not be adjusted in the current study. Second, doppler ultrasound remains the gold standard for RAO detection, providing definitive information on arterial flow and identifying anatomical issues such as thrombus or dissection. Therefore, the prevalence of distal and forearm RAO is likely underestimated by being palpable at the time of discharge in the present study. Third, obesity was defined as BMI ≥ 25 kg/m^2 in this study because the World Health Organization (WHO) Asia-Pacific region defined BMI ≥ 25 kg/m^2 as obese, although WHO defines obesity as a BMI ≥ 30 kg/m^2 in the Western populations. Therefore, the findings should be interpreted with caution when generalized to other ethnic groups.

Conclusions

In this subgroup analysis of the KODRA multicenter registry, there was no difference in the success rate of palpation-guided distal radial artery cannulation and crossover rate between the obese and non-obese groups. Moreover, the incidence of DRA-related complications was similar between the groups, with most cases being DRA-related hematoma cases limited to the hand, followed by rare cases of distal and forearm RAO. These results support that DRA is a feasible access site regardless of obesity.

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

Ethics statement: The study protocols were approved by the ethics committees of Yongin Severance Hospital (IRB No. 9-2020-0027) and other participating hospitals, following the principles of the revised Declaration of Helsinki. All patients provided written informed consent. This study was registered at ClinicalTrials.gov (NCT04080700).

Author contributions: Writing — original draft: R.J.W., S.-J.H., O.-H.L., writing-review and editing: E.I., D.-K. Ch., J.-W. L., B.-K.L., S.-Y.Y., S.Y.L., Ch.J.K., H.-Y.J., J.S.P., J.H.H., D.H.K., J.B.L., D.-K.K., J.H.B., S.-Y.L., S.-H.L., conceptualization, data curation, project administration, formal analysis, methodology, writing — original draft: Y.K.

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Conflict of interest: None.

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Supplementary material: Suppl. Tables 1–2.

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