Predictors and periprocedural outcomes of access crossover during primary percutaneous coronary interventions — a contemporary report from the Polish ORPKI registry

Łukasz Piątek¹, Karolina Piątek¹, Jacek Kurzawski², Marcin Sadowski¹, Krzysztof Malinowski³, Patrycja Cecha¹, Stanisław Bartuś³, Zbigniew Siudak¹

¹Collegium Medicum, Jan Kochanowski University, Kielce, Poland

²2nd Department of Cardiology, Świętokrzyskie Cardiology Center, Kielce, Poland

³2nd Department of Cardiology, Collegium Medicum, Jagiellonian University in Krakow, Kraków, Poland

Correspondence to:

Łukasz Piątek, MD, PhD, Collegium Medicum, Jan Kochanowski University, Żeromskiego 5, 25–369 Kielce, Poland, phone: +48 504 590 245, e-mail: piatas22@op.pl

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ABSTRACT

Background: The radial artery became preferable access for percutaneous coronary interventions (PCI). The latest European Society of Cardiology guidelines strongly recommended transradial access in patients with ST-segment elevation myocardial infarction (STEMI). Though, in a significant portion of the coronary artery, invasive procedure crossover to femoral is necessary.

Aims: This study aimed to determine the ratio, risk factors, and periprocedural outcomes of crossover from radial to femoral access during PCI in a contemporary STEMI registry.

Methods: Based on data from the Polish registry ORPKI, we analyzed 90245 patients with a diagnosis of STEMI that were intended to be treated invasively via transradial access between 2014 and 2019.

Results: In 1484 (1.6 %) individuals, a switch to femoral access was necessary during the procedure. The most important independent predictors of vascular crossover were female sex, previous coronary artery bypass graft, class 3 and 4 of the Killip scale, left main disease, as well as any complications during coronary angiography. In that cohort, the risk of bleeding at the puncture site was over 20--fold higher. Major disparities in periprocedural outcomes (death during procedure, cardiac arrest during PCI, Thrombolysis In Myocardial Infarction (TIMI) after PCI, and no-reflow) between these groups resulted from disparities in initial characteristics, and they were not associated with crossover itself.

Conclusions: Even though the risk of crossover to femoral is currently low, it appears to be indispensable to sustain operators' experience both in radial and femoral approaches to achieve the best outcomes in these patients.

Key words: crossover, transradial access, PCI, STEMI

INTRODUCTION

The radial artery has become preferable access for percutaneous coronary interventions (PCI) in the last decade [1]. The European Society of Cardiology (ESC) guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation confirmed that the radial approach is favored as long as an experienced operator is available [2]. It was confirmed in numerous previous trials and registries that transradial access (TRA) is associated with a lower rate of bleeding events and vascular complications,

as well as better outcomes in comparison to femoral artery puncture [1, 3–5]. Moreover, even patients after coronary artery bypass graft (CABG) achieved better periprocedural outcomes when the PCI is performed via a transradial approach [6]. On the other hand, radial access may be challenging because it is a smaller artery prone to spasms with often encountered anatomic abnormalities like vascular loop and tortuosity [7]. Based on the previous studies, the necessity to crossover from radial to femoral puncture seems to be unavoidable in a significant portion of coro-

WHAT'S NEW?

The most important independent predictors of vascular crossover are female sex, previous coronary artery bypass graft, class 3 and 4 of the Killip scale, left main disease, as well as any complications during coronary angiography. In crossover patients, the risk of bleeding at the puncture site was over 20-fold higher along with patient exposition to radiation and contrast. In this group, periprocedural outcomes, both angiographic and clinical, are substantially worse. Major disparities in periprocedural outcomes (death during procedure, cardiac arrest during percutaneous coronary interventions [PCI], thrombolysis in myocardial infarction after PCI, and no-reflow) between these groups resulted from disparities in initial characteristics, and they were not associated with crossover itself. It appears to be indispensable to sustain operators' proficiency both in radial and femoral approaches, especially when we revealed that crossover patients are the most challenging ones.

nary artery procedures. In some reports, the percentage of vascular access crossover was high, up to 11% in women cohorts [8]. Along with increasing proficiency of interventional cardiologists in radial-access procedures, the risk of radial approach failure is decreasing considerably, even though it is still an important issue. Based on previous studies, we already know that in Poland there are about 20 000 primary PCI in ST-segment elevation myocardial infarction (STEMI) each year [9], and the application of transradial access is high among Polish operators [10]. Therefore, we investigated the incidence, risk factors, and outcomes in patients after access crossover from radial to femoral during invasive treatment of acute myocardial infarction in Poland.

METHODS

This study cohort was based on the data prospectively collected in the National Registry of Invasive Cardiology Procedures (*Polski Ogólnopolski Rejestr Procedur Kardiologii Inwazyjnej* [ORPKI]). The registry was described elsewhere [6].

In this study, we included all consecutive patients admitted between 2014 and 2019, diagnosed with STEMI according to the current ESC guidelines [1], who were to undergo coronary angiography (CA), as well as percutaneous coronary intervention (PCI) via radial-artery access. In a part of this cohort, a switch of access site to the femoral artery was necessary during the procedure. An evaluation of baseline clinical characteristics, along with periprocedural details, as well as outcomes in both groups, radial access and crossover to femoral access, were performed. Baseline characteristics comprise age, sex, body weight; risk factors of coronary artery disease and comorbidities: diabetes, smoking, hypertension, kidney disease, psoriasis, chronic obstructive pulmonary disease; previous myocardial infarction, percutaneous coronary intervention, coronary artery bypass graft; signs of heart failure (Killip scale 1-4); prehospital cardiac arrest; results of angiography with an assessment of blood flow in the TIMI scale (0-3); and antiplatelet and anticoagulative therapy. Propensity score matching was applied for balancing disparities in the baseline characteristics between these two groups — all of the above factors were included in the matching model. Patients provided written informed consent for data collection, and the ORPKI registry was approved by the institutional review board. Due to the retrospective nature of the collected data and the registry, no ethics committee approval was required. The study protocol complied with the Declaration of Helsinki.

Statistical analysis

Continuous variables were summarized as means with standard deviations (SD) or medians with interguartile range (IQR) when appropriate. Nominal variables were summarized as counts and percentages. The groups were compared using the t-test for continuous variables or the χ^2 test for nominal variables of their non-parametric equivalences when appropriate. A logistic regression analysis was constructed to identify predictors of crossover. The final multiple model was constructed using a stepwise combined (forward/backward) technique with minimization of the Bayesian Information Criterion as a target. Results are presented as odds ratios with an associated 95% confidence interval. The level of statistical significance was set at an alpha value of <0.05. The propensity score was calculated using a multiple regression model that included covariates presented in Table 1 and Table 2. Matching was performed using a nearest neighbor algorithm. Statistical analysis was performed in R version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria) and JMP 15.2 (SAS Institute Inc., Cary, NC, US).

RESULTS

The application of transradial access in STEMI percutaneous intervention has considerably increased in the 2014–2019 period (Figure 1) and accounted for 72.4% of all cases. A total of 90 245 patients with a diagnosis of STEMI who we to be treated invasively via radial artery access were included in the study. Among them, in 1484 (1.6%) individuals a switch to femoral access was necessary during the procedure. A comparison between the crossover-to-femoral-access and radial-access cohorts was performed. The clinical characteristics of these groups are presented in Table 1. Patients in the crossover-to-femoral group were older by about two years. In that group, the percentage of females was remarkably higher than in the

Table 1. Baseline characteristics of crossover to the femoral and radial-access groups.

Variable	Crossover to femoral PCI (n = 1484)	Radial CA and PCI (n = 88 765)	<i>P</i> -value
Age, years, mean (SD)	66.81 (13.1)	64.58 (11.9)	<0.001
Male sex, n (%)	845 (57.0)	62020 (70.4)	<0.001
Weight, kg, mean (SD)	79.21 (17.5)	80.98 (16.5)	<0.001
Diabetes, n (%)	287 (19.3)	15138 (17.1)	0.022
Previous stroke, n (%)	68 (4.6)	2575 (2.9)	<0.001
Previous MI, n (%)	172 (11.6)	9833 (11.1)	0.53
Previous PCI, n (%)	167 (11.3)	9181 (10.3)	0.26
Previous CABG, n (%)	44 (3.0)	840 (1.0)	<0.001
Active smoking, n (%)	380 (25.6)	28 314 (31.9)	<0.001
Psoriasis, n (%)	8 (0.5)	422 (0.5)	0.70
Hypertension, n (%)	902 (60.8)	52 138 (58.7)	0.11
Kidney disease, n (%)	57 (3.8)	2410 (2.7)	0.013
COPD, n (%)	33 (2.2)	1507 (1.7)	0.13
Killip class 1, n (%)	1017 (80.1)	65 384 (86.4)	<0.001
Killip class 2, n (%)	146 (11.5)	7280 (9.6)	
Killip class 3, n (%)	53 (4.2)	1861 (2.5)	
Killip class 4, n (%)	54 (4.3)	1137 (1.5)	
Cardiac arrest at baseline, n (%)	64 (4.3)	2562 (2.9)	<0.001
Hypothermia at baseline, n (%)	4 (0.3)	86 (0.1)	0.06
Direct transport, n (%)	358 (24.1)	21 740 (24.5)	0.76

Abbreviations: CA, coronary angiography; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; PCI, percutaneous coronary intervention

Table 2. Characteristics of coronary angiogram in crossover to the femoral and radial-access groups

Variable	Measure	Crossover to femoral PCI (n = 1484)	Radial CA and PCI (n = 88 765)	<i>P</i> -value
Results of CA, n (%)	SVD	625 (42.2)	41 887 (47.2)	<0.001
	MVD	684 (46.2)	41 647 (47.0)	
	MVD + LMD	162 (11.0)	4994 (5.6)	
	LMD	11 (0.7)	137 (0.2)	
TIMI before PCI, n (%)	0	781 (54.1)	49 186 (57.6)	0.025
	1	238 (16.5)	12 168 (14.3)	
	2	232 (16.1)	12 708 (14.9)	
	3	194 (13.4)	11 293 (13.2)	
Thrombolysis during CA n (%)		0 (0.0)	78 (0.1)	0.64
Bivalirudin during CA, n (%)		2 (0.1)	47 (0.5)	0.19
FFR during CA, n (%)		0 (0.0)	75 (0.1)	0.64
IVUS during CA, n (%)		7 (0.5)	186 (0.2)	0.042
OCT during CA, n (%)		1 (0.1)	43 (0.1)	0.52
ASA during CA, n (%)		1083 (73.0)	65 055 (73.3)	0.79
UFH during CA, n (%)		720 (48.5)	46 320 (52.2)	0.005
LMWH during CA, n (%)		0 (0.0)	4 (0.0)	1.00
P2Y12 inhibitor during CA, n (%)	Clopidogrel	724 (48.8)	44 914 (50.6)	<0.001
	None	650 (43.8)	34 093 (38.4)	
	Ticagrelor	101 (6.8)	9364 (10.6)	
	Prasugrel	9 (0.6)	394 (0.4)	
Stroke during CA, n (%)		0 (0.0)	7 (0.0)	1.00
Dissection during CA, n (%)		4 (0.3)	98 (0.1)	0.09
Bleeding during CA, n (%)		7 (0.5)	12 (0.0)	<0.001
Cardiac arrest during CA, n (%)		28 (1.9)	377 (0.4)	<0.001
Allergic reaction during CA, n (%)		0 (0.0)	8 (0.0)	1.00

Abbreviations: ASA, acetylsalicylic acid; FFR, fractional flow reserve; IVUS, intravascular ultrasound; LMD, left main disease; LMWH, low-molecular weight heparin; MVD, multivessel disease; OCT, optical coherence tomography; SVD, single-vessel disease; UFH, unfractionated heparin; other — see Table 1

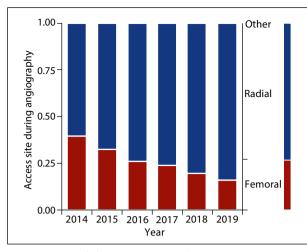


Figure 1. Transradial access in STEMI in the years 2014–2019 in Poland

Abbreviations: STEMI, ST-segment-elevation myocardial infarction

radial-access group. These patients more often had a history of diabetes, previous stroke, previous coronary artery bypass graft (CABG), and chronic kidney disease. Moreover, in that group, we found a higher prevalence of acute heart failure (Killip class 2, 3, and 4). Finally, the percentage of cardiac arrest before coronary angiography was substantially higher than in the radial-artery-access group.

The prevalence of a single-vessel disease was substantially higher in the radial group, whereas in the crossover-to-femoral group, there was a greater percentage of left main disease along with multi-vessel disease (Table 2). The utilization of intravascular ultrasonography (IVUS) during the coronary angiography and percutaneous coronary was higher in the group that changed to femoral access (Tables 2 and 3). In that cohort, we revealed a substantially higher risk of bleeding at the puncture site, which was over 20-fold higher than in patients with solely radial artery puncture (Table 3). Moreover, the total amount of contrast, as well as total radiation dose used during the invasive procedure, were remarkably larger in the crossover group (Table 3). The average time from first medical contact to balloon inflation was longer in the crossover group.

Even though there were no disparities in mean TIMI score before PCI between these groups, after the invasive procedure, the angiographic results were better in the radial group — the average TIMI score was higher, along with a lower percentage of TIMI-0 and TIMI-1 after PCI. The risk of cardiac arrest during PCI was almost 3-fold higher in the crossover group and the prevalence of death during PCI was almost 5-fold higher in that group despite there being no difference in the rate of no-reflow, coronary artery perforation, and allergic reaction (Tab.3).

After propensity score matching analysis, there were no longer disparities in major periprocedural outcomes (death, cardiac arrest during PCI, no-reflow, TIMI scale after PCI) between the crossover and radial groups. On the contrary, the amount of contrast, radiation, and bleeding at the puncture site were still more often encountered in crossover patients.

In univariate logistic regression, we found that the risk of crossover to femoral access is higher in females and patients with diabetes and kidney disease, but the most influential factors are previous CABG, serious clinical conditions (class 3 and 4 of Killip classification), cardiac arrest, left main disease, and bleeding from an initial puncture site (Table 4). Multivariable logistic regression revealed that the most important independent predictors of crossover from radial to femoral were female sex, previous CABG, class 3 and 4 of the Killip scale, left main disease, and any complications during coronary angiography (Table 5).

Table 3. Characteristics of percutaneous coronary intervention in crossover to the femoral and radial-access groups before and after propensity score matching

Variable	Crossover to femoral (n = 1484)	Radial CA and PCI (n = 88 765)	<i>P</i> -value	Crossover to femoral (PS) (n = 1296)	Radial CA and PCI (PS) (n = 1296)	<i>P</i> -value
IVUS during PCI, n (%)	15 (1.0)	393 (0.4)	0.005	8 (0.6)	6 (0.5)	0.79
P2Y12, Clopidogrel, n (%)	447 (69.7)	23 898 (68.4)	0.59	636 (49.1)	650 (50.2)	0.68
P2Y12, Prasugrel, n (%)	12 (1.9)	838 (2.4)		6 (0.5)	3 (0.2)	
P2Y12, Ticagrelor, n (%)	182 (28.4)	10225 (29.3)		97 (7.5)	89 (6.9)	
TIMI 0 after PCI, n (%)	57 (4.0)	1578 (1.8)	<0.001	48 (3.7)	35 (2.7)	0.06
TIMI 1 after PCI, n (%)	30 (2.1)	1069 (1.3)		26 (2.0)	24 (1.9)	
TIMI 2 after PCI, n (%)	81 (5.6)	3676 (4.3)		73 (5.6)	49 (3.8)	
TIMI 3 after PCI, n (%)	1274 (88.4)	79 444 (92.6)		1149 (88.7)	1188 (91.7)	
Total amount of used contrast, ccm, median (IQR)	200 (150–250)	150 (120–200)	<0.001	190 (150–250)	150 (120–200)	<0.001
Total radiation dose during procedure, mGy, median (IQR)	943 (530–1682)	754 (435–1266)	<0.001	937 (522–1677)	783 (456–1259)	<0.001
Death during procedure, n (%)	37 (2.5)	469 (0.5)	<0.001	27 (2.1)	16 (1.2)	0.12
No-reflow during PCI, n (%)	26 (1.8)	1128 (1.3)	0.10	20 (1.5)	25 (1.9)	0.55
Bleeding at the puncture site during CA or PCI, n (%)	16 (1.1)	46 (0.1)	<0.001	11 (0.8)	0 (0.0)	0.003
Cardiac arrest during PCI, n (%)	30 (2.0)	701 (0.8)	<0.001	25 (1.9)	16 (1.2)	0.21
Allergic reaction during PCI, n (%)	2 (0.1)	131 (0.2)	1.00	2 (0.2)	4 (0.3)	0.68
Coronary artery perforation during PCI, n (%)	5 (0.3)	167 (0.2)	0.21	5 (0.4)	4 (0.3)	1.00

Abbreviations: see Tables 1 and 2

Table 4. Univariate logistic regression — predictors of crossover to femoral

Variable	Measure	OR (95% CI)	P-value
Sex	Female	1.79 (1.61–1.99)	<0.001
Diabetes		1.17 (1.02–1.33)	0.025
Previous stroke		1.61 (1.26–2.06)	<0.001
Previous MI		1.05 (0.90-1.24)	0.54
Previous PCI		1.10 (0.93–1.29)	0.26
Previous CABG		3.20 (2.35–4.35)	<0.001
Active smoking		0.73 (0.65–0.83)	<0.001
Hypertension		1.15 (1.09–1.21)	<0.001
Kidney disease		1.43 (1.10–1.87)	0.013
COPD		1.32 (0.93–1.87)	0.14
Killip class	2 vs. 1	1.29 (1.08–1.56)	<0.001
	3 vs. 1	1.83 (1.38–2.42)	
	4 vs. 1	3.05 (2.31-4.04)	
IVUS during CA		2.26 (1.06-4.81)	0.06
OCT during CA		1.39 (0.19–10.11)	0.76
Coronary angiography	MVD vs. SVD	1.10 (0.99–1.23)	<0.001
	LMD vs. SVD	5.38 (2.90–10.00)	
	MVD + LMD vs. SVD	2.17 (1.82–2.59)	
Dissection during CA		2.45 (0.90-6.65)	0.12
Bleeding during CA		35.05 (13.78-89.16)	<0.001
Cardiac arrest CA		4.51 (3.06–6.64)	<0.001
Age, years		1.02 (1.01–1.02)	<0.001
Weight, kg		0.99 (0.99–1.00)	<0.001

Abbreviations: see Tables 1 and 2

Table 5. Multiple logistic regression — predictors of crossover to femoral

Variable	OR (95% CI)	P-value
Age (per 10 years)	1.05 (1.00–1.10)	0.05
Female sex	1.67 (1.49–1.87)	<0.001
Previous stroke	1.34 (1.02–1.73)	0.028
Previous CABG	2.55 (1.80–3.50)	<0.001
Active smoking	0.85 (0.75–0.97)	0.014
Killip class 2 (vs. 1)	1.18 (0.99–1.40)	0.06
Killip class 3 (vs. 1)	1.49 (1.11–1.95)	0.005
Killip class 4 (vs. 1)	2.22 (1.65–2.93)	<0.001
Coronary angiography MVD	1.02 (0.90–1.14)	0.79
Coronary angiography LMD	1.86 (1.54–2.23)	<0.001
Any complication during CA	3.55 (2.46–4.97)	<0.001

Abbreviations: see Tables 1 and 2

DISCUSSION

The main finding in our study is that the rate of access site crossovers from radial to femoral of 1.6% was considerably lower than in numerous previous analyses. Large registries revealed that the risk of a radial-approach failure was prominent, as high as 7.0 % in RIVAL [1], 5.8% in MATRIX [3], 9.6% in RIFLE-STEACS [4], and 3.7% in the STEMI-RADIAL [5] study. Also, in a meta-analysis of 16 rand-omized trials by Singh et al., the ratio of access crossover in STEMI patients accounted for 4.4% [11]. When we take into consideration the structure of our cohort (all patients with STEMI diagnosis with a significant portion of patients in a critical condition — after cardiac arrest in cardiogenic

shock or pulmonary edema), the observed rate of access site crossover appears to be more than satisfactory.

In our study, the most important independent predictors of crossover from radial to femoral were previous CABG, class 4 of the Killip scale, and left main disease. This is in accordance with the results some authors mentioned in the previous studies. Azzalini et al. [12] pointed out that Killip class 4 and cardiopulmonary resuscitation before arrival were associated with radial-access failure and the primary choice of the femoral artery. Sahincus et al. [13] presented in their analysis that female sex and anterior myocardial infarction were independent risk factors of vascular approach shift. In numerous past studies female sex was associated with a higher risk of access site crossover. In our study, the odds ratio for women to vascular access change was as high as 1.8 and that was consistent with the Turkish study [13]. It is easy to explain as long as the female radial artery has a smaller diameter and is prone to spasms. Finally, in our analysis, any complications during coronary angiography appeared to be the most influential factor for radial crossover to femoral. In previous studies, various causes of vascular access crossover were reported. Rubartelii et al. [14] pointed out failure in radial puncture, radial artery loop and other abnormalities, artery spasm, tortuosity of the brachiocephalic trunk, and suboptimal guiding catheter back-up. Also, a Canadian study [15] mentioned the same difficulties during transradial procedures. What is interesting, more than half of their cases were associated with inadequate puncture. Azzalini et al.

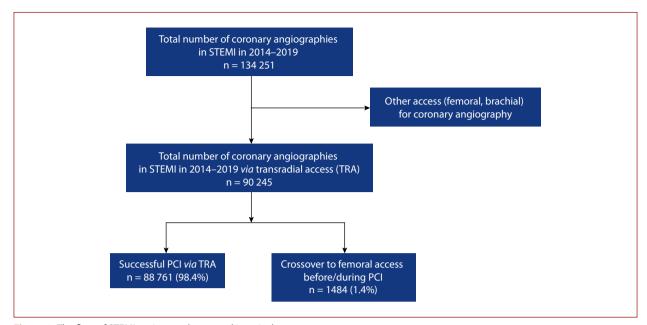


Figure 2. The flow of STEMI patients to be treated invasively Abbreviations: see Figure 1

[12] showed that failure to puncture accounted for 55% of all crossover cohorts. Le et al. [16] revealed that in the vast majority of cases (91.5%), the timing of radial artery crossover took place before achieving complete diagnostic coronary angiography, and only in few cases, vascular access switches were performed just before or during percutaneous coronary intervention.

One of the most important issues in patients in whom there was vascular access crossover during the procedure is a delay in successful coronary reperfusion. In our study, additional delay was about 18 minutes in comparison to the radial group. Results of the previous analysis varied significantly in that respect. Sahinkus et al. [11] reported that door-to-balloon-time in the crossover group was longer by about 17 minutes in comparison to successful radial access PCI. In a study from Montreal, Canada, in the crossover group, time to first device was longer of by 7.5 minutes and vascular access-related time of by 6.2 minutes, respectively [12]. On the other hand, Rubartelli et al. [14] mentioned that crossover was associated with a much longer door-to-balloon median time 75 minutes vs. 43 minutes in comparison to successful transradial PCI in STEMI patients. Huded et al. showed in their report that vascular crossovers do not compromise door-to-balloon time performance though [17].

In addition, we demonstrate numerous important implications of the access site crossover like the substantially higher risk of bleeding complication from puncture site along with patient exposition to radiation and contrast. Moreover, these patients achieved substantially worse periprocedural results, both angiographic (a lower TIMI scale and higher risk of no-reflow after PCI) and clinical (periprocedural death and cardiac arrest). All these factors may impact final outcomes. What is important, we revealed that in propensity score matching analysis, differences in major periprocedural outcomes (death, cardiac arrest during PCI, no-reflow, TIMI scale after PCI) between these groups resulted from disparities in initial characteristics, and they were not associated with crossover itself.

Additionally, we should be aware that the wider experience and utilization of radial access might be linked to worse outcomes of PCI performed via the femoral artery [10]. Moreover, in specific groups, like patients that underwent rotational atherectomy during the PCI, femoral access is associated with a lower rate of coronary artery perforation [18]. It appears to be indispensable to sustain operators' experience both in radial and femoral approaches, especially when we demonstrated that crossover patients are the most challenging ones.

The introduction of novel devices like sheathless catheters enabled operators to partially overcome the limitations of the transradial access, especially radial artery spasm and catheter trapping, which reduce the risk of crossover [19]. What is important, the sheathless catheter proved its feasibility and safety in STEMI patients, as well as in complex interventions via the radial artery [20, 21]. Moreover, numerous studies revealed that the preferable access site after initial radial-approach failure is contralateral radial, and it should be used as an alternative access site after initial radial-approach failure to reduce using the femoral approach [22].

CONCLUSIONS

Along with the wider experience in transradial percutaneous coronary interventions, the risk of crossover to the femoral approach has become low. Even though it remains an important issue especially in patients after previous CABG, in cardiogenic shock, in patients with left main disease, as well as in cases of complications during coronary angiography. Crossover is associated with worse periprocedural outcomes, but these mainly result from unfavorable baseline clinical characteristics.

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