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ORIGINAL ARTICLE

Trans-radial percutaneous coronary intervention for patients with severe chronic renal insufficiency and/or on dialysis

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Abstract

Periprocedural bleeding is associated with an increased risk of mortality during percutaneous coronary intervention (PCI), especially in patients with severe chronic renal insufficiency. Therefore, trans-radial intervention (TRI) should be considered in these patients; however, PCI operators usually avoid this approach because of the risk of radial artery occlusion. We aimed to investigate the associations of TRI and in-hospital complications in these patients. This study included 306 consecutive patients with severe chronic renal insufficiency and/or on dialysis who underwent PCI. Patients were prospectively enrolled and divided according to the access site into TRI group and trans-femoral intervention group. Severe renal insufficiency was defined as estimated glomerular filtration rate < 30 mL/min/1.73 m^2. Radial access was limited to the opposite side of the arteriovenous fistula in patients on hemodialysis. The primary study endpoint was the composite of in-hospital bleeding complications and death. TRI benefit was evaluated by inverse probability treatment weighted analysis. TRI was performed in 112 (37.3%) patients. TRI group included older patients with significantly lower rates of diabetes mellitus, dialysis, and three-vessel disease. Crossover to the other approach occurred only in TRI group (2.6%). The primary endpoint was significantly lower in TRI group (11.5% vs. 2.6%, $P = 0.006$). After an inverse probability treatment weighted analysis, TRI was an independent prognostic factor for a decrease in the primary endpoint (OR 0.19; 95% CI 0.051–0.73; $P = 0.015$). Radial artery occlusion occurred in three patients on dialysis (9.1%). TRI may determine better in-hospital outcomes in patients with severe chronic renal insufficiency and/or on dialysis.

Keywords Trans-radial approach · Percutaneous coronary intervention · Coronary artery disease · Dialysis · Renal insufficiency

Introduction

Previous studies revealed that periprocedural bleeding is the most common complication of percutaneous coronary intervention (PCI) and is associated with an increased risk of short-term and long-term mortality [1, 2]. Therefore, bleeding avoidance strategies, such as trans-radial intervention (TRI), should be considered, especially in patients with high bleeding risks, such as those with severe chronic renal insufficiency and/or on dialysis, because previous studies demonstrated a decreased rate of bleeding complications after PCI performed with TRI [1, 3–5]. However, PCI operators hesitate to choose TRI due to the increased risk of radial artery occlusion and general tendency to preserve possible hemodialysis access points for the future [6, 7].

Previous studies showed that 2-year primary and secondary patency rates of arteriovenous fistula in patients on

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hemodialysis were 51% and 64%, and radial artery occlusion rates after trans-radial catheterization were 1–10% [8–14]. On the other hand, preservation of possible hemodialysis access points for the future is controversial, because 5-year survival rate of patients with severe renal insufficiency and/or on dialysis is poor [15, 16]. Therefore, we consider that TRI would be advantageous in these patients despite the risk of radial artery occlusion, because it can decrease bleeding complications and early mortality rates [1].

The aim of this study was to investigate the associations of TRI and in-hospital complications in patients with severe renal insufficiency and/or on dialysis.

Methods

This study was an ongoing, prospective, cohort study designed to collect clinical background and outcome data of all PCI cases treated since 2009 in our institute. The institutional review board approved the study design and TRI performance in patients on dialysis. A nephrologist (K. H.) from our institute also approved TRI in patients on dialysis. Details were described in our previous paper [17]. Severe chronic renal insufficiency was defined as chronic kidney disease stage 4 and stage 5 (estimated glomerular filtration rate < 30 mL/min/1.73 m^2) [18]. All patients provided written informed consent, including a statement regarding possible radial artery occlusion, especially patients on dialysis. This study complied with the Helsinki Declaration for experiments involving humans. Data of approximately 150 variables of patients were collected from medical records. Any coronary device could be used to perform PCI. The decision to perform PCI was based on patient clinical assessment by the attending physician. Physician was not restricted to specific interventional or surgical techniques, such as vascular access site (TRI or trans-femoral intervention [TFI]), sheath size, or use of a specific stent or closure device.

Data of 306 consecutive patients with chronic kidney disease stages 4, 5, and 5D who underwent PCI between 2009 and 2017 were analyzed (Fig. 1). Patients with missing information regarding estimated glomerular filtration rate, estimated glomerular filtration rate > 30 mL/min/1.73 m^2, trans-brachial PCI, use of percutaneous cardiopulmonary support, and bidirectional approach for chronic total occlusion were excluded. All patients were divided into two groups according to the access site (TRI group or TFI group). Radial access was limited to the opposite side of arteriovenous fistula in patients on dialysis. Allen's test was not routinely performed because it was found not to affect hand ischemic complications after the procedure [19]. Baseline characteristics and clinical outcomes of patients from both groups were analyzed. The majority of the clinical variables were defined according to the National Cardiovascular Data Registry by the American College of Cardiology [20].

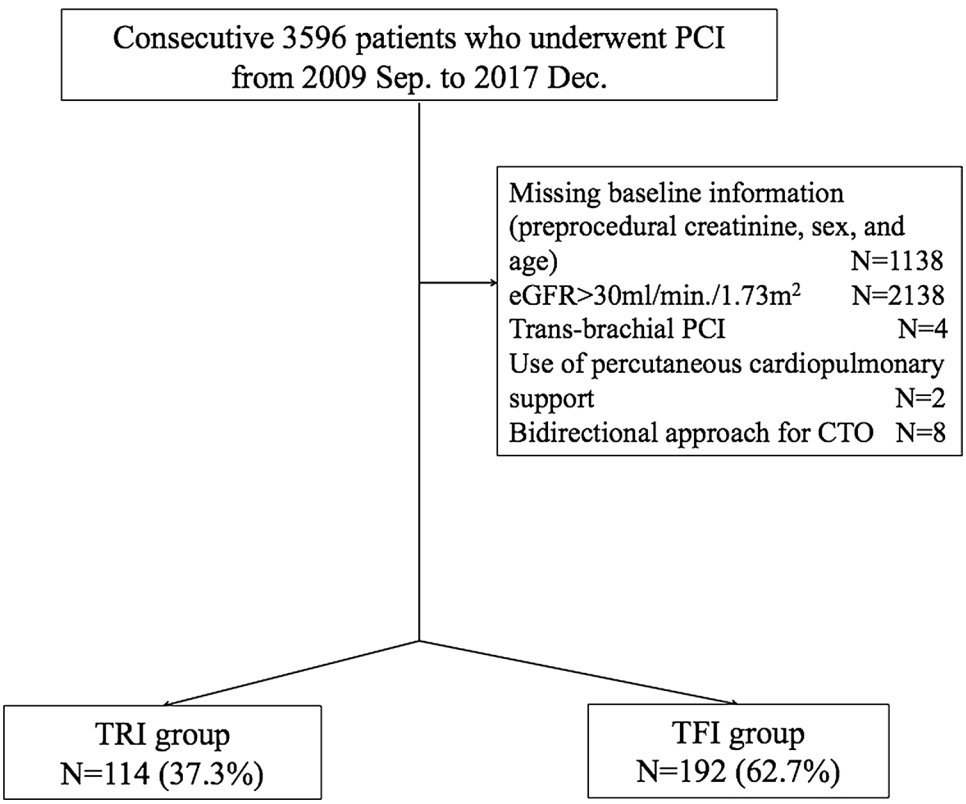

Fig. 1 Patients flowchart. *CTO* chronic total occlusion, *eGFR* estimated glomerular filtration rate, *PCI* percutaneous coronary intervention, *TFI* trans-femoral percutaneous coronary intervention, *TRI* trans-radial percutaneous coronary intervention

All patients received periprocedural anticoagulation with unfractionated heparin (Bivalirudin is not available in Japan) [1]. For PCI, a bolus of 5000 U was administered and additional heparin doses were used to maintain activated clotting time > 300 s [21]. Crossover was defined as the inability to complete the procedure and translation to another access site. For TRI, 5000 U of unfractionated heparin and 0.5–1.0 mg of nitroglycerin were administered intra-arterially after sheath insertion. All sheaths were removed after the procedures. Radial artery spasm was defined as the inability to advance the arterial sheath or to manipulate the catheters, or spasm resulting in patient discomfort requiring access site crossover [22]. Bleedsafe® (Medikit, Tokyo, Japan) hemostatic device was placed around the wrist. Radial artery occlusion was assessed by Barbeau's test for patients on dialysis [13]. A pulse oximeter sensor was placed over the index finger. Radial and ulnar arteries were compressed; subsequently, radial artery was released. When plethysmographic signal returned, radial artery patency was confirmed. This test was performed 24 h after the procedure. If radial artery occlusion was suspected, ultrasonography with duplex Doppler was performed to observe the absence of blood flow, after which radial artery occlusion was confirmed. These patients were additionally examined at 30 days after the procedures, because radial artery occlusion rates at 30 days were reportedly lower than those detected at 24 h [13].

The recommended antiplatelet therapy was long-term aspirin 81 mg daily, combined with a thienopyridine (prasugrel, clopidogrel, or ticlopidine). According to the study protocol, prasugrel was not used in patients on dialysis due to high bleeding risks [23].

The primary study endpoint was the composite of in-hospital bleeding complications and death. Bleeding complications were defined as bleedings requiring transfusion, prolonging hospital stay, and/or causing a decrease in hemoglobin level > 3.0 g/dL [24]. Further, bleeding complications were subdivided into puncture-site bleeding (external bleeding or a hematoma > 10 cm for femoral, or > 2 cm for radial access), retroperitoneal bleeding, gastrointestinal bleeding, genitourinary bleeding, or other bleeding. This bleeding definition is also consistent with Bleeding Academic Research Consortium grade 3A to C [25]. Other complications included severe coronary dissection or perforation, myocardial infarction after PCI, new-onset cardiogenic shock, new-onset heart failure, cerebral bleeding or stroke, cardiac tamponade, or other thrombotic events.

Continuous variables were expressed as mean and standard deviation, and categorical variables were expressed as percentage. Continuous variables were compared using Student's *t* test, and differences in categorical variables were examined using Chi-square test.

To assess the effect of TRI on the primary endpoint, inverse probability treatment weighted analysis was performed. To estimate a propensity score for the use of TRI, the following covariates were entered: sex, previous myocardial infarction, previous heart failure, diabetes mellitus, dialysis, cerebrovascular disease, peripheral artery disease, hypertension, smoking, dyslipidemia, active cancer, previous PCI, previous coronary bypass, heart failure at admission, cardiogenic shock at admission, cardiopulmonary arrest at admission, use of intra-aortic balloon pump, three-vessel disease, arterial sheath size ≥ 7-Fr, ST-elevation myocardial infarction, non-ST-elevation myocardial infarction/unstable angina, bifurcation lesion, type C lesion, chronic total occlusion, use of rotablator, body mass index < 18.5, and age. Then, calculated propensity score was used to derive inverse probability weights. The generalized estimating equation with the weight was used to estimate the odds ratio based on the inverse probability treatment weighted. First, all cases regardless of propensity score were analyzed to assess the utility of TRI for the primary endpoint, bleeding complications, and in-hospital mortality. Second, to conduct an additional inverse probability treatment weighted analysis, which includes non-extreme population, only cases within 0.1–0.9 of the propensity score distribution ($N = 198$, 64.7%) were analyzed [26].

For the first sensitivity analysis, we used a multivariate logistic regression analysis. TRI, dialysis, prior cerebrovascular disease, heart failure at admission, cardiogenic shock at admission, cardiopulmonary arrest at admission, use of intra-aortic balloon pump, acute coronary syndrome, age were entered as covariates. Second, we excluded patients with intra-aortic balloon pump, because the analysis without patients with intra-aortic balloon pump could prove the utility of TRI more precisely (all intra-aortic balloon pumps were inserted through femoral arteries in our institution). A multivariate logistic regression analysis was performed for the primary endpoint in patients without intra-aortic balloon pump. All statistical calculations and analyses were performed using SPSS version 24 (SPSS Inc., Chicago, IL, USA), and two-tailed *P* values < 0.05 were considered statistically significant.

Results

Overall, the mean age was 71.2 ± 9.6 years, and TRI was performed in 112 (37.3%) patients. Baseline clinical data for TRI group and TFI group are detailed in Table 1. TRI group included older patients with significantly lower rates of diabetes mellitus, dialysis, smoking, and three-vessel disease. Arterial sheath sizes were larger in the trans-femoral intervention group. Femoral vein sheath insertion, bifurcation lesion, and rotablator use were also significantly lower

Table 1 Baseline characteristics among all patients

	Trans-femoral intervention % ($N=192$)	Trans-radial intervention % ($N=114$)	P value
Baseline characteristics			
Age	70.0 ± 9.5	73.3 ± 9.6	0.003
Female	22.9% (44)	32.5% (37)	0.067
Body mass index	22.9 ± 3.5	23.6 ± 3.8	0.14
Body mass index < 18.5	8.9% (17)	7.0% (8)	0.57
Previous myocardial infarction	29.7% (57)	22.8% (26)	0.19
Previous heart failure	28.1% (54)	21.9% (25)	0.23
Diabetes mellitus	75.5% (145)	55.2% (63)	< 0.001
Dialysis	64.0% (123)	28.9% (33)	< 0.001
Cerebrovascular disease	10.4% (20)	17.5% (20)	0.074
Peripheral artery disease	26.6% (51)	18.4% (21)	0.11
Chronic lung disease	0.5% (1)	0.9% (1)	0.71
Hypertension	98.4% (189)	95.6% (109)	0.14
Smoking	37.5% (72)	25.4% (29)	0.030
Dyslipidemia	71.9% (138)	70.2% (80)	0.75
Active cancer	3.1% (6)	3.5% (4)	0.86
Previous PCI	45.3% (87)	38.6% (44)	0.25
Previous coronary bypass	7.8% (15)	3.5% (4)	0.15
Heart failure on admission	22.4% (43)	19.2% (22)	0.51
Cardiogenic shock on admission	8.3% (16)	3.5% (4)	0.099
Cardiopulmonary arrest on admission	2.6% (5)	0.9% (1)	0.29
Intra-aortic balloon pump	13.2% (25)	6.1% (7)	0.057
PCI indications			
ST-elevation MI	13.5% (26)	11.4% (13)	0.11
Unstable angina/non-ST-elevation MI	44.8% (86)	36.0% (41)	
Elective PCI	41.1% (79)	53.5% (61)	
Three-vessel disease	38.0% (73)	23.9% (27)	0.010
Arterial sheath size			< 0.001
5-Fr	1.0% (2)	1.8% (2)	
6-Fr	49.5% (95)	85.1% (97)	
7-Fr	33.3% (64)	13.1% (15)	
8-Fr	16.1% (31)	0.0% (0)	
Closure device	14.0% (27)	0.9% (1)	< 0.001
Femoral vein sheath insertion	35.9% (69)	9.6% (11)	< 0.001
Crossover	0.0% (0)	2.6% (3)	0.024
Pre-procedural aspirin	95.8% (184)	98.2% (112)	0.46
Pre-procedural clopidogrel	80.2% (154)	75.4% (86)	0.29
Pre-procedural ticlopidine	1.6% (3)	1.8% (2)	0.90
Pre-procedural prasugrel	3.1% (6)	14.0% (16)	0.001
Pre-procedural cilostazol	2.1% (4)	0.9% (1)	0.42
Type C lesion	43.8% (84)	32.5% (37)	0.051
Bifurcation lesion	18.2% (35)	3.5% (4)	< 0.001
Chronic total occlusion lesion	3.1% (6)	1.8% (2)	0.47
Thrombus aspiration	7.8% (15)	5.3% (6)	0.39
Balloon angioplasty (no stents)	20.8% (40)	16.7% (19)	0.37
Bare metal stent	3.6% (7)	1.8% (2)	0.34
Drug-eluting stent	74.0% (142)	81.6% (93)	0.13
Use of rotablator	20.3% (39)	4.4% (5)	< 0.001

PCI percutaneous coronary intervention, *MI* myocardial infarction

in the TRI group (Table 1). Crossovers to the other approach were identified only in the TRI group ($N=3$, 2.6%). Radial artery spasm after sheath insertion occurred in one patient, and crossover to trans-femoral intervention was necessary. Other two patients experienced inability to engage guiding catheters, which required crossover. Radial artery occlusion occurred in three patients out of 33 patients on dialysis who underwent TRI (9.1%). Radial artery occlusion was confirmed at both 24 h and 30 days after the procedure in three patients. All three patients had no symptoms of radial artery occlusion such as hand ischemia; 7-Fr arterial sheaths were inserted in two out of three patients and a 6-Fr arterial sheath was inserted in one patient.

The primary endpoint (a composite of bleeding complications and in-hospital death) was significantly lower in the TRI group (2.6% vs. 11.5%, $P=0.006$). In-hospital mortality and transfusion rates were also significantly lower in the TRI group (Table 2).

After an inverse probability treatment weighted analysis, TRI was an independent prognostic factor for a decrease in the primary endpoint even in an additional inverse probability treatment weighted analysis including only patients with 0.1–0.9 of the propensity score (all cases: OR 0.19; 95% CI 0.051–0.73; $P=0.015$, cases within 0.1–0.9 of the propensity score; OR 0.24; 95% CI 0.059–0.99; $P=0.050$). Bleeding complications and in-hospital mortality were also assessed by inverse probability treatment weighted analysis (Table 3). TRI was found to be an independent favorable predictor of in-hospital mortality.

As a sensitivity analysis with a multivariate logistic regression analysis, TRI remained an independent predictor of the primary endpoint (OR 0.12; 95% CI 0.021–0.70, $P=0.018$) as well as bleeding complications (OR 0.14; 95% CI 0.023–0.90, $P=0.039$) (Table 3). For the second sensitivity analysis, we excluded patients with intra-aortic balloon pump ($N=32$, 10.4%). In this population ($N=274$, 89.5%), TRI had a tendency to be a favorable predictor for a lower primary endpoint (OR 0.096; 95% CI 0.009–1.05, $P=0.055$) with a multivariate logistic regression analysis.

Discussion

The present study revealed TRI had advantages for in-hospital bleeding complications and death in patients with severe chronic renal insufficiency and/or on dialysis who undergo PCI with an inverse probability weighted analysis and a multivariate logistic regression analysis. Although this approach raised concerns about possible radial artery occlusion and loss of future access site for arteriovenous fistula, we adapted TRI in these patients to improve patients' outcomes.

Table 2 In-hospital outcomes among all patients

	Trans-femoral intervention % ($N=192$)	Trans-radial intervention % ($N=114$)	P value
In-hospital mortality	7.8% (15)	1.8% (2)	0.025
Cardiac death	5.7% (11)	1.8% (2)	0.096
Coronary dissection	1.6% (3)	0.0% (0)	0.18
Coronary perforation	0.0% (0)	0.0% (0)	n/a
Myocardial infarction	0.5% (1)	0.0% (0)	0.44
Cardiogenic shock	4.7% (9)	0.9% (1)	0.069
Heart failure	3.1% (6)	0.9% (1)	0.20
Cerebral infarction	1.0% (2)	0.0% (0)	0.27
Cardiac tamponade	0.0% (0)	0.0% (0)	n/a
Other thrombotic events	0.0% (0)	0.0% (0)	n/a
Transfusion	8.9% (17)	2.6% (3)	0.032
Bleeding all (within 72 h after PCI)	5.7% (11)	1.8% (2)	0.096
Puncture-site bleeding	2.6% (5)	0.0% (0)	0.082
Puncture-site hematoma	1.6% (3)	0.9% (1)	0.61
Peritoneal bleeding	0.5% (1)	0.0% (0)	0.44
Gastrointestinal bleeding	1.0% (2)	0.9% (1)	0.89
Genitourinary bleeding	0.0% (0)	0.0% (0)	n/a
Intracranial hemorrhage	0.0% (0)	0.0% (0)	n/a
Other bleeding	1.6% (3)	0.0% (0)	0.18
Bleeding complications and/or in-hospital death	11.5% (22)	2.6% (3)	0.006

PCI percutaneous coronary intervention

Table 3 Adjusted odds ratios of trans-radial intervention for bleeding complications and in-hospital death

	Bleeding complications and in-hospital death	Bleeding complications	In-hospital mortality
IPTW analysis OR (95% CI)	0.19 (0.051–0.73) $P=0.015$	0.29 (0.057–1.46) $P=0.13$	0.16 (0.033–0.73) $P=0.018$
IPTW analysis (PS 0.1–0.9) OR (95% CI)	0.24 (0.059–0.99) $P=0.050$	0.31 (0.057–1.70) $P=0.18$	0.23 (0.042–1.21) $P=0.082$
Multivariate logistic regression analysis	0.12 (0.021–0.70) $P=0.018$	0.14 (0.023–0.90) $P=0.039$	0.095 (0.007–1.33) $P=0.080$

IPTW inverse probability treatment weighted, *OR* odds ratio, *CI* confidential interval, *PS* propensity score

TRI might be used more frequently in these patients, which in turn might lead to a better patient's prognosis.

In the current practice, bleeding avoidance strategies are mandatory, especially for patients with high bleeding risk, such as those with severe chronic renal insufficiency [1, 4]. Previous studies have demonstrated that TRI could reduce bleeding complications and mortality rates [3, 27], whereas the current American Heart Association statement compromises a class III recommendation for the routine use of vascular closure devices to reduce the incidence of vascular complications [28]. However, PCI operators avoid choosing TRI in order to conventionally preserve the radial artery for a future arteriovenous fistula. This could induce a very difficult adaptation of operators with TRI in these patients [6]. On the other hand, the access point preservation for possible hemodialysis in the future is controversial, because of low 5-year survival rates reported in patients with severe chronic renal insufficiency and/or on dialysis [13, 14]. Moreover, since the number of angioplasties for arteriovenous fistula stenosis increased, we may increase arteriovenous fistula patency by using various devices, such as a cutting balloon, which could decrease the influence of radial artery occlusion [29, 30]. Although the data of in-hospital and TRI outcomes of patients with severe chronic renal insufficiency and/or on dialysis are scarce, our findings demonstrated that TRI could lead to better in-hospital outcomes in these patients. We might consider that TRI is advantageous to reduce the incidence of bleeding complications and early mortality, regardless of radial artery occlusion risk.

Adapting TRI in patients with severe renal insufficiency is challenging. The current consensus recommends access site preservation for future arteriovenous fistula creation and avoidance of TRI in these patients [31]. Wang and Asif [32] summarized the advantages and disadvantages of TRI for patients on dialysis as follows: (1) using TRI for patients on dialysis or with chronic kidney disease stage 4 or 5 is not conventionally recommended; (2) however, the potential benefit of TRI should be evaluated on a case-by-case basis (such as for cases with high bleeding risk or too small forearm veins for future creation of arteriovenous fistula); (3) TRI should be considered only on the contralateral side of arteriovenous fistula; (4) trans-brachial approach may be associated with a higher risk than TRI; and (5) when radial artery occlusion occurs, the proximal radial artery can be used if it is patent [33]. Previous studies showed a wide range of radial artery occlusion rates (1–10%) [8–14], which can be attributed to different patient characteristics. The use of a large-sized sheath could affect the radial artery occlusion rates [8]. In our study, the rate of radial artery occlusion was 9.1%, which was relatively high in recent reports, but within the range reported by previous studies [8–14]. To the best of our knowledge, there is a paucity of data in terms of radial artery occlusion in patients on dialysis who underwent PCI, showing the rate of radial artery occlusion after PCI in these patients is of great value. Arterial intimal thickening in patients on dialysis and larger arterial sheath size (2 cases out of 3: 7-Fr) that could induce arterial tears may be the reasons of radial artery occlusion [34–36]. Since we cannot conclude it is acceptable, we need to make every effort to decrease radial artery occlusion rates such as patent hemostasis, decrease in compression time, or ulnar compression [11–13]. Fortunately, we did not observe any cases of symptomatic hand ischemia complications due to radial artery occlusion; however, it is of high risk in patients on dialysis [37].

Recently, a more distal radial approach at the snuffbox has been suggested, to reduce the risk of thrombosis which results in radial artery occlusion at the forearm because antegrade blood flow would be preserved through the superficial palmar arch [38]. Although we did not try distal radial approach for patients with chronic severe renal insufficiency and/or on dialysis in this study, further investigation is warranted to investigate the safety and efficacy of distal radial approach for these patients.

This study has several limitations. First, this was an observational clinical trial and not a randomized trial. The use of TRI depended on the operator decision. We could not eliminate all confounding factors or the selection bias with inverse probability treatment weighted analysis. However, no randomized data to reveal the benefit of TRI in patients with severe chronic renal insufficiency and/or on dialysis are currently available, because a large randomized trial that

has addressed the benefit of invasive strategy has excluded patients with advanced chronic kidney disease [39]. Second, we only evaluated short-term in-hospital outcomes. Long-term outcomes of patients with radial artery occlusion were also not available. However, previous data showed that the poorer outcomes are likely to occur over a long-term follow-up [40]. Finally, we excluded patients with missing pre-procedural creatinine value. Since creatinine values of patients with normal renal function or early chronic kidney disease stages were not consistently collected, it might not affect our results.

In conclusion, TRI might lead to better in-hospital outcomes in patients with severe chronic renal insufficiency and/or on dialysis.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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