

Radial versus femoral artery access in patients undergoing PCI for left main coronary artery disease: analysis from the EXCEL trial



Shmuel Chen¹, MD, PhD; Björn Redfors¹, MD, PhD; Yangbo Liu¹, MS; Ori Ben-Yehuda^{1,2}, MD; Marie-Claude Morice³, MD; Martin B. Leon^{1,2}, MD; David E. Kandzari⁴, MD; Roxana Mehran^{1,5}, MD; Nicholas J. Lembo^{1,2}, MD; Adrian P. Banning⁶, MD; Béla Merkely⁷, MD, PhD, DSc; Arie Pieter Kappetein⁸, MD, PhD; Joseph F. Sabik 3rd⁹, MD; Patrick W. Serruys¹⁰, MD, PhD; Gregg W. Stone^{1,2*}, MD

1. Clinical Trials Center, Cardiovascular Research Foundation, New York, NY, USA; 2. NewYork-Presbyterian Hospital/Columbia University Medical Center, New York, NY, USA; 3. Ramsay Générale de Santé, Institut Cardiovasculaire Paris Sud, Paris, France; 4. Piedmont Heart Institute, Atlanta, GA, USA; 5. The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, NY, USA; 6. John Radcliffe Hospital, Oxford, United Kingdom; 7. Heart and Vascular Center, Semmelweis University, Budapest, Hungary; 8. Thoraxcenter, Erasmus MC, Rotterdam, the Netherlands; 9. Department of Surgery, UH Cleveland Medical Center, Cleveland, OH, USA; 10. Imperial College of Science, Technology and Medicine, London, United Kingdom

S. Chen and B. Redfors contributed equally to the drafting of this manuscript.

GUEST EDITOR: Alec Vahanian, MD, PhD; Department of Cardiology, Hôpital Bichat-Claude Bernard, and University Paris VII, Paris, France

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KEYWORDS

- femoral
- left main
- radial

Abstract

Aims: We sought to compare clinical outcomes and procedural characteristics with transradial access (TRA) versus transfemoral access (TFA) in patients who were treated with PCI for left main (LM) coronary artery disease.

Methods and results: The EXCEL trial was a prospective, international, open-label, multicentre trial that randomised 1,905 patients with LM disease and SYNTAX scores ≤ 32 to PCI with everolimus-eluting stents versus coronary artery bypass grafting. The present analysis cohort consisted of 931 patients undergoing PCI with TRA or TFA, but not both. The primary endpoint was a composite of death, myocardial infarction (MI), or stroke at three years. Multivariable Cox proportional hazards regression was used to adjust for differences in baseline covariates. PCI in EXCEL was performed exclusively with TRA in 248 (26.6%) patients and with TFA in 683 (73.4%) patients. TRA patients were younger and less likely to have hypertension and chronic kidney disease. The mean number of vessels and lesions treated was higher in TFA patients, although the SYNTAX score was similar in both groups. Patients undergoing TRA and TFA had similar 30-day rates of TIMI major or minor bleeding (2.4% versus 3.8%, respectively, $p=0.30$). At three years, TRA and TFA patients had similar rates of the primary endpoint (15.7% versus 14.8%, adjusted HR 1.11, 95% CI: 0.73-1.69, $p=0.64$), as well as the individual rates of death, MI, stroke, ischaemia-driven revascularisation and stent thrombosis.

Conclusions: In the EXCEL trial, PCI of LM disease with TRA was associated with comparable early and late clinical outcomes to TFA.

*Corresponding author: Columbia University Medical Center, Cardiovascular Research Foundation, 1700 Broadway, 9th Floor, New York, NY 10019, USA. E-mail: gs2184@columbia.edu

Abbreviations

AKI	acute kidney injury
BARC	Bleeding Academic Research Consortium
CABG	coronary artery bypass grafting
EES	everolimus-eluting stent
HR	hazard ratio
LM	left main
MI	myocardial infarction
PCI	percutaneous coronary intervention
TFA	transfemoral access
TIMI	Thrombolysis In Myocardial Infarction
TRA	transradial access

Introduction

The common practice of attaining arterial access via the femoral artery (transfemoral access [TFA]) for percutaneous coronary intervention (PCI) has been challenged in recent years by the demonstration in randomised trials that transradial access (TRA) reduces vascular complications, bleeding, and perhaps even mortality¹⁻⁶. However, much of the benefit was in patients with acute coronary syndromes, and some have argued that methodologic issues in these studies (including differences in antithrombotic regimens and operator experience) limit the validity of the results⁷. Nonetheless, relatively little has been reported on the outcomes of TRA in patients with complex or high-risk coronary artery disease. Modest-sized retrospective registries have compared outcomes of patients who underwent unprotected left main (LM) PCI using TRA versus TFA, in general reporting similar procedural success, shorter hospitalisation, reduced bleeding rates, and comparable long-term clinical safety and efficacy with TRA⁸⁻¹⁰. However, few data are available from prospective trials comparing these approaches in high-risk patients with LM disease.

We therefore sought to compare the early and late outcomes with TRA versus TFA in patients undergoing LM PCI from the large-scale, contemporary EXCEL (The Evaluation of XIENCE versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) trial¹¹.

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Methods

STUDY DESIGN AND STUDY POPULATION

The study design and primary results of the EXCEL trial have been described in detail previously^{11,12}. In brief, EXCEL was a prospective, international, open-label, multicentre, randomised trial that compared PCI with the cobalt-chromium everolimus-eluting XIENCE stent (Abbott Vascular, Santa Clara, CA, USA) to coronary artery bypass grafting (CABG) in 1,905 patients with unprotected LM disease and low or intermediate SYNTAX scores (≤ 32)¹². Key inclusion criteria were visually estimated LM stenosis $\geq 70\%$ or $\geq 50\%$ to $< 70\%$ with non-invasive or invasive evidence of haemodynamic significance, and consensus among the members of the Heart Team regarding eligibility and equipoise for revascularisation with either PCI or CABG. The trial was approved by the

institutional review board at each site, and all patients provided written informed consent.

The primary endpoint was the composite rate of death from any cause, stroke, or myocardial infarction (MI) at three years. The secondary endpoints were the same composite measure at 30 days, and the composite rate of death, stroke, MI or ischaemia-driven revascularisation at three years. The definitions of the component endpoints have been reported previously¹¹. An independent central events committee reviewed and adjudicated all major primary and secondary endpoint events, as well as stent thrombosis and graft occlusion. Thrombolysis In Myocardial Infarction (TIMI)-scale bleeding¹³, Bleeding Academic Research Consortium (BARC)-scale bleeding¹⁴, and vascular complications (defined as peripheral distal embolisation [non-cerebral], arterial rupture, dissection, occlusion, stenosis, perforation, aneurysm or pseudoaneurysm, arteriovenous fistulas, large haematomas requiring vascular surgery or blood transfusion, or failure of percutaneous access-site closure resulting in intentional [e.g., stent-graft] or surgical repair) were site reported and monitored, but not centrally adjudicated. All patients have presently reached the three-year follow-up time point.

STATISTICAL ANALYSIS

For the present study, we analysed the outcomes of patients who were randomised to and subsequently underwent PCI with TRA versus TFA. Patients who had both TRA and TFA were excluded. Unadjusted comparisons of baseline and procedure characteristics, medical history, and clinical events were conducted using the χ^2 test or Fisher's exact test for binary variables, t-test or Wilcoxon rank-sum test for continuous variables, and log-rank test for time-to-event variables. To account for the differences in baseline characteristics according to vascular access, clinical outcomes were compared in Cox proportional hazards regression models adjusted by a propensity score for TRA vs. TFA use and stratified by US vs. non-US site. The propensity score was calculated by logistic regression using the following covariates: age, sex, chronic kidney disease, peripheral vascular disease, chronic obstructive lung disease, left ventricular ejection fraction, diabetes mellitus, body mass index, prior transient ischaemic attack or stroke, congestive heart failure, SYNTAX score (angiographic core laboratory assessed), hypertension, hyperlipidaemia, anaemia, and anticoagulation used during PCI (heparin or bivalirudin). The variables distal LM bifurcation involvement (versus isolated ostial/shaft stenosis) and planned two-stent LM PCI strategy were added, and the variable anticoagulation used during PCI was excluded from the linear models for procedure duration, contrast amount, and radiation dose. All p-values are two-tailed, and a p-value < 0.05 was considered significant for all analyses. Statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

STUDY POPULATION

A total of 1,905 patients with LM disease were enrolled from 131 international centres, among whom 948 were randomised

to PCI. PCI was the first procedure performed in 935 patients. Two PCI patients who were treated by both TRA and TFA, and two other patients in whom other access routes were used were excluded. Thus, the analysis cohort consisted of 931 PCI patients, 248 (26.6%) of whom were treated exclusively by TRA and 683 (73.4%) of whom were treated exclusively by TFA. The use of TRA varied considerably between countries. TRA for LM PCI was used in only 7.4% (20/272) of PCI patients enrolled in the USA compared with 33.7% (178/528) enrolled in Europe and 48.5% (49/101) in Canada (**Supplementary Figure 1**).

PATIENT CHARACTERISTICS AND PROCEDURES

As shown in **Table 1**, TRA patients were younger, more often presented with stable angina, and had less chronic kidney disease than TFA patients. As shown in **Supplementary Table 1**, the mean number of vessels and lesions treated was higher in TFA patients, although the SYNTAX score was similar in both groups.

Table 1. Baseline and procedural characteristics.

	Radial access (n=248)	Femoral access (n=683)	p-value
Age, years	64.1±9.1	66.6±9.7	0.0005
Male sex	76.2 (189/248)	76.0 (519/683)	0.94
BMI, kg/m ²	28.0±4.4	28.7±5.2	0.36
Hypertension	69.2 (171/247)	76.4 (519/679)	0.03
Hyperlipidaemia	75.5 (185/245)	69.6 (468/672)	0.08
Diabetes	26.2 (65/248)	31.5 (215/683)	0.12
Insulin-treated	6.0 (15/248)	8.2 (56/683)	0.27
Current smoker	28.2 (70/248)	22.0 (149/678)	0.05
Prior MI (within 2 months)	13.8 (34/247)	14.6 (98/671)	0.75
Prior PCI	14.9 (37/248)	19.5 (133/681)	0.11
Chronic obstructive pulmonary disease	6.0 (15/248)	7.2 (49/682)	0.54
Congestive heart failure	6.0 (15/248)	7.3 (50/681)	0.49
Peripheral vascular disease	13.0 (32/247)	9.3 (63/681)	0.10
Creatinine clearance (ml/min)	94.8±32.0	88.3±32.6	0.003
Chronic kidney disease	10.3 (25/242)	19.8 (134/676)	0.0008
Haemodialysis	0.0 (0/248)	0.3 (2/683)	1.00
Left ventricular ejection fraction	57.8±8.8	56.7±9.9	0.28
Presenting clinical syndrome			
Recent MI (within 7 days)	15.0 (37/246)	15.1 (103/681)	0.97
Unstable angina	19.1 (47/246)	26.0 (177/681)	0.03
Stable angina	60.2 (148/246)	50.5 (344/681)	0.009
Site location: USA	8.1 (20/248)	36.9 (252/683)	<0.0001
Data expressed as % (numerator/denominator) or mean±standard deviation. All data are per patient unless otherwise noted. LM: left main coronary artery; MI: myocardial infarction; PCI: percutaneous coronary intervention			

The guide catheter most commonly used was 6 Fr in the TRA group and 7 Fr in the TFA group. Bivalirudin was more commonly used in TFA procedures. No significant differences were present in the rates of procedural complications or duration of hospitalisation between the groups.

CONTRAST VOLUME, PROCEDURE DURATION, AND RADIATION DOSE

TRA was associated with less contrast use than TFA (233.1±112.4 versus 263.7±131.4 mL; p=0.002), and the mean procedure time (from the start of local anaesthesia to procedure end, defined as the time of last guidewire removal) was significantly shorter in the TRA group (74.1±38.4 versus 83.1±43.5 min; p=0.006). Radiation dose did not differ significantly between the TRA and TFA groups (3.0±2.4 versus 3.2±2.4 Gy, respectively, p=0.22). After multivariable adjustment, contrast use was still less with TRA compared to TFA, a finding that was consistent in US and non-US sites (**Table 2**). Procedural duration was no longer different between groups after multivariable adjustment, although a significant interaction was present such that procedural duration was shorter with TRA at US sites but not at non-US sites. Radiation dose did not differ significantly between groups in the adjusted model.

Table 2. Procedural factors, adjusted models.

	Estimate (95% confidence interval)	p-value
Total contrast injected, mL		
TRA vs. TFA (n=812)	-45.7 (-66.5, -24.9)	<0.0001
US sites (n=244)	-108.8 (-176.7, -40.8)	0.002
Non-US sites (n=568)	-35.8 (-63.3, -18.6)	0.0004
Interaction		0.20
Procedure duration, min		
TRA vs. TFA (n=808)	-5.7 (-12.5, 1.1)	0.10
US sites (n=243)	-35.6 (-58.5, -12.8)	0.002
Non-US sites (n=565)	-3.5 (-10.7, 3.7)	0.34
Interaction		0.01
Total radiation dosage, Gy		
TRA vs. TFA (n=598)	-0.03 (-0.14, 0.09)	0.58
US sites (n=178)	-0.23 (-0.47, 0.13)	0.19
Non-US sites (n=420)	-0.01 (-0.14, 0.13)	0.84
Interaction		0.39
TFA: transfemoral access; TRA: transradial access		

CLINICAL OUTCOMES

At 30 days, the composite outcome measure of death, stroke, or MI had occurred in 6.0% and 4.5% of patients in the TRA and TFA groups, respectively (p=0.35) (**Table 3**). The rates of the individual components of this endpoint and stent thrombosis also did not differ significantly between groups (**Table 3**). Any bleeding at 30 days by both the TIMI and BARC scales was numerically lower with TRA compared with TFA; however, differences

in clinically important bleeding (TIMI major or minor or BARC 3-5) were not statistically significant (**Table 3**). The 30-day relative rates of BARC 2-5 bleeding were similar with TRA versus TFA in patients undergoing LM PCI with bivalirudin (1.7% versus 6.2%, respectively, HR [95% CI]=0.27 [0.04, 2.04]) and with heparin only (3.7% versus 5.5%, respectively, HR [95% CI]=0.67 [0.29, 1.57]) ($p_{\text{interaction}}=0.42$). Procedural vascular complications occurred in 2 (0.8%) TRA and 16 (2.3%) TFA patients ($p=0.13$).

At three years, the primary composite outcome of death, stroke, or MI had occurred in 15.7% and 14.8% of patients in the TRA and TFA groups, respectively ($p=0.72$) (**Table 3, Figure 1**). There were no significant differences between the groups in any of the

components of the primary endpoint, ischaemia-driven revascularisation, or stent thrombosis (**Table 3, Figure 1**). Any bleeding at three years by both the TIMI and BARC scales was marginally less with TRA compared to TFA, although the differences in major bleeding did not reach statistical significance (**Table 3, Figure 1**). After multivariable adjustment, no significant differences were observed between TRA versus TFA for the primary endpoint or any of the major ischaemic or bleeding outcome measures (**Table 4**).

Discussion

The major findings from the present analysis examining outcomes of PCI for unprotected LM disease according to different routes

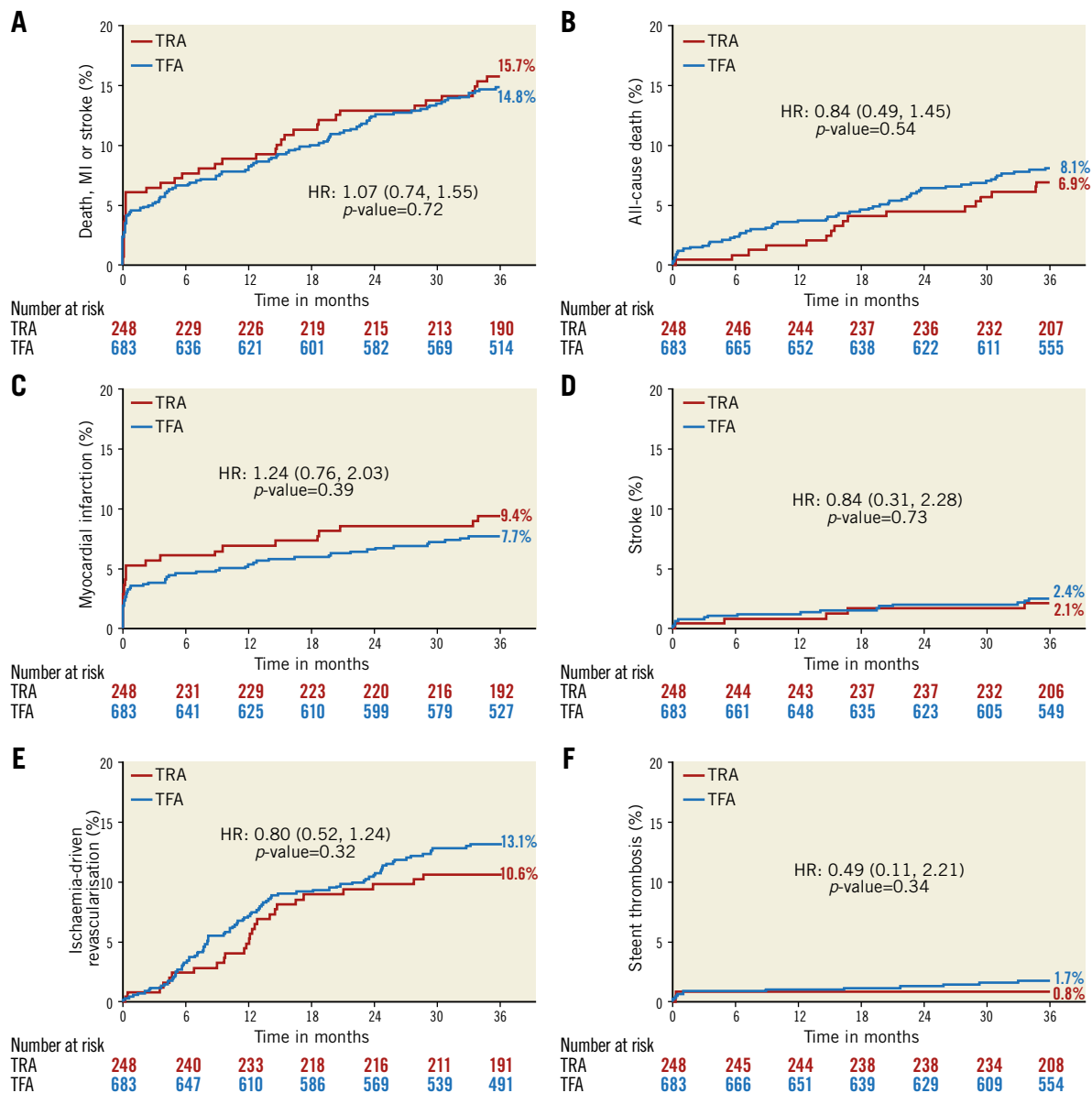


Figure 1. Kaplan-Meier time-to-first-event rates according to transradial or transfemoral access. A) Primary endpoint (death, myocardial infarction or stroke). B) All-cause death. C) Myocardial infarction. D) Stroke. E) Ischaemia-driven revascularisation. F) Definite or probable stent thrombosis.

Table 3. Thirty-day and three-year clinical outcomes.

	30-day event rates			3-year event rates		
	Radial access (n=248)	Femoral access (n=683)	p-value	Radial access (n=248)	Femoral access (n=683)	p-value
Primary endpoint (death, MI, or stroke)	6.0% (15)	4.5% (31)	0.35	15.7% (39)	14.8% (100)	0.72
Death	0.4% (1)	1.2% (8)	0.29	6.9% (17)	8.1% (54)	0.54
Myocardial infarction	5.2% (13)	3.5% (24)	0.24	9.4% (23)	7.7% (51)	0.39
Stroke	0.4% (1)	0.7% (5)	0.58	2.1% (5)	2.4% (16)	0.73
Revascularisation (all)	0.8% (2)	0.7% (5)	0.91	11.1% (27)	13.3% (87)	0.38
Ischaemia-driven	0.8% (2)	0.6% (4)	0.71	10.6% (26)	13.1% (86)	0.32
Non-ischaemia-driven	0.0% (0)	0.1% (1)	0.55	0.4% (1)	1.2% (8)	0.28
Stent thrombosis (definite or probable)	0.8% (2)	0.6% (4)	0.71	0.8% (2)	1.7% (11)	0.34
Definite	0.4% (1)	0.3% (2)	0.80	0.4% (1)	0.9% (6)	0.44
Probable	0.4% (1)	0.3% (2)	0.80	0.4% (1)	0.8% (5)	0.57
Bleeding	TIMI major, minor, or minimal	4.8% (12)	0.05	8.6% (21)	13.2% (89)	0.051
	TIMI major or minor	2.4% (6)	0.30	4.1% (10)	5.8% (39)	0.30
	BARC 1-5 (any bleeding)	4.4% (11)	0.07	7.3% (18)	13.0% (87)	0.02
	BARC 2-5	3.2% (8)	0.13	5.3% (13)	10.3% (69)	0.02
	BARC 3-5 (major bleeding)	0.8% (2)	0.07	1.6% (4)	4.3% (29)	0.053

Rates are Kaplan-Meier estimates, % (n events). BARC: Bleeding Academic Research Consortium; TIMI: Thrombolysis In Myocardial Infarction

of vascular access from the contemporary EXCEL trial are that: (i) TRA was used in approximately one quarter of patients, with considerable regional variation and differences in baseline characteristics compared to TFA, and (ii) after multivariable adjustment to account for these differences, there were no significant differences in the three-year risk of ischaemic events or major bleeding in patients undergoing PCI with TRA versus TFA. The present study thus supports the safety and efficacy of TRA for LM PCI.

While the utilisation of TRA has been increasing¹⁵, its overall use remains relatively low, particularly in the USA and especially in complex procedures, consistent with our finding that TRA was used in only 26.6% of LM PCI procedures performed in the trial between 2010 and 2014, including only 7.4% of patients enrolled from US sites. Patients for whom TRA was chosen also tended to

be lower risk than those in whom TFA was used, being younger, more likely having stable angina and preserved renal function, and having treatment of fewer lesions and vessels. Contrary to previous reports¹⁶, total procedure time was not greater with TRA, and in fact compared with TFA was shorter in the USA (but not elsewhere), perhaps reflecting differences in case complexity. Similarly, radiation exposure did not differ significantly between groups, a finding that is also contrary to earlier reports¹⁶. These discrepancies between the present and earlier studies may reflect increasing operator experience and greater proficiency with TRA over time, or they may be unique to LM PCI. Finally, the amount of contrast administered was lower with TRA than TFA, even after multivariable adjustment for patient and lesion complexity, which might be related to the fact that the guiding catheter used in TRA was smaller than in TFA. This finding further supports the feasibility of TRA in LM PCI and is consistent with previous reports of reduced acute kidney injury with TRA compared to TFA¹⁷. The fact that three-year clinical outcomes did not differ significantly between patients treated with TRA versus TFA implies that TRA utilisation did not impair the quality of the revascularisation or the long-term prognosis.

In most prior studies bleeding complications after PCI have been more frequent with TFA than TRA¹⁶, and have been associated with increased morbidity and mortality¹⁸⁻²⁰. Although bleeding was numerically less frequent after TRA in EXCEL, after multivariable adjustment, there was no significant difference in major bleeding between TRA and TFA (TIMI major or minor, or BARC types 3-5). Similarly, while there were fewer vascular complications with TRA compared to TFA, the difference did not reach statistical significance. The lack of significance may be

Table 4. Three-year clinical outcomes, propensity-adjusted models.

Outcome measure	Radial versus femoral	
	Hazard ratio (95% CI)	p-value
Primary endpoint (death, MI, or stroke)	1.16 (0.74, 1.79)	0.52
Death	1.10 (0.76, 1.59)	0.61
Myocardial infarction	1.32 (0.72, 2.42)	0.36
Stroke	0.58 (0.16, 2.10)	0.41
Ischaemia-driven revascularisation	1.18 (0.71, 1.94)	0.52
Bleeding, TIMI major or minor	0.70 (0.32, 1.50)	0.36
Bleeding, BARC 3-5	0.47 (0.14, 1.65)	0.24

BARC: Bleeding Academic Research Consortium; CI: confidence interval; TIMI: Thrombolysis In Myocardial Infarction

attributed to insufficient statistical power due to low event rates. Alternatively, the greater use of bivalirudin with TFA compared to TRA may have mitigated the bleeding advantage of TRA²¹⁻²³. The absence of a substantial difference in major bleeding complications between TRA and TFA may also underlie the similar mortality rates observed in the two groups in the present study, in contrast to reduced rates of bleeding and mortality with TRA in some prior trials in patients with acute coronary syndromes²⁴. Regardless of the mechanisms, LM PCI with TRA and TFA was found to result in comparable three-year rates of event-free survival in the EXCEL trial, supporting the feasibility, safety and efficacy of LM PCI with either vascular access route in patients with low and intermediate SYNTAX scores. An appropriately powered dedicated randomised trial would be required to determine whether there are modest differences favouring either TRA or TFA for this high-risk patient cohort.

Limitations

The choice of vascular access was not randomised and was left to the operator's best judgement. The present *post hoc* analysis should thus be considered hypothesis-generating. The EXCEL trial was not powered to examine differences in clinical outcomes according to the access site (TRA versus TFA). TFA patients were older and higher risk (greater proportions of chronic kidney disease and acute coronary syndromes, and more often requiring prophylactic haemodynamic support), and had more complex coronary anatomy and disease (greater number of vessels and lesions treated, and more frequent planned two-stent LM strategy). Although these variables were included in our multivariable models, we cannot rule out the presence of unmeasured confounders. Further studies are required to examine outcomes in subgroups of patients with LM disease, such as those with and without distal bifurcation involvement or heavy calcification. We also did not collect detailed data on operator volume or expertise with TRA versus TFA, and further studies are required to determine whether these factors have a major impact on the outcomes of LM PCI.

Conclusions

In conclusion, in patients undergoing LM PCI in the contemporary EXCEL trial, the choice of TRA versus TFA varied considerably across regions, and TRA was only used in approximately one quarter of cases. Nonetheless, TRA was safe and efficacious compared with TFA and may be considered appropriate for LM PCI when performed by suitably experienced operators.

Impact on daily practice

In the EXCEL trial, transradial access (TRA) and transfemoral access (TFA) for percutaneous coronary intervention of left main coronary artery disease (LMCAD) were associated with comparable early and late clinical outcomes. Both TRA and TFA appear to be safe and effective for the treatment of LMCAD.

Guest Editor

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Supplementary data

Supplementary Figure 1. Relative use of the transradial versus the transfemoral arterial access according to country/region.

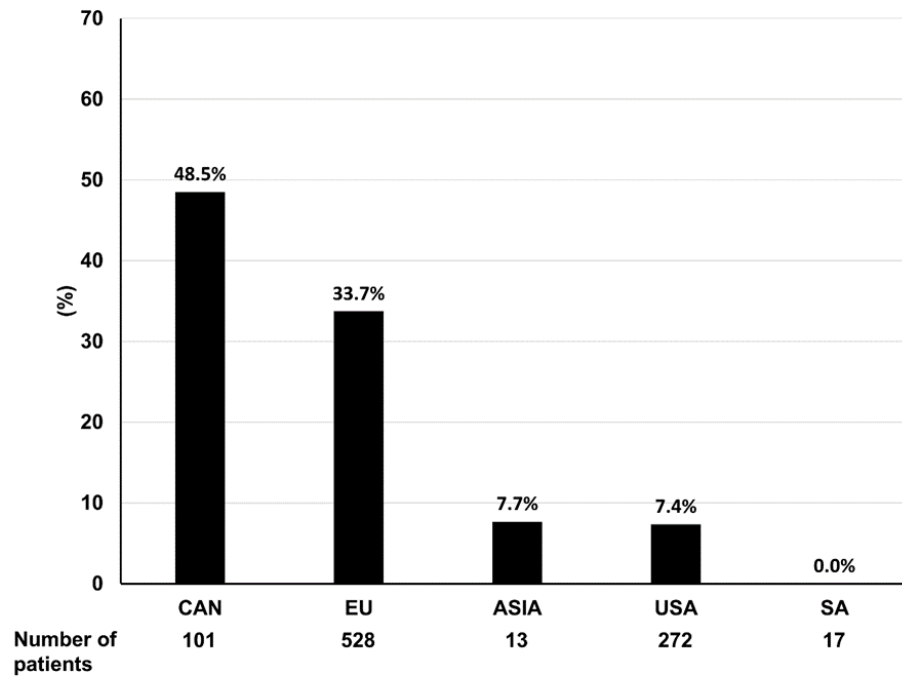
Supplementary Table 1. Angiographic and procedural characteristics.

The supplementary data are published online at:
http://www.pronline.com/eurointervention/143rd_issue/199



Supplementary data

Supplementary Figure 1. Relative use of transradial versus transfemoral arterial access according to country/region.



CAN: Canada; EU: Europe; SA: South America; USA: United States of America

Supplementary Table 1. Angiographic and procedural characteristics.

	Radial access (n=248)	Femoral access (n=683)	p-value
Number of non-LM diseased vessels			
1	37.6 (92/245)	31.9 (215/675)	0.11
2	34.3 (84/245)	37.0 (250/675)	0.44
3	10.2 (25/245)	14.7 (99/675)	0.08
SYNTAX score	26.0±6.2	27.0±6.2	0.31
SYNTAX score tertiles			
Low (0-22)	32.9 (78/237)	31.8 (211/664)	0.75
Intermediate (23-32)	44.7 (106/237)	42.2 (280/664)	0.49
High (≥33)	22.4 (53/237)	26.1 (173/664)	0.26
Left main disease			
LM diameter stenosis, %	67.1±10.7	66.9±11.8	0.80
Ostial lesion	35.3 (85/241)	34.1 (227/665)	0.75
Mid shaft lesion	43.2 (104/241)	43.5 (289/665)	0.93
Distal lesion (bifurcation or trifurcation)	81.7 (197/241)	79.4 (528/665)	0.44
Guide catheter size			
6 Fr	76.4 (188/246)	35.9 (244/680)	<0.0001
7 Fr	23.2 (57/246)	43.8 (298/680)	<0.0001
8 Fr	0.4 (1/246)	20.3 (138/680)	<0.0001
Bivalirudin anticoagulation	22.7 (60/264)	37.1 (275/742)	<0.0001
Glycoprotein IIb/IIIa inhibitor	7.2 (19/265)	6.8 (51/751)	0.83
Haemodynamic support used	1.9 (5/264)	6.4 (48/752)	0.005
Staged procedure(s) planned	6.8 (18/265)	9.6 (72/752)	0.17
LM stent delivery success, per stent	99.7 (335/336)	99.6 (1,051/1,055)	0.83
PCI of distal left main bifurcation	62.2 (153/246)	55.3 (374/676)	0.06
Provisional 1-stent strategy	79.1 (121/153)	59.1 (221/374)	<0.0001
Planned 2-stent strategy	20.9 (32/153)	40.9 (153/374)	<0.0001
Number of LM stents	1.4±0.7	1.5±0.8	0.0002
Total LM stent length, mm	26.8±16.8	28.9±17.0	0.050
Number of non-LM vessels treated	0.6±0.7	0.8±0.8	0.04
Number of non-LM lesions treated	0.8±1.0	1.0±1.1	0.02
Number of non-LM stents implanted	0.9±1.4	1.0±1.3	0.06
Procedural complications*	10.6 (28/265)	10.1 (76/752)	0.83
Hospitalisation duration, days	5.1±3.9	5.6±5.6	0.46

*Defined as occurrence of one of the following: chest pain lasting >10 minutes, ECG changes lasting >10 minutes, slow coronary flow, no reflow, distal embolisation, side branch closure (>2 mm side branch), acute vessel closure, perforation, stent thrombosis, cardiac tamponade requiring pericardial synthesis, cardiac arrest requiring CPR or defibrillation/cardioversion, ventricular arrhythmias requiring defibrillation or cardioversion, bradyarrhythmias or heart block requiring temporary pacemaker, intubation, hypotension requiring pressors or intra-aortic balloon pump (IABP), stroke, coronary dissection, aortic dissection or bleeding. Angiographic data are core laboratory derived.

All data are per patient unless otherwise noted.

LM: left main coronary artery; MI: myocardial infarction; PCI: percutaneous coronary intervention