# Special feature: Left Main Interventions

# Comparative effectiveness analysis of percutaneous coronary intervention versus coronary artery bypass grafting in patients with chronic kidney disease and unprotected left main coronary artery disease



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## **KEYWORDS**

# • death

- left main
- renal insufficiency

## Abstract

**Aims:** Outcomes according to the status of renal insufficiency have not been fully evaluated in left main coronary artery disease (LMCAD). In the present study therefore, we sought to evaluate clinical outcomes in patients with significant LMCAD stratified by the degree of renal insufficiency and the relative clinical outcomes after PCI and CABG stratified by the differential levels of renal function using data from the large multinational "all-comers" Interventional Research Incorporation Society-Left MAIN Revascularization (IRIS-MAIN) registry.

**Methods and results:** Among 4,894 patients with LMCAD, renal insufficiency was graded according to the estimated glomerular filtration rate (eGFR). The primary outcome was major adverse cardiac and cerebrovascular events (MACCE), defined as death, myocardial infarction, stroke, or any revascularisation. The patients were stratified into three groups according to eGFR: 3,824 (78%) in group 1 (eGFR  $\geq$ 60 ml·min<sup>-1</sup>·1.73 m<sup>2</sup>), 838 (17%) in group 2 (eGFR  $\geq$ 30 and <60), and 232 (5%) in group 3 (eGFR <30). At two years, after adjustment, compared with group 1, the risk of MACCE was significantly higher in group 2 (hazard ratio [HR] 1.46, 95% confidence interval [CI]: 1.18-1.79) and in group 3 (HR 3.39, 95% CI: 2.61-4.40). The p interaction for MACCE across groups was 0.20. The adjusted risk of MACCE was similar between percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) in groups 1 and 2. However, PCI was associated with a significantly higher risk of MACCE compared to CABG (HR 1.88, 95% CI: 1.08-3.25) in group 3.

**Conclusions:** The degree of renal insufficiency was proportionately associated with unfavourable outcomes in patients with LMCAD. In group 3, PCI was associated with a higher risk of MACCE compared with CABG. Also, the effect of PCI versus CABG on MACCE was consistent, with PCI being associated with less bleeding and CABG being associated with less repeat revascularisation.

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# **Abbreviations**

CABG	coronary artery bypass graft
CKD	chronic kidney disease
IRIS-MAIN	Interventional Research Incorporation Society-Left
	MAIN Revascularization
LMCAD	left main coronary artery disease
MACCE	major adverse cardiac and cerebrovascular events
PCI	percutaneous coronary intervention

## Introduction

Among several anatomical types of obstructive coronary artery disease (CAD), left main coronary artery disease (LMCAD) is associated with the worst clinical outcomes<sup>1</sup>. Coronary artery bypass graft (CABG) surgery has traditionally been the standard of care for revascularisation treatment of unprotected LMCAD. However, over the last two decades, percutaneous coronary intervention (PCI) has become an alternative strategy for selected patients with LMCAD<sup>2,3</sup>. Owing to a higher rate of major cardiovascular events and mortality in patients with significant LMCAD, identification of clinical factors associated with worse clinical outcomes and risk stratification is clinically important in the real world.

The relationship between chronic kidney disease (CKD) and an increased risk of cardiovascular events has been shown by many epidemiologic studies<sup>4,5</sup>. Furthermore, several studies have suggested that patients with CKD have poor outcomes after coronary revascularisation<sup>6,7</sup>. Previous studies have identified clinical risk factors associated with poorer outcomes in patients with LMCAD<sup>8-10</sup>. However, little is known about the effect of renal insufficiency on clinical outcomes in patients with LMCAD. In the present study therefore, we evaluated clinical outcomes in patients with significant LMCAD stratified by the degree of renal insufficiency and the relative clinical outcomes after PCI and CABG stratified by the differential levels of renal function using data from the large multinational "all-comers" Interventional Research Incorporation Society-Left MAIN Revascularization (IRIS-MAIN) registry.

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## Methods STUDY POPULATION

The study population was part of the IRIS-MAIN registry (ClinicalTrials.gov Identifier: NCT01341327). The IRIS-MAIN registry is a non-randomised, multinational, observational registry which consists of a cohort of consecutive patients with significant unprotected LMCAD who were treated with PCI, CABG, or medication alone. Data were collected on patients who were diagnosed as having significant LMCAD (>50% by visual estimation) at approximately 65 centres in the Asia-Pacific region. From the registry, 5,566 consecutive patients from January 2003 to September 2017 were evaluated. Among them, 118 patients who had incomplete data, 145 patients who did not have the creatinine level, and 164 patients who did not have angiographic data were excluded. After further excluding patients who had cardiogenic shock, prior CABG, or valvular heart disease, 4,894 patients were included in

the current analysis (**Figure 1**). The institutional review board at each hospital approved the use of clinical information in those patients for this study.

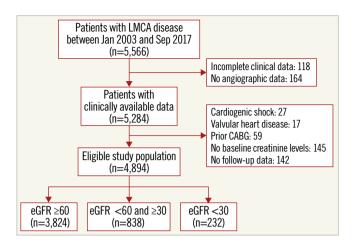


Figure 1. Study population.

Variables and outcome data were collected by specialised personnel using an electronic case report form at each centre. Monitoring and verification of registry data were periodically performed in participating hospitals by the staff of the coordinating centre (Clinical Research Center, Asan Medical Center, Seoul, South Korea). Follow-up was conducted during hospitalisation and at 1, 6, and 12 months after the index treatment and annually thereafter via an office visit or telephone contact.

#### OUTCOMES AND DEFINITIONS

The primary outcome was a major adverse cardiac and cerebrovascular event (MACCE), which was defined as a composite of death from any cause, myocardial infarction (MI), stroke, or any revascularisation. Death was considered as cardiac unless an unequivocal non-cardiac cause could be established. MI was defined as follows: if occurring within 48 hours following the index treatment, a combination of at least a fivefold increase in the CK-MB with either new pathological Q-waves or new bundle branch block, with either new graft or native coronary occlusion documented on angiography, new regional wall motion abnormality or loss of viable myocardium on imaging studies<sup>11,12</sup>. Stroke was defined as a loss of neurological function caused by an ischaemic or haemorrhagic event with residual symptoms at least 24 hours after the onset or leading to death and was confirmed by a neurologist on the basis of imaging modalities. Any revascularisation included any type of percutaneous or surgical revascularisation procedure, regardless of whether the procedure was performed on a target or non-target lesion. Thrombolysis In Myocardial Infarction (TIMI) major bleeding was defined as overt clinical bleeding associated with a drop in haemoglobin of greater than 5 g/dL or in haematocrit of greater than 15% (absolute). All events were based on the clinical diagnoses assigned by the patient's physician and were centrally adjudicated by an independent group of clinicians.

#### STATISTICAL ANALYSIS

Continuous variables were expressed as median (interquartile range), and categorical variables were presented as numbers and percentages. Differences between the groups, categorised according to the estimated glomerular filtration rate (eGFR), were compared using analysis of variance (ANOVA) or the Kruskal-Wallis test for continuous variables, and the chi-square test or Fisher's exact test for categorical variables as appropriate. *Post hoc* tests were performed using ANOVA with the Tukey method or the Kruskal-Wallis test with Bonferroni correction. Cumulative rates of clinical events were calculated using Kaplan-Meier survival analysis, and the log-rank test was used for comparisons across the groups.

A univariate Cox proportional hazards regression model was used to evaluate potential predictors of clinical outcomes. The proportional hazards assumption was checked for all screened covariates; no relevant violations were found. To assess the independent association of eGFR category to clinical outcome, multivariate Cox proportional hazards regression was performed using variables with a p-value of <0.10 in univariate analysis. Using the group of eGFR  $\geq 60$  ml/min/1.73 m<sup>2</sup> as the reference category, we estimated the hazard ratios and 95% confidence intervals for the groups of eGFR <60 and  $\geq$ 30 and eGFR <30 ml/min/1.73 m<sup>2</sup>. Finally, we compared the rates of primary outcome after PCI and CABG according to the eGFR at baseline. To adjust for the differences in baseline characteristics, multivariate Cox proportional hazards regression was performed using clinically relevant variables and statistically significant variables with a p-value <0.10 by univariate analysis. All reported p-values were two-sided and were not adjusted for multiple testing. All statistical analyses were performed using SPSS Statistics, Version 22.0 (IBM Corp., Armonk, NY, USA).

### Results

#### **BASELINE CHARACTERISTICS**

Patients were divided into three groups according to the eGFR at baseline: group 1 including patients with an eGFR ≥60 ml·min<sup>-1</sup>·1.73 m<sup>2</sup> (n=3,824, 78.1%), group 2 with an eGFR <60 and  $\geq$ 30 (n=838, 17.1%), and group 3 with an eGFR <30 (n=232, 4.7%). One hundred and twenty-one (121) patients (52%) in group 3 were on dialysis. Baseline clinical characteristics were substantially different across the three groups (Table 1). Group 3 had higher risk factor profiles. With regard to treatment strategy, PCI was most frequently used in the three groups, whereas medical therapy alone was most frequently selected in group 3. Regarding the information related to PCI, group 3 tended to have a higher proportion of second-generation drug-eluting stents (DES). The use of intravascular ultrasound (IVUS) during PCI was less frequent in group 3. There was no significant difference in the stent technique at the left main lesion among the three groups on the whole, while bifurcation stenting was more prevalent in groups 1 and 2 compared to group 3. In terms of drug therapy, antiplatelet agents and statins were less frequently used in group 3 at baseline as well as during follow-up (Supplementary Table 1).

#### **CLINICAL OUTCOMES**

During the median follow-up duration of 1,289 (interquartile range, 729-1,913) days, there were 314 deaths, 39 MIs, 70 cerebrovascular events, and 205 any revascularisation. Overall, the cumulative incidence of MACCE at two years was lowest in group 1 (9.1%) and highest in group 3 (36.2%). This trend was consistent regardless of whether the patient received CABG, PCI or medical therapy (**Figure 2**). The incidences of the individual outcome of death, MI, or stroke were significantly higher in patients with a higher degree of renal insufficiency, whereas the rate of any revascularisation was comparable among the three groups (4.2% in group 1 vs 3.8% in group 2 vs 4.7% in group 3, p=0.79). The incidence of major bleeding events (8.5% in group 1 vs 10.3% in group 2 vs 12.5% in group 3, p=0.043) was also associated in proportion to the severity of renal insufficiency (**Supplementary Table 2**).

The landmark analysis revealed that the difference of MACCE according to the eGFR occurred mostly within one year. According to the 30-day landmark analysis, there was no significant difference in the rate of MACCE between groups 2 and 3. However, after one year, patients in group 3 consistently had the highest risk of MACCE, whereas there was no significant difference between groups 1 and 2 (**Figure 3**). After multivariate adjustment for the baseline differences among the three groups, the adjusted risk of MACCE was significantly higher in group 3 compared with group 1 or group 2 and was driven mainly by the higher risks of death and MI (**Table 2**).

# PCI VERSUS CABG ACCORDING TO THE STATUS OF RENAL FUNCTION

The Kaplan-Meier two-year survival estimates for MACCE after PCI and CABG stratified by the status of baseline renal function are shown in Figure 4. The cumulative rates of MACCE did not differ between PCI and CABG among patients in group 1 or group 2. In contrast, there was a significantly higher rate of MACCE with PCI than with CABG in group 3 (38.5% vs 24.7% at two years, p=0.01, p for interaction=0.08). Clinical outcomes after adjusting for possible confounders using the Cox regression model are summarised in Table 3. The risk of MACCE was significantly higher with PCI than with CABG in group 3 (adjusted hazard ratio 1.88, 95% confidence interval [CI]: 1.08-3.25, p=0.02), whereas it was similar between PCI and CABG in patients in group 1 or group 2. Statistical interaction was not found between the status of renal function and revascularisation modality with regard to MACCE (p for interaction=0.20). The risk of any revascularisation tended to be higher with PCI, whereas the risk of TIMI major bleeding was higher with CABG regardless of eGFR level. The results of the sensitivity analysis excluding patients who received first-generation DES were largely consistent (Supplementary Table 3).

## Table 1. Baseline characteristics.

	Variable	eGFR ≥60 (N=3,824)	eGFR <60 and ≥30 (N=838)	eGFR <30 (N=232)	<i>p</i> -value
Demographics and	Age, years	64 (56, 70)	71 (64, 76)	69 (62, 74)	<0.001
laboratory findings	Male sex	2,969 (77.6)	622 (74.2)	163 (70.3)	0.01
	BMI, kg/m <sup>2</sup>	24.5 (22.7, 26.2)	24.6 (22.7, 26.4)	23.4 (21.4, 25.7)	<0.001
	Diabetes	1,244 (32.5)	388 (46.3)	180 (77.6)	< 0.001
	Hypertension	2,264 (59.2)	636 (75.9)	215 (92.7)	<0.001
	Dyslipidaemia	2,376 (62.1)	487 (58.1)	125 (53.9)	0.01
	Current/recent smoker	1,008 (26.4)	177 (21.1)	36 (15.5)	<0.001
	Prior myocardial infarction	324 (8.5)	104 (12.4)	27 (11.6)	<0.001
	Prior CHF	65 (1.7)	45 (5.4)	27 (11.6)	<0.001
	Prior PCI	583 (15.3)	158 (18.9)	47 (20.3)	0.01
	Atrial fibrillation/flutter	63 (1.7)	42 (5.0)	12 (5.2)	<0.001
	Cerebrovascular disease	271 (7.1)	100 (11.9)	36 (15.5)	<0.001
	PAD	163 (4.3)	83 (9.9)	25 (10.8)	<0.001
	Chronic lung disease	106 (2.8)	24 (2.9)	13 (5.6)	0.05
	Dialysis	0	0	121 (52)	<0.001
	HDL-C, mg/dL	41 (35, 48)	39 (32, 47)	35 (28, 43)	<0.001
	LDL-C, mg/dL	97 (73, 123)	90.35 (69, 117)	84 (63, 106)	<0.001
	CRP, mg/dL	0.14 (0.06, 0.44)	0.22 (0.08, 0.65)	0.62 (0.21, 2.00)	<0.001
Clinical diagnosis	Stable angina	1,607 (42.0)	316 (37.7)	77 (33.2)	0.00
	Acute coronary syndrome	2,217 (58.0)	522 (62.3)	155 (66.8)	0.004
Angiographic finding	LAD	1,770 (46.3)	334 (39.9)	92 (39.7)	<0.001
(%)	LCX	866 (22.7)	188 (22.4)	51 (22.0)	0.97
	RCA	481 (12.6)	104 (12.4)	22 (9.5)	0.38
Medications (%)	Aspirin	3,706 (97.2)	785 (94.1)	204 (88.3)	<0.001
	Clopidogrel	3,322 (87.2)	690 (82.9)	178 (77.4)	< 0.001
	Ticagrelor	102 (2.7)	20 (2.4)	4 (1.7)	0.63
	Prasugrel	45 (1.2)	7 (0.8)	3 (1.3)	0.66
	Beta-blocker	2,363 (63.1)	485 (59.2)	138 (59.7)	0.08
	Calcium channel blocker	2,173 (58.2)	465 (56.8)	111 (48.5)	0.02
	ACEi/ARB	1,234 (33.2)	333 (41.1)	117 (51.1)	< 0.001
	Statin	3,612 (95.3)	757 (91.3)	174 (75.0)	<0.001
Initial treatment (%)	Medical therapy	437 (11.4)	137 (16.4)	42 (18.1)	
	PCI	2,289 (59.9)	419 (50.0)	117 (50.4)	<0.001
	CABG	1,098 (28.7)	282 (33.6)	73 (31.5)	
Stent generation	First-generation DES	540 (23.7)	95 (22.9)	15 (12.8)	
Ū.	Second-generation DES	1,736 (76.3)	320 (77.1)	102 (87.2)	0.02
IVUS use during PCI (	-	1,850 (80.7)	306 (72.9)	85 (71.4)	< 0.001
GP IIb/IIIa inhibitor d		199 (8.7)	33 (7.9)	5 (4.2)	0.22
Stent technique at LM		440 (19.3)	76 (18.2)	23 (19.5)	
%)	LM to LAD crossover	1,219 (53.5)	218 (52.3)	68 (57.6)	0.81
	LM to LCX crossover	93 (4.1)	22 (5.3)	4 (3.4)	
	Two-stent technique	525 (23.1)	101 (24.2)	23 (19.5)	0.04
	Crush	336 (64.5)	63 (62.4)	12 (52.2)	
	Culotte	12 (2.3)	0	3 (13.0)	
	Other techniques	64 (33.2)	13 (37.6)	5 (34.8)	
	erquartile range) or n (%) ACEi: angi				

Values are median (interquartile range) or n (%). ACEi: angiotensin-converting enzyme inhibitor; ARB: angiotensin II receptor blocker; BMI: body mass index; CABG: coronary artery bypass grafting; CHF: congestive heart failure; CRP: C-reactive protein; DES: drug-eluting stent; eGFR: estimated glomerular filtration rate; HDL-C: high-density lipoprotein cholesterol; IVUS: intravascular ultrasound; LAD: left anterior descending artery; LCX: left circumflex artery; LDL-C: low-density lipoprotein cholesterol; LM: left main; PAD: peripheral artery disease; PCI: percutaneous coronary intervention

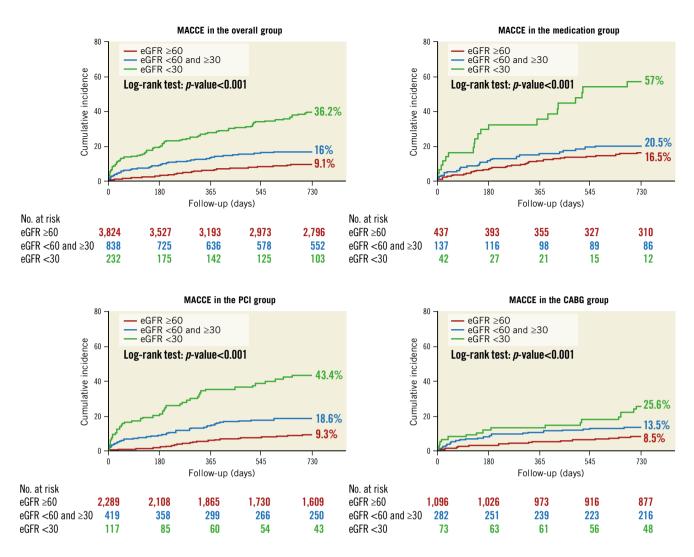
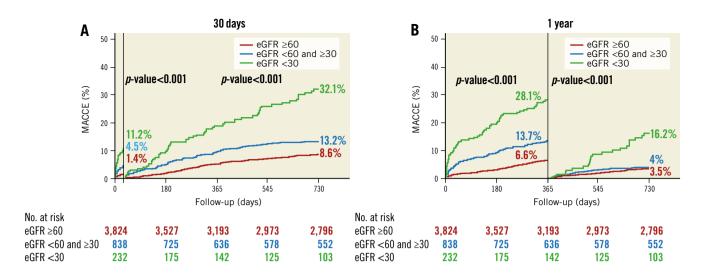


Figure 2. Kaplan-Meier curves of the primary composite outcome according to the levels of baseline renal function.

# Discussion

From this large, all-comers registry involving patients with LMCAD, we found that the severity of renal insufficiency was proportionately associated with an increased risk of serious adverse events, regardless of the initial treatment strategy. Among patients with preserved or moderate renal dysfunction, the risk of MACCE after PCI and CABG was comparable, whereas the MACCE risk was significantly higher with PCI than with CABG in patients with severe renal dysfunction. Although a statistically significant interaction was not observed, further studies are required to confirm this observation and to help guide decision making between CABG and PCI in LMCAD patients with CKD.

Although some studies have suggested a lesser association between renal function and clinical outcomes after PCI in patients with obstructive CAD<sup>13,14</sup>, the majority of studies have shown that patients with renal insufficiency were significantly associated with unfavourable outcomes<sup>7,15,16</sup>. However, patients with LMCAD were mostly excluded in prior studies, thus data on the clinical relevance of renal impairment in patients with such complex lesions were still lacking. In our study involving this high-risk group of patients, we found that renal insufficiency had a detrimental effect on outcomes including death and MACCE which was proportional to the levels of eGFR. Of note, patients with severe renal insufficiency showed higher cumulative event rates sustained beyond one year in the landmark analysis. The association between the severity of renal dysfunction and ischaemic cardiovascular events shown in our study is not surprising given the well-known biopathological features of renal dysfunction such as negative plaque characteristics, heightened states of arterial inflammation, or sympathetic nervous system activation<sup>17-20</sup>. However, our study adds more of a real-world explanation of this observation. Patients with a lower eGFR received suboptimal medical therapies of antiplatelet agents and statins, possibly because of concerns about pharmacokinetic issues of the drugs related to renal excretion and increased bleeding tendency. This treatment pattern seems to be in line with the preferential selection of medical therapy alone rather than PCI or CABG in LMCAD patients with severe renal insufficiency. Furthermore, less frequent use of IVUS-supported PCI



**Figure 3.** *Kaplan-Meier curves with landmark analyses of the primary composite outcome according to the levels of baseline renal function. A) At 30 days. B) At 1 year.* 

in patients with a lower eGFR may imply a more complicated or suboptimal procedure which may be related to a worse prognosis.

A comparison between PCI and CABG in patients with LMCAD and CKD has recently been reported in the subgroup analysis of the randomised EXCEL trial<sup>21</sup>. There were no significant differences between PCI and CABG in terms of death, stroke, or MI at three years after the procedures in patients with and without CKD. However, the results should be interpreted with caution as the number of CKD patients was relatively small (n=361) and the majority of the CKD patients had a moderate degree of renal impairment. Additional in our study was the inclusion of a larger number of real-world patients and the demonstration

Table 2. A	djusted ha	zard ratios	of clinical	outcomes.
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		2-	/ear		Multivaria	e analysis	;1		Multivaria	te analysis	s <sup>2</sup>
		Event	Rate, %	HR	959	% CI	<i>p</i> -value	HR	959	% CI	<i>p</i> -value
MACCE	≥60*	347	9.1	1.00			< 0.001	1.00	ĺ		< 0.001
	<60, ≥30	134	16.0	1.46	1.18	1.79	0.0004	1.43	1.16	1.77	0.0008
	<30	84	36.2	3.39	2.61	4.40	< 0.001	2.73	1.91	3.92	< 0.001
Death	≥60	154	4.0	1.00			< 0.001	1.00			
	<60, ≥30	89	10.6	1.78	1.36	2.34	< 0.001	1.83	1.39	2.40	< 0.001
	<30	71	30.6	4.23	2.78	6.41	< 0.001	4.36	2.85	6.67	< 0.001
Myocardial	≥60	25	0.7	1.00			< 0.001	1.00			
infarction	<60, ≥30	5	0.6	0.87	0.33	2.28	0.78	0.69	0.26	1.87	0.47
	<30	9	3.9	5.98	2.73	13.05	< 0.001	3.97	1.28	12.33	0.017
Any	≥60	162	4.2	1.00			0.74	1.00			
revascularisation	<60, ≥30	32	3.8	0.87	0.59	1.27	0.47	0.91	0.62	1.36	0.66
	<30	11	4.7	1.06	0.57	1.98	0.86	0.84	0.32	2.15	0.71
Stroke	≥60	44	1.2	1.00			0.15	1.00			
	<60, ≥30	20	2.4	1.64	0.94	2.85	0.08	1.58	0.90	2.77	0.11
	<30	6	2.6	1.79	0.74	4.31	0.20	2.30	0.86	6.19	0.10
TIMI major	≥60	325	8.5	1.00			0.03	1.00			0.18
bleeding	<60, ≥30	86	10.3	1.23	0.97	1.56	0.09	1.23	0.95	1.58	0.11
	<30	29	12.5	1.58	1.08	2.32	0.02	1.41	0.80	2.49	0.23

\*Values of estimated glomerular filtration rate. <sup>1</sup> Cox proportional hazards model with backward elimination method. <sup>2</sup> All baseline covariates were adjusted. CI: confidence interval; HR: hazard ratio; MACCE: major adverse cardiac and cerebrovascular events; TIMI: Thrombolysis In Myocardial Infarction

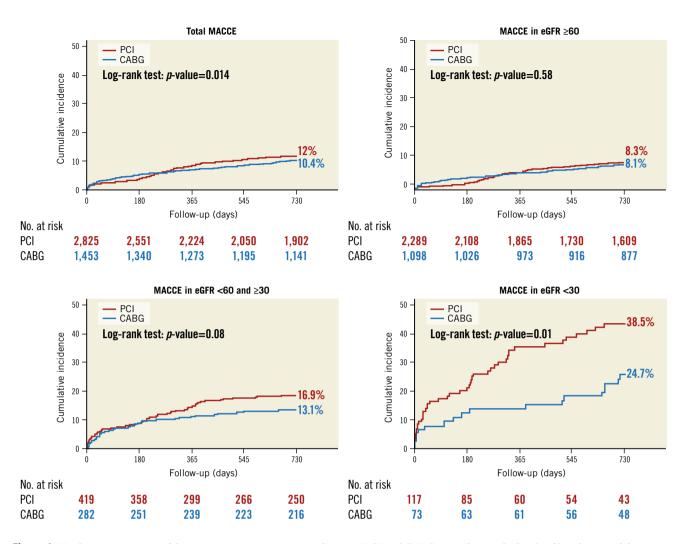


Figure 4. Kaplan-Meier curves of the primary composite outcome between PCI and CABG according to the levels of baseline renal function.

of the comparative effectiveness between PCI and CABG in LMCAD patients with severe renal dysfunction, who have usually been excluded from randomised trials. This higher-risk subgroup seemed to benefit more after CABG than after PCI in terms of serious ischaemic adverse events. A plausible explanation would be that patients with advanced renal impairment may have severe coronary artery characteristics including a higher degree of calcification and atherosclerotic plaque burden, and consequently may distinctly benefit from bypass grafts which provide a more durable and protective role against future ischaemic events. Because the presence of poor renal function is frequently encountered in daily clinical practice during Heart Team discussions concerning whether to opt for PCI or CABG, subsequent studies will be critical for the development of optimal treatment strategies according to the degree of CKD for high-risk patients with LMCAD.

## Limitations

This study has several limitations. First, there were different risk profiles, comorbidities, and anatomical disease extent or complexity in each CKD group as well as the PCI versus CABG groups (Supplementary Table 4-Supplementary Table 7). Although confounding covariates were adjusted in the multivariable models, the results are vulnerable to unmeasured confounders. Second, variables that are known in clinical practice to have a profound influence on the choice of revascularisation (e.g., SYNTAX score or patient frailty) were not available for this analysis. A lack of such information could have penalised the CABG group relative to the PCI group. Third, the number of patients included in group 3 was relatively small. Although the different outcome after PCI and CABG in these patients was one major finding of our study, interpretation of the results should be cautious, and the findings should be considered hypothesisgenerating only. Fourth, the impact of incomplete revascularisation on outcome between PCI and CABG could not be assessed as the registry does not capture this variable for CABG. Finally, relevant information regarding the renal outcomes such as acute renal failure or new requirement of dialysis was not available in our study.

	2-year even	t rate, n (%)		Crude risk			Adjusted risk	*	
Patient groups	Revascular	isation type							<i>p</i> for
rationi groups	PCI	CABG (reference)	HR	95% CI	<i>p</i> -value	HR	95% CI	<i>p</i> -value	interaction
Preserved renal function	n (eGFR >60)								
MACCE	190 (8.3)	89 (8.1)	1.07	0.83-1.38	0.58	1.11	0.86-1.43	0.42	0.20
Death	50 (2.2)	55 (5.0)	0.45	0.31-0.66	< 0.001	0.48	0.33-0.70	<0.001	0.01
Myocardial infarction	11 (0.48)	6 (0.55)	0.91	0.34-2.47	0.85	0.86	0.32-2.32	0.75	0.33
Any revascularisation	124 (5.4)	21 (1.9)	3.02	1.90-4.80	< 0.001	3.10	1.95-4.94	< 0.001	0.67
Stroke	22 (1.0)	16 (1.5)	0.67	0.35-1.28	0.23	0.74	0.39-1.41	0.35	0.76
TIMI major bleeding	28 (1.2)	289 (26.3)	0.04	0.03-0.06	< 0.001	0.04	0.03-0.06	< 0.001	< 0.001
Moderate renal dysfunc	tion (eGFR <60	and ≥30)							
MACCE	71 (16.9)	37 (13.1)	1.43	0.96-2.13	0.08	1.38	0.92-2.05	0.12	
Death	40 (9.5)	28 (9.9)	1.03	0.64-1.67	0.90	0.93	0.57-1.51	0.79	
Myocardial infarction	4 (1.0)	0	-	-	0.99	-	-	0.99	
Any revascularisation	24 (5.7)	4 (1.4)	4.53	1.57-13.1	0.005	4.42	1.53-12.8	0.006	
Stroke	11 (2.6)	8 (2.8)	0.98	0.39-2.44	0.97	0.94	0.38-2.35	0.90	
TIMI major bleeding	15 (3.6)	69 (24.5)	0.13	0.08-0.23	< 0.001	0.13	0.08-0.23	<0.001	
Severe renal dysfunctio	n (eGFR <30)								
MACCE	45 (38.5)	18 (24.7)	2.06	1.19-3.56	0.01	1.88	1.08-3.25	0.02	
Death	35 (29.9)	17 (23.3)	1.55	0.87-2.77	0.14	1.30	0.72-2.34	0.37	
Myocardial infarction	7 (6.0)	1 (1.4)	5.47	0.67-44.5	0.11	4.99	0.61-40.7	0.13	
Any revascularisation	8 (6.8)	1 (1.4)	6.81	0.85-54.4	0.07	6.77	0.85-54.1	0.07	
Stroke	2 (1.7)	3 (4.1)	0.49	0.08-2.93	0.43	0.45	0.08-2.70	0.38	
TIMI major bleeding	7 (6.0)	20 (27.4)	0.21	0.09-0.49	< 0.001	0.20	0.08-0.47	< 0.001	

\*Cox proportional hazards model with backward elimination method. CABG: coronary artery bypass grafting; CI: confidence interval; eGFR: estimated glomerular filtration rate; HR: hazard ratio; MACCE: major adverse cardiac and cerebrovascular events; PCI: percutaneous coronary intervention; TIMI: Thrombolysis In Myocardial Infarction

# Conclusions

The presence and severity of renal dysfunction were associated with an increased risk of serious adverse events in real-world patients with LMCAD. Among LMCAD patients with severe renal dysfunction, CABG was associated with a lower risk of MACCE as compared with PCI. Also, the effect of PCI versus CABG on MACCE was consistent, with PCI being associated with less bleeding and CABG being associated with less repeat revascularisation. Further studies are required to confirm the differential effect of PCI and CABG by degree of renal function, which may help to guide decision making in patients with LMCAD.

# Impact on daily practice

This analysis of the IRIS-MAIN registry showed the clinical implications of renal insufficiency in LMCAD patients. Patients with decreasing levels of renal function had higher risk profiles of baseline clinical, anatomical, and procedural characteristics and also had unfavourable clinical outcomes. According to the eGFR levels, CABG showed favourable results in patients with advanced renal insufficiency compared with PCI in LMCAD patients, while PCI and CABG showed no significant difference in patients with less severe renal insufficiency.

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# **Conflict of interest statement**

The authors have no conflicts of interest to declare.

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# Supplementary data

Supplementary Table 1. Medication use.

**Supplementary Table 2.** Two-year clinical outcomes according to the categories of baseline eGFR.

**Supplementary Table 3.** Sensitivity analysis excluding patients with first-generation DES.

**Supplementary Table 4.** Baseline characteristics in the overall population with PCI and CABG.

**Supplementary Table 5.** Baseline characteristics in patients with preserved renal function.

**Supplementary Table 6.** Baseline characteristics in patients with moderate renal dysfunction.

**Supplementary Table 7.** Baseline characteristics in patients with severe renal dysfunction.

The supplementary data are published online at: https://eurointervention.pcronline.com/ doi/10.4244/EIJ-D-18-01206



# Supplementary data

		Total		eC	GFR ≥60		eGFR	<60 and ≥3	60	(	eGFR <30	
Variable	PCI	CABG		PCI	CABG		PCI	CABG		PCI	CABG	
v un ubic	(N=2,825)	(N=1,453)	<i>p</i> -value	(N=2,289)	(N=1,098)	<i>p</i> -value	(N=419)	(N=282)	<i>p</i> -value	(N=117)	(N=73)	<i>p</i> -value
At discharge												
Aspirin	2,767 (98.1)	1,393 (96.4)	0.001	2,262 (99)	1,062 (97.1)	< 0.001	400 (95.7)	268 (96.1)	0.81	105 (89.7)	63 (87.5)	0.63
Statins	2,599 (93)	1,382 (95.5)	0.001	2,142 (94.6)	1,058 (96.7)	0.007	375 (90.6)	262 (93.6)	0.16	82 (70.1)	62 (84.9)	0.02
ACE inhibitors	1,095 (40.3)	335 (23.4)	< 0.001	855 (38.8)	218 (20.1)	< 0.001	176 (44)	86 (31.3)	0.001	64 (56.1)	31 (42.5)	0.07
Clopidogrel	2,568 (91.4)	1,229 (84.9)	< 0.001	2,098 (92)	946 (86.4)	< 0.001	370 (89.2)	230 (81.9)	0.006	100 (86.2)	53 (73.6)	0.03
ССВ	1,493 (54.5)	903 (62.9)	< 0.001	1,218 (54.8)	697 (64.2)	< 0.001	219 (53.9)	167 (60.3)	0.10	56 (49.1)	39 (53.4)	0.57
Beta-blocker	1,855 (67.3)	723 (50.6)	< 0.001	1,525 (68.2)	549 (50.9)	< 0.001	262 (64.7)	129 (46.6)	< 0.001	68 (58.6)	45 (61.6)	0.68
At 12 months												
Aspirin	2,185 (89.6)	1,144 (88.6)	0.36	1,827 (91.4)	892 (90)	0.23	296 (83.6)	208 (87)	0.25	62 (72.9)	44 (72.1)	0.91
Statins	2,595 (93.4)	1,392 (96.5)	< 0.001	2,149 (95.3)	1,066 (97.6)	0.001	366 (89.3)	262 (94.2)	0.02	80 (70.8)	64 (87.7)	0.007
ACE inhibitors	945 (38.8)	370 (27.8)	< 0.001	775 (38.9)	253 (25.1)	< 0.001	139 (39.7)	90 (35.4)	0.28	31 (33.7)	27 (38.6)	0.52
Clopidogrel	1,923 (79)	709 (55.1)	< 0.001	1,595 (79.9)	562 (56.8)	< 0.001	268 (75.7)	119 (50)	< 0.001	60 (71.4)	28 (45.9)	0.002
ССВ	1,306 (53.8)	719 (55.2)	0.40	1,091 (55.1)	558 (56.9)	0.36	175 (49.3)	132 (52.2)	0.48	40 (43.0)	29 (42.6)	0.96
Beta-blocker	1,571 (64.8)	677 (51.3)	< 0.001	1,308 (66.1)	525 (52.9)	< 0.001	217 (61.8)	119 (45.9)	< 0.001	46 (48.9)	33 (47.8)	0.89

Supplementary Table 1. Medication use.

At 24 months												
Aspirin	1,757 (81.4)	973 (84.1)	0.051	1,477 (83)	763 (86.2)	0.03	236 (78.4)	177 (82.7)	0.23	44 (55.7)	33 (56.9)	0.89
Statins	2,580 (93.3)	1,394 (96.3)	< 0.001	2,140 (95.3)	1,064 (97.3)	0.008	365 (89.9)	266 (95)	0.02	75 (65.8)	64 (87.7)	0.001
ACE inhibitors	822 (37.4)	347 (28.2)	< 0.001	682 (37.8)	248 (26.7)	< 0.001	118 (37.9)	83 (35.5)	0.55	22 (25.9)	16 (24.6)	0.86
Clopidogrel	1,431 (66.3)	452 (39.1)	< 0.001	1,200 (67.5)	359 (40.7)	< 0.001	192 (63.6)	71 (33)	< 0.001	39 (49.4)	22 (37.9)	0.18
ССВ	1,129 (51.9)	604 (50.8)	0.53	943 (53.2)	470 (52.5)	0.75	153 (48.9)	112 (48.5)	0.93	33 (37.9)	22 (34.9)	0.71
Beta-blocker	1,295 (60.1)	588 (48.4)	< 0.001	1,085 (61.5)	454 (49.9)	< 0.001	178 (58.2)	110 (45.8)	0.004	32 (37.2)	24 (37.5)	0.97

Values are n (%).

ACE: angiotensin-converting enzyme; CABG: coronary artery bypass grafting; CCB: calcium channel blocker; PCI: percutaneous coronary intervention

	eGFR ≥60	eGFR <60 and ≥30	eGFR <30	
	(N=3,824)	(N=838)	(N=232)	<i>p</i> -value
MACCE	347 (9.1)	134 (16.0)	84 (36.2)	< 0.001
Death from any cause	154 (4.0)	89 (10.6)	71 (30.6)	< 0.001
Cardiac death	122 (3.2)	73 (8.7)	53 (22.8)	< 0.001
Myocardial infarction	25 (0.7)	5 (0.6)	9 (3.9)	< 0.001
Stroke	44 (1.2)	20 (2.4)	6 (2.6)	0.008
Any revascularisation	162 (4.2)	32 (3.8)	11 (4.7)	0.79
TIMI major bleeding	325 (8.5)	86 (10.3)	29 (12.5)	0.04
TIMI minor bleeding	490 (12.8)	118 (14.1)	27 (11.6)	0.51

Supplementary Table 2. Two-year clinical outcomes according to the categories of baseline eGFR.

Values are shown as Kaplan-Meier estimates (number and percentage of events).

MACCE was defined as a composite of death, myocardial infarction, stroke, or any revascularisation. eGFR: estimated glomerular filtration rate; MACCE: major adverse cardiac and cerebrovascular events; TIMI: Thrombolysis In Myocardial Infarction

	2-year event	rate, n (%)		Crude risk		Adjusted risk <sup>*</sup>			
	Revascular	risation type							
Patient groups	PCI	CABG (reference)	- HR	95% CI	<i>p</i> -value	HR	95% CI	<i>p</i> -value	
Preserved renal function (eG	FR >60)								
MACCE	136 (7.8)	89 (8.1)	1.04	0.80-1.36	0.77	1.05	0.81-1.38	0.70	
Death	37 (2.1)	55 (5.0)	0.45	0.30-0.68	< 0.001	0.45	0.30-0.69	< 0.001	
Myocardial infarction	8 (0.5)	6 (0.5)	0.90	0.31-2.61	0.85	0.90	0.31-2.61	0.86	
Any revascularisation	86 (5.0)	21 (1.9)	2.87	1.78-4.62	< 0.001	3.00	1.86-4.84	< 0.001	
Stroke	19 (1.1)	16 (1.5)	0.79	0.40-1.53	0.48	0.83	0.43-1.62	0.59	
TIMI major bleeding	21 (1.2)	289 (26.3)	0.04	0.03-0.06	< 0.001	0.04	0.03-0.06	< 0.001	
Moderate renal dysfunction	$(eGFR < 60 and \ge 30)$								
MACCE	50 (15.6)	37 (13.1)	1.35	0.88-2.07	0.17	1.26	0.82-1.93	0.30	
Death	29 (9.1)	28 (9.9)	1.01	0.60-1.69	0.99	0.84	0.49-1.41	0.50	
Myocardial infarction	3 (0.9)	0 (0)	-	-	0.99	-	-	0.99	
Any revascularisation	14 (4.4)	4 (1.4)	3.58	1.18-10.88	0.02	3.73	1.23-11.34	0.02	
Stroke	10 (3.1)	8 (2.8)	1.19	0.47-3.03	0.71	1.18	0.47-3.01	0.72	
TIMI major bleeding	9 (2.8)	69 (24.5)	0.10	0.05-0.21	< 0.001	0.10	0.05-0.21	< 0.001	
Severe renal dysfunction (eG	FR <30)								
MACCE	39 (38.2)	18 (24.7)	2.10	1.20-3.67	0.01	1.74	0.99-3.06	0.06	
Death	32 (31.4)	17 (23.3)	1.70	0.94-3.06	0.08	1.30	0.71-2.37	0.39	
Myocardial infarction	7 (6.9)	1 (1.4)	6.65	0.82-54.16	0.08	6.65	0.82-54.2	0.08	
Any revascularisation	6 (5.9)	1 (1.4)	6.19	0.75-51.4	0.09	6.26	0.75-52.1	0.09	
Stroke	1 (1.0)	3 (4.1)	0.29	0.03-2.78	0.28	0.26	0.03-2.52	0.25	
TIMI major bleeding	7 (6.9)	20 (27.4)	0.24	0.10-0.56	0.001	0.22	0.09-0.52	0.001	

Supplementary Table 3. Sensitivity analysis excluding patients with first-generation drug-eluting stents.

\*Multivariate analysis: Cox proportional hazards model with backward elimination method.

CABG: coronary artery bypass grafting; CI: confidence interval; HR: hazard ratio; MACCE: major adverse cardiac and cerebrovascular events; PCI: percutaneous coronary intervention; TIMI: Thrombolysis In Myocardial Infarction

V	PCI	CABG	
Variable	(N=2,825)	(N=1,453)	<i>p</i> -value
Demographic and laboratory			
findings			
Age, years	63.8±10.7	64.7±9.0	0.003
Male sex	2,185 (77.4)	1,138 (78.3)	0.47
BMI, kg/m <sup>2</sup>	24.5±3.0	24.6±3.0	0.23
Diabetes	966 (34.2)	616 (42.4)	< 0.001
Hypertension	1,767 (62.5)	938 (64.6)	0.20
Dyslipidaemia	1,834 (64.9)	793 (54.6)	< 0.001
Current/recent smoker	686 (24.3)	384 (26.4)	0.13
Prior myocardial infarction	210 (7.4)	192 (13.2)	< 0.001
Prior CHF	62 (2.2)	49 (3.4)	0.02
Prior PCI	481 (17)	190 (13.1)	0.001
Atrial fibrillation/flutter	67 (2.4)	24 (1.7)	0.12
Cerebrovascular disease	221 (7.8)	119 (8.2)	0.67
PAD	106 (3.8)	113 (7.8)	< 0.001
Chronic lung disease	67 (2.4)	51 (3.5)	0.03
Dialysis	68 (2.4)	38 (2.6)	0.68
HDL-C, mg/dL	41 (34.8, 48)	39 (33, 46)	< 0.001
LDL-C, mg/dL	95 (71, 120)	97 (72, 123)	0.33
CRP, mg/dL	0.15 (0.06, 0.5)	0.16 (0.07, 0.485)	0.06
Clinical diagnosis			
Stable angina	1,237 (43.8)	490 (33.7)	< 0.001
Acute coronary syndrome	1,588 (56.2)	963 (66.3)	
Baseline eGFR			
eGFR (>60 ml·min <sup>-1</sup> ·1.73 m <sup>2</sup> )	2,289 (81)	1,098 (75.6)	< 0.001
eGFR (<60 and $\geq$ 30)	419 (14.8)	282 (19.4)	
eGFR (<30)	117 (4.1)	73 (5)	

Supplementary Table 4. Baseline characteristics in the overall population with PCI and CABG.

Values are mean±SD or n (%).

BMI: body mass index; CHF: congestive heart failure; CRP: C-reactive protein; eGFR: estimated glomerular filtration rate; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol; PAD: peripheral artery disease; PCI: percutaneous coronary intervention

X7	PCI	CABG	
Variable	(N=2,289)	(N=1,098)	<i>p</i> -value
Demographic and laboratory			
findings			
Age, years	62.3±10.5	63.6±8.9	< 0.001
Male sex	1,787 (78.1)	870 (79.2)	0.44
BMI, kg/m <sup>2</sup>	24.6±3.0	24.7±3.0	0.34
Diabetes	689 (30.1)	422 (38.4)	< 0.001
Hypertension	1,333 (58.2)	668 (60.8)	0.15
Dyslipidaemia	1,499 (65.5)	613 (55.8)	< 0.001
Current/recent smoker	578 (25.3)	312 (28.4)	0.05
Prior myocardial infarction	153 (6.7)	142 (12.9)	< 0.001
Prior CHF	29 (1.3)	22 (2)	0.10
Prior PCI	369 (16.1)	137 (12.5)	0.005
Atrial fibrillation/flutter	38 (1.7)	14 (1.3)	0.39
Cerebrovascular disease	152 (6.6)	76 (6.9)	0.76
PAD	63 (2.8)	71 (6.5)	< 0.001
Chronic lung disease	54 (2.4)	38 (3.5)	0.07
HDL-C, mg/dL	42.9±13.2	41.2±15.2	< 0.001
LDL-C, mg/dL	99.7±40.4	101.2±37	0.21
CRP, mg/dL	$0.6{\pm}1.4$	0.6±1.4	0.08
Clinical diagnosis			
Stable angina	1,024 (44.7)	382 (34.8)	< 0.001
Acute coronary syndrome	1,265 (55.3)	716 (65.2)	

Supplementary Table 5. Baseline characteristics in patients with preserved renal function.

Values are mean±SD or n (%).

BMI: body mass index; CHF: congestive heart failure; CRP: C-reactive protein; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol; PAD: peripheral artery disease; PCI: percutaneous coronary intervention

<b>X7</b> • 11	PCI	CABG		
Variable	(N=419)	(N=282)	<i>p</i> -value	
Demographic and laboratory				
findings				
Age, years	70.4±9.5	68.7±8.3	0.01	
Male sex	312 (74.5)	218 (77.3)	0.39	
BMI, kg/m <sup>2</sup>	24.6±3.0	24.7±3.2	0.72	
Diabetes	188 (44.9)	140 (49.6)	0.21	
Hypertension	322 (76.8)	203 (72)	0.15	
Dyslipidaemia	264 (63)	145 (51.4)	0.002	
Current/recent smoker	91 (21.7)	58 (20.6)	0.72	
Prior myocardial infarction	44 (10.5)	41 (14.5)	0.11	
Prior CHF	19 (4.5)	19 (6.7)	0.21	
Prior PCI	87 (20.8)	39 (13.8)	0.02	
Atrial fibrillation/flutter	22 (5.3)	8 (2.8)	0.12	
Cerebrovascular disease	51 (12.2)	32 (11.3)	0.74	
PAD	32 (7.6)	35 (12.4)	0.04	
Chronic lung disease	10 (2.4)	8 (2.8)	0.71	
HDL-C, mg/dL	40.8±11.5	38.6±9.8	0.05	
LDL-C, mg/dL	93.3±33.7	95.4±39.9	0.66	
CRP, mg/dL	$0.9{\pm}1.7$	$0.7{\pm}1.4$	0.68	
Clinical diagnosis				
Stable angina	174 (41.5)	88 (31.2)	0.006	
Acute coronary syndrome	245 (58.5)	194 (68.8)		

Values are mean±SD or n (%).

BMI: body mass index; CHF: congestive heart failure; CRP: C-reactive protein; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol; PAD: peripheral artery disease; PCI: percutaneous coronary intervention

Variable	PCI (N=117)	CABG (N=73)	<i>p</i> -value
findings			
Age, years	68.9±9.0	66.2±8.2	0.04
Male sex	86 (73.5)	50 (68.5)	0.46
BMI, kg/m <sup>2</sup>	23.3±2.9	24±3.1	0.17
Diabetes	89 (76.1)	54 (74)	0.75
Hypertension	112 (95.7)	67 (91.8)	0.34
Dyslipidaemia	71 (60.7)	35 (48)	0.09
Current/recent smoker	17 (14.5)	14 (19.2)	0.40
Prior myocardial infarction	13 (11.1)	9 (12.3)	0.80
Prior CHF	14 (12)	8 (11)	0.83
Prior PCI	25 (21.4)	14 (19.2)	0.72
Atrial fibrillation/flutter	7 (6)	2 (2.7)	0.49
Cerebrovascular disease	18 (15.4)	11 (15.1)	0.95
PAD	11 (9.4)	7 (9.6)	0.97
Chronic lung disease	3 (2.6)	5 (6.8)	0.26
Dialysis	64 (54.7)	37 (50.7)	0.59
HDL-C, mg/dL	41.7±52.8	35.7±11	0.81
LDL-C, mg/dL	87.4±32.9	87.5±31.5	0.80
CRP, mg/dL	$1.4{\pm}1.9$	1.2±1.8	0.52
Clinical diagnosis			
Stable angina	39 (33.3)	20 (27.4)	0.39
Acute coronary syndrome	78 (66.7)	53 (72.6)	

Supplementary Table 7. Baseline characteristics in patients with severe renal dysfunction.

Values are mean±SD or n (%).

BMI: body mass index; CHF: congestive heart failure; CRP: C-reactive protein; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol; PAD: peripheral artery disease; PCI: percutaneous coronary intervention