ORIGINAL ARTICLE

Major adverse cardiovascular events in patients undergoing percutaneous coronary intervention or coronary artery bypass graft with underlying chronic kidney disease

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Abstract

Objective: To assess early and late outcome in severe chronic kidney disease patients undergoing revascularisation.

Methods: The retrospective ambi-directional cohort study was conducted at Tabba Heart Institute, Karachi, and comprised data from May, 2012, to July,2016, related to severe chronic kidney disease patients with creatinine clearance <30ml/min or end-stage renal disease on haemodialysis who had undergone coronary artery bypass graft / percutaneous coronary intervention. Early outcome was in-hospital major adverse cardiac event, like mortality, stroke and new haemodialysis. Late outcome was major adverse cardiac event, like mortality, stroke, re-infarction and re-revascularisation. Data was analysed using Stata 12.1.

Results: Of the 228 patients with mean age of 64.2±10.8 years, 109(47.8%) with a maen age of 65.4±11.6 had undergone percutaneous coronary intervention, and 119(52.2%) with a mean age of 64.2±10.8 years had undergone coronary artery bypass graft. Overall mortality was 36(15.8%) patients; 15(13.7%) percutaneous coronary intervention, 21(17.6%)coronary artery bypass graft (p>0.05). Predictors of in-hospital adverse events were coronary artery bypass graft and cardiogenic shock (p<0.05). Follow-up was available in 181(94.3%) patients with a mean duration of 22.0±13.9 months. Heart failure and post-procedure stroke were independent predictors of late outcome (p<0.05).

Conclusion: Among patients with severe chronic kidney disease or end-stage renal disease undergoing revascularisation, percutaneous coronary intervention PCI was performed in patients with less complex anatomy or as emergency for acute ST-elevation myocardial infarction. Coronary artery bypass graft patients had higher early mortality, but improved late survival.

Keywords: Major adverse cardiovascular events, Chronic kidney disease, Revascularisation

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Introduction

[1]Among patients with severe chronic kidney disease (CKD) or end-stage renal disease (ESRD), cardiovascular disease (CVD) is the leading cause of death; accounting for around 45% of the total mortality.[1] CKD has been shown to be an independent risk factor for cardiovascular and overall mortality and is now considered a coronary heart disease (CHD) equivalent.[2] The prevalence of CKD is increasing across the world, which has led to an increasing population with concomitant CVD requiring treatment.[3]

Patients with severe CKD have a high prevalence of obstructive CHD with a subsequent accelerated process of atherosclerosis.[4] These patients tend to have more complex disease with both proximal and distal involvement, diffuse nature and presence of initial and later medial calcification.[5] Moreover, the mortality in CKD patients with CHD is very high, with 41-74% 2-year mortality after myocardial infarction (MI) and nearly 70-80% morality at 5 years in more recent series of coronary revascularisation.[6] Even with this awareness, severe CKD patients are poorly represented in randomised trials of cardiovascular therapies. Trials about benefits of revascularisation in addition to medical therapy for CHD patients excluded severe CKD and ESRD patients and similarly for patients who do require revascularisation, the preferred mode of revascularisation is only supported by registries and meta-analysis of retrospective observational trials.[6] Available data would suggest that patients undergoing percutaneous coronary intervention (PCI) may have a better short-term outcome, and patients undergoing coronary artery bypass graft (CABG) tend to do better over the intermediate term.[7,8] The European Society of Cardiology (ESC), the European Association of Cardiothoracic Surgery (EACS) and the American College of Cardiology/American Heart Association (ACC/AHA) guidelines on myocardial revascularisation recommend CABG over PCI in patients with moderate to severe CKD and multi-vessel disease (MVD) when surgical risk profile is acceptable and life expectancy is more than one year,[9,10] although the level of evidence supporting this recommendation is low.

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Additionally, disease burden patterns, expertise and skills of intervention cardiologist and cardiovascular surgeons and socioeconomic factors vary between different regions of the world. There is very limited data on patients with severe CKD or ESRD undergoing PCI or CABG that represents outcomes from a population or healthcare environment representing the South Asian region. The current study was planned to look at the patient characteristics, mode of revascularisation, early and late outcome in patients with severe CKD or ESRD who underwent coronary revascularisation.

Materials and Methods

The retrospective ambi-directional cohort study was conducted at Tabba Heart Institute, Karachi, and comprised consecutive data from May, 2012, to July, 2016, related to patients with severe CKD stage 4 or 5 with creatinine clearance <30ml/min or ESRD on haemodialysis who had undergone CABG / PCI. All patients were prospectively followed up for study outcomes through chart reviews and telephone calls from January 1, 2017, till December 30, 2017, by cardiology trainees and designated clinical research department data collectors. Revascularisation modality was decided by the treating physician. Patients who underwent revascularisation in the preceding 6 months, or patients having undergone both PCI and CABG in the same hospitalisation were excluded. After approval from the institutional ethics review committee, data was drawn from the institutional catheterisation(Cath)-PCI patient database which is modelled according to the standards of the United States National Cardiovascular Data Registry (NCDR) Cath-PCI registry.[11] The registry collects data prospectively on patient characteristics, clinical presentation, treatments and outcomes in patients undergoing coronary angiography and/or PCIs. All patients are prospectively followed up every six months after discharge for major adverse cardiac events (MACE). There is a comprehensive data quality programme, including both data quality report specifications for data capture and transmission and an auditing programme. The data collected is exported in a standard format. The complete definitions of all variables were prospectively defined by a committee of the American College of Cardiology (ACC).[11]

The institutional cardiac surgery database is also modelled in line with the standards of the Society of Thoracic Surgeons (STS) version 2.9.[12]The registry collects data on all patients undergoing cardiac surgical procedures. Data includes baseline characteristics, operative methods, discharge status and follow-up status. Standard data validation and quality methods are followed.Post-discharge follow-up is updated annually for MACE.

In the current study early outcome was in-hospital MACE, including all-cause in-hospital mortality, post-procedure stroke and requirement for fresh haemodialysis.

The late outcome included MACE, including all-cause mortality, stroke, re-infarction and target vessel revascularisation at follow-up.

Data was analysed using Stata ver. 12.1. Results were presented as mean±standard deviation (SD) for continuous variables and frequencies with percentages for categorical variables. Continuous data was compared by Student's t test, and proportions by Chi-square test. Estimated glomerular filtration rate (eGFR; ml/min/1.73 m^2) using initial serum creatinine of the patient was calculated by modification of diet in renal disease (MDRD) according to the formula: eGFR = 186 x serum Cr-1.154 x age-0.203 x 1.212 (if patient is black) of x 0.742 (if female).[13] Creatinine value of dialysis patients was not included in the initial creatinine and creatinine clearance calculation. Predicted mortality for CABG patients was calculated by the standard risk scores for CABG (STS score) from cardiac surgery registry[12] and for PCI patients from the NCDR predicted mortality risk calculator.[14] Stepwise multivariable logistic model was developed for clinically relevant variables to identify predictors of early outcomes and late outcomes. Results were presented as odds ratios (ORs) with 95% confidence interval (CIs) for early outcomes. Event-free survival (EFS) was estimated by the Kaplan-Meier method, and curve was compared with the log-rank test. Cox regression analysis was used for late outcomes and presented as hazard ratios (HRs) with 95% CIs. P<0.05 was considered statistically significant.

Results

Of the 228 patients, 109 (47.8%) had PCI and 119 (52.2%) had CABG. The overall mean age was 64.2±10.8 years and 144 (63.2%) were males. There was no significant difference between the two groups in terms of age (Table 1). Mean adjusted GFR was 21.1 ± 6.7 ml/min/1.73 m^2 and 36(15.8%) patients had ESRD on chronic dialysis. CABG group was more likely to have ESRD, diabetes and slightly lower mean left ventricular ejection fraction (LVEF) (p<0.05). Patients in PCI group were more likely to have a history of coronary revascularisation(p<0.05). Clinical presentation for index hospitalisation was acute myocardial infarction (AMI) with or without ST-segment elevation MI (STEMI) on electrocardiogram (ECG) in CABG group, while PCI patients were more likely to undergo urgent or emergency procedures [92(84.4%) vs. 66 (55.5%)].

In the PCI group, 32(29.4%) patients had severe left main or MVD. Single vessel PCI was performed in 91(83.5%) patients, with stent usage in 91.7% and drug-eluting stent

Table-1: Comparison of major variables and Univariate analysis among patients according to type of indication for the procedure (n=228).

Parameters	Overall n=228	PCI n=109 (47.8%)	CABG n=119 (52.2%)	*p*- value
Age in years*	64.2±10.8	65.4±11.6	63.1±10.0	0.09
Males	144 (63.2)	70 (64.2)	74 (62.2)	NS
Prior heart failure	23 (10.1)	9 (8.3)	14 (11.8)	NS
Smoker	31 (13.6)	17 (15.6)	14 (11.8)	NS
Dyslipidaemia	82 (35.9)	44 (40.4)	38 (31.9)	0.2
Hypertension	184 (80.7)	87 (79.8)	97 (81.5)	NS
Family history of premature CAD	23 (10.9)	12 (11.0)	11 (9.2)	NS
Diabetes mellitus	153 (67.1)	67 (61.5)	86 (72.3)	0.08
Prior cerebrovascular disease	6 (2.6)	3 (2.8)	3 (2.5)	NS
On Haemodialysis	36 (15.8)	14 (12.8)	22 (18.5)	0.2
LV Ejection fraction (%)*	40.5 ± 11.6	41.2±9.6	39.8± 13.0	NS
Prior revascularization	36 (15.8)	26 (23.8)	10 (8.4)	0.001
Prior history of MI	48 (21.1)	25 (22.9)	23 (19.3)	NS
Cardiogenic shock at time of revascularization	24 (10.5)	15 (13.8)	9 (7.6)	0.13
Initial creatinine (mg/dl)*	3.2±1.6	3.4±1.8	2.9±1.2	0.10
eGFR (ml/min/m^2)*	21.1±6.7	20.1±6.5	21.9±6.8	NS
SYNTAX score				
Overall mean*	24.7±13.5	16.2±6.8	35.9±11.7	<0.001
Low	64 (49.2)	62 (83.8)	2 (3.6)	
Intermediate	34 (26.2)	10 (13.5)	24 (42.9)	
High	32 (24.6)	2 (2.7)	30 (53.6)	
Total (available)	130 (100)	74 (100)	56 (100)	<0.001

*mean±SD; PCI: Percutaneous coronary intervention; CABG: Coronary artery bypass graft; CAD: Coronary artery disease; LV: Left ventricle; MI: Myocardial infarction; eGFR: Estimated glomerular filtration rate; SYNTAX: Synergy between PCI with Taxus and Cardiac Surgery.

(DES) in 76 (69.7%).Mean contrast volume was 105.4±79.3 and mean eGFR was 21.1±6.7ml/min/m^2. Mean ratio of contrast volume to eGFR was 5.9±1.16 (Table 2).

In the CABG group, 80 (67.2%)patients had left main or MVD. A median of 3 grafts with internal mammary graft were used in only 52 (43.7%) patients. The most common reasons for not utilising internal mammary artery graft were emergent CABG [47 (39.4%)], poor left anterior descending (LAD) artery target [42 (35.4%)] and in the remaining patients a surgeon's clinical assessment of impaired sternal blood supply or presence of arteriovenous (AV) fistula. Post-procedure atrial fibrillation (AF) occurred in 27 (22.7%) patients.

Synergy between PCI with Taxus and Cardiac Surgery (SYNTAX) scorewas available for 130 (57%) patients; 74(67.9%) PCI, and 56(47.1%) CABG. Mean SYNTAX score in the PCI group was 16.2±6.8 and in the CABG group it was 35.9±11.7. PCI patients were more likely to have SYNTAX score <22 [62(83.8%) vs. 2 (3.6%)] whereas CABG patients were more likely to have SYNTAX score >32 [30(53.6%) vs. 2 (2.7%)].

Table-2: Procedure details - PCI group (n=109) and CABG group (n=119).

Parameters	PCI n=109 (47.8%)	CABG n=119 (52.2%)
Procedure Presentation		
STEMI	41 (37.6)	22 (18.5)
≤24 hours	31 (75.6)	2 (1.7)
NSTEMI	59 (54.1)	67 (56.3)
≤24 hours	8 (13.6)	0(0.0)
Stable CHD	9 (8.3)	30 (25.2)
Urgent	59 (54.1)	57 (47.9)
Emergency	33 (30.3)	9 (7.6)
Anatomy		
Left main disease	4 (3.7)	29 (24.4)
Multi vessel disease	28 (25.7)	51 (42.9)
Single vessel disease	77 (70.6)	39 (32.8)
PCI Characteristics		
Only 1 stent used	76 (69.7)	-
DES	76 (69.7)	-
Single vessel PCI	91 (83.5)	-
Contrast volume (ml)*	105.4 ± 79.3	
Surgical Characteristics		
No. of graft used>=3	-	100 (84.0)
LIMA use	-	52 (43.7)

*mean±standard deviation (SD); PCI: Percutaneous coronary intervention; CABG: Coronary artery bypass graft; STEMI: ST-elevation myocardial infarction; NSTEMI: Non-ST-elevation myocardial infarction; CHD: Coronary heart disease; DES: Drug-eluting stent; LIMA: Left internal mammary artery.

Table-3: Early and late outcome details.

Parameters Early Outcomes (n=228)	PCI n=109 (47.8%)	CABG n=119 (52.2%)
New requirement for dialysis	2 (1.8)	15 (12.6)
Post op stroke	0 (0.0)	3 (2.54)
Atrial fibrillation	0 (0.0)	27 (22.7)
Death	15 (13.7)	21 (17.6)
Stent thrombosis	2 (1.4)	-
Parameters Late Outcomes (n=181)	**PCI n=85(46.9%)**	**CABG n=96 (53.1%)**
Death	11 (10.1)	8 (6.7)
Death within 30 days	4(3.7)	3 (2.5)
CVA	3 (2.7)	0 (0.0)
Re infarction	2 (1.8)	0 (0.0)
Repeat revascularization	1(0.9%)	0 (0.0)

PCI: Percutaneous coronary intervention; CABG: Coronary artery bypass graft; CVA: Cerebrovascular accident.

In terms of early outcome, overall mortality occurred in 36(15.8%) patients; 35 (97.2%) were of cardiac causes. Overall, PCI group had 15 (13.8%) deaths and CABG had 20 (16.8%). Actual mortality was higher compared to predicted mortality (17.6%) vs. (7.2%) in CABG group. There was no difference in actual mortality versus predicted mortality in PCI patients (13.8% vs. 13.7%). New requirement for dialysis was in 17 (7.5%) patients; 2(1.8%) PCI, 15(12.6%) CABG. Median length of stay in PCI patients was 4 days (interquartile range [IQR]: 4 days) whereas, median length of stay in CABG patients was 7 days (IQR: 5

Table-4: Predictors of early and late outcomes; Multivariable Analysis.

Parameters	Early outcome* (n=228)		Late outcome# (n=181)	
	OR (95%CI)	p- value	HR (95%CI)	p- value
Procedure (CABG)	2.4 (1.19 , 4.94)	0.01	-	-
Cardiogenic shock at time of revascularisation	9.50 (3.66 , 24.64)	<0.001	-	-
Congestive heart failure	-	-	8.43 (1.06, 66.90)	0.04
Post-procedure stroke	-	-	11.32 (2.37, 54.24)	0.002

OR: Odds ration; CI: Confidence interval; HR: Hazard ratio; CABG: Coronary artery bypass graft;
* Gender, hypertension, diabetes mellitus, dyslipidaemia, currently on haemodialysis, left ventricular ejection fraction, prior PCI, prior CABG,initial creatinine value and SYNTAX score were found statistically insignificant.
#Gender, hypertension, diabetes mellitus, currently on haemodialysis, left ventricular ejection fraction, prior PCI, prior CABG,cardiogenic shock at time of revascularization, initial creatinine value, revascularization status and SYNTAX score were found statistically non-significant

days).

A total of 52(47.7%) patients experienced composite early outcome, 19 (17.4%) in PCI group and 33(27.7%) in CABG group (p-<0.05). Multivariable predictors of early outcome were CABG as revascularisation modality (p=0.01) and cardiogenic shock at the time of revascularisation (p<0.001). Besides, 30-day mortality, including in-hospital mortality, was 19(18.5%) in PCI group, and 24(20.8%) in CABG.

In terms of late outcome, of the 192 (84.2%) patients discharged alive, follow-up was available for 181(94.3%); 85(90.4%) PCI and 96(98%) CABG. Mean follow-up duration was 22.0±13.9 months (range: 0.2-61 months). The incidence of MACE was 21(9.2%) during follow-up with 8(6.7%) events in CABG group and 13(11.9%) in PCI group. MACE occurrence was 19(8.3%) deaths; 11(10.1%) PCI, 8(6.7%)CABG, whereas the rest of MACE occurred in PCI group only (Table 3). There was no significant difference in survival and MACE-free survival between PCI and CABG groups (Figure). Congestive heart failure(CHF) (p=0.04) and post-procedure stroke (p=0.002) were independent predictors of adverse outcome at follow-up (Table 4).

Discussion

The current study looked at early and mid-term outcomes in 228 patients with severe CKD or ESRD who underwent coronary revascularisation over a 4-year period. Findings showed that in real life, when physicians are allowed to choose revascularisation modality in patients with severe CKD, patients with less complex coronary anatomy and need for emergency STEMI reperfusion get referred for PCI, whereas stable patients with complex coronary anatomy get selected for CABG. Early events were higher in CABG group primarily driven by higher need of new haemodialysis and post-procedure stroke. At mid-term follow-up, both groups had similar outcome.

Patients with severe CKD have increased cardiovascular and overall mortality.[15] Mildly elevated creatinine in the Heart Outcomes Prevention Evaluation (HOPE) trial was a marker of heightened cardiovascular risk and CKD is now considered a CHD equivalent.[16] Patients with worsening degree of CKD have increasing cardiovascular events with very high risk in ESRD. Traditional cardiovascular risk factors are more common in CKD patients accompanied by an amplified pro-inflammatory state mediating the enhanced coronary and systemic burden of atherosclerosis.[17] Deranged calcium and phosphate metabolism in advanced CKD and ESRD contributes to calcium deposition in the vasculature, including medial calcification in the coronary arteries.[18] There is resultant endothelial dysfunction, abnormal coronary perfusion and, along with increased atherosclerosis, lead to increased cardiovascular mortality(5).Diffusely diseased and calcified coronary arteries along with peripheral and cerebrovascular disease, advanced co-morbidities add to the technical difficulties and poor outcome with CABG and PCI.[19]

Patients undergoing CABG had a higher early event rate, including increased mortality and stroke, but do better in the intermediate term. Prior meta-analysis and systemic review have come to similar conclusions for patients with MVD undergoing revascularisation.[10] A review of 16 retrospective studies including over 30,000 patients, published over a 20-year period, showed that PCI patients had lower early mortality, but patients undergoing CABG had better survival and lower risk of MI and need for revascularisation over the long term.[6] A report from the New York state coronary and cardiac surgery reporting system described the outcome of 11,305 patients who underwent coronary revascularisation with underlying CKD and MVD. They also included a pre-specified propensity score-matched CABG and PCI pairs. Their findings also were better short-term outcome in PCI patients with CABG group having improved long-term mortality with lower risk of MI and repeat revascularisation.[20] More recent results from a European registry included 4,123 ESRD patients and showed higher 30-day mortality with CABG, but improved 1-year outcome compared to PCI.[7] The reason for higher mortality in patients undergoing CABG is multifactorial, with high burden of co-morbidities, such as diabetes and hypertension, immune-compromised state with increased risk of infection and sepsis, all contributing to it.[21] There is also a higher risk of arrhythmias and sudden cardiac death which is probably precipitated by anaemia, high output state from AV fistula, left ventricular hypertrophy, underlying CHD and haemodialysis-related electrolyte derangements.[22]

Our results also showed a higher risk of stroke in patients undergoing CABG. A review showed trend towards higher risk (p=0.05) of stroke in ESRD patients undergoing CABG, but similar risk in CKD patients compared to patients undergoing PCI.[23] In our study, 18.5% patients had ESRD which likely added to the higher incidence of stroke. There have been reports of both bleeding and ischaemic events.[24]

In our study the PCI patients had mostly low SYNTAX score, suggesting less complex coronary anatomy, and less co-morbidity.[25] At the same time, in 41 patients, index hospitalisation was for STEMI presentation; most of whom (75.6%) underwent emergency PCI within 24 hours of symptom onset. These patients had a higher risk of death and therefore an unfavourable influence on early survival. This is similar to results from a study where STEMI patients had a higher risk of death with an OR of 2.16.[7] Interestingly, the observed mortality in the PCI group compares favourably with the predicted mortality by the NCDR risk score, which is based on outcome from a North American population, suggesting appropriate provision of care. The incidence of new haemodialysis need was 1.8% in our study, which is significantly lower than NCDR PCI data where overall 4.2% ESRD patients needed haemodialysis and in STEMI subgroup, this proportion was slightly higher, 7.2%.[26,27] Since majority of our study population underwent PCI in acute coronary syndrome(ACS) setting, there was no time for prophylactic hydration therapy. Furthermore, due to emergent or urgent procedures and non-availability of creatinine levels, operators may not have strategised to reduce the volume of contrast. Due to above-mentioned factors, the rate of expected need for haemodialysis should have been higher in our study. Therefore, this low rate of haemodialysis in our PCI patients is likely a chance finding.

Of concern is that only single-vessel PCI was done in half of the patients with left main or multi-vessel CHD. This is similar to the results from the European registry, where only 13.5% patients underwent multi-vessel PCI even though 2- or 3-vessel disease was present in 75% of PCI patients.[7] There is extensive data that incomplete revascularisation leads to worse long-term outcome.[28] This is a clinical dilemma as complex PCI increases risk of acute kidney injury(AKI) with associated worse overall outcome.[29] Staged procedures or use of recently described zero-contrast dose PCI may be some options to improve this and perhaps achieve better long-term results in the PCI subset.[30] Even in the CABG patients, in our study the use of internal mammary artery (IMA) as a surgical conduit was in less than half of the patients. This is lower than reported.[10] There are reports that even in CKD and ESRD patients, use of IMA leads to better long-term outcome and surgeons should make maximum effort to use IMA conduits even in this high-risk population.[10]

The clinical presentation in our study was AMI in >90%. This is higher than 42-54% reported.[7,8] These patients are at higher risk of short-term and long-term adverse outcomes compared to nonacute coronary syndrome(non-ACS) patients. In a study, patients with ACS derived greater benefit from CABG compared to PCI with DES; HR 0.92 for predicting mortality in DES versus CABG.[8] Patients presenting with acute STEMI should still be treated with PCI because of a shorter presentation to treatment time. Lower frequency of patients with stable CHD in our study also suggests a more cautious utilisation of revascularisation. Whether or not these patients are undertreated is unclear as there are no randomised trials of medical therapy versus revascularisation in patients with severe CKD or ESRD.

Guideline-directed therapies, such as aspirin, beta blocker and statins, are less likely to be used in patients with severe CKD or ESRD.[31] Studies also showed that patients with severe CKD or ESRD are socio-economically disadvantageous.[32] CKD patients have complex coronary disease at the time of diagnosis.[4] In our study as well, majority of the patients presented with ACS and/or MVD, which is an indication that CKD patients tend to delay treatment unless CAD is well advanced.

There may be other characteristics unique to a patient population from a third world country that may impact early and late outcomes that have not been captured in a database modelled after a US registry. These may include lack of awareness of disease and its complication leading to delay in presentation or declining life-saving treatment, poor adherence to secondary prevention with lifestyle measures or medications, treatment avoidance by patients due to financial constraints in a self-pay healthcare economy without a national healthcare system, lack of availability or limited use of technologies to improve procedural outcome due to cost limitation, lack of expertise among cardiologist of advanced PCI techniques, cultural beliefs among patients or family members regarding undergoing PCI or surgical treatment, etc. Future studies on some of these aspects may provide information that may lead to improved outcome in such high-risk patients.

The current study had some limitations. Firstly, the data was collected from a single centre, resulting in limited generalisability of the findings, but this site was chosen because it provides standard cardiac care that is specialized, algorithmic and replicable. Secondly, the sample selection was restricted and resulted in a smaller sample size, which was again not a representative of the general population. However, the study had certain strengths. Firstly, the data was obtained from a standardised database following standard definitions. Secondly, no selection bias was present as all the patients meeting the inclusion criteria were included.

Due to overall small number of ESRD patients undergoing revascularisation, paucity of trial data on this subset and improved overall survival for ESRD due to renal replacement therapy, there is need to conduct studies with long-term follow-up to establish the most suitable revascularisation strategy which is both safe and efficacious for ESRD patients.

Conclusion

Patients with severe CKD and ESRD undergoing revascularisation had better early outcomes with PCI, but in the long term, outcomes with CABG were superior to PCI.

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