# **OUTCOMES OF** PCI USING DESs

Five-year outcomes of percutaneous coronary intervention using second generation drug-eluting stents for multivessel coronary artery revascularisation

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# INTRODUCTION

The selection of appropriate intervention for myocardial revascularisation in the elective setting should be undertaken based upon the outweighing by the expected benefits, in terms of survival or health outcomes to the expected negative consequences of the procedure.<sup>(1)</sup> Severe multivessel disease (MVD) has traditionally been treated with coronary artery bypass graft (CABG) surgery as the standard revascularisation strategy but this is not without the risks associated with bypass surgery.<sup>(2)</sup> The advent of percutaneous coronary intervention (PCI) has ushered in an era of comparatively non-invasive coronary revascularisation, but in the early years was limited to balloon angioplasty and the deployment of bare metal stents. These were complicated by significant restenosis rates and acute vessel closure.<sup>(3)</sup> Recent advances in PCI such as the advent of drug eluting stents (DESs) to maintain vessel patency,<sup>(4)</sup> as well as advances in CABG techniques<sup>(5)</sup> have improved the outcomes of revascularisation of patients with MVD, contributing to significant reductions in mortality and morbidity.<sup>(6)</sup> Optimisation of stent profiles and advances in

# ABSTRACT

Aim: This report evaluated outcomes of percutaneous coronary intervention (PCI) using drug-eluting stents (DESs) compared to coronary artery bypass grafts (CABG) for multivessel coronary artery disease (CAD). Methods: Sixty patients (43M, 17F); mean = 64.35 years (SD ± 10.4) who underwent PCI or CABG were followed up for 5 years. Revascularisation included 19 elective and 5 emergency cases. The composite outcome (defined as major adverse cardiac and cerebral events [MACCE]), and rates of repeat revascularisation were compared in each group using survival curves and adjusted Cox pro-portional hazard models.

Results: Nine (15%) patients sustained acute MI and 6 (10%) suffered a stroke during follow-up (PCI n=5, CABG n=4). There were 10 deaths (DVD n=2, TVD n=8) (6 CABG, 4 PCI). There was no difference in treatment effects between the 2 groups for time to MI, stroke, and angina (PCI 40% vs. CABG 23.3%, p=0.194). Adjusted 5-year risk of death (11.7% vs. 17.6%, OR=1.300, CI=0.313 - 5.404, p=1.000) and the composite of death, stroke and MI (51.3% vs. 44% p=0.566) were similar in the 2 groups. There was a higher rate of repeat revascularisation in PCI group (52.8% vs. 29.3%) (p=0.121.) Conclusions: PCI using DESs for patients with multivessel CAD showed similar outcomes to CABG. SA Heart<sup>®</sup> 2025:22:30-37

the drug delivery of DESs have reduced the neointimal response and in-stent stenosis, making it difficult to choose the appropriate revascularisation strategy in patients with multivessel CAD.<sup>(7)</sup>

Although several studies have shown favourable outcomes of PCI using DESs compared to CABG for multivessel CAD,<sup>(8.9)</sup> their short duration have not permitted evaluation of late stent stenosis and myocardial infarction (MI) rates in the longer term. Data are still limited on long-term (beyond 5 years) outcomes of PCI or CABG in patients with MVD. In South Africa, the ACCESS (Acute Coronary Events - a Multinational Survey of Current Management Strategies) registry described favourable clinical outcomes (mortality, re-admission rates, and severe bleeding episodes) at I year in subjects with ACS, half of whom received DESs for the culprit lesion.(10) This study examined the safety and outcomes of major adverse cardiovascular and cerebrovascular events (MACCE) at 5 years in patients undergoing PCI using second generation DESs compared to CABG for multivessel CAD.

# **MATERIALS AND METHODS**

Consenting patients between the ages of 30- and 90-years-old with multivessel coronary artery disease undergoing coronary revascularisation with PCI (using second generation DESs) or CABG over a 2-month period (February - March 2013) were recruited for study at the St. Augustine's Hospital Heart Centre, Durban, South Africa. Twenty-one (35%) patients had chronic stable angina and 12 (20%) patients had ACS. Patients who underwent prior CABG or valve surgery, those who had MI within 24 hours and those with cardiogenic shock were excluded (Table I). The choice of revascularisation strategy (PCI or CABG) was made by the attending cardiologist and surgeon. PCI was performed using only the second generation DESs. Dual antiplatelet therapy using aspirin and clopidogrel in standard regimens were prescribed for at least 6 months duration. Surgery was performed using standard bypass techniques and harvesting the internal thoracic artery for revascularisation of the left anterior descending artery and saphenous vein grafts for the remaining vessels. Follow up was performed at 6 monthly intervals in the first year and thereafter yearly for 5 years and endpoint outcomes documented.

Diabetes mellitus was diagnosed according to guidelines published by the American Diabetes Association<sup>(11)</sup> and hypertension was defined as a blood pressure ≥140/90mmHg on 3 consecutive visits or patients who were on antihypertensive medication.<sup>(12)</sup> Dyslipidaemia was diagnosed in patients who

TABLE I: Patient selection.				
Patient selection	PCI	CABG		
Total who underwent coronary angiograms (n=225)	162	63		
Exclusions	132	33		
Single vessel disease	59	0		
Valvular heart disease / surgery	16	17		
Prior CABG	0	15		
Multivessel disease treated with medication only	47	0		
Coronary artery dissection	10	0		
Declined procedure	0	I		
Patients selected for study	30	30		

were on chronic anti-lipid drugs or documented on diagnosis from medical records and classified using the criteria from the Third National Cholesterol Education Programme and Adult Treatment Panel III guidelines (NCEP-ATP III).<sup>(13)</sup> The BMI was calculated as weight / height<sup>2</sup> and defined as elevated if it was >25.0kg/m.<sup>(14)</sup> A history of smoking was present if there was previous or current use of cigarettes or tobacco products.

Multivessel disease was defined by the presence of ≥50% diameter stenosis in 2 or more major epicardial coronary arteries and categorised as double vessel disease (DVD) or triple vessel CAD.<sup>(15)</sup> Total arterial occlusion was defined as the complete obstruction (99%) of a coronary artery, corresponding to the Thrombolysis In Myocardial Infarction (TIMI) flow risk score of TIMI 0 or TIMI 1.<sup>(16)</sup> The composite endpoints of major cardiac and cerebrovascular adverse events (MACCE) was defined as the composite outcome of death, non-fatal myocardial infarction, stroke, repeat revascularisation, and angina.<sup>(17)</sup> Cardiac death was described as death due to a cardiovascular event or sudden unexplained death caused by a sudden change in heart rhythm.<sup>(15)</sup> Myocardial infarction was defined according to the Third Universal Classification of MI which encompasses ST segment elevation (STEMI), non-ST segment elevation (NSTEMI), and unstable angina.<sup>(18)</sup> Stroke was classified according to the American Stroke Association as either ischaemic or haemorrhagic.<sup>(17)</sup> Repeat revascularisation was defined as repeat CABG or PCI of the previously stented vessels.<sup>(17,18)</sup>

# **STATISTICAL ANALYSIS**

Considering a paired t-test for pre- and post-variable comparisons at a 5% level of significance, a sample size of 60 patients was calculated to achieve a power of 80% and to show an effect size of 0.50 for the difference in pre- and post-intervention means.<sup>(19)</sup> At least 30 subjects undergoing each revascularisation procedure were therefore required for this analysis.

The IBM SPSS software, version 25 was used for statistical analyses. The risk factor profile and baseline characteristics of the patients in the 2 treatment groups were compared with the t-test for continuous variables and with the chi-square statistics or Fisher exact test for categorical variables. Treatment-related differences in the immediate complications and long-term outcomes between the 2 procedures were analysed using  $G^*Power$  version  $3^{\scriptscriptstyle (18)}$  to test the difference between 2 independent group means using a 2-tailed test, a medium effect size (d=.05), and an alpha of .05 in all patients. Differences in the long-term rates of the study outcomes between groups were assessed using Cox regression. Kaplan-Meier curves were constructed for the 5-year outcomes of the composite endpoint of death, MI and stroke as well as for recurrence of angina. Adjusted covariates included the patients' ages and gender, the presence or absence of clinical parameters and coexisting conditions, left ventricular function, and the number of diseased vessels. All reported p-values are 2-sided, and p-values <0.05 were considered statistically significant.

Full ethical approval was obtained from the Durban University of Technology Institutional Research Ethics Committee (ethical clearance number: IREC 016/19). All patients provided written informed consent before enrolment.

### RESULTS

### **Baseline characteristics**

During the 2-month period (February - March 2013), 225 patients underwent coronary angiography at the St. Augustine's Hospital Cardiac Catheterisation Laboratory. Of these 225 patients, 162 patients underwent PCI with DESs (Xience Alpine, Xience Prime, Xience Pro, Xience V, Xience Sierra and Onyx) and 63 patients underwent CABG surgery. There were 165 patients who did not meet the inclusion criteria and were excluded (PCI n=132, CABG n=33). The remaining 60 patients (males n=43 and females n=17) with multivessel coronary artery disease (PCI group n=30 and CABG group n=30) comprised the study group (Figure I). The mean age in these 60 subjects (43 M, 17 F) was 64.35 years (SD  $\pm$  10.4) with M:F ratio of 2.53:1. There was no difference in the age distribution between the 2 groups (p=0.531). The majority 39 (65%) of the study sample were Indians, followed by 15 (25%) Whites, 4 (6.6%) Africans and 2 (3.3%) of mixed ethnicity (Coloured). Premature CAD (<55yr in males and <65yr in females) was present in 9 subjects in the PCI group and 7 in the CABG group.

The baseline clinical characteristics showed no difference in the risk profile and comorbid diseases between the 2 groups (Table II). The most common risk factor was hypertension (66.6%) followed by dyslipidaemia (46.6%), cigarette smoking (43.3%) and diabetes mellitus (36.6%). There was also no difference in the mean ejection fraction (55.10% vs. 49.13%; p=0.612) between the PCI and CABG groups prior to revascularisation respectively.

The baseline angiographic characteristics of the study sample are shown in Table III. Double vessel disease was present in 22 subjects (36%) and triple vessel disease in 38 (63%) of the total sample (n=60). The left anterior descending (LAD) artery was the most common major epicardial vessel involved (88.3%).



TABLE II: Baseline characteristics of the study sample.

Variable	PCI n (%)	CABG n (%)	Odds ratio <sup>*</sup>	95% CI	p-value
Mean age, (years)	64.35 ± 10.4			1.000	186
Gender					
Male	17 (56.6)	24 (80)	4.266	0.908 - 4.109	0.798
Female	13 (43.3)	6 (20)	0.259	0.056 - 1.599	0.146
Hypertension	20 (66.6)	20 (66.6)	1.000	0.342 - 2.926	1.000
Diabetes	11 (36.6)	(36.6)	1.000	0.350 - 2.858	1.000
Elevated BMI	19 (63.3)	20 (66.6)	0.798	0.216 - 2.819	0.198
Dyslipidaemia	15 (50)	13 (43.3)	0.765	0.277 - 2.114	0.796
Smoker	13 (43.3)	13 (43.3)	1.000	0.360 - 2.777	1.000
Previous heart failure	5 (16.6)	7 (23.3)	1.522	0.423 - 5.472	0.748
Chronic kidney disease	3 (10)	2 (6.6)	0.643	0.100 - 4.153	1.000
Cerebrovascular or carotid artery disease	2 (6.6)	7 (23.3)	4.261	0.806 - 22.532	0.145
Peripheral vascular disease	7 (23.3)	2 (6.6)	0.235	0.044 - 1.241	0.145
Recent MI (1 - 8 days before treatment)	16 (53.3)	17 (56.6)	0.800	0.215 - 2.972	1.000
ECG findings					
Sinus rhythm	21 (70)	25 (83.3)	2.143	0.622 - 7.387	0.360
Atrial fibrillation	6 (20)	4 (13.3)	0.615	0.155 - 2.450	0.731
Paced rhythm	3 (10)	2 (6.6)	0.643	0.100 - 4.153	0.601
Ejection fraction					
<40%	5 (16.6)	8 (26.6)			
40% - 50%	5 (16.6)	5 (16.6)			
≥50%	20 (66.6)	17 (56.6)			
Mean EF (%)	50.10	49.13			0.612

MI: mvocardial infarction.

\* The ORs and Cls are for the PCI group relative to the CABG. There was no difference in clinical characteristics and comorbid conditions between the 2 groups.

Seventy two percent of the study sample had lesions in the circumflex (CX) artery and 78.3 percent in the right coronary artery (RCA). There was no difference in proximal LAD involvement (p=0.131) and in left main stem disease between the groups (23.3% vs. 23.3%; p=1.000). Subjects with double vessel disease (DVD) were dominant in the PCI group compared to the CABG group (56.6% vs. 16.6%, p=0.039), while triple vessel disease (TVD) was more common in the CABG group (83.3% vs 43.3%, p=0.129).

# **Procedural characteristics**

There were 81 bypass grafts performed surgically and a total of 73 coronary lesions stented by PCI. Eighty percent of the CABG group underwent off-pump surgery and 93.3% had revascularisation of the left anterior descending artery with the internal mammary artery. During PCI, 111 second generation drug eluting stents were deployed (Xience Alpine, Xience Prime, Xience Pro, Xience V, Xience Sierra and Onyx). Overall,

the average lesion length was  $24.32 \pm 6.67$ mm. Approximately 33.3% of the study sample had stents implanted for double vessel disease and 36.6% of the study sample had stents implanted for triple vessel disease. Procedural success was obtained in all subjects in both groups with no major in-hospital complications occurring immediately post revascularisation and up to the time of hospital discharge. There were no differences between the groups in the major procedural complications (bleeding, hypotension and worsening renal function requiring dialysis) (Table IV).

### **Clinical endpoints**

The median follow-up was 5.1 years (interquartile range (IQR): 4.1 - 6.2 years) for the overall sample (Figure 1). Complete follow-up was obtained in 88.3% of the overall sample (88.8% for DES and 88% for the CABG group, p=0.16).

Follow-up coronary angiography for chest pain, recurrence of angina and myocardial infarction was performed in 32 patients

<b>TABLE III:</b> Baseline angiographic findings showing lesion location and extent of disease.					
CAD vessel characteristics	Total % / 60	PCI n	CABG n	p-value	
Affected coronary vessel					
Left anterior descending	88.3*	24	29	0.399	
Circumflex	71.7*	19	24	0.126	
Right coronary	78.3*	22	25	0.266	
Diagonal branch	3.3	I	I	0.075	
Ramus branch	11.7	4	3	0.500	
Obtuse marginal branch	13.3	3	5	0.353	
Posterolateral branch	3.3	I.	I	1.000	
Left main stem	23.3	7	7	1.000	
Extent of coronary artery disease					
Double vessel disease	36.6	17**	5	0.039**	
Triple vessel disease	63.3	13	25	0.129	
Lesion location in LAD					
With proximal LAD	83.3	22	28	0.131	
Without proximal LAD	15	8	I.	0.269	
Mid LAD	48.3	17	12	0.267	
Distal LAD	41.7	16	9	0.128	
Total occlusions					
LAD	18	2	9	0.163	
Circumflex	13	3	5		
Right coronary	12	4	2		
Ramus branch	3	I	I		
Obtuse marginal branch	2	0	I		

\*Most lesions were in the major epicardial vessels and involving the proximal LAD. \*\* Vessel involvement was similar in both treatment groups but double vessel coronary artery disease was more frequent in the group who underwent PCI.

<b>TABLE IV:</b> Major procedural complications during   revascularisation.			
Complication	PCI n (%)	CABG n (%)	
Periprocedural death	0 (0)	0 (0)	
Periprocedural MI	2 (6.6)	I (3.3)	
Bleeding / haematoma	3 (10)	2 (6.6)	
Cardiogenic shock	0 (0)	2 (6.6)	
Hypotension	5 (16.6)	7 (23.3)	
Requiring dialysis	2 (6.6)	5 (16.6)	
Stroke	0 (0)	0 (0)	
Procedural failure	0	0	

PCI: percutaneous coronary intervention, CABG: coronary artery bypass graft surgery, MI: myocardial infarction.

Table IV illustrates the major procedural complications between the 2 revascularisation groups.

(PCI n=19 and CABG n=13). There was no difference in the angina recurrence between the 2 groups (PCI 40% vs. CABG 23.3% p=0.194). In the PCI group in-stent (n=9) and insegment (n=5) restenosis was managed by repeat PCI with 51 stents deployed in 14 patients. In the CABG group, 27 stents were deployed in 12 patients. Repeat revascularisation was higher in PCI group than in the CABG group (52.8% vs. 29.3% respectively) but this finding was not significant (OR=0.446, CI=0.159-1447, p=0.121).

Nine of the 60 subjects (15%) patients sustained acute MI and 6 patients (10%) suffered a stroke during follow up (PCI n=5, CABG n=4). There was no difference in the rate of MI (p=0.058) or stroke (p=1.000) (Table V) between the PCI and CABG groups. Ten subjects demised (DVD n=2, TVD n=8) and of these 6 underwent CABG and 4 PCI (11.7%).

# TABLE V: Endpoint analysis at 5 years.

	PCI n=30 (%)	CABG n=30 (%)	OR	95% CI	p-value
MACCE*	51.3%	44%	0.506		0.566
Death	4 (11.7)	6 (17.6)	1.300	0.313 - 5.404	1.000
Myocardial infarction	5 (14.6)	4 (11.7)	0.348	0.115 - 1.055	0.058
Stroke	3 (8.8)	3 (8.8)	1.000	0.226 - 4.431	1.000
Angina	12 (35.2)	7 (20.5)	0.507	0.180 - 1.422	0.194
Repeat revascularisation	18 (52.8)	10 (29.3)	0.446	0.159 - 1.447	0.121

\*MACCE was defined as the composite outcome of death, nonfatal MI, stroke, repeat revascularisation and angina.<sup>(24)</sup> There was no difference in MACCE or in any of its component endpoints between the 2 groups

After adjustment for baseline differences using multivariableadjusted Cox regression analysis, the 5-year risk of death (11,7 vs. 17.6%, HR=1.300, CI=0.313-5.404, p=1.000) and the composite of death, MI or stroke (51.3% vs. 44% HR 0.506 CI 0.180-1.422, p=0.566) were similar in the 2 groups. (Table IV) The Kaplan-Meier curves showing the time to onset of the major events and to revascularisation are shown in Figure 1.

There was no difference in the treatment outcomes in the highrisk subgroups (diabetes mellitus, ejection fraction <50% and age >65 years) between the PCI and CABG groups. There was also no difference in the rates of death (13.3% vs. 13.3%, p=1.000) and the composite outcome of death, MI, or stroke (40% vs. 26.6%, p=0.785) and the rate of repeat revascularisation (33.3% vs. 20%, p=0.789) among patients with TVD. There were no significant differences between the PCI and CABG groups in the rates of death (13.3% vs. 13.3%, p=1.000) and the composite outcome of death, MI, or stroke (40% vs. 26.6%, p=0.785) and rate of repeat revascularisation (33.3% vs. 20%, p=0.789) among patients with TVD. In subjects with double vessel disease unadjusted rates of death were similar in both groups, whereas the composite of death, MI or stroke (30% vs. 16.6%, p=0.026) and the rate of repeat revascularisation (26.6 vs. 6.6%, p=0.006) was significantly higher in the PCI compared to the CABG group respectively. Among patients with DVD who had proximal LAD involvement, the composite outcome of death, MI and stroke (20% vs. 10%, p=0.024) and rate of repeat revascularisation (16.6% vs. 3.3%, p=0.005) was higher in the PCI group compared to the CABG group.

# DISCUSSION

This single centre study showed that PCI using second generation DES for multivessel disease (MVD) could be undertaken safely with low cardiovascular event rates and no immediate post-procedural mortality. The immediate procedural complication rate as well as the long term (5-year) rate for the composite outcome of death, myocardial infarction or stroke were similar in both PCI and CABG groups. These findings are in keeping with that of several large studies such as The Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX),<sup>(20)</sup> Premier of Randomised Comparison of Bypass Surgery vs. Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease (PRECOMBAT),<sup>(21)</sup> and Evaluation of XIENCE vs. Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularisation (EXCEL)<sup>(22)</sup> trials which have shown similar mortality and safety outcomes in the 2 groups. In SYNTAX $^{(20)}$  the composite outcome of safety (death, MI, or stroke) was comparable to CABG at I year, but the stroke rate was significantly higher in the CABG group; PCI using first generation DESs was associated with more frequent revascularisation. In our study we showed no increase in stroke in the CABG group, but the rate of repeat revascularisation in our study was lower, though not significant, at 5 years in the CABG group. Our findings are at variance with 2 large recent studies of revascularisation in patients with TVD which found that FFRguided PCI using the zotarolimus stent was not non-inferior to CABG with respect to the incidence of a composite of death, myocardial infarction, stroke, or repeat revascularisation at | year.(23,24)

These findings are in contrast with earlier observational studies comparing PCI using first-(20) and second-generation(21) DES with CABG for multivessel revascularisation which revealed inconsistent findings.<sup>(25)</sup> While a few studies have indicated that mortality and safety outcomes were similar for PCI and CABG,<sup>(22)</sup> registries have found a lower rate of survival after PCI with DES than after CABG.(21,22) The effect of unmeasured confounding factors related to case selection may explain some of the discordance in these registry results.<sup>(20)</sup> Two recent randomised trials, the EXCEL<sup>(25)</sup> and Nordic-Baltic-British Left Main Revascularisation (NOBLE)<sup>(27)</sup> trials have compared PCI using second-generation DES with CABG in patients with unprotected left main stem coronary artery disease. The EXCEL<sup>(26)</sup> trial showed that PCI with the everolimus DES was non-inferior to CABG for the composite endpoint of death, stroke, or MI at 3 years, whereas the NOBLE<sup>(27)</sup> trial showed that the 5-year risk of MACCE was higher after PCI. The NOBLE study suggests this could be due to the different stents used in the 2 trials, biolimus DES with biodegradable polymer in the NOBLE trial<sup>(27)</sup>, and Xience durable polymer everolimus-eluting stents (EES) in the EXCEL trial.<sup>(26)</sup>

In our study the composite outcome of death, MI and stroke (20% vs. 10%, p=0.024) as well as rate of repeat revascularisation was significantly higher among patients with DVD who had proximal LAD involvement who underwent PCI group compared to the CABG. Our study findings are similar to the Bypass Surgery vs. Everolimus Eluting Stent Implantation for Multivessel Coronary Artery Disease (BEST)<sup>(3)</sup> trial, in which PCI with a second-generation DES (everolimus drug-eluting stent) was associated with increased risk of MI and repeat revascularisation, without any mortality difference when compared with CABG.<sup>(28)</sup> These findings were confirmed by Bangalore, et al.<sup>(4)</sup> who found that the outcomes of PCI with the everolimus drugeluting stent was similar to that associated with CABG. In that study PCI was associated with a higher risk of myocardial infarction (among patients with incomplete revascularisation) but a lower risk of stroke, and a similar risk of death associated with CABG.<sup>(4)</sup>

In our study we also analysed the relative treatment effects in subsets of patients with major high-risk clinical factors such as diabetes mellitus, abnormal ventricular function, and age >65 years. While there was no difference in the 5-year adjusted rates of the composite of death, MI, or stroke between the 2 groups, the rate of repeat revascularisation appeared to be higher after PCI, but this difference was not significant. This was similar to a recent meta-analysis of 5 trials<sup>(29)</sup> which reported similar long-term mortality after PCI with DES compared with CABG in patients, with no significant differences in cardiac death, stroke, or MI between these groups. To some extent the risk factor profile of our subjects may partly explain this finding since almost two thirds of our sample in each group were of Asian Indian ancestry with a high prevalence of major cardiovascular risk factors. South Africans Indians are known to have a very high risk for atherosclerotic CAD,<sup>(30)</sup> related to risk factor clustering and those with established CAD have a very high prevalence of type 2 diabetes.<sup>(31)</sup> The high prevalence of type 2 diabetes in our sample (36.6%) may explain the need for more frequent revascularisation in our PCI subjects compared to CABG since 3 clinical trials<sup>(32,33,34)</sup> have established that CABG is the preferred strategy in type 2 diabetes compared to PCI. In a meta-analysis, Bangalore, et al.<sup>(4)</sup> found a clear long-term survival benefit in choosing CABG over PCI for patients with multivessel coronary artery disease, especially when complicated by diabetes or higher SYNTAX score.<sup>(4)</sup> The BARI-2D trial<sup>(35)</sup> aimed to compare 2 major treatment approaches, coronary revascularisation vs. intensive medical therapy, and insulin sensitisation vs. insulin provision strategies. The BARI-2D trials<sup>(35,36)</sup> reported a significantly lower rate of the composite of all-cause death, myocardial infarction, or stroke between revascularisation and the medical strategy in the CABG group, but not in the PCI group. Similarly, another meta-analysis which sought to compare the effect of PCI and medical therapy with medical therapy alone in patients with stable CAD reported that PCI with medical therapy was not associated with a reduction in death, non-fatal MI, unplanned revascularisation or angina compared with medical therapy alone.<sup>(37)</sup> Another systematic review showed a clear advantage for CABG in patients with multivessel disease, with lower mortality rates in CABG especially in patients with diabetes and higher SYNTAX scores.(38)

The strength of our study lies in the evaluation of long-term outcomes in a sample of predominantly Asian Indian subjects with a high risk factor prevalence, particularly type 2 diabetes. Among patients with treated diabetes the 10-year follow up of the BARI trial confirmed that CABG conferred long-term survival benefit over PCI with balloon angioplasty,<sup>(39)</sup> whereas the 2 initial strategies were equivalent regarding survival for patients without diabetes. While it is now well established that diabetics have a more diffuse and complex coronary vasculopathy and appear to have better outcomes after revascularisation with CABG compared to PCI,<sup>(39)</sup> it is reassuring that the 10-year follow up of diabetic subjects in the SYNTAX study has shown that CABG did not lower the risk of all cause death at 10 years compared to PCI.<sup>(40)</sup> Our findings suggest that the use of second generation DESs may offer outcomes similar to CABG in diabetic (and non-diabetic) subjects.

# LIMITATIONS OF THE STUDY

This study has the limitations inherent to a non-randomised, open label, single-centre analysis. The study was conducted in a select group of subjects and therefore our findings may not be applicable to the general population of subjects with CAD. Twenty seven percent of the subjects undergoing coronary angiography at the centre in the 2-month period were included

in the study, yielding a small sample size of 60 participants which included both participants with recent myocardial infarction and stable CAD. Because the study was not randomised, selection bias probably accounted for more patients with TVD being referred for CABG, while the PCI group had more double vessel disease. Also, we did not examine the stenotic lesion complexity in the 2 groups in this analysis nor were the endpoints adjudicated by an independent committee. The results of our subgroup analysis must also be interpreted with caution because of the smaller number of subjects without adequate power for subgroup analysis. In addition, we did not examine the influence of other confounding parameters such as adherence to lifestyle behaviourial changes and control of risk factors such as diabetes, hypertension and lipid parameters which may have contributed to event rates. Finally, we did not examine outcomes based on risk scores since evaluation of individual patient risk levels prior to intervention using a formal scoring system such as the EUROSCORE or SYNTAX<sup>(28)</sup> was not performed in this study.

# CONCLUSION

This study shows that subjects undergoing revascularisation with PCI using second-generation DESs have immediate and 5-year safety outcomes that were comparable to CABG in terms of the composite endpoint of death, stroke and MI. The higher composite event rate in subjects with DVD with proximal LAD involvement call for a larger, randomised comparison of the 2 revascularisation strategies, adjusting for behavioural factors and risk scores between the 2 groups. This will help clarify the long-term safety and efficacy of PCI using second generation DES compared to CABG for multivessel disease.

### Conflict of interest: none declared.

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