International Journal of Cardiology 296 (2019) 21–25

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Late clinical outcomes of unselected patients with diabetic mellitus and multi-vessel coronary artery disease

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A R T I C L E I N F O

Article history:
Received 18 January 2019
Received in revised form 27 June 2019
Accepted 10 July 2019

Keywords:
Diabetes mellitus
Multi-vessel disease
Revascularization

A B S T R A C T

Background: The Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multi-Vessel Disease (FREEDOM) clinical trial randomized only a proportion of screened patients with diabetes mellitus (DM) and multi-vessel disease (MVD).
Methods and results: We determined late rates of death, non-fatal myocardial infarction (MI) and stroke in all 430 patients with DM who had MVD identified on angiographic screening for the FREEDOM Trial, which recruited from June 2006 –March 2010 at Liverpool Hospital, Sydney, Australia. Mortality at 6 years [median] was 23% among 192 FREEDOM-eligible patients and 26% among 238 FREEDOM-ineligible patients, of whom 139 [58%] had prior. CABG (mortality 31%). Overall, 196 (45%) had percutaneous coronary intervention (PCI), 127 (30%) underwent coronary artery bypass grafting (CABG) (who were 4 years younger; $p = 0.003$), and 107 (25%) had neither procedure of whom 80 were considered unsuitable for revascularization. Mortality was 26% post-PCI 16%, post-CABG and 33% among those who did not undergo revascularization ($p = 0.01$). On multivariable analyses, factors associated with late mortality were older age, hypertension and not undergoing CABG (all $p < 0.05$). Factors associated with late MI were presented with an acute coronary syndrome, whereas patients that underwent treatment with either PCI or CABG had less late MI (all $p < 0.05$).
Conclusion: Among consecutive diabetic patients with MVD, at a median of 6-years CABG was associated with better survival and fewer non-fatal MI outcomes compared to PCI.

1. Introduction

Among patients with diabetes mellitus (DM), Coronary Heart Disease (CHD) is the leading cause of death and morbidity, and myocardial revascularization procedures have been shown to be beneficial in relieving symptoms, and in selected patients, improve survival [1]. Both coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) improve outcomes when performed early in patients with acute coronary syndromes (ACS) [2]. In addition, these procedures are recommended in patients with stable CHD and multi-vessel disease (MVD), particularly with significant proximal left anterior descending (LAD) stenosis [3,4]. Increased survival following CABG compared to PCI has been reported in diabetic patients with MVD [5–7]. Post-hoc analyses of the Bypass Angioplasty Revascularization Investigation (BARI) trial found patients with DM had lower mortality when randomised to CABG compared to balloon angioplasty [8]. Over a decade later, in the Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multi-vessel Disease (FREEDOM) trial, late mortality was lower among 899 patients randomized CABG compared to that in 902 undergoing PCI with drug eluting stents (DES) [5]. Also in BARI-2D trial sub-group analyses, patients treated with CABG surgery had less major cardiovascular events compared to patients treated with PCI [9]. A subsequent meta-analysis found CABG is superior to PCI in patients with DM and MVD with respect to cardiovascular outcomes [10–12].

Due to exclusion criteria [5,13], which meant only a minority screened, patients with diabetes were randomized in the FREEDOM

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https://doi.org/10.1016/j.ijcard.2019.07.038
0167-5273/

trial, we studied the late outcomes of all DM patients with MVD identified on angiography during the recruitment period for the FREEDOM trial at our hospital.

2. Methods

The study cohort included consecutive diabetic MVD patients who had angiographic screening for the FREEDOM trial, from June 2006 to March 2010 inclusive at Liverpool Hospital, Sydney, Australia (e-component). This project (QA 09/046) was approved by the South West Sydney Local Health District Human Research Ethics Committee. Patients with diabetes were classified as meeting, or not meeting, eligibility criteria for FREEDOM [5], on angiographic and/or clinical grounds. Of note, MVD was angiographically defined in FREEDOM as a proximal stenosis of ≥70% in ≥2 of 3 major arteries; LAD, Left circumflex (LCx), and right coronary artery (RCA) proximal to the crux. All patients had Synergy between PCI with Taxus and Cardiac Surgery (SYNTAX) scores calculated including those post-CABG, if they had pre-CABG angiograms available for analyses [13]. The FREEDOM trial excluded patients with prior CABG, those with ≥50% left main stenosis (LMS) and chronic total occlusions (CTO) with a low likelihood of PCI success. Also, clinical exclusions were severe co-morbidities (with life expectancy <5 years), a recent myocardial infarction (MI) with elevated CKMB levels, including ST-elevation (STEMI) within 72 h, PCI with stent implantation within 6 months, heart failure or disabling stroke, or a planned concomitant procedure such as valve repair or replacement [13].

In our cohort, the revascularization strategy usually involved 'heart team' discussions with interventional and attending cardiologists, and cardiac surgeons, and consideration of patients' preferences, including the suitability or appropriateness of undertaking a revascularization procedure. Techniques used in CABG and PCI were at the proceduralists' discretion, though the use of drug eluting stents (DES), except for the patients randomized in FREEDOM, was based on our institution's selective use criteria as previously described [14]. A patient in whom neither PCI nor CABG was performed within 1 year were classified as receiving medical therapy alone. Patients were recommended to receive aspirin and clopidogrel for at least 1 year, aspirin indefinitely, statins to achieve an LDL cholesterol of <1.8 mmol/L, diabetic medications to achieve an HBA1c <7%, and anti-hypertensives including ACE Inhibitors to achieve a BP <130/85 mmHg [11,14].

Baseline characteristics of patients were obtained from pre-existing departmental electronic and hospital databases. Follow-up information was obtained from reviewing hospital electronic records, from their referring cardiologists or primary care physicians, or from direct patient contact. The clinical outcomes were all-cause mortality and non-fatal MI and stroke; a composite endpoint of death/MI/stroke. Myocardial infarction was defined according to the definition in the Arterial Revascularization Therapy Study (ARTS) [7]. Stroke was defined as a focal neurologic deficit lasting ˃24 h and with imaging evidence of cerebral infarction or haemorrhage. Hypertension was defined as receiving antihypertensive treatment or blood pressure ˃130/85 mmHg, hypercholesterolaemia was defined as receiving lipid-lowering treatment or total cholesterol level ˃4.0 mmol/L.

Data was expressed as mean and standard deviations or for continuous variables that were not normally distributed, as median and inter-quartile range [IQR]. All analyses were performed using Statistical Package for Social Sciences, version 24 (SPSS Inc., Chicago, Illinois). All statistical tests were 2-tailed and *p*-values <0.05 were considered statistically significant. Odds ratio and 95% confidence interval were calculated for comparisons of categorical variables between groups. Univariate analyses included baseline clinical and angiographic features. From the study cohort, only patients who had complete key data fields and 1-year follow-up were included in the multivariable analyses (23 patients did not have 1 year follow-up, and 10 did not have a revascularization date). Cox regression modelling was used for the multivariable analyses, and Kaplan-Meier analyses using log-rank testing was used to compare between group differences. Variables included were: categorical age, gender, hypertension, hypercholesterolaemia, triple vessel disease, prior MI and CABG, LMS ≥50% and clinical presentation (ACS compared to stable CHD). Propensity analyses were also performed to assess whether outcome differences could be explained by differences in baseline characteristics [15] between those undergoing CABG and PCI. Pairs of treated and untreated subjects were matched using 1:1 greedy matching using a caliper width of 0.15 of the standard deviation of the logit of the propensity score; 82 (68%) of the 121 subjects undergoing CABG with complete data were matched to a subject undergoing PCI with a similar propensity score. Variables included in the propensity score were: age, gender, hypertension, hyper-cholesterolaemia, prior MI, prior CABG, clinical presentation (stable CHD vs unstable Angina vs NSTEMI vs STEMI), LMS > 50%, Triple-Vessel disease and SYNTAX score. Systematic differences between treated and untreated subjects in the original sample were substantially reduced or eliminated in the matched sample. The absolute standardized differences for the 12 baseline covariates ranged from a low of 0.01 to a high of 0.11 compared to 0.00 to 0.71 prior to matching.

3. Results

Of 1263 diabetic patients who underwent angiographic screening, 430 had MVD (e-component). Of patients with MVD, 192 (45%) were considered eligible for FREEDOM of whom 25 (13%) were randomized, and 238 (55%) were FREEDOM-ineligible; baseline clinical and angiographic characteristics are shown in Table 1. Among the 238 ineligible patients 139 (58%) had prior CABG, of whom 85% had at least one of these 3 angiographic exclusions (43 (18%) had ≥50% LMS and 22 (9%) had ≥1 unsuitable CTOs). Of all 430 patients with MVD, 127 (30%) underwent CABG at median 4 months [interquartile range: 1.3–5.6], 196 (45%) underwent PCI median of 2 months [interquartile range 0.1–3.4], and 107 (25%) had 'medical treatment' (did not undergo either procedure); (e-component). Patients who underwent CABG were 4 years younger (P = 0:001), whereas those who had prior CABG more frequently did not undergo revascularization (p < 0.001). Of those with no revascularization, 80 had no suitable revascularization targets, or 27 had at least 1 lesion that was amendable for PCI (defined as >70% stenosis), such as branches too small for PCI, or a CTO of RCA or LCx arteries or branches and had patent left internal mammary graft (LIMA). There was no difference in mortality between patients with potentially revascularizable arteries and those without. Of the 139 patients who had prior CABG, 114 patients had a LIMA graft of whom 107 had patent LIMAs; there were no patency associated differences in mortality.

For all 430 diabetic patients with MVD, at a median of 6 years [interquartile range 4.2–7.0] all- cause mortality was 25%, 23% for FREEDOM eligible and 26% FREEDOM ineligible patients; p = 0.45 (Table 2). Among patients' who underwent CABG, mortality was 16%, compared with 26% for those post-PCI and 33% for those who had no revascularization (p = 0.009). Kaplan-Meier unadjusted survival curves according to revascularization procedures for all-cause mortality, non- fatal MI and the composite of death/MI/stroke showed patient survival began to diverge after 5 years (Fig. 1). Patients treated by CABG had the lowest rate of non-fatal MI as compared to the other treatment approaches (p = 0.016). Also, patients undergoing CABG were associated with having the lowest rate of death/MI/stroke composite (p < 0.001). 24.57% for ACS and 24.74% for Stable CHD.

On multivariable analyses (Table 3), factors associated with increased late mortality were older age, hypertension and not undergoing CABG (all p < 0.05). Factors associated with high rates of late MI were, a presentation with an ACS and triple vessel disease, whereas in patients that underwent either PCI or CABG had less late MI (all p < 0.05). Factors associated with late composite outcome of death, MI or stroke were presented with an ACS, triple vessel disease, LMS ≥50% and patients that had no revascularization procedures (all p < 0.05). Additional analyses of patients undergoing PCI or CABG were performed (Fig. 1), and log-rank p-values for survival were 0.020, for non-fatal MI were 0.021 and for the composite of death MI and stroke 0.003.

Additional propensity analyses of patients undergoing PCI or CABG were performed. Patients treated by PCI had higher rates of mortality (HR 1.94; 95% CI, 1.02–3.70, p = 0.045), MI (HR 2.87; 95% CI,1.12–7.31, p = 0.028) and the composite of death/non-fatal MI/stroke (HR 1.80; 95% CI, 1.11–2.92, p = 0.017). The multivariable Cox regression was repeated on the matched sample, and found that patients treated by PCI had higher rates of mortality (HR 2.27; 95% CI, 1.08–4.77, p = 0.03), MI (HR 3.35; 95% CI,1.06–10.6, p = 0.04) and the composite of death/non-fatal MI/stroke (HR 2.11; 95% CI, 1.19–3.73, p = 0.011).

4. Discussion

In this study, we found that among consecutive diabetic patients with MVD, those who underwent CABG as advised by their clinicians lived longer and had less MIs, even after multivariable adjustment for baseline characteristics including age. Also, overall mortality at 6 years was 25.4%, or 4.2% per year, which was ¬50% higher per annum than those late follow-up of the randomized FREEDOM trial recently reported an annual mortality of ~2.7% [16]. Our unselected cohort appears to have reduced survival, which is a common finding when outcomes of patients in clinical trials are compared to those in 'reference' patient populations from which they were recruited.

Table 1
Baseline clinical and angiographic characteristics.

Baseline characteristics	Overall (n = 430)	FREEDOM eligible (n = 192)[a]	FREEDOM ineligible (n = 238)	P value	MT (n = 107)	PCI (n = 196)	CABG (n = 127)	P value
Age		66 [58–73]	66 [61–73]	0.205	69 [62–75]	67 [59–74]	63 [58–70]	0.001
Male Gender	310(72%)	127(66%)	183(77%)	0.014	80(75%)	137(70%)	93(73%)	0.628
Hypertension[b]	380(88%)	172(90%)	208(87%)	0.482	89(83%)	176(90%)	115(91%)	0.151
Hypercholesterolaemia[c]	335(78%)	152(79%)	183(77%)	0.572	78(73%)	164(84%)	93(73%)	0.031
Prior MI	210(49%)	98(51%)	112(47%)	0.411	49(46%)	89(45%)	72(57%)	0.108
Prior CABG	139(32%)	0(0%)	139(58%)	<0.001	76(71%)	59(30%)	4(3%)	<0.001
Stable CHD	194(45%)	92(48%)	102(43%)	0.710	50(47%)	89(45%)	55(43%)	0.154
Unstable Angina	89(21%)	36(19%)	53(22%)		22(21%)	44(22%)	23(18%)	
NSTEMI	118(27%)	52(28%)	66(27%)		31(29%)	44(22%)	43(34%)	
STEMI	29(7%)	12(6%)	17(7%)		4(4%)	19(10%)	6(5%)	
LMS ≥ 50%	79(18%)	0(0%)	79(33%)	<0.001	22(21%)	22(11%)	35(28%)	0.001
Triple-Vessel Disease	210(49%)	81(42%)	129(54%)	0.013	49(46%)	83(42%)	78(61%)	0.003
Syntax Score	41 [20–53]	44 [36–53]	40 [17–53][d]	0.003	36 [14–50]	40 [25–51]	50 [38–56]	<0.001

Data presented as mean or number (%).MI: Myocardial Infarction; CABG: Coronary Artery Bypass Graft; CHD = Coronary Heart Disease; NSTEMI: Non-ST Elevated Myocardial Infarction; STEMI: ST Elevated Myocardial Infarction; Revasc: Revascularization; LMS = Left Main Stenosis.
[a] Patients were deemed FREEDOM eligible if they met clinical and angiographic criteria (though CKMB may have been elevated at angiography).
[b] Hypertension defined as arterial pressure ≥ 130/85 mmHg or on antihypertensive treatment.
[c] Hypercholesterolaemia defined as total cholesterol level ≥ 4.0 mmol/L or on lipid- lowering treatment.
[d] Data presented for patients with prior CABG (N = 139/238). SS was 12 [7–18] on 55 patients who had available pre-CABG angiography, using a non-validated CABG syntax score (CSS) method [19].

Interestingly, there are several differences in characteristics between FREEDOM-eligible and FREEDOM-ineligible patients, including ~1/3 of all diabetic with MVD in our unselected cohort had prior CABG, which represented ~60% of those who were FREEDOM-ineligible. Secondly, patients undergoing CABG were 4 years younger than those who had PCI, and while we adjusted for baseline characteristics including age and prior CABG, treatment CABG was still associated with a lower death rate. Also, the SYNTAX trial registry reported that patients undergoing PCI were ~5 years older than those who had CABG [17]. Notwithstanding age differences in these non- randomized cohorts, many randomized trials such as FREEDOM trial, Coronary Artery Revascularization in Diabetes (CARDIA) and ARTS I & II Trial have reported that CABG was associated with increased survival, further supporting CABG as the preferred treatment for diabetic patients with MVD [5–7].

Survival rates were similar among those who underwent PCI and medical therapy alone consistent with the findings to the BARI 2D trial [9]. However, we found that diabetic patients with MVD receiving PCI had a significantly lower rate of non-fatal MI compared to those not undergoing revascularization and MI has an attributable risk for late mortality. This is consistent with the recently reported cohort studies of revascularization among similar patients from British Columbia, Canada [18]. Our survival curves appear to be diverging after 5 years, though there was a median 4 year age difference in the PCI, compared to CABG cohorts. Similar findings have been recently reported among patients who had late follow up (median 8 years) from the FREEDOM randomized trial. Those patients with prior CABG were lower rates of MI than in patients who did not have prior CABG. This could be due to LIMA grafts remaining free of atherosclerosis, as well as lifestyle modification [19].

The FREEDOM trial recommend complete revascularization, or at least the likelihood of revascularization equipoise between PCI and CABG [13], for patients to be suitable for randomization. We did not examine completeness of revascularization which can influence late outcomes [20]. In contrast there was higher rates of non-fatal MI in the patients who had ACS as the angiographic indication, compared to those with stable CHD. Vulnerable coronary plaques are often associated with mild stenoses [16], and frequently are not detected unless intra-coronary imaging is performed; in contrast to stable stenotic plaques readily detectable on coronary angiography [21,22]. As, both CABG and PCI were associated with lower MI rates than no revascularization, and as MIs have an attributable risk for late mortality, trial(s) examining late outcomes after revascularization in ACS patients with DM are warranted. Of note the timing of performance of PCI was earlier post-presentation than CABG and this may have contributed to differences reported here, and if in post-ACS patients CABG was performed, earlier findings may have been different [23].

Our study has other limitations. Firstly, in our diabetic cohort, ~12% had PCI with bare metal stents which may have been preferred over first generation DES due to compliance issues, co- morbidities or large coronary artery diameter. Secondly, while multivariable analyses cannot adjust for all potential confounders, and though our findings are broadly congruent with trials of diabetic patients with MVD [9], the differences in patient characteristics among those undergoing PCI and CABG may not have been fully accounted for. These include physician-directed performance of revascularization procedures, or not. Unfortunately, ejection fraction was not always available and so indices of ventricular fraction could not be included in multivariable analyses. We did not determine reasons why only 13% of FREEDOM-eligible patients were randomized, despite translating consent forms into the major 4 non-English languages in our multicultural area of South West Sydney, Australia, though patients with a non-English speaking background disproportionately represented in among these patients (91/192). Also, FREEDOM randomization required the CKMB level to not be elevated at the time of randomization, and an ACS presentation

Table 2
Late clinical outcomes.

Characteristics	Overall (n = 430)	FREEDOM eligible (n = 192)	FREEDOM ineligible (n = 238)	P-value	No revascularization (n = 107)	PCI (n = 196)	CABG (n = 127)	P-value
All-cause death	106(25%)	44(23%)	62(26%)	0.454	35(33%)	51(26%)	20(16%)	0.009
Non-fatal MI	54(13%)	19(10%)	35(15%)	0.135	20(19%)	26(13%)	8(6%)	0.016
Stroke	19(4%)	6(3%)	13(6%)	0.241	5(5%)	8(4%)	6(5%)	0.953
Death/Non-fatal MI/Stroke	175(41%)	69(36%)	106(45%)	0.071	58(54%)	83(42%)	34(27%)	<0.001

MI: Myocardial Infarction; PCI = Percutaneous Coronary Intervention; CABG = Coronary Artery Bypass Graft ≠ Patients were deemed FREEDOM eligible if they met clinical and angiographic criteria (though CKMB may have been elevated at angiography).

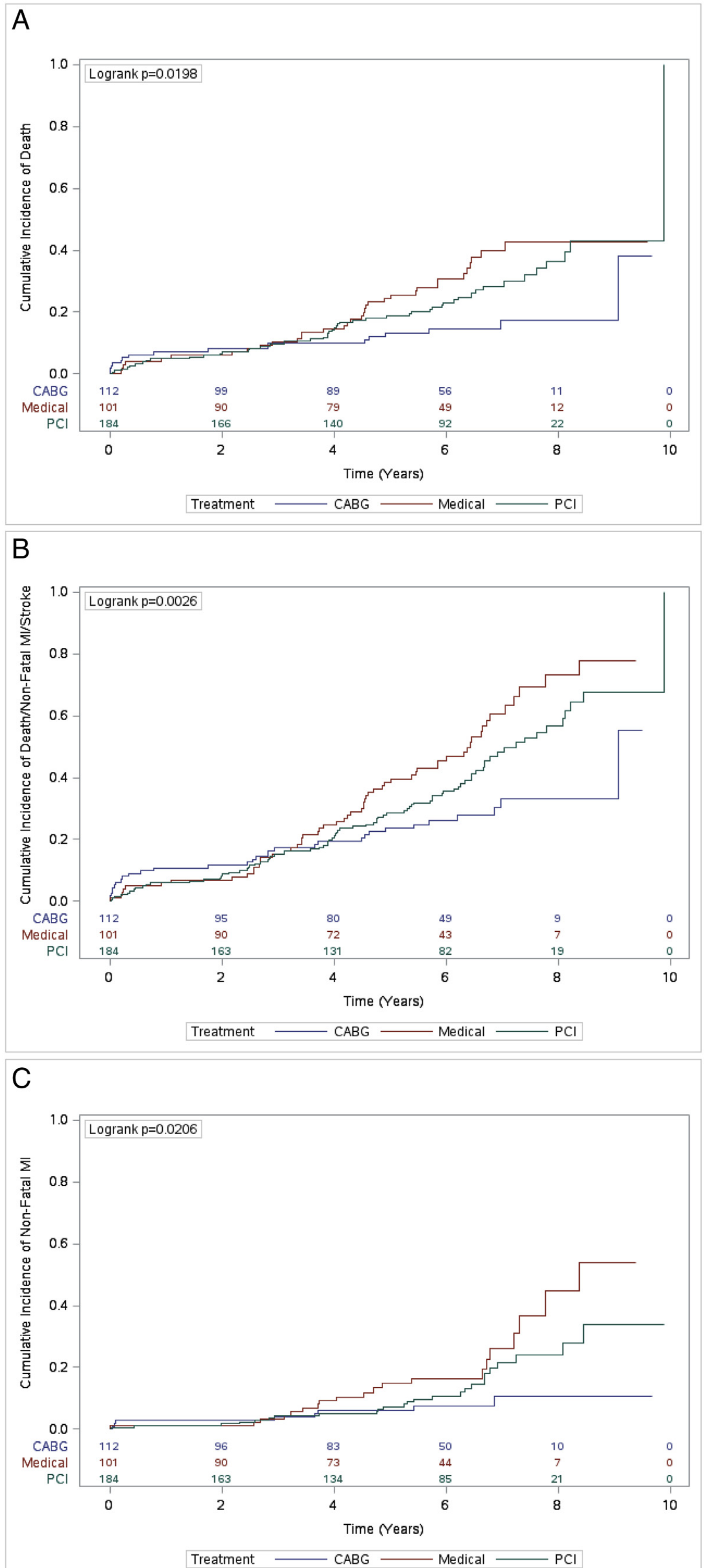

Fig. 1. Kaplan-Meier unadjusted late survival Kaplan-Meier curves in cohort patients according to treatment coronary bypass grafting, percutaneous coronary intervention or medical therapy. Patients were excluded due to missing information such as missing date of treatment (n = 9) or follow-up <1 year (n = 21), thus a total of 400 patients were in these analyses. Cumulative incidences of (A) All-causes of death, (B) composite of death, (C) Non- fatal myocardial infarction (MI), MI and stroke. P values were calculated using log-rank test.

Table 3
Adjusted hazard ratios.

	Death				Non-fatal MI				Composite of death/non-fatal MI/stroke			
	P-value	HR	95.0% CI		P-value	HR	95% CI		P-value	HR	95.0% CI	
			Lower	Upper			Lower	Upper			Lower	Upper
Age (Compared to < 55):												
<55												
55–64	0.620	1.247	0.521	2.983	0.451	1.368	0.606	3.088	0.461	1.231	0.709	2.137
65–74	0.086	2.063	0.903	4.713	0.081	0.405	0.146	1.117	0.613	1.153	0.664	2.005
>75	0.018	2.821	1.195	6.662	0.893	0.935	0.353	2.478	0.046	1.803	1.010	3.219
Male gender	0.303	0.798	0.518	1.227	0.883	1.051	0.542	2.037	0.396	0.863	0.614	1.213
Hypertension	0.002	2.550	1.423	4.568	0.082	0.156	0.019	1.264	0.065	1.606	0.971	2.656
Cholesterolaemia	0.104	1.564	0.913	2.679	0.963	0.979	0.404	2.376	0.457	1.179	0.764	1.820
Triple vessel disease	0.207	1.308	0.862	1.983	0.020	1.977	1.113	3.511	0.010	1.522	1.104	2.096
Prior MI	0.096	0.689	0.445	1.068	0.915	1.033	0.566	1.885	0.224	0.814	0.584	1.134
Prior CABG	0.377	0.788	0.465	1.336	0.078	0.490	0.221	1.082	0.104	0.708	0.467	1.074
LMS ≥50%	0.120	1.528	0.895	2.609	0.053	2.157	0.990	4.700	0.029	1.594	1.049	2.423
ACS (vs. stable CHD)	0.507	1.150	0.761	1.737	0.018	2.068	1.134	3.774	0.009	1.531	1.113	2.106

MI = Myocardial Infarction; PCI = Percutaneous Coronary Intervention; CABG = Coronary Artery Bypass Graft; LMS = Left main Stenosis; ACS = Acute Coronary Syndrome; CHD = Coronary Heart Disease.

occurred in 100/192 otherwise FREEDOM-eligible patients; adhoc PCI may have been performed for logistic reasons. There were no significant differences in patients who did not have revascularization targets compared among those who had revascularization targets. Finally, there was a low frequency of non-fatal stroke patients which limits the analyses of this clinical outcome.

In summary our cohort of unselected patients with type 2 diabetes and MVD, with long term follow up, overall mortality was ¬50% higher than those in the FREEDOM trial suggesting our patients were at higher risks. We also found improved survival and less non-fatal MI associated with CABG compared to PCI. PCI was associated with fewer non-fatal MI and increased survival compared to no revascularization.

Declaration of Competing Interest

There are no conflicts of interest to disclose.

Acknowledgments

We thank the staff of the cardiology department, cardiologists and general practitioners who kindly provided follow-up information on their patients. We would also like to thank Dr. Khatijah Binti Ahamed Mustafa for her helpful suggestions.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2019.07.038.

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