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Comparison of Percutaneous Coronary Intervention with Drug Eluting Stents Versus Coronary Artery Bypass Grafting in Patients With Multivessel Coronary Artery Disease: Meta-Analysis of Six Randomized Controlled Trials

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Abstract

Objective—Comparing outcomes of percutaneous coronary intervention (PCI) with drug eluting stent (DES) and Coronary Artery Bypass Grafting (CABG) in patients with multivessel Coronary Artery Disease (CAD) using data from randomized controlled trials (RCT).

Background—PCI and CABG are established strategies for coronary revascularization in the setting of ischemic heart disease. Multiple RCT have compared outcomes of the two modalities in patients with multivessel CAD.

Methods—We did a meta-analysis from six RCT in the contemporary era comparing the effectiveness of PCI with DES to at 1 year, 2 years and 5 years respectively.

Results—Compared to CABG, at one year PCI was associated with a significantly higher incidence of TVR (RR= 2.31; 95% CI: [1.80–2.96]; $P<0.0001$), lower incidence of stroke (RR= 0.35; 95% CI: [0.19–0.62]; $P=0.0003$), and no difference in death (RR= 1.02; 95% CI: [0.77–1.36]; $P=0.88$) or MI (RR= 1.16; 95% CI: [0.72–1.88]; $P=0.53$). At 5 years, PCI was associated with a higher incidence of death (RR= 1.3; 95% CI: [1.10 – 1.54]; $P=0.0026$) and MI (RR= 2.21; 95% CI: [1.75–2.79]; $P<0.0001$). While the higher incidence of MI with PCI was noticed in both diabetic and non-diabetics, death was increased mainly in diabetic patients.

Conclusion—In patients with multi-vessel CAD, PCI with DES is associated with no significant difference in death or MI at 1 or 2 years. However at 5 years, PCI is associated with higher incidence of death and MI.

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Conflict of interest:

We declare that we have no conflicts of interest.

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Keywords

Percutaneous coronary intervention; Coronary Artery Bypass Grafting; Drug Eluting Stents; Randomized Control Trials; Meta-Analysis

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Introduction

Percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) are established strategies for coronary revascularization in the setting of ischemic heart disease. Although CABG was the standard of care for patients with multivessel disease, the improvement of interventional techniques, the introduction of bare metal stents (BMS) and later drug eluting stents (DES) led to increased use of PCI in managing patients with multivessel disease. Several randomized controlled trials (RCTs) compared the two strategies in the plain old balloon angioplasty (POBA) era,^{1–6} the BMS era,^{7–10} and the contemporary DES era.^{11–16}

While data in the DES era comes from RCT comparing DES vs. CABG are consistent in reporting increase incidence of Major cardiac and cerebral Events (MACCE) especially in diabetic patients among all trials, that is not the case for long-term data on the incidence of death, MI and stroke at 5 years. As while SYNTAX showed a non-significant difference in the composite of death/MI/stroke between the two strategies at 5 years in both diabetic and non-diabetic groups, FREEDOM showed a higher incidence of this composite in diabetic patients treated with PCI.

Using meta-analysis to pool data from multiple RCTs provides a more precise assessment of the effects of treatment, and also increases the number of patients within clinical subgroups of interest, often providing adequate statistical power to evaluate outcomes in these subgroups.¹⁷ The only meta-analysis of data exclusively derived from RCTs comparing PCI and CABG in stable ischemic heart disease included only patients from either the pre DES, or those from the left main subgroup or combined diabetes subgroup from the BMS with those in the DES era.^{17–19} Data from the pre DES meta-analysis contributed important comparisons of mortality rates resulting from the two strategies; but did not provide information on other important outcomes including myocardial infarction (MI), target vessel revascularization (TVR) and stroke. These data also did not include patients managed with DES, and thus are not representative of contemporary percutaneous management of multivessel disease.

This study reports results from a meta-analysis of six RCTs evaluating outcomes in patients receiving PCI with DES versus CABG in the contemporary era.

Methods

Relevant studies were identified through electronic searches of MEDLINE and the Cochrane Central Register of Controlled Trials databases from 01/01/2003 to 05/31/2013. The start date was defined as 01/01/2003 as the FDA approved DES use in 2003.²⁰ The search strategy used the terms “percutaneous coronary intervention,” “stent(s),” “drug-eluting

stent,” “sirolimus-eluting stent,” or “paclitaxel-eluting stent,” paired with “coronary artery bypass graft.” In addition, we searched bibliographies of relevant studies, reviews, editorials, letters, and meeting abstracts. The analysis was restricted to include only prospective RCTs or pre-specified sub-analyses from RCTs that randomized patients to PCI with DES versus CABG; and reported both safety and efficacy outcomes. The quality of the identified studies was assessed with respect to control for confounders, measurement of exposure, completeness of follow-up, and blinding. We followed a coring system based on a check list derived from recommended criteria recommended by the QUOROM (The Quality of Reporting of Meta-analyses) and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines to assess the quality of the trials used in this meta-analysis.^{21,22}

Two reviewers (ZF and WZ) independently extracted data from the list of included studies. Extracted data included authorship, study period, publication year, study design, study region, baseline characteristics of patients, sample size, clinical events, and duration of follow-up. The following outcomes were extracted: all-cause death, myocardial infarction [MI], stroke [cerebrovascular accident (CVA)], and target vessel revascularization [TVR]. Major cardiac and cerebral Events (MACCE) data were excluded as they were reported differently by each trial.

A random effects model meta-analysis following the DerSimonian-Laird method was used to determine relative risks for the PCI and CABG groups for each endpoint.²³ This method treats study affiliation as a random effect and considers both the within-study variance and the between-study variance. Heterogeneity (inconsistency of results among studies) was assessed using the DerSimonian-Laird I² statistic, which calculates the proportion of between-study variability that cannot be attributed to sampling variation.²⁴ All meta-analyses were conducted with R statistical software for Windows with the package meta (R Foundation for Statistical Computing, Vienna, Austria).

Results

The initial search identified 123 potential articles. Of these, 6 were RCTs that included patient treated with DES.^{11–16} Five of the 6 trials included only DES patients in the PCI arm.^{11–14,16} One trial included both BMS and DES but reported separate comparisons of DES to CABG for the two groups.¹⁵ Outcomes at one year were reported by all 6 trials.^{11–16} Four of the six trials reported 2-year outcomes,^{11–14} and 3 trials reported 5-year outcomes.^{12,25,26} Table-1 shows the patients characteristics of each of these RCT. The six trials included 1-year outcomes for 5123 patients. Longer-term follow-up reports displayed some discrepancy in reporting between different trials, so a cohort of 4498 patients from four trials was used to compare outcomes at 1 and 2 years.^{11–14} Another cohort of 4202 patients from three trials was used to compare outcomes at 1 and 5 years.^{12,25,26} Table-2 shows the patients characteristics of these 3 cohorts.

1-Year Cohort Results

Outcomes for all clinical endpoints at one year appear in Figure-1. There were no significant differences in death (3.7% vs. 3.6%; RR= 1.02; 95% CI: [0.77 – 1.36]; P= 0.88) or MI

(4.5% vs. 3.3%; RR= 1.16; 95% CI: [0.72 – 1.88]; P= 0.53). PCI was associated with a significantly higher incidence of TVR (11.6% vs. 4.8%; RR= 2.31; 95% CI: [1.80 – 2.96]; P=<0.0001) and a significantly lower incidence of stroke (0.55% vs. 1.9%; RR= 0.35; 95% CI: [0.19 – 0.62]; P=0.0003).

2-Year Cohort Results

The results at 1 year in this cohort were not significantly different from 1 year data reported from all 6 trials. At 2 years (Figure-2) there was no significant difference in either death (6.5% vs. 5.2%; RR= 1.31; 95% CI: [0.83 – 2.08]; P= 0.25) or MI (5.6% vs. 4 %; RR= 1.21; 95% CI: [0.70 – 2.11]; P= 0.5). PCI also remained associated with a significantly lower incidence of stroke (1.3% vs. 2.3%; RR= 0.55; 95% CI: [0.35 – 0.87]; P=0.01).

5-Year Cohort Results

As noted in Table-1, this cohort differed from the full six-study cohort in the following ways: 1) the majority (96.5%) but not all patients undergoing PCI received DES. 2) this group had a higher prevalence of diabetes than either of the other cohorts (67.9 % vs. 63.2% and 61% in the 1 and 2 year cohorts respectively). At 1 year, there was no difference in death (3.8% vs. 3.6%; RR= 1.05; 95% CI: [0.77 – 1.44]; P= 0.75), but there was a higher incidence of MI (5.6% vs. 3.4%; RR= 1.56; 95% CI: [1.16 – 2.09]; P= 0.003), and a lower incidence of stroke (0.7% vs. 2.1%; RR= 0.34; 95% CI: [0.18 – 0.64]; P= 0.005). However at 5 years in this cohort (Figure-3), PCI was associated with a significant increase in both death (13% vs. 10%; RR= 1.3; 95% CI: [1.10 – 1.54]; P=0.003) and MI (10.3% vs. 4.6%; RR= 2.21; 95% CI: [1.75 – 2.79]; P= <0.0001). PCI remained associated with a significantly lower incidence of stroke (2.3% vs. 3.8%; RR= 0.6; 95% CI: [0.42 – 0.86]; P=0.005).

PCI vs. CABG in Diabetics vs. Non Diabetics in the 5 years Cohort

Comparing the 5 years results of diabetics vs. non-diabetics in this cohort showed quite a difference. At 1 year there was no difference in death (4.11% vs. 4.16%; RR= 0.97; 95% CI: [0.68 – 1.38]; P= 0.8497), MI (5.98% vs. 3.74%; RR= 1.27; 95% CI: [0.75 – 2.15]; 0.3714), but PCI was associated with a lower incidence of stroke (0.76% vs. 2.05%; RR= 0.40; 95% CI: [0.19 – 0.81]; P= 0.0118). However at 5 years (Figure-4) PCI was associated with a significantly increased incidence of death (13.56% vs. 9.96%; RR= 1.36; 95% CI: [1.11 – 1.66]; P=0.0033) and MI (10.2% vs. 5.3%; RR= 2.01; 95% CI: [1.54 – 2.62]; P <0.0001). PCI was still associated with a significantly lower incidence of stroke (2.36% vs. 4.03%; RR= 0.59; 95% CI: [0.39 – 0.89]; P=0.013).

The results of the non-diabetic subgroup of this cohort were reported by the SYNTAX investigators.^{27,28} At 1 year there was no difference in death (2.6 vs. 1.6 %; RR= 1.65; 95% CI: [0.76–3.58]; P= 0.20) or MI (4.8% vs. 2.9%; RR= 1.64; 95% CI: [0.94–2.86]; 0.08), but a lower incidence of stroke with PCI (0.5% vs. 2.2%; RR= 0.21; 95% CI: [0.06–0.72]; P= 0.006). However at 5 years, although PCI was associated with a significantly higher incidence of MI (9.9% vs. 3.4%; P < 0.001), PCI was associated with no significant difference in the incidence of death (12.0% vs. 10.9%; P = 0.48) and stroke (2.2% vs. 3.5%; P = 0.15).

Discussion

In this meta-analysis of RCTs comparing outcomes following PCI or CABG in patients with multivessel disease, PCI was non-inferior to CABG at 1 and 2 years for the outcomes of death and MI. At 5 years PCI was associated with higher incident of death and MI. PCI was consistently associated with lower incidence of stroke and a higher incidence of TVR.

This meta-analysis points out differences between PCI with DES and CABG in the clinically important outcomes of death, MI and stroke. While both the individual trials and the meta-analysis revealed that TVR was higher with PCI than with CABG, most clinicians and patients would accept that risk, as they consider TVR a less significant adverse outcome than death, MI or stroke. Some clinicians would group TVR with numerous other secondary adverse outcomes such as bleeding, renal injury, or atrial fibrillation.¹⁸ Data on risk of death, MI and stroke will clearly play a larger role in assessing treatment options for multivessel coronary artery disease.

Although both SYNTAX and CABG reported a higher incidence of MACCE at 5 years, data about the incidence of death, MI and stroke at 5 years was not consistent between these 2 studies even in the diabetic subgroup. In SYNTAX at 5 years there was no significant difference reported at 5 years in any of the individual outcomes of death, MI, or stroke between PCI and CABG in either the diabetic or non-diabetics subgroups.²⁸ On the other hand, in FREEDOM trial PCI was associated with higher incidence of death and MI with a lower incidence of stroke when compared to CABG.¹²

In a previous meta-analysis of RCTs comparing PCI and CABG in the pre-DES era that involved 10 trials (6 with POBA and 4 with BMS) over a median follow-up of 5.9 years, there was no difference in mortality (16% vs. 15%; hazard ratio [HR] 0.91, 95% CI: [0.82–1.02]; $p=0.12$).¹⁷ However the results of this meta-analysis do not reflect contemporary treatment as many of these patients were treated either with BOPA (67%) or BMS (37%), and CABG exhibited a lower use of internal mammary artery grafts (83%). In addition, the studies included in the earlier meta-analysis represented a much lower risk patient group than that seen in our study. For example, only 17% of the patients in the earlier meta-analysis had diabetes as compared to 25% and 32%, in SYNTAX¹¹ and PRECOMBAT¹³ respectively. Optimal medical therapy of CAD has also evolved substantially since completion of the studies included in the earlier meta-analysis, potentially impacting the outcomes of patients and making the old meta-analysis less relevant to the contemporary era.

The single meta-analysis from the contemporary era reported only 1-year data on patients with left main disease included in four RCTs.¹⁸ The data from this meta-analysis were consistent with the 1-year results from our meta-analysis, reporting that PCI was associated with a non-significant difference in death or MI, higher incidence of TVR and a lower rate of stroke.

The mortality data reported after 1 and 5 years in our analysis are similar to those reported from the contemporary real world data reported by ASCERT study.²⁹ ASCERT showed that although there was no difference in mortality between PCI and CABG at 1 year, there

was a significant difference in favor of CABG at 4 years (16.4% vs. 20.8%; RR= 0.76; 95% CI, 0.75 to 0.78). This mortality difference was noted as early as 2 years (8.7% vs. 11.2%; RR= 0.78; 95% CI, 0.76 to 0.80), however all patient in the ASCERT database were older than 65 years which is above the average age in our population. However, despite the consistency of these results with the present analysis, relying on data from observational registries can lead to incorrect conclusions resulting from unassessed confounding variables.¹⁸ Our meta-analysis provides short, intermediate and long-term data on large patient cohorts built from recent RCTs. Using data exclusively from recent RCTs allows our findings to be applied to assessing treatment choices under a contemporary standard of care.

Multiple clinical trials and meta-analysis showed that the higher incidence of death and MI in diabetic patients with PCI when compared to CABG without identifying the pathophysiology behind it. Several assumptions has been made to explain this, some has attribute the effect to the use of the left internal thoracic artery (LIMA) that offer long-term durability and mortality benefit. Others presumed that this difference to the association of CABG with more complete revascularisation that bypass several atherosclerotic or vulnerable plaques, providing coronary protection against progressive proximal coronary stenosis. This impact might be vital in diabetic patients with more progressive and diffuse coronary disease.¹⁹ On the other hand, the increase risk of stroke in CABG can be explained by the association of cardiopulmonary bypass with increase risk of air embolism and atheroembolism especially in patients with signi cant aortic plaque burden. Therefore maneuver that avoid the use of cardiopulmonary bypass as off-bump bypass and/or decrease aortic manipulation may lead to lower postoperative stroke risk.³⁰

There are several limitations to our meta-analysis. First as with any other meta-analysis the results are affected by variation in study design, endpoint definitions, endpoint reporting and possible publication bias. Second, because of the different design and reporting by different trials, data from the four trials could not be followed consistently as one cohort over 5 years. We tried to minimize the last disadvantage by studying the outcomes of separately specified cohorts for the three outcome periods. Third, although we were able to define a 100% DES population for the 1-year and 2-years cohorts, we had to include a small percentage of BMS patients (3.55%) in the 5-year cohort. Fourth, we used published event rates for each trial as opposed to individual patient data. Access to individual patient data would have enabled further subgroup analyses and propensity analyses to account for differences in pre-procedural risk to minimize potential bias. Fifth, the DES used in these trials are first and second generation DES. There are no trials done so far on the third generation DES that is used more widely in the contemporary era. Finally, as we were limited by the different reporting of endpoints, we were unable to risk stratify the patient population we studied according to anatomical difference based on their SYNTAX score and/or number of vessels involved.

Conclusion

In patients with multivessel CAD, PCI was consistently associated with higher rates of TVR but with fewer CVAs compared with CABG. PCI with DES was associated with a non-significant difference in death and MI at one year. However, by 5 years, rates of death and

MI were significantly higher in the diabetic patients treated with PCI. In non-diabetic patients there was a higher incidence of MI, but not of death with PCI.

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A – Death

B – MI

C – TVR

D – Stroke

Figure 1.
1 year Cohort Results: PCI vs. CABG from 6 RCT trials.

A – Death

B – MI

C – Stroke

Figure 2.

2 year Cohort Results: PCI vs. CABG from 4 RCT4 trials.

A – Death

B – MI

C – Stroke

Figure 3.
5 years Cohort Results: PCI vs. CABG from 3 trials at 5 year.

A – Death

B – MI

C – Stroke

Figure 4.

5 years Diabetic Patients Cohort Results: PCI vs. CABG 3 trials at 5 year.

RCT of PCI with DES vs. CABG

Table 1

	SYNTAX ¹¹	FREEDOM ¹²	PRE-COMBAT ¹³	VA CARD ¹⁴	CARDIA ¹⁵	Boudriot et al ¹⁶
Population	General	Diabetics	Left Main	Diabetics	Diabetics	Left Main
Study Size	1800	1900	600	198	502	201
Diabetics	25%	100%	32%	100%	100%	36%
DES stent use	100%	100%	100%	100%	71%	100%
Primary outcome	Composite of death, MI, stroke and TVR at 12 months	Composite of death, MI, stroke at 2 years.	Composite of death, MI, stroke and TVR at 12 months	Composite of death and MI at 2 years	Composite of death, MI, stroke and TVR at 12 months	Freedom of death, MI and TVR at 12 months
Secondary outcomes	Death, MI, stroke and TVR	Composite of death, MI, stroke and TVR.	Death, MI, stroke and TVR	Death, MI, stroke and TVR	Death, MI, stroke and TVR	Death, MI and TVR
Primary outcome Results	MACCE at 12 months: Higher in the PCI group (17.8% vs. 12.4%; P = 0.002)	The primary outcome at 5 years: Higher in the PCI group (26.6% vs. 18.7%; P = 0.005.	MACCE at 12 months: Higher in the PCI group (8.7% vs. 6.7%; P=0.01)	Primary outcome at 2 years: Under-powered (HR: 0.89; 95% CI: 0.47–1.71)	Primary outcome at 1 year: No Difference (HR: 1.25, 95% CI: 0.75–2.09; P = 0.39)	Primary outcome at 1 year: Higher in the PCI group (19% vs. 13.9%; P = 0.19 for non-inferiority)
Revascularization rate	Higher in PCI group (13.5% vs. 5.9%, P<0.001)	Higher in PCI group (12.6% vs. 4.8%; P<0.001)	Higher in PCI group (9.0% vs. 4.2%; P=0.02)	Under-powered (HR: 0.93; 95% CI: 0.42–2.07)	Higher in PCI group (HR: 1.77, 95% CI: 1.11–2.82; P = 0.02)	Higher in PCI group (14% vs. 5.9%; non-inferiority P = 0.35)
Follow-up period	1, 2, 3, 4 and 5 years	1, 2 and 5 years	1 and 2 years	1 and 2 years	1 and 5 years	1 year
Inclusion Period	2006–2007	2005–2010	2004–2009	2006–2010	2002–2007	2003–2009
EuroSCORE	3.8±2.6	2.8±2.4	2.6±1.8	N/A	N/A	N/A
SYNTAX score	28.7±11.5	26.1±8.6	N/A	22.1 ±8.6	N/A	23.50 (14.8–29.0)

Table 2

Patients Characteristics

Patients Characteristics	1 year Cohort		2 years Cohort		5 years Cohort	
	PCI	CABG	PCI	CABG	PCI	CABG
Number of patients	2605	2587	2257	2241	2110	2092
Age	63.8±8.1	64.2±8.2	63.2±9.1	63.2±9.0	64.2 ± 9	63.9 ± 9
Male	1916 (73.6%)	1965 (76%)	1712 (75.9%)	1697 (75.7%)	1569 (74.4%)	1559 (75.5%)
Diabetes	1606 (61.7%)	1633 (63.3%)	1387 (61.5%)	1355 (60.5%)	1569 (74.4%)	1559 (75.5%)
Smoking	509 (19.6%)	550 (21.3%)	426 (18.9%)	457 (20.4%)	401 (19.0%)	441 (21.1%)
< 3 vessel disease	771 (29.7%)	766 (29.6%)	635 (28.1%)	622 (29%)	602 (28.5%)	596 (28.4%)
>3 vessel disease	1824 (70.3%)	1821 (70.4%)	1622 (71.9%)	1619 (71%)	1508 (71.5%)	1496 (71.6%)