Current Clinical Outcomes of Percutaneous Coronary Intervention and Coronary Artery Bypass Grafting

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Background. Randomized trials have compared coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI). However, results of these trials in select patients may not accurately reflect current clinical practice using drug-eluting stents (DES) and off-pump CABG. We undertook a prospective registry of coronary revascularization by CABG on-pump and off-pump, and PCI with or without DES, to determine clinical outcomes.

Methods. All patients undergoing isolated coronary revascularization in 8 community-based hospitals were enrolled. Preprocedural, intraprocedural, and postprocedural data were captured, with outcomes obtained at 18 months by patient and physician contact, and the Social Security Death Index.

Results. The study enrolled 4336 patients, 71.2% PCI and 28.8% CABG. DESs were used in 2249 PCIs (73.1%), and 596 CABG procedures (47.8%) were off-pump. Inci-

dence of major adverse cardiac events at 18 months was 14.7% for CABG vs 23.3% for PCI ($p < 0.001$). Cardiac death and myocardial infarction had similar rates. The need for repeat revascularization was significantly less with CABG (6.2% vs 13.6%, $p < 0.001$). Hazard ratio of CABG to PCI was 0.76 (95% confidence interval, 0.571 to 0.872). CABG outcome was similar on-pump and off-pump, as was repeat revascularization with DES (12.1%) vs BMS (14.9%; $p = 0.096$). Overall event-free survival was 85.3% in CABG and 76.8% in PCI ($p < 0.001$).

Conclusions. Rates of repeat revascularization were significantly higher for PCI than for CABG, but mortality and myocardial infarction were the same. There were no significant differences in outcomes between DES and BMS or between on-pump and off-pump CABG.

(Ann Thorac Surg 2008;86:496–503)
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Revascularization for coronary artery disease has shifted significantly during the past two decades from a surgical approach, coronary artery bypass grafting (CABG), to percutaneous coronary intervention (PCI). Currently, approximately three of every four coronary revascularizations are performed by PCI [1]. The recent introduction of drug-eluting stents (DESs) has further catalyzed this shift from surgical to catheter-based approaches [2]. Two general approaches currently exist for surgical revascularization, on-pump and off-pump CABG, and two options exist for PCI, bare metal stents (BMSs) and DESs.

Much of the evidence for determining procedural outcomes, and therefore selecting the proper revascularization strategy for an individual patient, comes from randomized controlled trials (RCTs) comparing approaches [3–6]. Although RCTs represent the highest level of evidence-based medicine (level A), they are subject to trial design bias by preferentially enrolling relatively low-risk patients, resulting in a high degree of selectabil-

ity. Only about 4% of patients screened for inclusion in RCTs comparing CABG vs PCI have actually been enrolled in these trials [3–11]; however, the results in trials of these highly selective patients are frequently extrapolated or generalized to the population as a whole.

The validity of this "generalizability" of the results in these select patients to the population as a whole is questionable. This is particularly currently relevant as an estimated 60% to 70% of DES usage is now "off label," without RCT evidence of outcomes in these patients. In a similar manner, RCTs of CABG performed on-pump or off-pump are subject to the same limitations as are pivotal trials of BMSs vs DESs. Doubts about whether the outcomes in the "real world" for coronary revascularization by either catheter-based or surgical approaches correlate with the RCTs has been raised by analysis of large population outcomes databases [2, 12–14]. We hypothesize that the results of coronary revascularization as performed in routine clinical practice may differ from the outcomes of RCTs.

Material and Methods

All patients undergoing isolated coronary revascularization in a 6-month period between February 1 and July 31, 2004,

Total

4,336 patients

CABG

1,247 (28.8%)

PCI

3,089 (71.2%)

12 - unknown

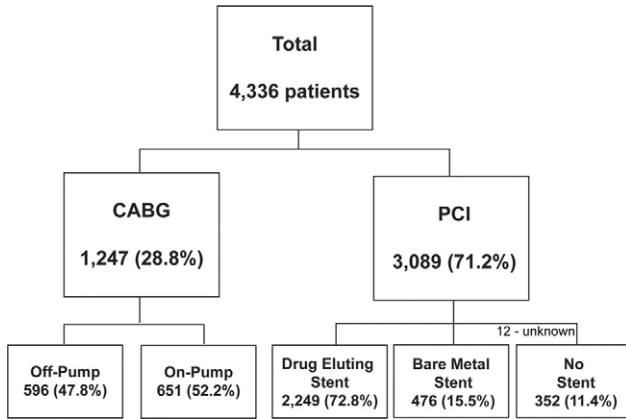| Off-Pump 596 (47.8%) | On-Pump 651 (52.2%) | Drug Eluting Stent 2,249 (72.8%) | Bare Metal Stent 476 (15.5%) | No Stent 352 (11.4%) |

Fig 1. Flow chart shows the initial study enrollment. (CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention.)

in 8 community-based hospitals in the HCA Hospital System (HCA Inc, Nashville, TN) were prospectively enrolled (Appendix). The institutions were all nonacademic community-based centers located in the southern and southeastern United States. All institutions participated in both The Society of Thoracic Surgeons (STS) National Cardiac Database and the American College of Cardiology (ACC) databases, and additional information was collected in a customized, centralized database. Preoperative, intraoperative, and postoperative procedural data were captured, and follow-up was obtained by direct patient or physician contact by the study sites. The study was approved locally with exempt status by each individual center's Institutional Review Board (IRB), and the data were sent to the coordinating study center. All information transfer met with Health Information Patient Privacy Act (HIPPA) compliance guidelines.

CABG procedures were defined as either being performed on-pump or off-pump, and in all PCI, the determination was made whether the patient received a DES or BMS. Patients who received both types of stent were analyzed with the DES group.

Exclusion criteria included patients undergoing any concomitant procedure (except transmyocardial laser revascularization) or undergoing "salvage" PCI or CABG.

Follow-up was performed at 6, 12, and 18 months and was obtained by direct patient contact and, when that was not possible, by physician contact. Additional mortality outcomes were obtained from the Social Security Death Index. The major clinical end point was major adverse cardiac events (MACE), which included death, myocardial infarction (MI), or the need for repeat revascularization by CABG or PCI. When the study was initiated, the issue of stent thrombosis was not paramount. During the follow-up period of this study, this complication has assumed significant clinical relevance. All clinical events were retrospectively adjudicated using current Academic Research Council (ARC) definitions. Stent thrombosis is reported as a composite of ARC definite and probable.

A quality of life analysis was also performed. The Medical Outcomes Study 12-Item Short-Form Health Survey

(SF-12) was used to summarize the general physical and mental health status of patients. The 12 questions in the SF-12 are designed to measure an individual's perceived health across eight health dimensions: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. Answers to those questions are combined (weighted) into physical and mental component summary scales, both of which are transformed to have a mean of 50 and a standard deviation (SD) of 10 in the general population.

Statistical Analysis

All data were input into a customized database. For statistical analysis, data were exported to SAS 9.1.3 software (SAS Institute, Cary, NC). Continuous variables were compared using t tests. Categoric variables were analyzed using the χ^2 or the Fisher exact test when the

Table 1. Study Population and Demographics

Category	PCI, No (%) or Mean ± SD	CABG, No (%) or Mean ± SD	p Value
Patients	3089 (71.2)	1247 (28.8)	
Age	63.5 ± 12.4	63.6 ± 10.6	0.98
Female	955 (31.3)	378 (30.5)	0.62
Caucasian	2535 (82.7)	1043 (84.0)	0.44
Current smoker	706 (22.9)	320 (26.9)	0.006
CAD, family history	1477 (47.9)	612 (49.1)	0.46
Diabetes	1013 (32.8)	437 (35.0)	0.16
Hypercholesterolemia	2076 (67.3)	677 (54.3)	<0.001
Renal failure	135 (4.4)	61 (4.9)	0.46
Dialysis	41 (1.3)	20 (1.6)	0.50
Hypertension	2294 (74.3)	982 (78.8)	0.002
Cerebrovascular accident	137 (4.5)	89 (7.1)	<0.001
Chronic lung disease	357 (11.6)	162 (13.0)	<0.001
Peripheral vascular disease	270 (8.8)	147 (11.8)	0.002
Cerebrovascular disease	558 (18.1)	130 (10.4)	<0.001
Previous CABG	618 (20.0)	62 (5.0)	<0.001
Previous PCI	990 (32.1)	222 (17.8)	<0.001
Myocardial infarction	815 (26.4)	418 (34.1)	<0.001
Congestive heart failure	235 (7.6)	99 (8.0)	0.72
Angina	2701 (88.0)	1075 (86.4)	0.14
Cardiogenic shock	29 (0.9)	9 (0.7)	0.49
Arrhythmia	73 (2.5)	94 (7.6)	<0.001
Pre-op β-blockers	1577 (51.8)	803 (65.0)	<0.001
Pre-op inotropes	50 (1.6)	15 (1.2)	0.30
Status[a]			
Elective	2016 (66.9)	533 (43.1)	<0.001
Urgent	565 (18.8)	657 (53.1)	
Emergency	431 (14.3)	47 (3.8)	
Ejection fraction	0.528 ± 0.16	0.497 ± 0.121	<0.001

[a] Definitions are those used by The Society of Thoracic Surgeons (STS) Adult Cardiac Database.

CABG = coronary artery bypass grafting;   CAD = coronary artery disease;   PCI = percutaneous coronary intervention.
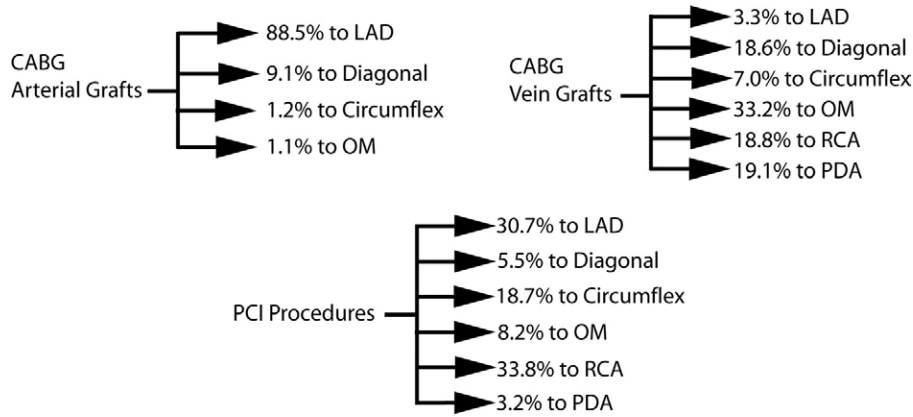
Fig 2. Distribution of graft and stent target vessels in study cohort is shown. (CABG = coronary artery bypass grafting; LAD = left anterior descending artery; OM = obtuse marginal artery; PCI = percutaneous coronary intervention; PDA = posterior descending artery; RCA = right coronary artery.)

number of expected responses in a cell was small. Kaplan-Meier analysis of time to events was used. Risk adjustment was performed using Cox proportional hazard analysis. Data from the SF-12 study are presented as mean ± SD and median scores, with the groups compared across procedures using Wilcoxon rank sums.

Results

The study enrolled 4336 patients (Fig 1), of whom 3089 (71.2%) were treated with PCI and 1247 (28.8%) with CABG. A DES was used in 73.1% of the patients undergoing PCI, and 596 CABG patients (47.8%) underwent off-pump procedures. The demographics of the two study groups are listed in Table 1. There were no significant differences in sex, age, race, preexisting renal failure, or diabetes mellitus. The PCI group had better left ventricular function. Their procedures were more often elective or emergency, but they had higher rates of previous PCI, and CABG. The CABG group had a higher incidence of triple-vessel disease than the PCI group, where nearly one-half of the patients had single-vessel disease (Table 2).

Figure 2 shows the distribution of the target vessels for the CABG and PCI grafts. In the patients undergoing CABG, 92.2% received at least 1 arterial graft, with 11.5% receiving all arterial revascularization. Patients had a mean number of 3.18 ± 1.12 (range, 1 to 8) bypasses, with 1.15 ± 0.67 arterial and 2.02 ± 1.16 vein grafts per patient. The mean number of grafts per patient was 3.39 ± 1.02 in those undergoing on-pump CABG and 2.94 ± 1.17 for the off-pump patients. The mean number of stents used per patient in the PCI group was 1.34 ± 0.79 (range, 1 to 6).

There was no difference between DESs and BMSs patients in number of stents used per patient.

Overall procedural and clinical outcomes are in Table 3. Completeness of follow-up at 18 months was 90.8% overall, with 91.8% in the CABG cohort and 90.3% in the PCI patients by direct contact. The Social Security Death Index was used for complete mortality follow-up. Procedural mortality, postprocedural mortality to 18 months, and overall mortality was not significantly different between CABG and PCI (Table 4). Mortality was also not significantly different between on-pump and off-pump CABG and between DES and BMS use (Table 5). Event-free survival by Kaplan-Meier analysis by CABG and PCI is shown in Figure 3 and for each subgroup (PCI-DES, PCI-BMS, CABG on-pump, CABG off-pump) in Figure 4. At 18 months, rates for event-free survival were PCI-BMS, 80.6% ± 1.8%; PCI-DES, 87.7% ± 0.7%; off-pump CABG, 87.3% ± 1.4%; and on-pump CABG, 90.8% ± 1.2% (Fig 4).

No difference was found in the incidence of MI among the various groups or in the composite end point of death and MI. There was, however, a significant increased need for repeat revascularization in the PCI group compared with patients undergoing CABG (13.6% vs 6.2%, $p < 0.001$; Table 4). Although repeat revascularization was lower in patients receiving DESs vs BMSs (12.1% vs 14.9%, $p = 0.096$), this did not reach statistical significance (Table 5). There was no difference in any outcome between on-pump and off-pump CABG. Clopidogrel use at 18 months was 61.2% in the PCI group (60.8% BMS, 61.3% DES, $p = 0.88$) and 24.2% in CABG patients ($p < 0.001$).

Because this was an observational study, treatment

Table 2. Severity of Disease in Coronary Artery Bypass Graft and Percutaneous Coronary Intervention Patients

Diseased Vessel	CABG, %	PCI, %	p Value	Off-pump, %	On-pump, %	p Value
1-vessel	9.7	48.1		16.1	5.6	
2-vessel	30.5	32.3	< 0.001	34.7	27.8	< 0.001
3-vessel	59.8	19.6		49.2	66.6	

CABG = coronary artery bypass grafting;   PCI = percutaneous coronary intervention.
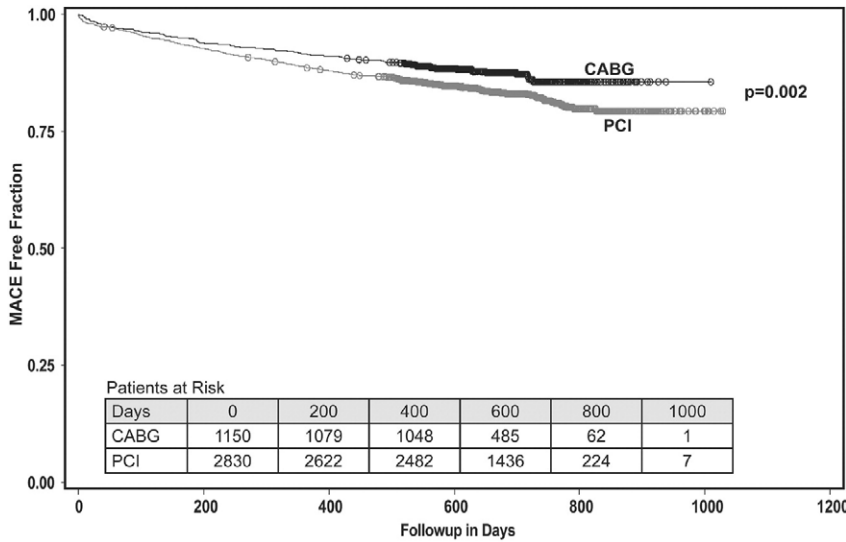
Fig 3. Kaplan-Meier curves show accumulation of major adverse cardiac events (MACE) in patients receiving percutaneous coronary intervention (PCI, gray line) compared with CABG (black line) vs time.

was at the discretion of the treating physician. However, controlling for variables that are significantly different between the CABG and PCI groups, including operative status, previous CABG, previous PCI, previous MI, valve operations, or stroke, presence of cerebral or peripheral vascular disease, or current smoker, the hazard ratio for MACE by Cox analysis of CABG to PCI was 0.76 (95% confidence interval, 0.571 to 0.872).

Analysis of the subgroup with diabetes mellitus demonstrated that in both CABG and PCI, the outcomes were worse for diabetic patients than for nondiabetic patients (Table 6). Neither off-pump CABG nor DESs offered any particular benefit compared with nondiabetic patients.

According to the ARC definitions of definite or probable stent thrombosis, 19 BMS patients (4.2%) had stent thrombosis compared with 65 DES patients (2.9%; $p = 0.12$). The SF-12 quality of life survey was performed at 12 months in 371 patients (32%) undergoing CABG and 922 (33%) undergoing PCI (Table 7). The SF-12 physical component scores were significantly superior to general population scores adjusted for age, whereas the mental component scores were the same as the general population.

Comment

PCI is being increasingly favored as the initial treatment strategy for coronary revascularization by both interventional cardiologists and patients. The recent introduction of DESs has further catalyzed this shift in revascularization strategy toward percutaneous approaches. In this observational study in which patients were enrolled in 2004 just after the introduction of DESs into clinical practice, 71% of patients underwent PCI, and 72.8% of these procedures used at least one DES.

RCTs represent the highest order of evidence-based medicine (level A). The RCTs comparing CABG vs PCI have repeatedly shown no differences in mortality between the two treatment strategies but have shown an increased need for repeat revascularization by PCI [3–11]. The shortcomings of these trials, however, are that they

Table 3. Major Procedural Complications

Complication[a]	PCI (n = 3089), No. (%)	CABG (n = 1247), No. (%)	p Value
Peri-op death	47 (1.5)	22 (1.8)	0.38
Peri-op MI	8 (0.3)	4 (0.3)	0.75
Renal failure	20 (0.7)	38 (3.1)	<0.001
Requiring dialysis	4 (0.1)	11 (0.9)	
Stroke, permanent	4 (0.1)	9 (0.7)	0.003
Gastrointestinal	20 (0.7)	18 (1.5)	0.002

[a] Expressed as percentage of all patients undergoing procedure.

CABG = coronary artery bypass grafting;   MI = myocardial infarction; PCI = percutaneous coronary intervention.

Table 4. Major Adverse Cardiac Events at 18 Months After Procedure

Patients With Follow-up	PCI (n = 2790)	CABG (n = 1145)	p Value
Follow-up, %	90.30	91.80	
Death, No. (%)	237 (8.5)	87 (7.6)	0.35
Periprocedural death[a]	47 (1.7)	22 (1.9)	0.61
Late death	190 (6.8)	65 (5.7)	0.2
Myocardial infarction, No. (%)	50 (1.8)	19 (1.7)	0.77
Repeat revascularization, No. (%)	379 (13.6)	66 (6.2)	< 0.001
By CABG, %	2.20	0.50	< 0.001
By PCI, %	9.30	5.50	< 0.001
MACE, No. (%)	666 (23.2)	172 (14.7)	< 0.001

[a] Expressed as percentage of all patient with follow-up for calculation of major adverse cardiac events.

CABG = coronary artery bypass grafting;   MACE = major adverse cardiac events;   PCI = percutaneous coronary intervention.

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Table 5. Clinical Results at 18 Months by Revascularization Procedure

	Off-pump (n = 538) No. (%)	On-pump (n = 607) No. (%)	p Value	BMS,[a] (n = 451) No. (%)	DES,[a] (n = 2121) No. (%)	p Value
Mortality	47 (8.7)	40 (6.6)	0.17	47 (10.4)	165 (7.8)	0.064
Peri-op	10 (1.9)	12 (2.0)	0.88	9 (2.0)	33 (1.6)	0.5
Late	37 (6.9)	28 (4.6)	0.1	38 (8.4)	132 (6.2)	0.087
MI	7 (1.3)	12 (2.0)	0.38	8 (2.0)	34 (1.7)	0.61
Revascularization	28 (5.2)	38 (6.2)	0.45	69 (14.9)	259 (12.1)	0.096
By CABG	4 (0.7)	3 (0.5)	0.59	14 (3.1)	43 (2.0)	0.16
By PCI	24 (4.4)	35 (5.7)	0.32	55 (12.0)	216 (10.1)	0.23
MACE	82 (14.9)	90 (14.5)	0.82	125 (26.5)	460 (21.2)	0.012

[a] 218 patients in PCI group with follow-up had angioplasty but no stent.

CABG = coronary artery bypass grafting;   MACE = major adverse cardiac events;   MI = myocardial infarction;   PCI = percutaneous coronary intervention.

include only relatively small patient cohorts that are underpowered to show a mortality difference and that the follow-up period is relatively short so that any potential survival advantage with CABG may not yet be detected. Outcomes from single-center and large population studies have shown a mortality benefit from CABG compared with PCI that appears to increase with longer follow-up of 3 to 5 years [2, 12–15].

Despite the relatively large number of patients in this study (> 4000) and high rate of follow-up (> 90%) supplemented by mortality data from the Social Security Death Index, we were unable to discern any mortality advantage at this relatively short 18-month period of follow-up with either therapy. Overall survival at 18 months was 92.4% in the CABG group and 91.5% in the PCI patients. This is significantly less than the Arterial Revascularization Therapies (ARTS) trial, the most recent RCT comparing the two treatments, in which survival at 1 year was 97.2% for CABG and 97.5% for PCI [3]. The reintervention rate in the ARTS trial, which used BMSs only, was 16.8% at 1 year and 13.6% in this observational series in which 76% of the PCI patients received DESs. This represents some improvement but is significantly less than recent single-digit restenosis rates reported by pivotal DES trials. Target vessel revascularization was 8.6% with sirolimus stents in the SIRIUS trial (SIRolImUS-coated stent in treatment of patients with de novo coro-

nary artery lesions) [16] and 4.7% with the Taxus stent (Boston Scientific, Natick, MA) in the Taxus IV trial [17]. Most recently, the ARTS II trial reported repeat reintervention rates of 8.5% at 1 year, with an 89.5% event-free survival [18]. With an estimated 60% to 75% of DES usage now off label (ie, not in patients typically included in these randomized trials), we believe that the event rates reported in our observational study are more reflective of real world outcomes than those reported in the pivotal RCTs.

We also demonstrated that the outcomes by all treatment approaches were worse in diabetic patients compared with nondiabetic patients. However, the incidence of major adverse events was proportionately the same relative to each other by each revascularization approach.

We also compared the outcomes of patients treated with DESs with those with BMSs. The composition of the groups receiving both treatments was relatively uniform and again demonstrated no significant difference in mortality or MI, but did show a significantly less need for repeat revascularization (12.1% vs 14.9%, $p = 0.096$) in the patients receiving DES. Although stent thrombosis was not a major issue at the initiation of this study, all adverse events in the PCI group were retrospectively adjudicated to determine the incidence of stent thrombosis by current criteria [19]. We found no increase in stent thrombosis in the DES group compared with BMSs, but the overall

Fig 4. Kaplan-Meier curves show accumulation of major adverse cardiac events (MACE) by treatment groups receiving on-pump and off-pump (top two lines) coronary artery bypass grafting compared with patients undergoing percutaneous coronary intervention with bare metal stents (BMS) and drug-eluting stents (DES).
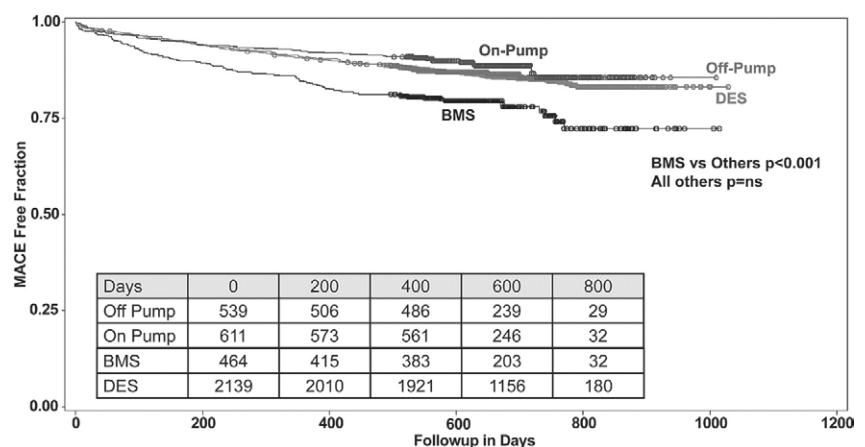

Days	0	200	400	600	800
Off Pump	539	506	486	239	29
On Pump	611	573	561	246	32
BMS	464	415	383	203	32
DES	2139	2010	1921	1156	180

Table 6. Clinical Outcomes in Diabetic and Nondiabetic Patients

Patients	CABG No. (%)	PCI No. (%)	p Value
Diabetic			
Patients, No.	398	909	
MI	9 (2.3)	20 (2.2)	0.95
Revascularization	29 (7.2)	141 (15.3)	<0.001
By CABG	3 (0.8)	29 (3.2)	0.009
By PCI	26 (6.5)	112 (12.2)	0.002
Mortality	39 (9.8)	91 (10.0)	0.91
Peri-op	8 (2.0)	18 (2.0)	0.97
Late	31 (7.8)	73 (8.0)	0.88
Total MACE	77 (18.6)	252 (26.8)	0.001
Nondiabetic			
Patients, No	747	1879	
MI	10 (1.3)	30 (1.6)	0.63
Revascularization	37 (4.9)	238 (12.5)	<0.001
By CABG	4 (0.5)	45 (2.4)	0.002
By PCI	33 (4.4)	193 (10.2)	<0.001
Mortality	48 (6.4)	146 (7.8)	0.23
Peri-op	14 (1.9)	29 (1.5)	0.55
Late	34 (4.6)	117 (6.2)	0.096
Total MACE	95 (12.5)	414 (21.5)	<0.001

CABG = coronary artery bypass grafting; MACE = major adverse cardiac events; MI = myocardial infarction; PCI = percutaneous coronary intervention.

incidence was higher (3.1%) than the lower incidence reported in the pivotal trials and equivalent to that found in industry registries (2.7% for Cypher [Cordis Corporation; Miami, FL] and 3.6% for Taxus at 1 year).

Likewise, numerous RCTs of off-pump vs on-pump CABG have been done, and 37 RCTs and three meta-analyses of these RCTs have been published [20–21]. No mortality difference was found between the two groups even in meta-analyses; however, these are still under-powered to show a difference. As with the DES trials, relatively low-risk patients are enrolled in surgery trials. The 1- or 2-year mortality in off-pump vs on-pump CABG was 2.3% and 2.6%, which is significantly lower than the 6.6% and 8.7% we observed in this study. As CABG is performed in the real world clinical setting, we also found no difference in death or major adverse events in on-pump vs off-pump CABG.

We found that quality of life was superior to an age-matched referenced population for physical well-being and equivalent for mental well-being but that CABG and PCI did not differ significantly from each other. Any potential adverse effects on quality of life from the two revascularization approaches, periprocedural invasiveness for CABG, and need for repeat revascularization by PCI appear to have largely resolved by 18 months.

Limitations

This study is limited because it is observational in nature and is therefore subject to treatment bias. Despite this limitation, demographic analysis of the study groups show that for the major demographic factors of age, sex, race, and presence of diabetes, the four treatment groups were relatively uniform. Despite the inclusion of more than 4000 patients in this study, it is still underpowered to detect any potential mortality benefit.

Another limitation is the ability to achieve only 90% follow-up. The Sunbelt has a mobile population, and higher rates of follow-up were not achievable. The relatively short period of follow-up is also a limitation. An observation period of 18 months is still too short to detect differences in major outcomes, as has been seen in observational studies with large populations. We intend to obtain additional funding for continued follow-up for at least a 5-year period.

Summary

Coronary revascularization, as currently practiced in the real world clinical setting, generally leads to good outcomes. Overall, however, the outcomes were inferior in both treatment groups from the standpoint of death and need for repeat revascularization at 18 months compared with RCT results. Although the results with each revascularization approach were inferior to those in RCTs and industry-sponsored registries, relative to each other, the outcomes were similar. RCTs are sufficient to demonstrate initial proof of concept of therapies in selective homogeneous populations, but observational studies demonstrate different results in the more heterogeneous real world of clinical use.

We found no differences in any outcomes between on-pump and off-pump CABG. Patients who received DESs had less need for repeat revascularization than patients who received BMSs, but this was not statistically significant. We also found no mortality difference between CABG and PCI; however, this potential benefit of CABG has only been apparent in larger population studies with longer follow-up.

Table 7. Quality of Life Outcomes as Measured by Medical Outcome Study 12-Item Short-Form Health Survey

Score	CABG Mean ± SD (median)	PCI Mean ± SD (median)	Reference Score Mean ± SD	p Value
Physical score	46.0 ± 11.7 (50.75)	44.9 ± 10.9 (47.70)	38.8 ± 10.0	0.01
Mental score	54.8 ± 8.2 (57.23)	54.4 ± 8.8 (57.23)	48.3 ± 10.1	0.70

CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention; SD = standard deviation.

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Appendix

Study Centers

Centennial Medical Center	
Principal Investigator:	Phil Brown, MD
Data Coordinators:	John Waters, Pam Boyce
Central Florida Regional Hospital	
Principal Investigator:	George Palmer, MD
Data Coordinators:	Connie Shaw, Wanda Shaver
Denton Regional Medical Center	
Principal Investigator:	Tea Acuff, MD
Data Coordinators:	Dawn Kregel, Vonnie George
Henrico Doctor's Hospital	
Principal Investigator:	Marc Katz, MD
Data Coordinators:	Stephanie Allen, Donna Mead, Ann Robertson
JFK Medical Center	
Principal Investigator:	Jay Midwall, MD
Data Coordinators:	Gail Grasso
Medical City Dallas Hospital	
Principal Investigator:	Michael J. Mack, MD
Data Coordinators:	Angela Riley, Kathy Rodkey
Medical Center of Plano	
Principal Investigator:	James R. Edgerton, MD
Data Coordinators:	Lori Hutchins-Sams
Plaza Fort Worth Medical Center	
Principal Investigator:	Karamat Choudhry, MD
Data Coordinators:	Susan Williams

DISCUSSION

DR ROBERT A. GUYTON (Atlanta, GA): I appreciate the study and I think it is an excellent study. If you don't mind, Mike, I am going to put on the hat of a cardiologist and ask you the question that some of our cardiology colleagues might ask you, and that is, that the things that are important to me are dying or having a stroke. You have a significantly higher stroke rate with coronary bypass, you have got an equivalent death rate, and I don't mind having two revascularizations because my total time out of work is less with two PCIs compared with one coronary bypass. So it seems to me that your study presents data that would argue in favor of the use of drug-eluting stents rather than coronary bypass, and as this is the question that we were often asked to answer over the last 2 months, I am posing this to you so that you can answer it for the audience.

Thank you.

DR MACK: Thank you for that very relevant question, Robert. What the audience may not know is that Robert and I have spent a lot of time the last couple of months looking at outcomes of CABG vs PCI, and I think both of us are very conversant with the field, and Robert's point is the absolute crucial one. I have two responses.

First, this study did not show exactly what I anticipated. On the front end, when I went to obtain funding, my preconceived surgical bias was there are a lot of adverse events with PCI that we never know about and I will bet that at the end of this, CABG outcomes are going to be much better. Indeed, they weren't, and the numbers are the numbers. This I think is as close to what the real world is as one can be, and we have looked at this every which way, and I am absolutely confident that these are the numbers.

Secondly, as I alluded to at the end, despite the fact that this is over 4000 patients with relatively complete follow-up, it is too small a study with too short a follow-up and therefore is underpowered to detect a difference in mortality, or stroke, between the two groups. If one wants to detect a mortality benefit with a 2% incidence and you are looking to detect a 20% difference, it would take 88,000 patients to be adequately powered. It takes almost that many patients to detect a difference for stroke. And as I said, in New York and Northern New England, it has taken 3 to 5 years to show that there is a mortality benefit, and I think 18 months is too short a period of time for us to be able to say that there is no difference in mortality between the two groups.