Annals of Internal Medicine | Review

Systematic Review: The Comparative Effectiveness of Percutaneous Coronary Interventions and Coronary Artery Bypass Graft Surgery

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Background: The comparative effectiveness of coronary artery bypass graft (CABG) surgery and percutaneous coronary intervention (PCI) for patients in whom both procedures are feasible remains poorly understood.

Purpose: To compare the effectiveness of PCI and CABG in patients for whom coronary revascularization is clinically indicated.

Data Sources: MEDLINE, EMBASE, and Cochrane databases (1966–2006); conference proceedings; and bibliographies of retrieved articles.

Study Selection: Randomized, controlled trials (RCTs) reported in any language that compared clinical outcomes of PCI with those of CABG, and selected observational studies.

Data Extraction: Information was extracted on study design, sample characteristics, interventions, and clinical outcomes.

Data Synthesis: The authors identified 23 RCTs in which 5019 patients were randomly assigned to PCI and 4944 patients were randomly assigned to CABG. The difference in survival after PCI or CABG was less than 1% over 10 years of follow-up. Survival did not differ between PCI and CABG for patients with diabetes in the 6 trials that reported on this subgroup. Procedure-related strokes were more common after CABG than after PCI (1.2% vs. 0.6%; risk difference, 0.6%; $P = 0.002$). Angina relief was greater after CABG than after PCI, with risk differences ranging from 5% to 8% at 1 to 5 years ($P < 0.001$). The absolute rates of angina relief at 5 years were 79% after PCI and 84% after CABG. Repeated revascularization was more common after PCI than after CABG (risk difference, 24% at 1 year and 33% at 5 years; $P < 0.001$); the absolute rates at 5 years were 46.1% after balloon angioplasty, 40.1% after PCI with stents, and 9.8% after CABG. In the observational studies, the CABG–PCI hazard ratio for death favored PCI among patients with the least severe disease and CABG among those with the most severe disease.

Limitations: The RCTs were conducted in leading centers in selected patients. The authors could not assess whether comparative outcomes vary according to clinical factors, such as extent of coronary disease, ejection fraction, or previous procedures. Only 1 small trial used drug-eluting stents.

Conclusion: Compared with PCI, CABG was more effective in relieving angina and led to fewer repeated revascularizations but had a higher risk for procedural stroke. Survival to 10 years was similar for both procedures.

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Coronary artery bypass graft (CABG) surgery and catheter-based percutaneous coronary intervention (PCI), with or without coronary stents, are alternative approaches to mechanical coronary revascularization. These 2 coronary revascularization techniques are among the most common major medical procedures performed in North America and Europe: In 2005, 261 000 CABG procedures and 645 000 PCI procedures were performed in the United States alone (1). However, the comparative effectiveness of CABG and PCI remains poorly understood for patients in whom both procedures are technically feasible and coronary revascularization is clinically indicated.

In patients with left main or triple-vessel coronary artery disease with reduced left ventricular function, CABG is generally preferred because randomized, controlled trials (RCTs) have shown that it improves survival compared with medical therapy (2, 3). In patients with most forms of single-vessel disease, PCI is generally the preferred form of coronary revascularization (4), in light of its lower clinical risk and the evidence that PCI reduces angina and myocardial ischemia in this subset of patients (5). Most RCTs comparing CABG and PCI have been conducted in populations with coronary artery disease between these extremes, namely patients with single-vessel, proximal left anterior descending disease; most forms of double-vessel disease; or less extensive forms of triple-vessel disease.

We sought to evaluate the evidence from RCTs on the comparative effectiveness of PCI and CABG. We included trials using balloon angioplasty or coronary stents because quantitative reviews have shown no differences in mortality or myocardial infarction between these PCI techniques (6, 7). We also included trials using standard or minimally invasive CABG or both procedures (8, 9). We sought to document differences between PCI and CABG in survival, cardiovascular complications (such as stroke and myocardial infarction), and freedom from angina. Finally, we re-

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Context

The relative benefits and harms of coronary artery bypass graft surgery (CABG) versus percutaneous coronary intervention (PCI) are sometimes unclear.

Contribution

This systematic review of 23 randomized trials found that survival at 10 years was similar for CABG and PCI, even among diabetic patients. Procedural strokes and angina relief were more common after CABG (risk difference, 0.6% and about 5% to 8%, respectively), whereas repeated revascularization procedures were more common after PCI (risk difference, 24% at 1 year).

Caution

Only 1 small trial used drug-eluting stents. Few patients with extensive coronary disease or poor ventricular function were enrolled.

—The Editors

viewed selected observational studies to assess the generalizability of the RCTs.

METHODS

Data Sources

We searched the MEDLINE, EMBASE, and Cochrane databases for studies published between January 1966 and August 2006 by using such terms as *angioplasty, coronary,* and *coronary artery bypass surgery*, as reported in detail elsewhere (10). We also sought additional studies by reviewing the reference lists of included articles, conference abstracts, and the bibliographies of expert advisors. We did not limit the searches to the English language.

Study Selection

We sought RCTs that compared health outcomes of PCI and CABG. We excluded trials that compared PCI alone or CABG alone with medical therapy, those that compared 2 forms of PCI, and those that compared 2 forms of CABG. The outcomes of interest were survival, myocardial infarction, stroke, angina, and use of additional revascularization procedures. Two investigators independently reviewed titles, abstracts, and the full text as needed to determine whether studies met inclusion criteria. Conflicts between reviewers were resolved through re-review and discussion. We did not include results published solely in abstract form.

Data Extraction and Quality Assessment

Two authors independently abstracted data on study design; setting; population characteristics (sex, age, race/ethnicity, comorbid conditions, and coronary anatomy); eligibility and exclusion criteria; procedures performed; numbers of patients screened, eligible, enrolled, and lost to follow-up; method of outcome assessment; and results for each outcome. We assessed the quality of included trials by using predefined criteria and graded their quality as A, B, or C by using methods described in detail elsewhere (10). In brief, a grade of A indicates a high-quality trial that clearly described the population, setting, interventions, and comparison groups; randomly allocated patients to alternative treatments; had low dropout rates; and reported intention-to-treat analysis of outcomes. A grade of B indicates a randomized trial with incomplete information about methods that might mask important limitations. A grade of C indicates that the trial had evident flaws, such as improper randomization, that could introduce significant bias.

Data Synthesis and Analysis

We used random-effects models to compute weighted mean rates and SEs for each outcome. We computed summary risk differences and odds ratios between PCI and CABG and the 95% CI for each outcome of interest at annual intervals. Because the results did not differ materially when risk differences and odds ratios (10) were used and the low rate of several outcomes (for example, procedural mortality) made the risk difference a more stable outcome metric (11, 12), we report here only the risk differences.

We assessed heterogeneity of effects by using chi-square and I^2 statistics (13). When effects were heterogeneous ($I^2 > 50\%$), we explored the effects of individual studies on summary effects by removing each study individually. We assessed the possibility of publication bias by visual inspection of funnel plots and calculated the number of missing studies required to change a statistically significant summary effect to not statistically significant (11). We performed analyses by using Comprehensive Meta-Analysis software, version 2.0 (Biostat, Englewood, New Jersey).

Inclusion of Observational Studies

We also searched for observational data to evaluate the generalizability of the RCT results, as reported in detail elsewhere (10). In brief, we included observational studies from clinical or administrative databases that included at least 1000 recipients of each revascularization procedure and provided sufficient information about the patient populations (such as demographic characteristics, preprocedure coronary anatomy, and comorbid conditions) and procedures performed (such as balloon angioplasty vs. bare-metal stents vs. drug-eluting stents).

Role of the Funding Source

This project was supported by the Agency for Healthcare Research and Quality. Representatives of the funding agency reviewed and commented on the study protocol and drafts of the manuscript, but the authors had final responsibility for the design, conduct, analysis, and reporting of the study.

Results

We identified 1695 potentially relevant articles, of which 204 merited full-text review (**Appendix Figure**, available at www.annals.org). A total of 113 articles reporting on 23 unique RCTs met inclusion criteria (**Table 1** [14–126]). These trials enrolled a total of 9963 patients, of whom 5019 were randomly assigned to PCI and 4944 to CABG. Most trials were conducted in Europe, the United Kingdom, or both locations; only 3 trials were performed in the United States. The early studies (patient entry from 1987 to 1993) used balloon angioplasty as the PCI technique, and the later studies (patient entry from 1994 to 2002) used stents as the PCI technique. Only 1 small trial of PCI versus CABG used drug-eluting stents (116). Nine trials limited entry to patients with single-vessel disease of the proximal left anterior descending artery, whereas the remaining 14 trials enrolled patients with multivessel disease, either predominantly (3 trials) or exclusively (11 trials).

The quality of 21 trials was graded as A, and 1 trial (117) was graded as B. One trial (116) was graded as C because randomization may not have been properly executed (details are available elsewhere [10]). We performed sensitivity analyses by removing these studies from the analysis, and our summary results did not change statistically significantly.

The average age of the trial participants was 61 years, 27% were women, and most were of European ancestry. Roughly 20% had diabetes, half had hypertension, and half had hyperlipidemia. Whereas approximately 40% of patients had a previous myocardial infarction, few had heart failure or poor left ventricular function. Among studies that enrolled patients with multivessel coronary disease, most had double-vessel rather than triple-vessel disease.

Revascularization procedures were performed by using standard methods for the time the trial was conducted (**Table 1**). Among patients with multivessel disease, more grafts were placed during CABG than vessels were dilated during PCI. Among patients assigned to PCI, stents were commonly used in the recent studies, but in the earlier trials, balloon angioplasty was standard. Among patients assigned to CABG, arterial grafting with the left internal mammary artery was frequently done, especially in more recent trials. Some studies used minimally invasive, direct coronary artery bypass and off-pump operations to perform CABG in patients with single-vessel left anterior descending disease (**Table 1**).

Short-Term and Procedural Outcomes

Survival (within 30 days of the procedure) was high for both procedures: 98.9% for PCI and 98.2% for CABG. When data from all trials were combined, the survival difference between PCI and CABG was small and not statistically significant (0.2% [95% CI, −0.3% to 0.6%]) (**Figure 1**). These results were unchanged after exclusion of AWESOME (Angina With Extremely Serious Operative Mortality Evaluation) (28) and the Myoprotect I (104) trial, which enrolled patients who were more acutely ill.

The rate of procedural stroke (reported in 15 randomized trials) was higher after CABG (1.2%) than after PCI (0.6%) (**Figure 1**). The difference between PCI and CABG in procedural stroke was 0.6% (CI, 0.2% to 1%) ($P = 0.002$). Procedural myocardial infarction was not assessed in a consistent manner across trials of PCI and CABG. The pooled PCI–CABG difference in freedom from procedural myocardial infarction was small and not statistically significant (0.1% [CI, −1.0% to 1.2%]).

Long-Term Outcomes

Survival

Follow-up in the RCTs ranged from 6 months to 13 years. Overall survival across all randomized trials was similar between CABG and PCI at 1 year (96.4% vs. 96.5%) and 5 years (90.7% vs. 89.7%) of follow-up. The absolute survival difference between PCI and CABG at each time point was less than 1%. The 4 trials that reported longer follow-up (62, 80, 88, 110) showed no consistent change in the PCI–CABG survival difference after 5 years. We found no evidence of probable publication bias.

The comparative survival benefit did not differ significantly when randomized trials were subdivided into those enrolling patients with single-vessel proximal left anterior descending disease and those enrolling patients with multivessel disease (**Figure 2**). Among trials of multivessel disease, PCI and CABG results did not differ substantially for trials using balloon angioplasty versus trials using stents (**Figure 3**).

Other Long-Term Outcomes

Angina relief was more common after CABG than after PCI at 1, 3, and 5 years after the procedure. At 1 year, the proportion of patients without angina was 75% in PCI-assigned patients and 84% in CABG-assigned patients; at 5 years, this value increased to 79% in PCI-assigned patients but remained 84% percent in CABG-assigned patients. The PCI–CABG risk difference ranged from 5% to 8% between 1 and 5 years after the procedure ($P < 0.001$).

A greater proportion of patients who had CABG was without repeated coronary revascularization (96.2% at 1 year and 90.2% at 5 years) compared with patients who had PCI (73.5% at 1 year and 53.9% at 5 years for balloon angioplasty trials and 59.9% at 5 years for stent trials). Patients who received PCI required 24% more repeated procedures than CABG recipients at 1 year ($P < 0.001$) and 33% more repeated procedures at 5 years ($P < 0.001$). Although the trials consistently favored CABG, the results were statistically heterogeneous ($I^2 = 93$ at 1 year, and $I^2 = 78$ at 5 years). This difference between PCI and CABG was greater in trials that used balloon angioplasty (−37% [CI, −42% to −31%]) than in trials that used coronary stents (−27% [CI, −39% to −16%]), although

Table 1. **Overview of Randomized, Controlled Trials***

Study (Reference)	Location	Extent of Disease†	Enrollment Period	Follow-up, *y*
AMIST (14)	United Kingdom	SVD	1999–2001	2
ARTS (15–27)	Canada, United Kingdom, Europe, South America	MVD	1997–1998	5
AWESOME (28–35)	United States	MVD	1995–2000	5
BARI (36–64)	United States, Canada	MVD	1988–1991	10
CABRI (65–71)	United Kingdom, Europe	MVD	1988–1992	4
EAST (72–81)	United States	MVD	1987–1990	8
ERACI I (82, 83)	South America	MVD	1988–1990	3
ERACI II (84–86)	South America	MVD	1996–1998	5
GABI (87–89)	Europe	MVD	1986–1991	13
Drenth et al. (90–93)	Europe (Groningen, the Netherlands)	SVD	1997–1999	4
Goy et al. (94, 95)	Europe (Lausanne, Switzerland)	SVD	1989–1993	5
Diegeler et al. (96, 97); Thiele et al. (98)	Europe (Leipzig, Germany)	SVD	1997–2001	5
MASS (99, 100)	South America	SVD	1988–1991	5
MASS II (101–103)	South America	MVD	1995–2000	5
Myoprotect I (104)	Europe	MVD	1998–2001	1
Octostent (105–107)	Europe	MVD	1998–2000	1
Cisowski et al. (108, 109)	Europe (Poland)	SVD	2000–2001	2
RITA (110–115)	United Kingdom	MVD	1988–1991	6.5
Hong et al. (116)	Asia (Seoul, Korea)	SVD	2003	0.5
Kim et al. (117)	Asia (Seoul, Korea)	SVD	2000–2001	1
SIMA (118)	Europe	SVD	1994–1998	2.4
SoS trial (119–125)	Canada, United Kingdom, Europe	MVD	1996–1999	3
French Monocentric Study (126)	Europe	MVD	1989–1993	5

* AMIST = Angioplasty versus Minimally Invasive Surgery Trial; ARTS = Arterial Revascularization Therapies Study; AWESOME = Angina with Extremely Serious Operative Mortality Evaluation; BARI = Bypass Angioplasty Revascularization Investigation; CABG = coronary artery bypass grafting; CABRI = Coronary Angioplasty versus Bypass Revascularization Investigation; EAST = Emory Angioplasty versus Surgery Trial; ERACI = Argentine randomized trial of percutaneous transluminal coronary angioplasty versus coronary artery bypass surgery in multivessel disease; GABI = German Angioplasty Bypass Surgery Investigation; MASS = Medicine, Angioplasty, or Surgery Study; MIDCAB = minimally invasive direct coronary artery bypass; MVD = multivessel disease; NS = not specified; PCI = percutaneous coronary intervention; RITA = Randomized Intervention Treatment of Angina; SIMA = Stenting versus Internal Mammary Artery Study; SoS = Stent or Surgery; SVD = single-vessel disease.
† Patients were classified as having SVD if all patients in the trial had SVD; all other patients were classified as having MVD.
‡ Although not explicitly stated, this value was assumed to be 100%, because surgical protocol required use of the left internal mammary artery.
§ Surgeon's choice of median sternotomy or left anterior thoracotomy.
‖ Drug-eluting stent.

patients undergoing PCI with stents still required more repeated procedures than did patients undergoing CABG.

Ten studies reported myocardial infarction rates in long-term follow-up, which increased among all patients between 1 and 5 years, but at a somewhat higher rate for PCI recipients. At 5 years, the mean (±SE) rate of myocardial infarction was 11.9% ± 3.0% for PCI recipients and 10.9% ± 2.6% for CABG recipients. The summary differences in myocardial infarction between PCI and CABG were less than 1%.

Comparative Effectiveness

Most trials did not report outcomes in subgroups, and even fewer performed formal statistical interaction tests to gauge whether outcomes varied in a statistically significant manner by clinical characteristics. Outcomes were reported by 5 or more trials only for the subgroups defined by diabetes, age, sex, smoking, and number of diseased vessels. Evidence was insufficient to evaluate whether hypertension, race, obesity, renal dysfunction, peripheral vascular disease, previous coronary revascularization procedures, clinical presentation, or left ventricular function affected the comparative outcomes of PCI and CABG, because each of these characteristics was reported in only 1 to 3 trials (10).

Outcomes by age were examined by BARI (Bypass Angioplasty Revascularization Intervention) (57), AWESOME (31), and a pooled analysis of 4 stent trials (ARTS [Arterial Revascularization Therapies Study], ERACI II [second Argentine randomized trial of percutaneous transluminal coronary angioplasty versus coronary artery bypass surgery in multivessel disease], MASS II [Second Medicine, Angioplasty, or Surgery Study], and SoS [Stent or Surgery]) (127). Overall, older patients had more procedural complications, especially stroke. Long-term survival after PCI or CABG did not differ significantly among patients older than 65 years of age compared with younger patients, but very few patients older than 75 years of age were enrolled.

Table 1—**Continued**

Patients Randomly Assigned, *n*		Patients Receiving Assigned Treatment, *n* (%)		Completeness of Follow-up (PCI/CABG), %/%	PCI Using Stents, %	Type of Surgery	CABG Using Arterial Grafts, %
PCI	CABG	PCI	CABG				
50	50	48 (96.0)	46 (92.0)	92.0/98.0 at 1 year; NS at 2 years	97.9	MIDCAB	100‡
600	605	593 (98.8)	579 (98.7)	98.3/96.5	100	Standard CABG	93
222	232	213 (95.9)	215 (92.7)	NS	54	Surgeon's choice§	76
915	914	904 (98.8)	892 (97.6)	97 for entire population at 7 years	0	Standard CABG	82
541	513	522 (96.5)	478 (93.2)	99.6 for entire population at 1 year	0	Standard CABG	81
198	194	196 (99.0)	193 (99.5)	100/100	0	Standard CABG	86
63	64	55 (87.3)	56 (87.5)	98.4/95.3 at 1 year; NS at 3 years	0	Standard CABG	77
225	225	222 (98.7)	208 (92.4)	100/100	100	Standard CABG	89
182	177	176 (96.7)	161 (91.0)	90.7/92.7	0	Standard CABG	37
51	51	51 (100)	48 (94.1)	100/100	100	MIDCAB	100‡
68	66	68 (100)	59 (89.4)	NS	0	Standard CABG	100
110	110	110 (100)	110 (100)	98.2/98.2	100	MIDCAB	100
72	70	NS	NS	100/100	0	Standard CABG	100
205	203	194 (94.6)	198 (97.5)	100/100 for mortality	68.3	Standard CABG	92
23	21	23 (100)	21 (100)	NS	100	Standard CABG (17), off-pump (4)	NS
138	142	131 (94.9)	136 (95.8)	NS	100	Surgeon's choice§	100
50	50	50 (100)	50 (100)	100/100	100	MIDCAB	100‡
510	501	493 (96.7)	490 (97.8)	99.0/98.8	0	Standard CABG	74
119	70	NS	NS	99.2/98.6	100‖	MIDCAB	100‡
50	50	50 (100)	50 (100)	NS	100	MIDCAB	100
63	60	62 (98.4)	54 (90)	98.4/98.3	100	MIDCAB	98
488	500	480 (98.4)	487 (97.4)	99.0/99.4	100	Standard CABG	93
76	76	76 (100)	76 (100)	NS	0	Standard CABG	58

Six trials reported on comparative survival among patients with diabetes (**Figure 4**). Whereas BARI reported a survival advantage for CABG among patients with diabetes (37, 64), the other 5 trials did not. At 5 years, the mean (±SE) summary survival rate was 79.2% ± 5.8% for PCI recipients and 82.2% ± 5.6% for CABG recipients. When we combined all trials, survival in patients with diabetes at 5 years was higher for CABG by only 0.2%, but the confidence bounds of this estimate were wide (−8.8% to 8.3%).

Outcomes in patients with double-vessel disease were compared with those in patients with triple-vessel disease in BARI (40), EAST (Emory Angioplasty versus Surgery Trial) (80), ERACI II (86), and the pooled analysis of the stent trials (127). In each instance, the survival advantage of CABG was greater for triple-vessel disease than for double-vessel disease, but the difference between CABG and PCI was not statistically significant in any trial.

No sex-based difference in survival (55) or cardiovascular events (127) was observed between PCI and CABG. Similarly, cigarette smoking was not associated with a difference in outcomes between the interventions (38, 62, 127).

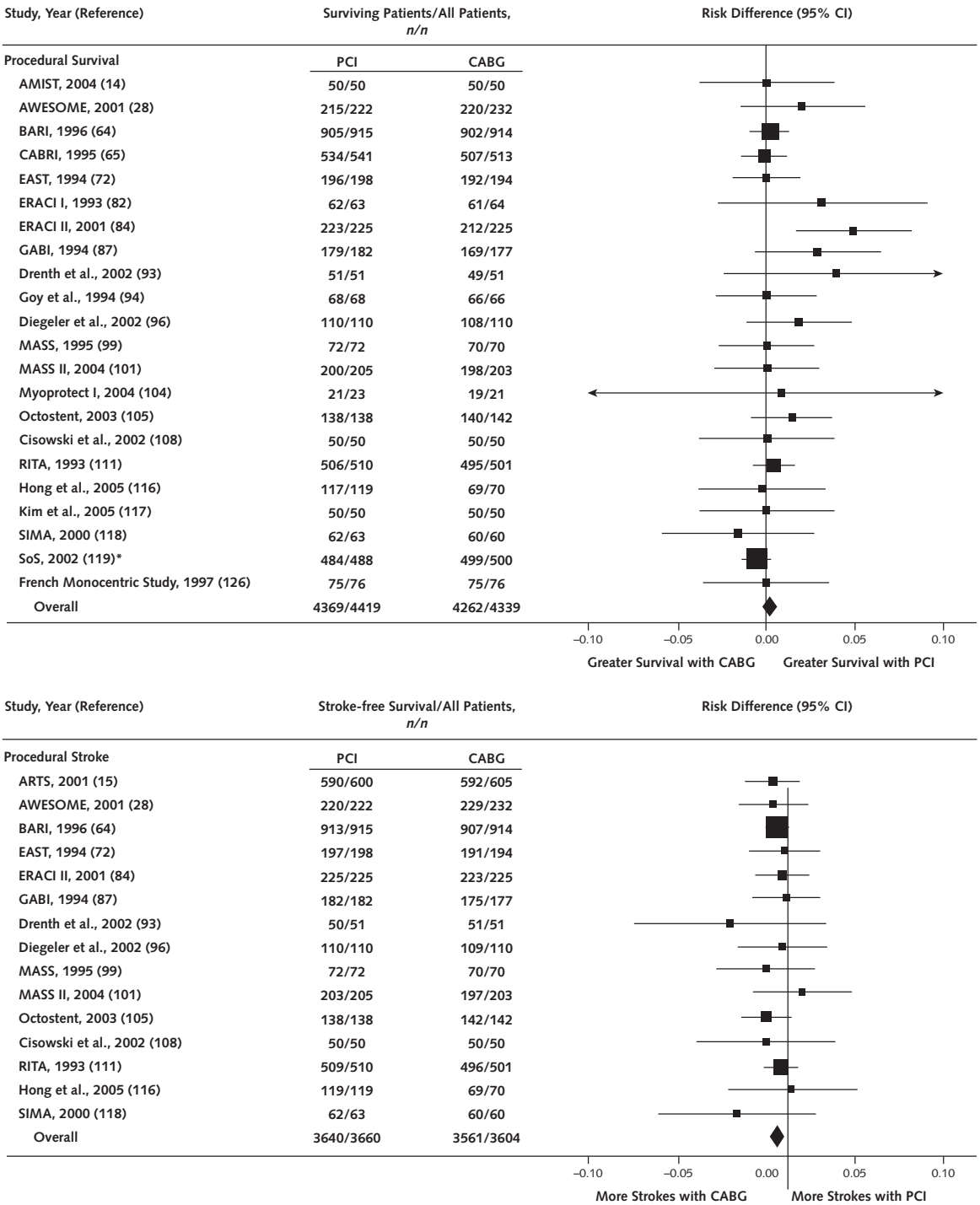
Mortality Rates in Clinical Registries

Five major clinical registries (128–132) included more than 1000 patients who received PCI and 1000 patients who received CABG, reported long-term survival patterns, and used multivariable statistical methods to adjust for clinical differences in patients selected for PCI and CABG (**Table 2**). These registries reported striking differences in the patients selected for these 2 procedures: Most patients with single-vessel disease received PCI, and most patients with triple-vessel disease received CABG. Across the spectrum of disease severity, the CABG–PCI hazard ratio for mortality ranged from 0.48 to 0.86 favoring CABG (128, 129). The CABG–PCI hazard ratio was affected by the extent of coronary disease. In the Duke University Medical Center registry (130), the CABG–PCI hazard ratio varied from 2.1 among patients with the least severe disease to 0.45 in patients with the most severe disease. Similar variations in the hazard ratio according to severity of disease were reported by various investigators using the Alberta, Canada (131); northern New England (129); and New York State (132) registries. In the patients with intermediate extent of disease who were most similar to patients enrolled in randomized trials, the studies based on data from clinical registries reported CABG–PCI hazard ratios close to 1.0.

DISCUSSION

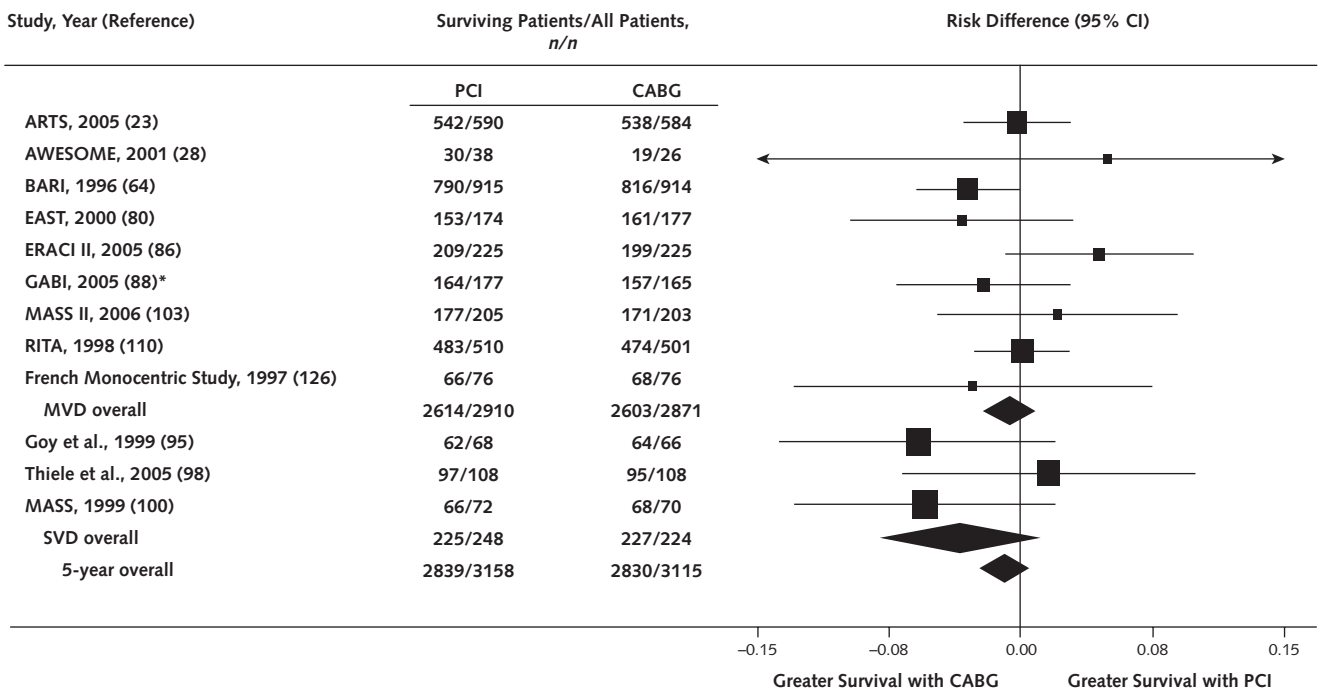
Our review of 23 randomized trials found that long-term survival did not statistically significantly differ be-

Figure 1. **Procedural survival (*top*) and stroke risk (*bottom*).**



The size of each box is proportional to the sample size of the trial. Bars represent 95% CIs. The I^2 statistic was <1 for both procedural survival and procedural stroke risk. AMIST = Angioplasty versus Minimally Invasive Surgery Trial; ARTS = Arterial Revascularization Therapies Study; AWESOME = Angina with Extremely Serious Operative Mortality Evaluation; BARI = Bypass Angioplasty Revascularization Investigation; CABG = coronary artery bypass grafting; CABRI = Coronary Angioplasty versus Bypass Revascularization Investigation; EAST = Emory Angioplasty versus Surgery Trial; ERACI = Argentine randomized trial of percutaneous transluminal coronary angioplasty versus coronary artery bypass surgery in multivessel disease; GABI = German Angioplasty Bypass Surgery Investigation; MASS = Medicine, Angioplasty, or Surgery Study; PCI = percutaneous coronary intervention; RITA = Randomized Intervention Treatment of Angina; SIMA = Stenting versus Internal Mammary Artery Study; SoS = Stent or Surgery. *Survival data were abstracted from Kaplan–Meier curves.

Figure 2. **Five-year survival in patients with single-vessel disease (*SVD*) versus multivessel disease (*MVD*).**



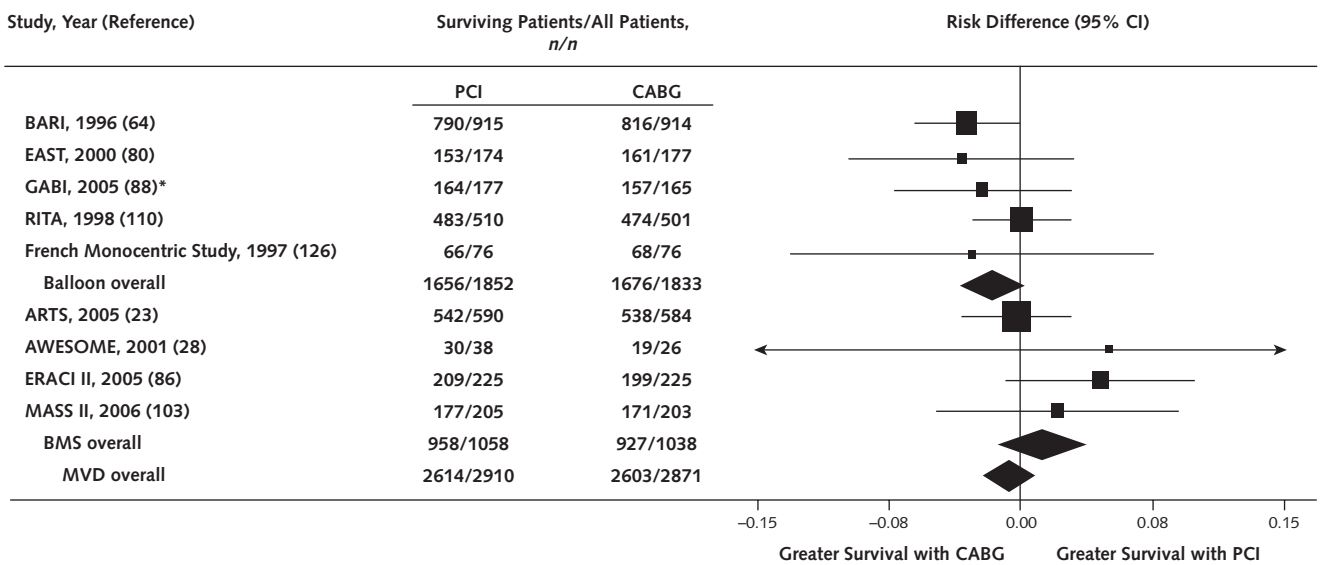
The size of each box is proportional to the sample size of the trial. Bars represent 95% CIs. The I^2 statistic for 5-year survival was 13 among SVD trials and 14 among MVD trials. ARTS = Arterial Revascularization Therapies Study; AWESOME = Angina with Extremely Serious Operative Mortality Evaluation; BARI = Bypass Angioplasty Revascularization Investigation; CABG = coronary artery bypass grafting; EAST = Emory Angioplasty versus Surgery Trial; ERACI = Argentine randomized trial of percutaneous transluminal coronary angioplasty versus coronary artery bypass surgery in multivessel disease; GABI = German Angioplasty Bypass Surgery Investigation; MASS = Medicine, Angioplasty, or Surgery Study; PCI = percutaneous coronary intervention; RITA = Randomized Intervention Treatment of Angina. *Data were abstracted from Kaplan–Meier curves.

tween PCI and CABG among patients in whom coronary revascularization is clinically indicated and in whom both procedures are technically feasible. Despite this similarity in long-term survival, several distinct differences between these alternative coronary revascularization procedures may affect the choice of procedure. The short-term risk for stroke was higher with CABG than with PCI, yet the frequency of angina was lower after CABG than after PCI over 5 years. Patients who received CABG also underwent fewer repeated revascularization procedures than did patients who received PCI, even when coronary stents were used.

Coronary revascularization methods continue to be refined, so that evaluation of the outcomes of PCI and CABG remains a moving target. Percutaneous coronary intervention has evolved from its initial reliance on balloon angioplasty techniques to use of bare-metal stents and, more recently, drug-eluting stents. Although these refinements in PCI technique have progressively reduced restenosis and the need for repeated coronary revascularization procedures, they have not reduced the rate of mortality or myocardial infarction after PCI (6, 7). Consequently, the earlier trials of PCI versus CABG continue to provide pertinent evidence about the "hard outcomes" of greatest importance after coronary revascularization. Techniques and outcomes of CABG have also improved over time (134, 135), and several large ongoing randomized trials are comparing contemporary PCI with contemporary CABG (for example, FREEDOM [Future Revascularization Evaluation in Patients With Diabetes Mellitus; ClinicalTrials.gov registration number NCT00086450], SYNTAX [SYNergy Between PCI With TAXUS and Cardiac Surgery; ClinicalTrials.gov registration number NCT00114972], and VA CARDS [Coronary Artery Revascularization in Diabetes; ClinicalTrials.gov registration number NCT00326196]).

Randomized trials enroll patients who meet strict inclusion and exclusion criteria and are conducted in centers chosen to have excellent clinical results and high procedure volumes. The perennial question about all randomized trials is whether their results can be generalized to less selected patient populations and practice settings. The randomized trials of PCI and CABG enrolled few patients who were older than 75 years of age; had poor left ventricular function, heart failure, or ongoing clinical instability; or had undergone previous CABG or PCI procedures. The results of the randomized trials, and our synthesis of those results, do not necessarily apply to these and other populations that were not well represented.

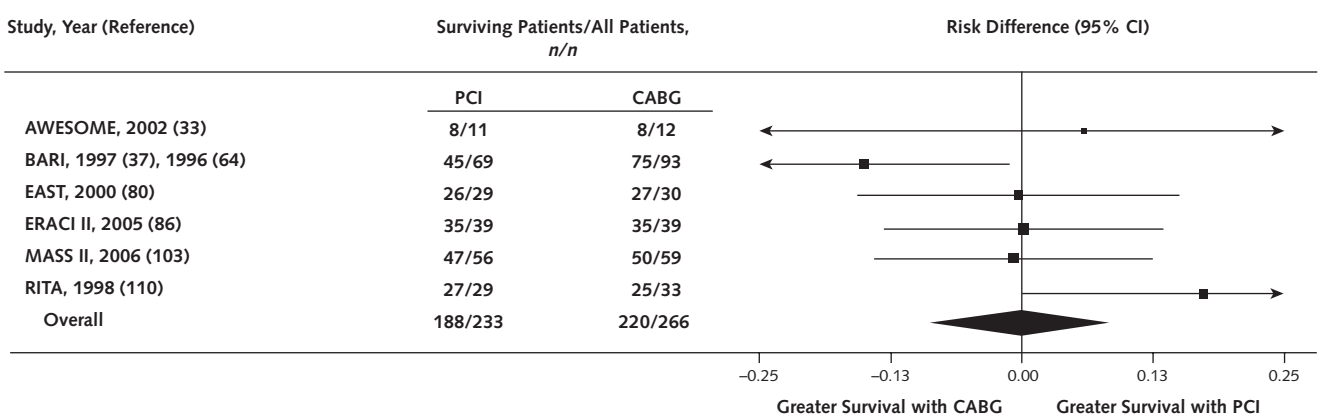
Figure 3. **Five-year survival with balloon angioplasty or stents versus coronary artery bypass grafting (*CABG*) in patients with multivessel disease (*MVD*).**



The size of each box is proportional to the sample size of the trial. Bars represent 95% CIs. The I^2 statistic for 5-year survival was 10 among MVD trials using balloon angioplasty and <1.0 among trials using stents. ARTS = Arterial Revascularization Therapies Study; AWESOME = Angina with Extremely Serious Operative Mortality Evaluation; BARI = Bypass Angioplasty Revascularization Investigation; BMS = bare-metal stent; CABG = coronary artery bypass grafting; EAST = Emory Angioplasty versus Surgery Trial; ERACI = Argentine randomized trial of percutaneous transluminal coronary angioplasty versus coronary artery bypass surgery in multivessel disease; GABI = German Angioplasty Bypass Surgery Investigation; MASS = Medicine, Angioplasty, or Surgery Study; PCI = percutaneous coronary intervention; RITA = Randomized Intervention Treatment of Angina. *Survival data were abstracted from Kaplan–Meier curves.

The greatest difference between patients enrolled in the clinical trials and those in typical practice was the requirement that both PCI and CABG be technically feasible and provide adequate revascularization in all randomly assigned patients. In large clinical registries, patients selected for PCI differ in important ways from patients chosen for

Figure 4. **Five-year survival in patients with diabetes.**



The size of each box is proportional to the sample size of the trial. Bars represent 95% CIs. The I^2 statistic was 40. All studies that reported comparative effectiveness data for patients with diabetes were included in this analysis, not just studies that reported comparative outcomes for patients with and without diabetes. Hazard ratios from the German Angioplasty Bypass Surgery Investigation for death after PCI or CABG were reported to not differ between patients with or without diabetes; however, these data were not shown. AWESOME = Angina with Extremely Serious Operative Mortality Evaluation; BARI = Bypass Angioplasty Revascularization Investigation; CABG = coronary artery bypass grafting; EAST = Emory Angioplasty versus Surgery Trial; ERACI = Argentine randomized trial of percutaneous transluminal coronary angioplasty versus coronary artery bypass surgery in multivessel disease; MASS = Medicine, Angioplasty, or Surgery Study; PCI = percutaneous coronary intervention; RITA = Randomized Intervention Treatment of Angina.

Table 2. **Long-Term Survival in Major Clinical Registries***

Study, Year (Reference)	Location of Clinical Registry	Centers, *n*	Enrollment Period	PCI Recipients, *n*	CABG Recipients, *n*	Extent of Disease, %			Overall CABG–PCI Hazard Ratio	Subgroup Hazard Ratio Range†
						Single Vessel	Double Vessel	Triple Vessel		
Hannan et al., 2005 (133)	New York State	35	1997–2000	22 102	37 212	0	80	20	NR	0.64–0.75
Hannan et al., 1999 (132)	New York State	32	1993–1995	29 930	29 646	40	28	32	NR	0.6–1.7
Jones et al., 1996 (130)	Duke University Medical Center	1	1986–1990	2924	3890	37	32	32	NR	0.4–2.1
Malenka et al., 2005 (129)	Northern New England	5	1994–2001	4295	10 198	0	60	40	0.86	0.60–0.98
Dzavik et al., 2001 (131)	Alberta, Canada	4	1995–1998	3540	3782	0	31	70	0.81	0.3–1.43
Pell et al., 2001 (128)	Scotland	6	1997–1999	4775	5115	23	18	59	0.48	NR

* CABG = coronary artery bypass grafting; NR = not reported; PCI = percutaneous coronary intervention.
† The CABG–PCI hazard ratio from most severe to least severe coronary artery disease.

CABG: Most patients treated with PCI have single-vessel coronary disease, whereas most patients treated with CABG have triple-vessel or left main coronary disease, and many have reduced left ventricular function (136, 137). The patients enrolled in clinical trials generally had an extent of coronary disease that fell between these 2 extremes, and the results of randomized trials may not apply to patients with less extensive or more extensive coronary disease.

Our finding of similar long-term survival after randomization to PCI or CABG differs from the findings of studies based on several large clinical registries, which have reported improved survival after CABG (**Table 2**). These large clinical registry studies were observational, nonrandomized comparisons, however, and are inherently less reliable than randomized trials because strong selection biases may be present that even sophisticated statistical adjustment techniques cannot remove. Clinical registry studies have shown that the extent and severity of coronary disease, which are the major factors determining selection for PCI versus CABG, strongly affect relative survival after PCI or CABG (129–131). In an analysis of information from the Duke University Medical Center database, survival after PCI and CABG was equivalent among patients who had an intermediate extent of coronary disease, similar to that of patients eligible for randomization in trials of PCI versus CABG (130). These observations suggest that the seemingly disparate results of randomized trials and clinical registries can be reconciled by taking into account that the overall outcomes in clinical registries are heavily weighted by the larger number of events in the higher-risk patients with the most extensive disease—who seem to have better outcomes after CABG than after PCI—whereas overall outcomes in the randomized trials were assessed in intermediate-risk patients—in whom CABG and PCI outcomes were also similar in clinical registries (130).

The potential for variation in the comparative effectiveness of treatments according to patient characteristics is very important to clinical decision making. Large clinical trials now commonly report relative risk reductions in several subgroups of interest, as well as in the overall population, but statistically significant variations in subgroup outcomes are distinctly unusual. Significant variations in treatment effect are very difficult to demonstrate because statistical power is reduced by the smaller sample sizes in subgroups, and patient selection narrows the range of variation in key clinical variables, which may further reduce the power to detect subgroup effects on outcome.

Although the comparative effectiveness of PCI and CABG in patient subgroups was our particular focus (10), we found that outcomes in key clinical subgroups were reported too infrequently to permit drawing reliable conclusions about most clinical characteristics of interest. The most extensive evidence pertains to patients with diabetes and those with triple-vessel versus double-vessel disease.

The adverse prognostic effect of diabetes has been reported consistently in patients undergoing coronary revascularization procedures and may be due to more extensive coronary disease at the time of revascularization, more rapid progression of coronary atherosclerosis in follow-up, or both factors. The finding of BARI that CABG reduced mortality compared with PCI among patients with diabetes, but not among patients without diabetes (64), has resulted in much debate. Summary data from 7 randomized trials that reported outcomes in this subgroup (**Figure 4**) shows that the overall survival advantage of CABG over PCI in patients with diabetes was small (0.9%) and was not statistically significant, but with wide CIs. This result is consistent with reports from several clinical registries that comparative survival after PCI and CABG is similar in patients with diabetes (138–140). Our finding supports the conclusion that there is clinical equipoise on this question, and that the ongoing randomized trials comparing CABG and PCI in patients with diabetes (such as

FREEDOM [ClinicalTrials.gov registration number NCT0086450], VA CARDS [ClinicalTrials.gov registration number NCT00326196], and CARDia [Coronary Artery Revascularization in Diabetes; 141]) are warranted.

Four randomized trials reported a larger difference in survival between CABG and PCI in patients with triple-vessel disease than in patients with double-vessel disease. Although this evidence is inconclusive, it is provocative in light of the strong and statistically significant effect of the extent of coronary disease on the relative hazard after PCI or CABG reported by the Duke database and other large clinical registries (129, 130, 133). This hypothesis could be tested by pooling individual patient–level data from randomized trials of PCI and CABG conducted in patients with multivessel disease.

Our study has limitations. It is a quantitative overview and is necessarily limited to the analysis of aggregate data from published trials. Subgroup data were incompletely and inconsistently reported; our analysis of subgroup effects may therefore be subject to publication bias if subgroups were selected for publication based in part on the outcomes. Five-year outcomes from the SoS trial (119) have not yet been published and were not available for analysis. Most important, no results from large ongoing trials using drug-eluting stents have been published.

Our analysis has identified numerous gaps in evidence of the comparative effectiveness of PCI and CABG that are opportunities for future research. The paucity of published data of PCI and CABG outcomes according to patient characteristics suggests the value of a collaborative pooling of individual patient–level data from the randomized trials to enhance statistical power to identify subgroup effects and to reduce publication bias by including data from all trials. Clinical trials are also needed to assess whether the availability of drug-eluting stents has affected the comparative efficacy of PCI and CABG. These trials, which are under way, are particularly needed because pooled studies suggest no difference in survival and freedom from myocardial infarction between bare-metal stents and drug-eluting stents over the medium term. Recent safety concerns about drug-eluting stents emphasize the need for extended follow-up and trials large enough to detect clinically meaningful differences in outcomes.

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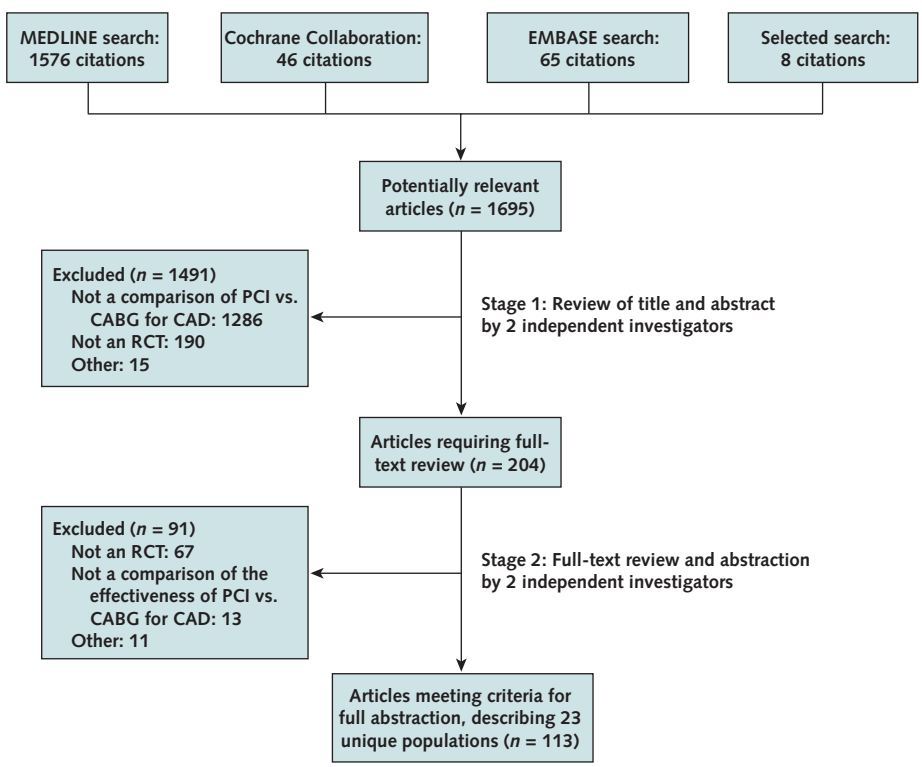
Appendix Figure. **Study flow diagram.**



CABG = coronary artery bypass grafting; CAD = coronary artery disease; PCI = percutaneous coronary intervention; RCT = randomized, controlled trial.