Coronary Bypass Surgery Performed off Pump Does Not Result in Lower In-Hospital Morbidity Than Coronary Artery Bypass Grafting Performed on Pump

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Background—There is increasing evidence that cardiopulmonary bypass (CPB) may be responsible for the morbidity associated with coronary artery bypass grafting (CABG) surgery. Recent developments in cardiac stabilization devices have made CABG without CPB feasible. However, there is conflicting evidence to date from published trials comparing outcomes between CABG performed with and without CPB, with some trials indicating an advantage to the avoidance of CPB and others showing little benefit.

Methods and Results—In a single-center randomized trial, 300 patients requiring CABG surgery at a single institution were prospectively randomized to have the procedure performed with CPB (n = 150) or on the beating heart (n = 150). Exclusion criteria for the trial included emergency procedure, concomitant major cardiac procedures, ejection fraction <30%, and reoperation. In-hospital outcomes were analyzed on an intention-to-treat basis. A mean of 3.0 ± 0.9 grafts were performed in the CPB group compared with 2.8 ± 0.9 grafts in the beating-heart group (P = 0.06). There were no significant differences between the CPB group and the beating-heart group in mortality (0.7% versus 1.3%; P = 1.0), transfusion (8.7% versus 9.3%), perioperative myocardial infarction (0.7% versus 2.7%; P = 0.37), permanent stroke (0% versus 1.3%; P = 0.50), new atrial fibrillation (32% versus 25%; P = 0.20), and deep sternal wound infection (0.7% versus 0%; P = 1.0). The mean time to extubation was 4 hours, the mean stay in the intensive care unit was 22 hours, and the median length of hospitalization was 5 days in both groups (P = NS).

Conclusions—In contrast to published trials, we were unable to demonstrate any advantage with CABG performed without CPB in terms of patient morbidity. Excellent results can be obtained with either surgical approach. (Circulation. 2004;109:887-892.)

Key Words: coronary disease □ revascularization □ cardiopulmonary bypass

Coronary artery bypass grafting (CABG) performed with cardiopulmonary bypass (CPB) has become a well-established treatment modality for patients with coronary artery disease.1 However, there has been increasing evidence that CPB may be responsible for some of the morbidity associated with CABG surgery. The systemic inflammatory reaction initiated by the extracorporeal circuit results in mechanical trauma to blood, activation of various immunologic cascades (complement, cytokines), impaired hemostasis, and impaired neurological, renal, and gastrointestinal function.2,3 Furthermore, aortic cannulation, cross-clamping, and CPB can result in microembolization and macroembolization with subsequent neurological injury and other end-organ injury, including global myocardial ischemia/reperfusion injury.4 Thus, it has been proposed that CABG surgery would be safer if CPB could be avoided.

The development of new cardiac stabilization devices has allowed for the creation of safe and reproducible coronary anastomoses on the beating heart.5-7 Several large, nonrandomized, retrospective case series comparing CABG surgery performed on the beating heart (off pump) and conventional CABG surgery performed with CPB (on pump) have indicated an advantage to CABG surgery without CPB; however, selection bias toward lower-risk cases in CABG without CPB remains an issue.8-14 The largest randomized studies published to date are conflicting, with some demonstrating decreased length of hospitalization and myocardial enzyme release,15 whereas others demonstrate decreased incidence of atrial fibrillation, length of hospitalization, and blood-product utilization with CABG surgery performed on the beating heart.16,17 The most recent trial demonstrated decreased blood-product requirement, myocardial enzyme release, and length of hospitalization in beating-heart surgery patients.18 Of the 3 published trials, 2 are single-surgeon experiences,
and as such, the potential for bias in end points that are
discretionary treatments (decision to extubate, discharge, and
transfuse) is an important consideration. Moreover, the
majority of these trials excluded high-risk patients, which brings
into question the generalizability of the results.

The present study was designed and powered to detect
significant differences in the following 3 major outcomes:
- blood-product requirements,
- length of hospitalization,
- prolonged mechanical ventilation.

It is, to the best of our knowledge, the largest single-center randomized controlled
study comparing CABG surgery performed on the beating
heart with CABG surgery using CPB.

Methods

Study Design and Patients

Between August 1999 and March 2003, 300 patients requiring
CABG surgery at a single institution were prospectively recruited
and, after they gave informed consent, were randomized to have the
procedure performed on the beating heart (off-pump) or with CPB
(on-pump). Indications for CABG surgery were based on a weekly
peer review process, which involved a cardiologist, cardiac surgeons,
and cardiac radiologists. Individual patients were queued for surgery
on the basis of objective criteria as described previously.20 Exclusion
criteria for the trial included emergency procedure (requiring imme-
diate surgery), concomitant major cardiac procedures, ejection frac-
tion <30%, and reoperation. The study was approved by the Capital
Health Research Ethics Board.

Six of 9 surgeons in this center participated in the study. Randomization
envelopes were generated by computerized block randomization to beating-heart (off-pump) CABG surgery or surgery
with CPB (on-pump). The block size varied from 8 to 20 patients and
was unknown to the study participants. Randomization was per-
formed intraoperatively after a preliminary inspection of the coro-
nary anatomy to better ensure that a beating-heart procedure
could be performed safely. Intraoperative reasons for nonrandom-
ization included intramyocardial vessels, very poor quality of distal
vessels, and hemodynamic instability with manipulation of the heart.
Once randomized, patients were allowed to cross over between
groups when it was judged by the treating surgeon that the procedure
assigned was unfeasible, for technical or hemodynamic reasons.

Surgical Technique

A median sternotomy was performed in all patients. Beating-heart
surgery was performed in a standardized fashion as described
previously.20 Briefly, 3 traction sutures were placed in the posterior
pericardium for retraction, followed by placement of a commercially
available tissue stabilizer (Medtronic Octopus and Coroné Cor-
vase). With the advent of the Octopus III (Medtronic), posterior
pericardial traction sutures were no longer necessary. A nontrau-
matic, small bulldog clamp was then applied to the target vessel
proximal to the anatomotic site to achieve hemostasis after arteri-
otomy. All anastomoses were constructed with a continuous-suture
technique with 7-0 or 8-0 monofilament sutures.

CABG surgery performed with CPB was done in a standardized
fashion with ascending aortic cannulation and 2-stage venous can-
nulation of the right atrium. During CPB, the mean arterial pressure
target was set at 60 mm Hg, and body temperature was allowed to
drift to a minimum of

37 °C. Intermittent cold-blood cardioplegic
(1:4 blood to crystalloid with maximal K+ concentration 22 mEq/L)
was delivered antegrad via the aortic root unless otherwise
indicated.

In either the CPB or beating-heart approaches, the choice of
conduits and construction of composite grafts was based on surgeon
preferences rather than fixed criteria. Arterial conduits were har-
vested with minimal trauma (nonskeletonized internal mammary
artery), and all were treated with either a Papaverine solution or
nitroglycerin/calcium channel blocker (Verapamil) solution before
use.

Heparin was given at a dose of 300 IU/kg to achieve target
activated clotting time >450 seconds in the CPB group compared with
100 IU/kg in the beating-heart group. On completion of anastomoses, both groups received protamine sulfate to reverse the
effects of heparin and return the activated clotting time to preoper-
ative levels. No special blood conservation techniques were used
other than nonhemic prime, retransfusion of all contents of the
oxygenator at the end of CPB, and acceptance of normovolemic
anemia. Postoperatively, nonhemic volume expanders were used
routinely.

Postoperative Management

All postoperative cardiac surgery patients were taken to a dedicated
cardiovascular intensive care unit (ICU). Each patient was required to
meet standard criteria before extubation and before transfer to the
intermediate care unit. The need for a perioperative blood-product
transfusion was determined on an individual, patient-by-patient
basis. There was no rigid transfusion trigger for the use of homolo-
gous blood products; however, in general, patients were not trans-
fused until serum hemoglobin was <70 mg/dL, unless they were
considered at risk clinically for decreased oxygen delivery. Overall
transfusion rates were captured for blood products given intraoper-
avely and postoperatively. Preoperative transfusions were not
included in this analysis. Similarly, patients were generally not
transferred from the ICU if they were considered at risk clinically for
decreased oxygen delivery. Discharged patients were transferred to
an intermediate-care or general-care ward under the care of the same
team. All patients were monitored continuously for a minimum of
24 hours.

All patients received intravenous nitroglycerin (0.1 to 8 µg · kg⁻¹ · min⁻¹)
infusions for the first 24 hours unless they were hypotensive
(systolic blood pressure <90 mm Hg). Oral nifedipine (Adalat 10 mg
PO QID or Adalat XL 30 mg/d) was prescribed for all patients
receiving a radial artery graft beginning on day 1 after surgery for a
period of 3 to 6 months. Other routine medications included daily
aspirin and resumption of cholesterol-lowering agents, β-blockers,
and ACE inhibitors as appropriate.

Data Collection

Perioperative patient variables were collected prospectively by 3
time-full research assistants. An elective case was defined as a
patient waiting at home before the procedure; in-house cases were
defined as hospitalized patients requiring surgery; urgent cases were
defined as cases in which surgery was deemed necessary within 24
hours to prevent further clinical deterioration; and emergent/emer-
gent salvage cases were those patients who required an immediate
operation. A 12-lead ECG was recorded before the operation, at 2
hours after surgery, and then when clinically indicated. ECG criteria
for perioperative myocardial infarction were new Q wave (0.04 ms
in at least 2 leads or ECG ST changes in association with significant
creatine kinase–MB enzyme release.

Data Analysis

All analyses were performed with the Statistical Analysis Systems
software package (SAS, release 8.2). Groups were analyzed on an
intention-to-treat basis. Descriptive statistics included continuous
data, χ² test, Wilcoxon rank sum test, and Fisher exact test.
Statistical significance was defined as a probability value of less than
0.05. On the basis of current literature, the present trial was powered
to detect significant differences in the following 3 major outcomes:
- blood-product requirements,
- length of hospitalization,
- prolonged mechanical ventilation. The power calculations translated into an
absolute risk reduction of 11% in blood-product requirements
(relative risk reduction of 60%), 15% in prolonged hospitalization
(defined as >6 days; relative risk reduction 40%), and 12% in
prolonged mechanical ventilation (defined as >10 hours; relative
risk reduction 53%) in favor of CABG patients whose procedure was performed on the beating heart.

Results

A total of 933 patients were eligible for the trial during the study period, of whom 400 patients were approached, which resulted in 351 patients who consented to participate. Of these, 51 were not randomized because their cases were assigned to a nonparticipating surgeon (n=27) or because of patient-related issues such as intramyocardial vessels or intraoperative hemodynamic instability (n=24). A total of 300 patients were randomized to undergo CABG surgery performed on CPB (n=150) or on the beating heart (n=150; Figure). Twenty-one patients did not receive the assigned intervention. Twenty were originally assigned to the beating-heart group, but because of hemodynamic instability (n=5), or inability to place the stabilizer because of obesity (n=1), they were crossed over to the CPB group. One patient assigned to the CPB group was crossed over to the beating-heart group because of extensive aortic disease. All analyses were performed on an intention-to-treat basis.

Preoperative patient characteristics were similar in both groups and are illustrated in Table 1. For the entire cohort, the average age of patients was 63 (range 38 to 87) years, with 26% aged >70 years. Thirty-three percent of patients were diabetic, 14% had moderate left ventricular dysfunction, 48% had a history of previous myocardial infarction, and 71% had 3-vessel coronary artery disease. The urgency of the procedure was elective in 77%, “in-house” or hospitalized in 21%, and urgent in 2% of the randomized patients.

A mean of 3.0±0.9 grafts were performed in the CPB group compared with 2.8±0.9 grafts in the beating-heart group (P=0.06; Table 2). There were no significant differences between CABG performed with CPB or with beating heart with regard to complete arterial revascularization (64% versus 68%; P=0.46), and avoidance of aortic proximal anastomoses (53% versus 55%; P=0.64). Patients who underwent CABG with CPB had a mean pump time of 97 minutes (range 76 to 113 minutes) and clamp time of 69 minutes (range 50 to 87 minutes).

Three patients died in the hospital, for an overall mortality rate of 1%, with no significant differences between groups (0.7% versus 1.3%; Table 3). Similarly there were no signifi-

<table>
<thead>
<tr>
<th>TABLE 1. Preoperative Patient Characteristics</th>
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<tbody>
<tr>
<td>Characteristic</td>
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<tr>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Age, y</td>
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<tr>
<td>Range</td>
</tr>
<tr>
<td>&gt;70 years, %</td>
</tr>
<tr>
<td>Female gender, %</td>
</tr>
<tr>
<td>Diabetes, %</td>
</tr>
<tr>
<td>Renal failure, %</td>
</tr>
<tr>
<td>Hypertension, %</td>
</tr>
<tr>
<td>Hypercholesterolemia, %</td>
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<tr>
<td>Peripheral vascular disease, %</td>
</tr>
<tr>
<td>Cerebrovascular disease, %</td>
</tr>
<tr>
<td>COPD, %</td>
</tr>
<tr>
<td>Previous CABG, %</td>
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<tr>
<td>Previous MI, %</td>
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<tr>
<td>Ejection fraction, %</td>
</tr>
<tr>
<td>&gt;50%</td>
</tr>
<tr>
<td>30–50%</td>
</tr>
<tr>
<td>CCS class, %</td>
</tr>
<tr>
<td>I</td>
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<tr>
<td>II</td>
</tr>
<tr>
<td>III</td>
</tr>
<tr>
<td>IV</td>
</tr>
<tr>
<td>Status, %</td>
</tr>
<tr>
<td>Elective</td>
</tr>
<tr>
<td>In-house</td>
</tr>
<tr>
<td>Urgent &lt;24 hours</td>
</tr>
<tr>
<td>Current smoking, %</td>
</tr>
<tr>
<td>LM stenosis (&gt;50%), %</td>
</tr>
<tr>
<td>Diseased vessels, %</td>
</tr>
<tr>
<td>Single</td>
</tr>
<tr>
<td>BMI, mean (SD), kg/m²</td>
</tr>
<tr>
<td>Preoperative hemoglobin, mean (SD)</td>
</tr>
<tr>
<td>Preoperative atrial fibrillation, %</td>
</tr>
</tbody>
</table>

CPD indicates chronic obstructive lung disease; MI, myocardial infarction; CCS, Canadian Cardiovascular Society; LM, left main; and BMI, body mass index.

icant differences between the CPB group and the beating-heart group in perioperative myocardial infection (0.7% versus 2.7%; P=0.37), permanent stroke (0% versus 1.3%; P=0.50), new atrial fibrillation (32% versus 25%; P=0.20), and deep sternal wound infection (0.7% versus 0%; P=1.0). Additional morbidity outcome and composite outcome (mortality/perioperative intra-aortic balloon pump/myocardial infarction/stroke/prolonged ventilation) also failed to demonstrate significant differences between the 2 surgical approaches (Table 3).

The use of any blood products perioperatively was similar in both groups, with an overall transfusion rate of 9% (Table
TABLE 2. Graft, Conduits, and Surgical Characteristics of Randomized Patients

<table>
<thead>
<tr>
<th>Patient Characteristic</th>
<th>CPB Group (n=150)</th>
<th>Beating-Heart Group (n=150)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIMA, %</td>
<td>96.7</td>
<td>97.3</td>
<td>1.00</td>
</tr>
<tr>
<td>RIMA, %</td>
<td>44.7</td>
<td>40.7</td>
<td>0.48</td>
</tr>
<tr>
<td>Radial artery, %</td>
<td>28.0</td>
<td>34.7</td>
<td>0.21</td>
</tr>
<tr>
<td>Complete arterial grafts, %</td>
<td>64.0</td>
<td>68.0</td>
<td>0.46</td>
</tr>
<tr>
<td>Zero proximals, %</td>
<td>52.7</td>
<td>55.3</td>
<td>0.64</td>
</tr>
<tr>
<td>Distal anastomosis, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>4.0</td>
<td>4.7</td>
<td>...</td>
</tr>
<tr>
<td>2</td>
<td>23.3</td>
<td>33.3</td>
<td>...</td>
</tr>
<tr>
<td>3</td>
<td>42.0</td>
<td>38.0</td>
<td>...</td>
</tr>
<tr>
<td>4</td>
<td>26.7</td>
<td>20.7</td>
<td>...</td>
</tr>
<tr>
<td>≥5</td>
<td>4.0</td>
<td>3.3</td>
<td>0.37</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>3.0 (0.9)</td>
<td>2.8 (0.9)</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>3 (2–4)</td>
<td>3 (2–3)</td>
<td>0.06</td>
</tr>
</tbody>
</table>

LIMA indicates left internal mammary artery; RIMA, right internal mammary artery; and IQR, interquartile range.

4). The mean time to extubation was 4 hours, the mean ICU stay was 22 hours, and the median length of hospitalization was 5 days in both groups (P=NS). Similarly, the incidence of prolonged mechanical ventilation, defined as >10 hours, was not significantly different between the CPB group (9.3%) and the beating-heart group (12%; P=0.45).

Discussion

Several large case series have suggested morbidity benefit, cost benefit, reduced length of hospitalization, and even mortality benefit for patients undergoing beating-heart CABG surgery compared with CABG performed with CPB.10,12–14,21 More recent retrospective studies, using more sophisticated statistical tools such as case matching and propensity score analysis, have also suggested that beating-heart surgery is associated with decreased morbidity manifested by reduction in transfusion requirement, infection, length of hospitalization, renal failure, and encephalopathy but not mortality.8,9 However, despite the use of sophisticated statistical tools designed to allow valid comparisons, the inherent bias toward fitter patients for beating-heart CABG may not have been adequately addressed by these techniques.

To date, 3 randomized controlled trials have been performed that compared CABG surgery with or without CPB. All of these studies have been modest in size (197 to 281 patients), 2 have been single-surgeon studies, and all have studied relatively limited patient populations, which calls into question the generalizability of the results to “average” cardiac surgeons with “typical” CABG practices. Furthermore, the only significant differences in outcomes have been nearly exclusively in discretionary therapeutic end points (blood transfusion, time to extubation, time in ICU, and time in hospital), for which bias concerning the assignment to on- or off-pump bypass may have altered thresholds for intervention or discharge.15,16,18,22 The largest published trial (n=281) was a multicenter trial limited to young patients with normal ejection fraction and with 1- or 2-vessel coronary artery disease. The authors reported shorter time to extubation (3 versus 9 hours) and reduced length of hospitalization (6 versus 7 days) in beating-heart patients. Transfusion rates were lower intraoperatively (3% versus 13%) but not postoperatively (28% versus 29%). There were no other morbidity or mortality differences.15 Ascione et al16,17 reported a concatenation of two 100-patient, single-surgeon trials in low-risk patients with low rates of diabetes, peripheral vascular disease, and 3-vessel coronary artery disease. This group showed lower blood transfusion rates (33% versus 53%), reduced length of hospitalization (5 versus 7 days), and decreased incidence of atrial fibrillation in beating-heart patients (12% versus 37%).16,17 Most recently, Puskas et al,18 in a single-surgeon trial, attempted to address these criticisms by randomizing 197 relatively unselected patients (no shock patients, no redo CABG, preoperative intra-aortic balloon pump) and reported reduced length of hospitalization (5 versus 6 days), shorter time to extubation, and lower transfusion rates (26% versus 44%). A recent meta-analysis of all randomized controlled trials failed to show significant benefit of CABG performed on the beating heart versus with CPB.23

The present randomized controlled trial comparing CABG surgery performed on the beating heart versus CPB is the largest to date, with 300 patients randomized. In the present study, more than 30% of patients were diabetics, and the majority had Canadian Cardiovascular Society angina class III/IV and had critical lesions in all 3 coronary distributions. Thus, contrary to the studies by Ascione et al16,17 and Van Dijk et al,15 the present patient population may have been more representative of current CABG practices, and unlike the studies by Puskas et al18 and Ascione et al16,17 we were not limited to a single-surgeon experience. We report an overall mortality rate of 1%, which was not significantly different between groups and which compares favorably to TABLE 3. Primary and Secondary Outcomes

<table>
<thead>
<tr>
<th></th>
<th>CPB Group (n=150)</th>
<th>Beating-Heart Group (n=150)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined outcome*</td>
<td>6 (4.0)</td>
<td>9 (6.0)</td>
<td>0.43</td>
</tr>
<tr>
<td>In-hospital mortality</td>
<td>1 (0.7)</td>
<td>2 (1.3)</td>
<td>1.0</td>
</tr>
<tr>
<td>Intraoperative/postoperative IABP</td>
<td>1 (0.7)</td>
<td>2 (1.3)</td>
<td>1.0</td>
</tr>
<tr>
<td>Perioperative MI</td>
<td>1 (0.7)</td>
<td>4 (2.7)</td>
<td>0.37</td>
</tr>
<tr>
<td>Stroke</td>
<td>0 (0.0)</td>
<td>2 (1.3)</td>
<td>0.50</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>1 (0.7)</td>
<td>6 (4.0)</td>
<td>0.12</td>
</tr>
<tr>
<td>New postoperative atrial fibrillation</td>
<td>48 (32.0)</td>
<td>38 (25.3)</td>
<td>0.20</td>
</tr>
<tr>
<td>Deep sternal infection</td>
<td>1 (0.7)</td>
<td>0 (0.0)</td>
<td>1.0</td>
</tr>
<tr>
<td>Return to OR for bleeding</td>
<td>3 (2.0)</td>
<td>2 (1.3)</td>
<td>1.0</td>
</tr>
<tr>
<td>Inotropes leaving OR</td>
<td>18 (12.0)</td>
<td>19 (12.7)</td>
<td>0.86</td>
</tr>
<tr>
<td>Return to OR for graft occlusion</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Recatheterization or angioplasty</td>
<td>1 (0.7)</td>
<td>2 (1.3)</td>
<td>1.0</td>
</tr>
</tbody>
</table>

IABP indicates intra-aortic balloon pump; MI, myocardial infarction; and OR, operating room. In-hospital patient outcomes including a composite outcome (mortality, IABP, MI, stroke, or prolonged mechanical ventilation). Values are n (%).

*Mortality/IABP/MI/stroke/long ventilation.
previously published studies. In the present series, a large proportion of patients had complete arterial revascularization (66%), with many having no proximal anastomoses onto the aorta (54%). The mean or median number of grafts per patient was slightly lower for beating-heart patients (not significant), but that may reflect the fact that a larger number of patients did not have 3-vessel disease in the beating-heart group. Similar findings were noted by Van Dijk et al.15

We demonstrate that very low transfusion rates (9.3% versus 8.7%) can be achieved without special measures in first-time isolated CABG, with no additional benefit derived from beating-heart surgery. Our findings differed markedly from those of existing studies, which demonstrate at least a transient reduction in transfusion rates with beating-heart surgery. All of those trials had markedly higher transfusion rates than the present study, even in the beating-heart arm (28% versus 29% in the study by van Dijk et al,15 33% versus 53% in the study by Ascione et al,16 and 26% versus 44% in the study by Puskas et al18). It is evident that the discretionary end point of blood-product utilization after cardiac surgery varies tremendously despite the publication of transfusion guidelines.24–26

Contrary to previous published trials, we were unable to demonstrate any differences in the time to extubation, length of ICU stay, or length of hospitalization, which suggests little benefit attributable to beating-heart surgery. Additionally, in the present study, the median time to extubation of 4 hours, ICU stay of 22 hours, and median length of hospitalization of 5 days demonstrated in both groups all compare favorably with those of existing studies, which demonstrate at least a transient reduction in transfusion rates with beating-heart surgery. All of those trials had markedly higher transfusion rates than the present study, even in the beating-heart arm (28% versus 29% in the study by van Dijk et al,15 33% versus 53% in the study by Ascione et al,16 and 26% versus 44% in the study by Puskas et al18). It is evident that the discretionary end point of blood-product utilization after cardiac surgery varies tremendously despite the publication of transfusion guidelines.24–26

In conclusion, we have shown that in a randomized controlled trial of 300 patients to CABG surgery with or without CPB, we have been unable to demonstrate any significant differences in short-term mortality or morbidity outcomes. Excellent results can be obtained with both surgical approaches, ie, CABG surgery on the beating heart or with CPB.

Acknowledgments

This study was supported by the Maritime Heart Center. We would like to thank the following individuals, who were instrumental in enabling the completion of this trial: Dr Claudio DiQuinzio (Head of Cardiac Anesthesia), on behalf of all cardiac anesthesia members, and Karen Ferrera (booking office).

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_Circulation_. 2004;109:887-892; originally published online February 2, 2004;
doi: 10.1161/01.CIR.0000115943.41814.7D

_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2004 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

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