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Fewer Grafts Performed in Off-Pump Bypass Surgery: Patient Selection or Incomplete Revascularization?

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Background. Comparisons of off-pump (OPCAB) versus conventional on-pump coronary artery bypass (CCAB) consistently report fewer grafts per patient with OPCAB. Performing fewer grafts than indicated based on angiographic assessment could result in incomplete revascularization. We questioned whether OPCAB influenced surgeons to perform fewer grafts than needed.

Methods. Preoperative angiographic and surgical data were collected prospectively on 945 patients undergoing coronary artery bypass grafting (370 OPCAB, 575 CCAB) at 8 hospitals between February 1, 2004, and July 31, 2004. The number of grafts needed per patient was determined from the reported number of vessels with angiographic stenoses of 50% or greater, and compared with the number received per patient, stratified by coronary artery bypass grafting technique.

Results. The OPCAB and CCAB groups were demographically similar. The mean number of grafts needed per patient was significantly less in the OPCAB group

In an effort to decrease morbidity and mortality associated with coronary artery bypass grafting (CABG), there has been a resurgence in the past decade in the use of off-pump coronary artery bypass (OPCAB) as an alternative to conventional coronary artery bypass (CCAB) [1]. Although there are numerous clinical studies attesting to the benefits of OPCAB, a number of questions persist regarding the safety, efficacy, and equivalency of revascularization with OPCAB compared with CCAB [2]. Consequently, adoption of OPCAB has reached a plateau during the past few years, with only 20% of all CABG procedures in the United States in 2004 performed off-pump [3].

Large multicenter studies comparing OPCAB and CCAB consistently show a higher mean number of bypass grafts performed in CCAB patients compared with OPCAB patients [3–14]. It remains unclear, however, whether the decreased number of grafts seen in OPCAB versus CCAB is owing to patient selection, as suggested

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Address correspondence to Dr Magee, Medical City Dallas Hospital, 7777 Forest Lane, Suite A-323, Dallas, TX 75230; e-mail: mmagee@csant.com. (2.95 versus 3.48), accounting for fewer grafts received in that group (2.75 versus 3.36). The ratio of grafts (received/ needed) was the same in both groups. Patients receiving more than three grafts were more likely to have CCAB (71.2%), whereas those receiving fewer than three grafts were almost as likely to have OPCAB as CCAB (55.5%). The rate of 1-year major adverse events (death, myocardial infarction, repeat revascularization) was the same in OPCAB and CCAB (15.5% versus 14.1%; p = 0.57).

Conclusions. Completeness of revascularization, determined by comparing the number of grafts performed to the number needed, was equivalent in OPCAB and CCAB patients, and 18-month clinical outcomes were equivalent. Preferential selection of patients needing more bypass grafts to CCAB results in the lower mean number of grafts per patient with OPCAB.

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in a recent study of The Society of Thoracic Surgeons National Database [15]. Alternatively, it has been proposed that fewer bypass grafts are performed in OPCAB patients because of the technical challenges of the procedure, resulting in incomplete revascularization [7, 14, 16]. Puskas and colleagues [17], in a randomized singlesurgeon comparison of OPCAB and CCAB, proposed an index of complete revascularization defined as a ratio of the number of bypass grafts performed to the number of diseased vessels as a measure of completeness of revascularization. Using a similar methodology, we sought to determine the comparative completeness of revascularization in OPCAB and CCAB in patients prospectively enrolled in a revascularization registry [13].

Patients and Methods

The CARE (Coronary Artery Revascularization) registry included all patients undergoing isolated coronary revascularization in a 6-month period between February 1 and July 31, 2004, in eight hospitals in the HCA Hospital System (HCA, Inc, Nashville, TN); patients were prospectively enrolled. The institutions were all nonacademic centers located in the southern and southeastern

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United States (Appendix). All institutions participated in both The Society of Thoracic Surgeons National Adult Cardiac Database and the American College of Cardiology 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, and the data were sent to the coordinating study center. All information transfer met with Health Insurance Portability and Accountability Act compliance guidelines.

Exclusion criteria included patients undergoing any concomitant procedure (except transmyocardial laser revascularization) or undergoing CABG on a salvage basis. 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 cardiac death, myocardial infarction, and need for repeat revascularization by either CABG or percutaneous coronary intervention.

This subanalysis examines all the CABG procedures in the study performed either on-pump or off-pump to compare the ratio between the number of grafts actually performed during the procedure and the number of coronary arteries with significant disease (50% or more decrease in the luminal diameter on angiography).

Data Analysis

All data were input into a customized database. Lesions were recorded for left main, left anterior descending, diagonals (three branches), obtuse marginals (three

Table 1. Preoperative Demographics

Variable	Off-Pump $(n = 370)$	$\begin{array}{l} \text{On-Pump} \\ (n = 575) \end{array}$	p Value
Male	265 (71.6%)	395 (68.7%)	0.34
Diabetics	118 (31.8%)	199 (34.6%)	0.39
Renal failure on dialysis	8 (2.2%)	6 (1.1%)	0.16
Operative status			
Elective	145 (39.8%)	212 (37.1%)	0.18
Emergency	9 (2.5%)	27 (4.7%)	
Urgent	210 (57.7%)	333 (58.2%)	
Current smoker	99 (28.2%)	152 (28.3%)	0.99
Previous CABG	11 (3.0%)	34 (5.9%)	0.04
MI within 7 days	62 (16.8%)	130 (22.6%)	0.03
Age (y)	63.4 ± 11.1	63.5 ± 10.1	0.85
EF	0.51 ± 0.12	0.48 ± 0.12	< 0.001
STS predicted risk of mortality (PROM) (%)	2.14 ± 3.54	2.44 ± 3.11	0.19

CABG = coronary artery bypass grafting; EF = ejection fraction; MI = myocardial infarction; STS = The Society of Thoracic Surgeons.

	Table 2.	Distribution	of Arterial	and Sa	phenous	Vein	Grafts
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	Arterial Grafts		Vein Grafts	
Graft Target	Off-Pump	On-Pump	Off-Pump	On-Pump
LAD	88.7%	88.4%	2.5%	3.9%
Diagonal	8.9%	8.6%	18.6%	20.0%
Circumflex	1.2%	1.9%	37.2%	6.2%
Obtuse marginal	1.2%	1.1%	32.4%	33.4%
RCA			19.2%	18.1%
PDA			20.2%	18.4%

 $LAD = left \ anterior \ descending \ coronary \ artery; \qquad PDA = posterior \ descending \ artery; \qquad RCA = right \ coronary \ artery.$

branches and ramus), right coronary artery, posterior descending, and posterior lateral. All graft conduits involving mammary (either or both), radial, or gastroepiploic arteries or saphenous vein were also recorded. The total number of lesions and grafts was calculated for each patient, and the ratio (index of complete revascularization, ICRV) determined. If the number of bypass grafts performed equaled the total number of vessels with significant disease, the ratio was 1. Patients having fewer grafts performed than the number of vessels with angiographically significant disease had a ratio less than 1.

Data presented for number of arterial, vein, and total grafts per patients were calculated based on the total number of grafts and total number of patients. Conversely the index of revascularization was calculated on a per patient basis and then means and 95% confidence limits obtained. This prevented patients having or needing a large number of grafts from biasing the data. Each patient then had equal weighting in the mean. This approach calculated how many patients had complete revascularization, regardless of how many grafts were needed.

Statistical Analysis

For statistical analysis, data were exported from the database to SAS 9.1.3 (SAS Institute, Cary, NC) [18]. Continuous variables were compared using Student's *t* tests. Categorical variables were analyzed using the χ^2 or the Fisher's exact test when the number of expected responses in a cell was small.

Table 3. Index of Revascularization

Off-pump		On-pump		
Index	95% CI	Index	95% CI	<i>p</i> Value
All surgeons–all patients 1.03	(0.97 to 1.08)	1.07	(1.03 to 1.10)	0.19
Surgeons 1%–25% off-pump				
0.78	(0.66 to 0.90)	1.09	(1.05 to 1.14)	< 0.001

CI = confidence interval.



Fig 1. Fraction of each surgeon's cases performed on-pump (black bars) and off-pump (white bars).

Results

A total of 1,245 patients in the CARE registry underwent CABG between February 1 and July 31, 2004, of which 945 (76%) had sufficient angiographic and intraoperative data for analysis. Of these 945 patients, 575 patients (61%) were on-pump and 370 patients (39%) were off-pump.

The OPCAB and CCAB patient groups were similar with the exception that the on-pump patient group had a higher proportion of patients with prior CABG, recent myocardial infarction (within 7 days), and a lower mean ejection fraction (Table 1).

According to The Society of Thoracic Surgeons National Database definition of single-, double-, and triple-vessel disease, there were 92 patients with single-vessel disease of which 60 (65.2%) were operated on off-pump and 32 (34.8%), on-pump. Of the 287 patients with double-vessel disease, 127 (44.3%) underwent off-pump revascularization and 160 (55.8%), on-pump revascularization. Finally, 566 patients had triple-vessel disease, of which 383 (68%) were revascularized on-pump and 183 (32.3%), off-pump.

The distribution of target vessels bypassed with either arterial or venous grafts was similar in both OPCAB and CCAB groups (Table 2).

The CARE registry included 37 surgeons with widely varied degrees of OPCAB adoption and use (Fig 1). Seven surgeons performed all their reported procedures onpump, 3 surgeons performed all their reported procedures off-pump, and the remaining 27 surgeons selected



Fig 2. Fraction of cases performed off-pump (light gray bars) or onpump (dark gray bars) by number of lesions needing grafting.

Variable	Off-Pump $(n = 342)$	$\begin{array}{l} \text{On-Pump} \\ \text{(n = 539)} \end{array}$	p Value
Mortality	32 (9.4%)	36 (6.7%)	0.15
Perioperative	6 (1.8%)	10 (1.9%)	0.91
Late mortality	26 (7.6%)	26 (4.8%)	0.09
Myocardial infarction	3 (0.9%)	11 (2.0%)	0.38
Revascularization	19 (5.5%)	31 (5.7%)	0.90
by CABG	1 (0.3%)	3 (0.6%)	0.57
by PCI	18 (5.3%)	28 (5.2%)	0.97
MACE	54 (15.5%)	78 (14.1%)	0.57

Table 4. Major Adverse Cardiac Events in Off-Pump andOn-Pump Patients at 18 Months

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

a variable percentage of patients for off-pump or onpump CABG.

The mean number of vessels with angiographically significant lesions and therefore the number of bypass grafts needed was less in the OPCAB group (2.95 \pm 1.22) than in the CCAB group (3.48 \pm 1.24). The proportion of patients selected for either OPCAB or CCAB based on the number of vessels with significant disease needing bypass is shown graphically in Figure 2. Patients needing more than three bypass grafts were more likely to be selected for CCAB. The mean number of grafts performed was 2.75 \pm 1.12 off-pump (1.17 \pm 0.62 arterial and 1.58 \pm 1.15 vein grafts) in the OPCAB group and 3.36 \pm 1.01 (1.12 \pm 0.65 arterial and 2.24 \pm 1.09 vein grafts) in the CCAB group.

For each patient, the number of bypass grafts performed was divided by the number of coronary arteries with angiographically significant disease (number of grafts needed) to calculate an ICRV (Table 3). The ICRV was similar in both groups with a ratio of 1.03 (95% confidence interval, 0.97 to 1.08) for the off-pump group and 1.07 (95% confidence interval, 1.03 to 1.10) for the on-pump group (Table 3). However, surgeons who selectively used OPCAB in less than 25% of their patients had a significantly lower ICRV in their OPCAB patients (0.78) compared with the CCAB group (1.09).

Using the Social Security Death Index, medical records, and patient contact by telephone, outcomes data were collected at 18 months after surgery with respect to cardiac death, myocardial infarction, and revascularization. Overall clinical outcomes at 18 months after surgery, as determined by the end points of mortality, myocardial infarction, and repeat revascularization as well as the MACE composite end point incorporating all three variables, were similar (Table 4).

To determine whether complete or incomplete revascularization had an effect on outcomes, the MACE outcome data were stratified by index value.

In comparing patients with and without complete revascularization (ICRV < 1 versus ICRV \ge 1), there was a trend toward increased MACE in patients without complete revascularization (ICRV < 1; Table 5).

When stratified by procedure, only OPCAB and not CCAB patients with an ICRV less than 1 had a statistically significant increase in MACE compared with patients with an ICRV greater than or equal to 1 (Fig 3).

Comment

Numerous clinical studies comparing off-pump and conventional on-pump CABG have shown benefit to the OP-CAB technique, but these studies also reveal limitations of OPCAB that likely have hindered widespread adoption [3, 12, 19-21]. No large, prospective, randomized multicenter trial exists comparing the two techniques, nor will there likely be such a trial completed in the future. We are therefore left with retrospective analyses, such as the CARE registry, to attempt to discern the relevant relative benefits and limitations of OPCAB in clinical practice. Off-pump CABG is technically more challenging with an associated significant learning curve. These technical challenges may influence both the selection of patients for OPCAB as well as the conduct of the operation, potentially introducing unintended compromise of the procedure and associated worse outcomes [7, 14].

In the CARE registry, as in other large CABG studies, the average number of bypass grafts performed in OPCAB patients was less compared with CCAB [11–14]. The average number of major coronary arteries with angiographically significant stenoses (>50%) was also less in OPCAB patients, resulting in an equivalent index of revascularization in the OPCAB and CCAB groups [1, 17, 22]. We and others have shown previously that the need for increasing numbers of bypass grafts is a factor in selecting patients for CCAB versus OPCAB. This study suggests a similar influence on selection, as those patients needing three or more bypass grafts were more often selected for CCAB.

The OPCAB and CCAB groups shared similar demographics and risk factors that might influence outcomes, and the 18-month outcomes as measured by cardiac mortality, myocardial infarction, need for repeat revascularization, and the combined end point (MACE) were

 Table 5. Major Adverse Cardiac Events at 18 Months in

 Patients With Index of 1 or Greater and Index Less Than 1

Variable	Index ≥ 1 (n = 597)	Index < 1 (n = 284)	p Value
Mortality	40 (6.7%)	28 (9.9%)	0.10
Perioperative	9 (1.5%)	7 (2.5%)	0.32
Late mortality	31 (5.2%)	21 (7.4%)	0.20
Myocardial infarction	10 (1.7%)	6 (2.1%)	0.65
Perioperative	4 (0.7%)	0	0.31
Late	6 (1.0%)	6 (2.1%)	0.22
Revascularization	28 (4.7%)	15 (5.3%)	0.70
by CABG	3 (0.5%)	1 (0.4%)	1.00
by PCI	25 (4.2%)	14 (4.9%)	0.65
MACE	68 (11.4%)	45 (15.9%)	0.06

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

ADULT CARDIAC



Fig 3. Variation in major adverse cardiac events (MACE) with change in index for offpump and on-pump patients. (MI = myocardial infarction; Revasc = revascularization.)

similar in both groups. Incomplete revascularization has been shown to result in poorer outcomes; therefore the equivalent outcomes observed in the OPCAB and CCAB groups associated with equivalent indices of revascularization is predictable. When we compare outcomes in all patients with incomplete revascularization (ICRV < 1) to those with complete revascularization (ICRV > 1), the result is again predictable, with those patients incompletely revascularized demonstrating poorer outcomes at 18 months. When this was stratified by procedure, the negative effect of incomplete revascularization on 18month outcomes was limited to the OPCAB group. The reason that incomplete revascularization had a greater impact on 18-month outcomes in the OPCAB patients is unclear, and is beyond the scope of this subgroup analysis.

In an effort to determine the influence of OPCAB experience on incomplete revascularization, we looked at the relationship between individual surgeons' practice mix of OPCAB and CCAB and the incidence of incomplete revascularization with each technique. Surgeons who use OPCAB in greater than 25% of their CABG patients were equally likely to achieve complete revascularization regardless of whether OPCAB or CCAB was selected. Conversely surgeons who use OPCAB in fewer than 25% of their CABG patients were less likely to achieve complete revascularization in their OPCAB patients compared with their CCAB patients. Furthermore, as previously mentioned, these OPCAB patients who are not completely revascularized are more likely to have poorer outcomes at 18 months.

The CARE registry reflects current practice in nonacademic medical centers, representing surgeons with varied degrees of OPCAB use. This study has the limitations of being a nonrandomized retrospective substudy analysis designed to address the association of incomplete revascularization with the decreased number of bypass grafts observed in selected OPCAB patients. We conclude that it is selection of patients requiring fewer grafts for OPCAB, and not performance of fewer than needed grafts resulting in incomplete revascularization, that accounts for the commonly observed lower number of bypass grafts performed in off-pump compared with on-pump CABG. Caution should be exercised by surgeons who seldom use OPCAB, as there may be a tendency to achieve less than complete revascularization with OPCAB, resulting in a significant effect on patient outcomes.

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DISCUSSION

DR HENDRICK B. BARNER (St. Louis, MO): The authors are to be congratulated for a nicely presented timely report which puts to rest the charge that off-pump is associated with incomplete revascularization. Their intuitively likely conclusion required the authoritative confirmation, which we have just heard. The 2005 report in *Circulation* from the American Heart Association Council on Cardiovascular Surgery and Anesthesia stated that fewer grafts were placed, or seemed to be placed, with off-pump and implied that there was incomplete revascularization with off-pump. This was a true statement but did not address the true issue, which we have just heard presented. Thus, fewer diseased vessels is the reason for fewer grafts being placed. Michael Mack's group has again presented an important observation.

DR JOHN S. IKONOMIDIS (Charleston, SC): Mitchell, I would make the argument that this paper does not show that the frequency of incomplete revascularization is the same in both groups, because you showed that those patients that underwent OPCAB (off-pump coronary artery bypass) had fewer diseased vessels at the start and were preferentially selected for OPCAB if the number of potential targets were smaller. If you had conducted this study in a purely randomized fashion, what would have happened if some of those patients that had more targets had undergone OPCAB, and do you think that that would have affected completeness of revascularization?

DR MAGEE: Well, I think what was also observed in this study was the fact that less-experienced off-pump surgeons are more inclined to incompletely revascularize their patients, and so I do analysis and consensus statement from the 2004 ISMICS Consensus Conference [review]. Innovations: Technology & Techniques in Cardiothoracic & Vascular Surgery 1(1): 3–27, Fall 2005.

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Appendix

Study Centers

Centennial Medical Center, Nashville, TN Central Florida Regional Hospital, Sanford, FL Denton Regional Medical Center, Denton, TX Henrico Doctor's Hospital, Richmond, VA JFK Medical Center, Atlantis, FL Medical City Dallas Hospital, Dallas, TX Medical Center of Plano, Plano, TX Plaza Fort Worth Medical Center, Ft. Worth, TX

think that the effect of experience is significant. I think in a randomized trial, which has been done, a single-surgeon experience, Puskas out of Emory randomized his patients, and he in fact showed that the same number of grafts was done in both groups. That is the only significant study that has been published in the literature that showed the same number of grafts in both groups. So I think in a broad experience, if every surgeon, even those included with a limited experience with off-pump surgery, were to be randomized, then I think there would be in fact an increased number of incompletely revascularized patients in the off-pump group.

DR IKONOMIDIS: I think your point is well taken. You cannot look at the results published by experienced OPCAB surgeons as reflective of what is going on in the real world. The combination of the nonrandomization in this trial in addition to your finding that inexperienced surgeons are more likely to incompletely revascularize their patients really makes the argument that there are a lot of off-pump coronary bypasses being performed in which patients are incompletely revascularized.

DR MAGEE: Well, I think that is certainly possible. We did show that the distribution of grafts was the same in both groups and that the outcomes were the same. But I do think it is a good point that experience is important, and those surgeons who have less experience with off-pump surgery should consider the risks of putting those patients on-pump versus the risks of incompletely revascularizing them.

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