PREOPERATIVE RISK MODELS FOR MINIMALLY INVASIVE CORONARY BYPASS: A PRELIMINARY STUDY

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Objective: Available risk assessment models are designed for standard coronary artery bypass grafting. We hypothesized that minimally invasive coronary bypass could improve on predicted outcome in extremely high-risk patients (Parsonnet score > 20%) by the current risk models. **Methods:** From September 1996 to September 1997, 27 consecutive extremely high-risk patients underwent minimally invasive coronary bypass. Seventeen patients were male; age was 73 ± 12 years, and 63% of patients were older than 75 years. Left ventricular ejection fraction was $33.7\% \pm 15\%$ and 63% had an ejection fraction of less than 35%. The predicted 30-day mortality according to the System 97 model was $25.6\% \pm 11.3\%$. The Parsonnet risk score was $36.2\% \pm 11\%$; the predicted length of stay in the hospital was 15.3 ± 3 days. The predicted risk of stroke according to the Multicenter Perioperative Stroke Risk Index was $22.3\% \pm 11.7\%$. **Results:** Minimally invasive coronary bypass was isolated in 20 patients and integrated with angioplasty and stenting in 7 patients. The observed 30-day mortality was 0% ($P < .01$ vs predicted); at an average follow-up of 10.8 ± 4.1 months, 26 patients (96.3%) are alive without angina; one patient with acquired immunodeficiency syndrome died on postoperative day 40 of acute pancreatitis. No patient had a stroke or neurologic deficit ($P < .01$ vs predicted). Patency of internal thoracic artery anastomosis was confirmed by angiography in all 27 patients. No patient required reoperation. Eighteen patients (67%) were extubated in the operating room. The observed length of hospital stay after minimally invasive coronary bypass was 3.8 ± 2.6 days ($P < .01$ vs predicted). **Conclusion:** On the basis of our results on a relatively small series of patients, we suggest that risk models geared for standard coronary bypass grafting may not be appropriate for minimally invasive coronary bypass. (J Thorac Cardiovasc Surg 1998;116:584-9)

The success and aggressive application of percutaneous coronary revascularization techniques¹ has contributed at least in part to the increase of the mean age and risk profile for patients referred for coronary artery bypass grafting (CABG).² Despite refinement of

surgical and anesthesiology techniques, patients with significant preoperative risk factors are at increased risk of dying or having complications after CABG. The major cause of complications during CABG is related to the use of cardiopulmonary bypass (CPB) and cardioplegia,³ which in turn may lead to perioperative myocardial infarction in 5% to 10% of patients. Furthermore, hemodilution, reduced mean perfusion pressure to the brain during CPB,⁴ cannulation, and clamping and manipulation of the aorta required for construction of proximal anastomoses expose patients to the risk of stroke.⁵

Minimally invasive CABG (MICABG) through a minithoracotomy without CPB recently has been introduced successfully into clinical practice.⁶ We⁷ and others⁸ have demonstrated decreased resource use and improved results of MICABG compared with standard CABG. On the basis of these results, we hypothesized

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Table I. Baseline clinical characteristics in 27 patients

Age (y)	73 ± 12
Age > 75 y (%)	63
Sex (%)	
Female	37
Male	63
LVEF (%)	33.7 ± 15
Unstable angina (%)	85
Prior CABG (%)	7.4
No. of diseased vessels	
One (%)	4
Two (%)	33
Three (%)	33
Left main (%)	30

LVEF, Left ventricular ejection fraction; CABG, coronary artery bypass graft.

that MICABG, perhaps by avoiding CPB, could improve results in patients in whom CABG is a high-risk procedure. Inasmuch as the available risk assessment models are designed for standard CABG, we also hypothesized that these models would not be able to accurately predict the outcome when MICABG was performed instead of the standard CABG.

Methods

Patient population. From September 1996 to September 1997, 108 MICABG procedures were performed at the University of Pittsburgh Medical Center by 2 surgeons (M.Z. and B.P.G.). Among these 108 patients, 27 (25%) had a Parsonnet risk score⁹ greater than 20%; these consecutive 27 “extremely high-risk”¹⁰ patients are the focus of the present observational study.

Patient demographics are listed in Table I and risk factors present in these patients (not mutually exclusive) are listed in Table II. Twenty patients (20/27, 74%) had been turned down as candidates for standard CABG by 1 or more surgeons because of anticipated prohibitive risk. The remaining 7 patients were never referred for conventional CABG by the cardiologist and would have been deemed to be candidates for medical therapy if MICABG were not available. All patients were in Canadian Cardiovascular Society angina class III or greater or had objective evidence of ischemia.

Risk assessment models and definitions. The risks that were assessed were (1) 30-day mortality; (2) perioperative stroke; and (3) prolonged hospital stay after the procedure.

The risk of dying (30-day mortality) after CABG was calculated with the use of the “System 97”¹¹; this model, unlike other models currently used, has been shown to approximate the observed mortality after CABG extremely well and recently has been extensively validated (Bernstein AD, personal communication, December 10, 1997).

The risk of prolonged hospital stay after CABG was calculated by means of a regression equation based on the Parsonnet score.² The correlation coefficient between observed length of stay after CABG and the Parsonnet score is

Table II. Risk factors (not mutually exclusive)

Risk factor	Percent of patients
CHF	67
Severe PVD	63
Severe COPD	70
Renal dysfunction	55
Age > 75 y	63
LVEF < 35(%)	63
Previous CVA	74

CHF, Congestive heart failure; PVD, peripheral vascular disease; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; CVA, cerebrovascular accident.

Table III. Predicted versus observed risks

	Predicted	Observed	P value
Mortality (%)	25.6 ± 11.3	0	<.001
Stroke (%)	22.3 ± 11.7	0	<.001
LOS (d)	15.3 ± 3	3.9 ± 3.5	<.001

LOS, Length of hospital stay.

very high ($r = 0.976$). Length of hospital stay is also a good predictor of complication rate and of resource use.⁷

The risk of perioperative stroke was calculated by the Multicenter Perioperative Stroke Index (McSPI).¹² The McSPI has been validated from a population of 2107 patients by the use of the bootstrap technique, a valuable method for validating predictive scales. The predicted risks of 30-day mortality, prolonged hospital stay, and perioperative stroke for the 27 patients are listed in Table III.

Multivessel coronary artery disease was defined as greater than 70% luminal narrowing in the distribution of more than 1 major coronary artery (eg, left anterior descending [LAD], right coronary artery, or circumflex). The goal of revascularization was not to obtain necessarily a “complete” revascularization, but rather a “functionally adequate” one.¹³ Functionally adequate revascularization was defined as revascularization of all stenoses of more than 70% in vessels with a diameter greater than 1.5 mm that served viable myocardium. Vessels serving infarcted ventricular territory, as demonstrated by either akinesis on the ventriculogram or fixed perfusion defects on thallium myocardial scintigraphy, were not considered functionally important. For stenoses in the intermediate range of severity (40%-60% luminal narrowing),¹⁴ revascularization was undertaken only if stress thallium¹⁵ or coronary flow reserve studies¹⁶ showed evidence of flow limitation.

Surgical technique. MICABG was performed through a 3-inch minithoracotomy in the fourth or fifth intercostal space under direct vision of the surgeon, without removal of any costal cartilage or rib. Anesthesia was induced with propofol (2-3 mg/kg) and maintained with modest doses of fentanyl (15-25 µg/kg) and rocuronium (0.4 mg/kg). Intravenous infusion of diltiazem (3-5 mg/h), as an ischemic preconditioning agent, was used in all patients. A left-sided double-lumen endotracheal tube was used in all cases to facilitate left inter-

Table IV. *Revascularization strategy*

Isolated MICABG	20 patients (74%)
Integrated MICABG/PTCA	7 patients (26%)
Same day	5 patients (5/7, 71%)*
POD 1 or 2	2 patients
Stent	4 patients
PTCA only	3 patients
Site	
LMCA	1 patient
Circumflex	4 patients
Diagonal	1 patient
RCA	1 patient
MICABG LITA-LAD	27 patients
Anastomosis time	14 ± 2.3 min
Operation time (skin-to-skin)	122.6 ± 28 min
Extubation in OR	18 patients (67%)

MICABG, Minimally invasive coronary artery bypass; PTCA, percutaneous transluminal coronary angioplasty; POD, postoperative day; LMCA, left main coronary artery; RCA, right coronary artery; LITA, left internal thoracic artery; LAD, left anterior descending coronary artery; OR, operating room.

*If left main coronary stenosis, MICABG was always performed first.

nal thoracic artery (LITA) harvest circumferentially as a pedicle for its entire length from the subclavian artery takeoff to the bifurcation (average length of LITA pedicle = 15 cm). A dedicated LITA retractor (CardioThoracic Systems Inc, Cupertino, Calif) was successfully used and provided excellent exposure of the entire bed of the LITA. The heparin dose used was 100 IU/kg. After division of the distal LITA, a 1/4-force atraumatic bulldog vascular occluder (Applied Medical, Laguna Hills, Calif) was used to interrupt LITA flow. The LITA-LAD anastomosis was performed with a mechanical stabilizer (CardioThoracic Systems) without harmful pharmacologic manipulation of the heart rate¹⁷; the average heart rate during the anastomosis was 72 beats/min. The LITA-LAD anastomosis was performed with 2 separate 8-0 polypropylene sutures at the heel and toe (double-parachute technique) with a 6.5-mm needle with the help of a carbon dioxide blower used very sparingly and set at a flow not higher than 5 L/min to avoid damage to the coronary endothelium. Before final tying of the suture, the anastomosis was probed with a nonocclusive 1-mm Parsonnet probe in 3 directions: proximal LAD, distal LAD, and proximal LITA; furthermore, the LITA was flushed through the open suture line before final tying of the knot to eliminate the potential for thrombus formation at the site of application of the vascular occluder. On completion of the anastomosis, the flow pattern of the LITA was immediately analyzed with a customized ultrasound transit-time flowmeter (Transonic Systems Inc, Ithaca, NY) as previously described by us.¹⁸ Extubation was attempted in all cases in the operating room. Postoperative pain control was achieved by a preoperatively placed epidural catheter or by intercostal nerve block when an epidural catheter was contraindicated (eg, with intravenous heparin infusion). In patients with normal renal function, an age-adjusted bolus of ketorolac was administered intravenously before reversal of neuromuscular blockade. Compared with more routine

MICABG, when dealing with high-risk patients we are especially careful to avoid even brief episodes of hypotension; thus a mean arterial pressure greater than 80 mm Hg is actively maintained by means of phenylephrine and volume infusions. Furthermore, arterial oxygen saturation is maintained higher than 95% and manipulation of heart rate is avoided. LITA-LAD anastomotic patency was confirmed angiographically in all 27 patients within 48 hours of MICABG. Our MICABG follow-up protocol included exercise or pharmacologic stress thallium myocardial scintigraphy, Doppler echocardiography of LITA flow,¹⁹ and physical examination at 1 month.

Statistical analysis. Data were expressed as mean ± standard deviation. Comparison between predicted and observed length of stay in the hospital was performed by means of the sign test. For comparison of observed and predicted number of events, the *P* value was computed by means of a permutation test, that is, the probability of observing no events in the study population given each patient's predicted probability of the event. We note here and in the discussion that the predicted probabilities of events have an inherent variability that is relatively high. Although the comparisons remained significant under robustness calculations using the lower 95% confidence limit for each patient's estimate as the predicted value, the *P* values reported are nevertheless approximate.

The protocol for MICABG and integrated coronary revascularization was approved by the Institutional Review Board of the University of Pittsburgh, and informed consent was obtained from all patients.

Results

Characteristics of the operations performed are listed in Table IV. In 7 patients (7/25, 28%), MICABG was integrated with percutaneous coronary revascularization of non-LAD coronary arteries in the cardiac catheterization laboratory.^{20,21} Details of MICABG and integrated coronary revascularization strategy are listed in Table IV. All patients in whom a stent was used in conjunction with integrated coronary revascularization received aspirin and ticlopidine (250 mg by mouth twice a day) for 1 month after revascularization. All patients survived MICABG (30-day mortality = 0): at a mean follow-up of 10.8 ± 4.1 months, the survival is 96.3% (1 patient with acquired immunodeficiency syndrome died on postoperative day 40 of acute pancreatitis).

The predicted 30-day mortality for this cohort of patients according to the System 97¹¹ was 25.6% ± 11.3% (*P* < .01 vs observed; Table III).

Three patients (11%) had postoperative atrial fibrillation. One patient required reintubation on postoperative day 2 for bradycardia (β-blocker overdose). One patient had temporary worsening of renal dysfunction (creatinine level rose from 2.0 to 3.3 mg/dL) after integrated coronary revascularization with the use of contrast material. One patient was readmitted to the hospital on postoperative day 15 for upper gastrointestinal

Fig 1. Length of stay, observed versus predicted.

tract bleeding that was treated conservatively. Another patient, in whom a 95% stenosis of the proximal subclavian artery was detected before MICABG, underwent successful stent placement with reduction of the stenosis from 95% to 5% and subsequently underwent successful MICABG.

In another patient with severe peripheral vascular disease, a total occlusion of the proximal subclavian artery was detected after MICABG at the time of the control LITA angiogram; interestingly, this patient did not have any blood pressure gradient between the right and left arm before the operation, most likely because of compensatory circulation from a large patent vertebral artery. This patient underwent successful carotid-subclavian bypass on postoperative day 2 after MICABG to prevent a future steal phenomenon and was discharged home on postoperative day 4.

LITA-LAD patency was confirmed in all 27 patients (27/27, 100%) by contrast angiography. Patency was also confirmed by intraoperative transit-time flowmetry and postoperative Doppler flow study. The postprocedure hospital stay was 3.9 ± 3.5 days (range 2-16 days), compared with a predicted hospital stay based on the Parsonnet score of 15.3 ± 3 days ($P < .01$ vs predicted) (Table III and Fig 1). No patient had a postoperative stroke or major neurologic event after the procedure (stroke incidence = 0%), compared with a predicted risk of stroke according to the McSPI of $22.3\% \pm 11.7\%$ ($P < .01$ vs predicted). At a mean follow-up of 10.8 ± 4.1 months, all 26 surviving patients are free of recurrent angina and myocardial infarction.

Discussion

The risk profile of patients being referred for surgical coronary revascularization has been steadily increasing in severity during this decade.² Recent studies suggest that elderly patients with greater comorbidities and

advanced cardiovascular disease benefit more from cardiac surgery than from medical therapy,^{22,23} yet they paradoxically have greater morbidity and mortality after cardiac surgery.^{24,25} Despite the 30 years that have elapsed since the first CABG was performed by Favaloro in 1967, and myriad subsequent refinements in technique, major complications continue to be associated with CABG, resulting in prolonged hospitalizations and resource use. Because the majority of complications after CABG are related to the use of CPB, a revascularization strategy that eliminates CPB would seem a logical solution, especially in high-risk patients, provided that equivalent effectiveness can be demonstrated. MICABG provides such an alternative, although it is limited in its scope to the anterolateral left ventricular coronary distribution (LAD, diagonal, ramus intermedius).²⁶ To provide a “functionally adequate” revascularization¹³ for patients with multivessel coronary artery disease, we have previously described an approach that we called “integrated coronary revascularization,” which combines MICABG LITA-LAD with angioplasty of non-LAD coronary lesions.²⁰

We hypothesized that a coronary revascularization strategy that eliminates CPB, such as isolated or integrated MICABG, would yield superior results in high-risk patients compared with those of standard CABG. We used the Parsonnet risk score⁹ to screen a consecutive group of patients who received MICABG at our institution during a 12-month period; 27 patients with a Parsonnet score greater than 20% were identified. Ideally, a randomized study design would be best to assess the relative merits of standard CABG and MICABG in this “extremely high-risk”¹⁰ cohort.

Unfortunately, 74% of patients in our group had been turned down as candidates for standard CABG by 1 or more surgeons because of anticipated prohibitive risk; the remaining 7 patients were never referred for con-

ventional CABG by the cardiologist. Therefore we decided to test the observed outcome after MICABG against the best risk assessment models available for these patients. The outcomes assessed were 30-day mortality, prolonged hospital stay (and resource use), and stroke.

We observed no mortality, no stroke, and a postprocedural hospital stay of 3.9 days in our 27 extremely high-risk patients, figures that compare very favorably with the predicted outcomes had standard CABG been used. The short-term (10.8 months) follow-up results are encouraging, with a 96.3% survival and a 100% freedom from coronary events in all surviving patients. Length of stay in the hospital appears to be prolonged if major problems occur after the operation with any organ system. Multiple studies have used length of stay as a measure of resource use²⁷; our reduced length of hospital stay is most likely due to the absence of major organ complications after MICABG. Stroke after CABG is a devastating complication.²⁸ The reported overall incidence of stroke for standard CABG ranges widely from 0.8% to 3.2% in retrospective studies and from 1.5% to 5.2% in prospective studies.²⁹ The mortality rate from stroke in patients who have had CABG ranges from 0% to 38%. In a recent study, stroke dramatically increased the mean hospital stay from 8.7 days to 25.2 days. The mortality rate for patients having a stroke was 19.2% compared with 4.2% of the overall study population.²⁹ Arom and associates³⁰ reported a 12% incidence after MICABG; they relied on pharmacologic bradycardia using esmolol and adenosine boluses to minimize the motion of the beating heart. It is possible that the drastic reduction in cardiac output during pharmacologic bradycardia¹⁷ can result in hypoperfusion to the brain and ischemic stroke. The absence of stroke in our very high-risk patients undergoing MICABG, even when the predicted incidence by McSPI was 22%, is most likely due to the careful avoidance of pharmacologic bradycardia, maintenance of high mean arterial pressure (>80 mm Hg) throughout the operation, and optimal arterial oxygen saturation.

A limitation of the formal comparisons of observed-to-expected rates of events and hospital stay is that relatively few of the patients in the CABG cohorts used to calculate rate estimates were high risk. As a result, the variability of the estimated outcomes for our small group of patients having MICABG is quite high. The highly significant *P* values in this report must therefore be regarded as approximate, because they do not rigorously take this variability into account. Our primary goal in this report, however, is to point out the extremely low event rates and short hospital stay associated with MICABG, rather than to carry out a formal statistical comparison or quantify the expected reduction of risk.

In conclusion, MICABG, isolated or integrated with percutaneous intervention, improves outcome in extremely high-risk patients requiring coronary revascularization and does not correlate with the expected outcome based on risk assessment models geared for standard CABG. Despite the small size of our patient population, we suggest that MICABG has the potential to expand the benefit of surgical coronary revascularization to patients with otherwise inoperable heart disease. Long-term follow-up of these clinical results is therefore warranted.

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