MINIMALLY INVASIVE PORT-ACCESS CORONARY ARTERY BYPASS GRAFTING WITH EARLY ANGIOGRAPHIC FOLLOW-UP: INITIAL CLINICAL EXPERIENCE

Greg H. Ribakove, MD
Jeffrey S. Miller, MD
Richard V. Anderson, MD
Eugene A. Grossi, MD
Robert M. Applebaum, MD
Wayne M. Cutler, MD
Patricia M. Buttenheim, MA
F. Gregory Baumann, PhD
Aubrey C. Galloway, MD
Stephen B. Colvin, MD

Objective: New techniques for minimally invasive coronary artery bypass grafting have recently emerged. The purpose of this study was to determine the safety and efficacy of Port-Access (Heartport, Inc., Redwood City, Calif.) coronary revascularization and to evaluate with angiography the early graft patency rate with this new approach. **Methods:** From October 1996 to May 1997, 31 patients underwent Port-Access coronary artery bypass grafting with an anterior minithoracotomy and endovascular-occlusion cardiopulmonary bypass. There were 26 men and 5 women with a mean age of 62 years (range 42 to 82 years). Fifteen patients underwent single bypass; 12 patients underwent double bypass, and 4 patients underwent triple bypass. Bypass conduits included the left internal thoracic artery ($n = 30$), right internal thoracic artery ($n = 2$), radial artery ($n = 10$), and saphenous vein ($n = 6$). Three sequential grafts were used. Angiographic studies of the bypass grafts were performed in 27 of 31 patients (87%). **Results:** There were no deaths, neurologic deficits, myocardial infarctions, or aortic dissections. Conversion to sternotomy was not required in any case. There were two reoperations for bleeding, one reoperation for tamponade, and one reoperation for pulmonary embolus. Postoperative angiography revealed anastomotic patency of the left internal thoracic artery to left anterior descending artery in 26 of 26 grafts (100%) with overall anastomotic patency in 43 of 44 grafts (97.7%). **Conclusion:** These results demonstrate that Port-Access coronary artery bypass can be performed accurately and safely with acceptable morbidity. This approach allows for multivessel revascularization on an arrested, protected heart with excellent anastomotic precision and reproducible early graft patency. (J Thorac Cardiovasc Surg 1998;115:1101-10)

Recent advances in minimally invasive surgical techniques have revolutionized the fields of general and thoracic surgery; however, methods of

minimally invasive cardiac surgery were slow to develop. This was in part due to the high degree of accuracy and precision required for cardiac operations as well as the need for cardiopulmonary bypass (CPB) and myocardial protection for most cardiac surgical procedures. For new techniques of minimally invasive cardiac surgery to be widely applicable, methods of less invasive extracorporeal perfusion, aortic occlusion, and cardioplegia delivery had to be developed.

The Port-Access (Heartport, Inc., Redwood City, Calif.) technique involves a newly developed system for endovascular CPB and myocardial protection with cardioplegic arrest. This system uses femoral arterial and venous access for CPB and a transfemoral endoaortic balloon occlusion catheter for aortic occlusion and cardioplegia delivery, allowing the surgeon to perform bypass procedures on an arrested, protected heart through a minithoracotomy

From the Division of Cardiothoracic Surgery, Department of Surgery, Division of Cardiology, Department of Medicine, and Department of Anesthesia, New York University Medical Center, New York, N.Y.

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Address for reprints: Greg H. Ribakove, MD, 530 First Ave., Suite 6D, New York University Medical Center, New York, NY 10016.

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Fig. 1. Under fluoroscopy, dilution contrast solution is injected through the endosinus catheter (ESC) and its position is confirmed with a coronary sinus angiogram (CSA). The TEE probe is also seen.

incision. Anticipated advantages to the patient include avoidance of a median sternotomy, a smaller incision and scar, less pain, an improved cosmetic result, a shorter hospital stay and recovery time, and a decrease in overall cost. Clearly, however, the excellent long-term graft patency rates and minimal morbidity and mortality rates associated with conventional coronary artery bypass grafting (CABG)¹⁻³ must not be compromised for the sake of patient comfort, cosmesis, or cost containment. The purpose of this study was therefore to determine the safety and efficacy of Port-Access CABG and to evaluate with angiography the early graft patency rates with this new approach.

Patients and methods

Patients. Between October 1996 and May 1997, 31 patients underwent Port-Access CABG through an anterior minithoracotomy. During this period no patient who underwent Port-Access CABG was excluded from this study, and no patient refused to undergo Port-Access CABG because postoperative angiography would be required. There were 26 men and five women with a mean age of 62 years (range 42 to 82 years). Fifteen patients underwent single bypass, 12 patients underwent double bypass, and 4 patients underwent triple bypass. Of the 31 patients, 29 received a left internal thoracic artery (LITA) graft to the left anterior descending (LAD) coronary artery through a left anterior minithoracotomy; one patient underwent grafting of the right internal thoracic artery (RITA) to the right coronary artery (RCA) through a right anterior minithoracotomy, and one patient underwent LITA and RITA grafting with a left and right anterior minithoracotomy. A radial artery ($n = 10$), saphenous vein ($n = 6$), or sequential graft ($n = 3$) was

used for multivessel procedures; the LITA served as the site for the proximal anastomosis in all cases. Coronary arteries bypassed included the LAD ($n = 30$), diagonal ($n = 4$), circumflex ($n = 5$), obtuse marginal ($n = 5$), ramus ($n = 2$), RCA ($n = 3$), posterolateral ($n = 1$), and posterior descending ($n = 1$). All patients underwent femoral cannulation and perfusion, aortic occlusion, and cardioplegic arrest with the Port-Access endovascular CPB system.

The patients in this series were evaluated before the operation by the referring cardiologist and by one of four cardiac surgeons trained in the Port-Access technique. Patients with single-vessel coronary artery disease who were not candidates for angioplasty were evaluated for the Port-Access approach. Patients with multivessel disease were considered selectively, depending on the number of grafts required and the proposed distal sites. Exclusion criteria for the Port-Access approach included evidence of significant arterial or venous peripheral vascular disease or evidence of significant atherosclerotic disease of the aorta. The presence of significant vascular disease may preclude safe femoral artery cannulation, retrograde perfusion, or placement of the endoaortic occlusion catheter in the ascending aorta and may result in a potential risk for retrograde aortic dissection or stroke.

A variety of methods were used to evaluate the peripheral vascular system, including history and physical examination. Approximately one half of the patients had an aortogram with runoff performed at the time of coronary angiography. Direct palpation of the common femoral artery was performed at the time of the groin dissection in all patients. Two patients found to have moderate disease of the femoral artery at the time of groin dissection underwent angiography on the operating room table using a 5F pigtail catheter via the femoral artery before proceeding with the chest incision. Angiography demonstrated minimal atherosclerotic disease of the aortic bifurcation, iliac artery, and common femoral arteries; both

Fig. 2. Drawings show (A) a left anterior minithoracotomy; the fourth costal cartilage has been removed, exposing the LITA immediately below. **B,** The midportion of the LITA is used as the source of inflow for additional conduits. Initially the LITA is not divided but is occluded proximally and distally. For each proximal anastomosis, a 3 to 4 mm longitudinal incision is made in the lateral surface of the LITA. **C,** The anastomoses between the LITA and additional conduits are performed with continuous 8-0 Prolene (Ethicon, Inc., Somerville, N.J.) suture. Depending on the size and flow characteristics of the LITA, one or two Y grafts with either saphenous vein or radial artery can originate from the LITA in this fashion.

patients underwent successful Port-Access CABG. In addition, intraoperative transesophageal echocardiography (TEE) was used in all cases for evaluation of the thoracic aorta before femoral cannulation and insertion of the endoaortic occlusion balloon.

Preoperative risk factors included hypertension in 19 patients (61%), diabetes in 10 patients (32%), smoking in 6 patients (19%), obesity in 4 patients (13%), hypercholesterolemia in 13 patients (42%), chronic renal failure in 1 patient (3%), stroke in 2 patients (6%), and myocardial infarction in 10 patients (32%). The mean preoperative ejection fraction was 51%. Eleven patients had previously

undergone angioplasty (35%) with a mean time between angioplasty and surgery of 9.6 months. Five of these patients had coronary stents placed, and seven patients underwent more than one angioplasty procedure. One patient underwent angioplasty and stenting of a mid-circumflex lesion and was referred for Port-Access LITA to LAD coronary artery bypass. One patient who underwent a single bypass procedure had a previous bypass procedure through a median sternotomy.

Operative technique. After induction of general anesthesia, patients were intubated with a double-lumen endotracheal tube. Arterial pressure was monitored in both

Fig. 3. Illustration of the dual port Endoarterial Return (Heartport, Inc.) cannula with its obturator. The cannula is inserted into the femoral artery over a guidewire. One port is used for peripheral CPB, and the other port is used to pass the endoaortic occlusion balloon.

right and left radial arteries. This is essential because the endoaortic occlusion balloon may migrate and occlude the innominate artery, and repositioning of the endoaortic balloon may be necessary. Antegrade cardioplegia was used for most cases; however, retrograde cardioplegia was used for complex multivessel procedures. When retrograde cardioplegia was used, an 8.5F coronary sinus catheter (Endocoronary Sinus; Heartport, Inc.) was placed through an introducer sheath in the right internal jugular vein and advanced into the coronary sinus under TEE and fluoroscopic guidance. The coronary sinus catheter was injected with dilute contrast material, and an angiogram was obtained to confirm its position in the coronary sinus (Fig. 1). Before placement of the coronary sinus catheter, the patients were systemically given heparin 100 U/kg to prevent clot formation on the catheter.

Access to the heart was achieved through a 5 to 8 cm anterior minithoracotomy. An inframammary incision was made; the fourth costal cartilage was removed, and the pleural space was entered (Fig. 2, A). The ITA was mobilized as a pedicle under direct vision from the inferior border of the fifth costal cartilage distally to the subclavian vein proximally. The radial artery or saphenous vein was harvested in the standard fashion when additional conduits were needed for multivessel procedures. Papaverine-soaked gauze pads were placed on the radial artery during harvesting, and the vessel was gently distended with dilute papaverine after removal. In addition, these patients received intravenous calcium channel blockers during the operation and for 24 hours after the operation, at which time they received oral calcium channel blockers.

The ITA was occluded proximally and distally (Fig. 2, B), and the proximal anastomoses were placed on the midportion of the LITA with 8-0 polypropylene sutures (Fig. 2, C). Once the proximal anastomoses were completed, the LITA was divided distally and gently injected with dilute papaverine solution and occluded. The pericardium was opened and the LAD was identified. Groin dissection was carried out simultaneously in preparation for femoral vessel cannulation. After additional systemic heparinization, the femoral artery was cannulated through a transverse arteriotomy with a 23F or 21F dual-limb

arterial cannula (Endoarterial Return; Heartport, Inc.; Fig. 3). Venous drainage was achieved by advancing a 28F or 21F long venous cannula (DLP, Inc., Grand Rapids, Mich.) from the femoral vein into the right atrium under TEE guidance. The distal tip of the venous cannula was positioned in the superior vena cava. Venous drainage was augmented with a centrifugal pump (Medtronic Bio-Medicus, Eden Prairie, Minn.) in the venous side of the CPB circuit, which resulted in a well-decompressed heart. For this reason, the endopulmonary vent (Endopulmonary Vent; Heartport, Inc.), which can be placed via the jugular vein and into the pulmonary artery, was not used in most of the Port-Access procedures at this institution.

Next, a 10.5F triple-lumen, endoaortic balloon occlusion catheter (Endoaortic Clamp; Heartport, Inc.) was inserted through the side port of the femoral artery cannula (Fig. 4). For the initial five patients, fluoroscopy was used to advance the endoaortic occlusion balloon up the descending aorta and into the ascending aorta approximately 2 to 3 cm above the aortic valve. For the most recent patients, however, TEE was used to position these catheters and is currently used exclusively for positioning of the catheters from the femoral vessels. However, when difficulty is encountered passing the catheters from the femoral vessels, both fluoroscopy and TEE should be used. Aortic root and balloon pressure monitoring lines, aortic root suction, and the cardioplegia line were connected to the lumens of the endoaortic occlusion catheter. The femoral arterial cannula, femoral venous cannula, and endoaortic balloon occlusion catheter were all carefully inserted and advanced over a guidewire with the Seldinger technique.

Bypass was initiated and patients were cooled to 25° to 30° C. The target vessels were identified and marked. The balloon of the endoaortic occlusion catheter was inflated 2 to 3 cm above the aortic valve under TEE guidance (Fig. 5). Early in the series an aortic root angiogram with the endoaortic occlusion balloon inflated had been obtained; however, with TEE and bilateral radial artery monitoring, our experience suggests that the balloon can be adequately positioned and monitored without the routine use of fluoroscopy or aortic root angiography. Cold blood cardioplegia was used in all patients. Retrograde cardioplegia was administered to two patients through the coronary sinus catheter. The remainder of the patients received antegrade cardioplegia. After cardioplegic arrest, the distal anastomoses were performed with running 7-0 or 8-0 polypropylene sutures with standard instruments. Additional doses of cardioplegic solution were administered after the completion of each distal anastomosis. Before deflation of the Endoaortic Clamp, a ventricular pacing wire and a left pleural 32F chest tube were placed. A decompressed, flaccid heart aids in the placement of the chest tube and pacing wire.

The Endoaortic Clamp was then deflated; rewarming was completed, and the patients were weaned from bypass. The femoral cannulas were removed and the femoral vessels were repaired. The thoracotomy incision was closed in three layers. No attempt was made to approximate the third and fifth ribs. The patients were reintubated with a single-lumen endotracheal tube and transported to the cardiac surgery recovery room.

Postoperative course. On arrival in the recovery room, blood samples, chest radiographs, and electrocardiograms were obtained on all patients. The patients were extubated several hours after the operation and were placed in a chair the evening of the operation when feasible. Chest tubes were removed the following morning. Patients were transferred to the surgical floor where early mobilization and ambulation was encouraged. Before discharge from the hospital, patients underwent coronary angiography for evaluation of the CABGs.

Results

Of 32 patients taken to the operating room for the Port-Access approach, 31 patients underwent Port-Access CABG. One patient was noted intraoperatively at the time of groin dissection to have severe atherosclerosis of the femoral artery and was converted to minimally invasive direct coronary artery bypass (MIDCAB). For the Port-Access procedures, the mean CPB time was 83.7 minutes (70% confidence interval [CI] = 77.6% to 89.7%); the mean clamp time was 45.1 minutes (70% CI = 41.2% to 49.0%); the mean time to extubation was 10.1 hours (70% CI = 8.3 to 11.9 hours), and the mean hospital stay was 9.0 days (70% CI = 7.4 to 10.7 days; median = 6.5 days; range 3 to 42 days). Of the 23 patients who were discharged within 7 days of the operation, 15 were employed and 8 were retired; the mean time between operation and return to work for the 15 employed patients was 14.2 days.

There were no deaths, neurologic deficits, myocardial infarctions, or aortic dissections. Conversion to sternotomy was not required in any case. There were two reoperations for bleeding (6.4%). One patient was bleeding from a radial artery side branch, and the other patient was bleeding from an LITA side branch. One patient (3.2%) required reoperation for tamponade on postoperative day 3; no active bleeding was identified in this patient. One patient who underwent a triple bypass procedure was noted on postoperative angiography to have a severe stenosis in an unbypassed diagonal artery. The patient was asymptomatic without evidence of ischemia. Later, however, he experienced the acute development of severe dyspnea and respiratory failure; a pulmonary angiogram showed a massive pulmonary embolus. He underwent emergency median sternotomy, pulmonary embolectomy, and grafting of the diagonal coronary artery. Additional complications included empyema necessitating decortication in one patient (3.2%), effusion necessitating thoracentesis in one patient (3.2%), and transient atrial fibrillation in one patient (3.2%). One patient (3.2%) with chronic renal failure had an

Fig. 4. Illustration of the endoaortic occlusion balloon catheter shows the three lumens. One lumen is used to inflate the balloon and occlude the aorta. The second lumen is used to measure the aortic root pressure. The third lumen is used to deliver antegrade cardioplegia when indicated. This lumen can also be connected to suction to vent the aortic root. In addition, the guidewire used for insertion of the endoaortic occlusion balloon is passed through this lumen.

infection of the peritoneal dialysis catheter after the operation and remained in the hospital for 4 weeks.

Before discharge from the hospital, 27 of 31 patients (87%) underwent coronary angiography for evaluation of the bypass grafts. There were no complications associated with postoperative angiography. Significant spasm was noted in 3 of 10 radial artery grafts (30%). Angiography revealed patency of the LITA to LAD coronary artery anastomosis in 26 of 26 grafts (100%) with overall anastomotic patency in 43 of 44 grafts (97.7%). One radial artery to RCA anastomosis was occluded. This patient underwent successful angioplasty and stenting of the native RCA and remained asymptomatic in the postoperative period. A postoperative angiogram of a Port-Access triple bypass procedure is shown in Fig. 6. The LITA was grafted in a sequential fashion to the diagonal and LAD coronary artery, and the

Fig. 5. TEE is used to position the endoaortic occlusion balloon in the ascending aorta. This longitudinal view of the ascending aorta shows the balloon of the endoaortic occlusion catheter (EAC) inflated 2 to 3 cm above the aortic valve (AV). The left atrium (LA) is also seen.

radial artery was grafted from the LITA to the circumflex artery.

Discussion

CABG via a median sternotomy with CPB is a well-established procedure and has been shown to provide excellent long-term graft patency with acceptable morbidity and mortality rates.¹⁻³ Recently, however, several alternative and innovative techniques for minimally invasive coronary revascularization have been developed. The early approach to minimally invasive coronary revascularization involved CABG on the beating heart. The beating heart technique was initially performed through a median sternotomy⁴⁻⁸ and later through a less invasive minithoracotomy.⁹⁻¹³ Early results have been encouraging with the limited anterior small thoracotomy or MIDCAB procedure in select patients. The technique, however, appears to be applicable only to patients with single-vessel coronary disease, a group that accounts for a very small percentage of the overall cardiac surgical population. Furthermore, there is clearly a potential for decreased anastomotic precision with the beating heart technique through a minithoracotomy, and no study to date has been published that has used routine postoperative angiography to evaluate graft patency in these patients. Similarly, several other clinical experiences with minimally invasive coro-

nary bypass with anterior mediastinotomies, hemisternotomies, and parasternotomies have been reported without routine angiographic studies to determine graft patency.¹⁴⁻¹⁶

The Port-Access system was developed to allow surgeons to perform minimally invasive cardiac surgery on an arrested, protected heart through a minithoracotomy incision. This endovascular system for CPB and myocardial protection uses femoral arterial and venous cannulation for peripheral perfusion and a transfemoral Endoaortic Clamp for aortic occlusion and antegrade delivery of cardioplegic solution. In addition, a transjugular coronary sinus catheter can be placed into the coronary sinus for retrograde cardioplegia when indicated. Finally, a transjugular Endopulmonary Vent can be advanced into the pulmonary artery for cardiac venting. With this newly developed system, the heart can be stopped, decompressed, and protected, allowing the surgeon to use standard anastomotic techniques while working through a minithoracotomy incision.

Before clinical use, the Port-Access system was tested extensively in the Stanford University and New York University (NYU) research laboratories.¹⁷⁻¹⁹ A clinical study of Port-Access CABG was initiated at NYU in October 1996. The purpose of this study was to determine the safety and efficacy of Port-Access CABG and to evaluate with angiography the early graft patency rate with this new approach. Patients with single or multivessel coronary artery disease without evidence of peripheral vascular disease were considered for the Port-Access approach. As the cardiologists at this institution have become more familiar with the selection criteria for Port-Access surgery, they have more frequently obtained an aortogram with runoff during initial cardiac catheterization to evaluate the aorta, iliac, and femoral arteries for evidence of atherosclerotic disease.

The Port-Access procedures were performed by one of four cardiothoracic surgeons trained in the Port-Access technique (G.H.R., E.A.G., A.C.G., S.B.C.) and represent their initial clinical experience with the Port-Access technique for CABG. Similarly, the transjugular catheters were placed by one of four anesthesiologists trained in this approach. Fluoroscopy was used routinely in conjunction with TEE to place the transjugular coronary sinus catheter when retrograde cardioplegia was indicated. For this reason, TEE is currently used exclusively at this institution for positioning of the catheters from the femoral vessels. When difficulty is encountered passing the catheters from the femoral vessels, both

Fig. 6. Postoperative angiogram of a Port-Access triple-vessel bypass with (A) a sequential LITA anastomosis to the LAD coronary artery and diagonal (*DIAG*). The proximal anastomosis between the LITA and radial artery (*RA*) is also demonstrated. **B**, The anastomosis between the RA and circumflex (*CIRC*) is widely patent as well.

fluoroscopy and TEE should be used. When the femoral arterial cannula or Endoaortic Clamp cannot be easily and atraumatically placed, retrograde perfusion should be abandoned completely because the risk of retrograde aortic dissection or stroke may be significant. Under these circumstances, the thoracotomy incision should be extended or a sternotomy should be performed, and central aortic cannulation and crossclamping should be used. No patients in this series required central cannulation or crossclamping, extension of the thoracotomy, or conversion to sternotomy.

With the Port-Access approach, single and multivessel coronary artery bypass procedures were feasible. All coronary arteries, except the RCA, were readily accessible through a left anterior minithoracotomy. In patients requiring CABG to the proximal RCA, a second right anterior minithoracotomy or a standard sternotomy should be used. The LITA served as the site for proximal anastomosis in all cases of multivessel bypass. This approach is supported by the work of Calafiore and co-investigators,²⁰ who used the ITA for inflow for the

radial artery or inferior epigastric artery in 226 patients undergoing myocardial revascularization. At a mean follow-up of 18.5 months, the cumulative patency rate of the radial artery grafts was 93.1% and of the inferior epigastric artery grafts was 95.7%. These authors suggested that it may actually be better to use the LITA instead of the aorta for the proximal anastomosis in certain cases. First, the proximal anastomosis on the ascending aorta may result in a mismatch between the relative wall thickness of the conduit and aorta. In addition, the aortic wall is frequently diseased, especially in elderly patients. These conditions could lead to early graft failure caused by technical factors. Second, arterial grafts that are placed with the proximal anastomosis on the ascending aorta are exposed to a rate of rise of ventricular pressure that is different from their natural position. This increased wall stress could result in intimal hyperplasia and be the basis for early or late graft failure.²⁰

The initial clinical results of the Port-Access approach are encouraging. Although several patients with significant complications were hospital-

ized for 4 to 6 weeks, most patients who underwent Port-Access CABG were ready for discharge within 3 to 4 days after the procedure. The seemingly long mean hospital stay of 9.0 days reflects those patients with protracted hospital courses and the extra hospital day required for postoperative arteriography. The mean hospital stay for the most recent seven patients who underwent the Port-Access approach was 4.2 days. Furthermore, most patients are returning to work within 2 to 3 weeks of their procedure.

There were no deaths in this series. There were no neurologic deficits, which may be attributed to careful patient selection and intraoperative evaluation of the aorta with TEE. Furthermore, some investigators have suggested that aortic occlusion with an endovascular balloon may be less traumatic than an external crushing clamp and may result in fewer strokes.¹⁹ In addition, there were no perioperative myocardial infarctions, and myocardial protection during balloon occlusion CPB and cardioplegic arrest was excellent. Finally, there were no cases of aortic dissection with the Port-Access technique for coronary revascularization.

The major goal of this study was to evaluate the feasibility and effectiveness of the Port-Access approach in terms of postoperative graft patency as determined by angiography, the gold standard for anastomotic evaluation. Before discharge from the hospital, 27 of 31 patients (87%) underwent coronary angiography for evaluation of the CABGs. Three patients refused postoperative angiography, despite prior agreement, and one patient who had an empyema did not undergo postoperative catheterization. Despite several recent reports^{21, 22} demonstrating excellent patency rates of the radial artery conduit with careful handling of the graft during harvesting, gentle hydrostatic dilation, and extensive use of calcium channel blockers, angiography in this series demonstrated significant spasm in 3 of 10 radial artery grafts (30%). These grafts were treated with intracoronary injections of nitroglycerin and increasing infusions of calcium channel blockers with complete resolution of the spasm. In one of these patients, the diltiazem (Cardizem) drip had been inadvertently discontinued; however, the other two patients were given routine infusions of diltiazem 5 mg/hr.

Angiography revealed patency of the LITA to LAD coronary artery anastomosis in 26 of 26 grafts (100%) with an overall anastomotic patency in 43 of 44 grafts (97.7%). One radial artery to RCA graft was occluded. During careful evaluation of all preoperative and postoperative cardiac catheteriza-

tions, it was noted that all coronary artery lesions considered bypassable preoperatively were successfully bypassed with the exception of the diagonal artery previously discussed. This emphasizes that the Port-Access technique is widely applicable to single and multivessel revascularization, that complete revascularization is achievable with this approach, and that "culprit" vessel bypass is not necessary with the Port-Access system.

Limitations of this study include the relatively small number of patients presently available for inclusion and the lack of a prospective clinical trial comparing the Port-Access approach to the sternotomy approach for cardiac surgery. Currently at this institution, a prospective study comparing Port-Access coronary and valve procedures to conventional open-chest procedures is underway. That protocol is designed to compare the procedures with respect to pain, morbidity, hospital stay, recovery time, return to work, and cost. Our evolving system for gathering all relevant cost data was insufficiently complete at the time of this study to permit comprehensive cost analysis. In addition, mediators of systemic inflammatory response and markers of nutritional requirements and endocrine response are being assessed. Finally, the adequacy of cardiac deairing is being evaluated with the use of TEE, transcranial Doppler monitoring, and neuropsychiatric testing in patients undergoing coronary and valvular procedures with the Port-Access and median sternotomy approaches.

These initial results suggest that Port-Access CABG with an endovascular system for CPB and cardioplegic arrest can be performed accurately and safely in appropriately selected patients. This approach allows for multivessel revascularization on an arrested, protected heart with a high level of anastomotic precision and reproducible early graft patency. On the basis of this early experience, ongoing clinical trials to further demonstrate the safety and efficacy of the Port-Access system are clearly indicated. As experience with the Port-Access system grows and its clinical use is expanded, this technique will be progressively refined, and the Port-Access approach will become increasingly applicable to a wide range of cardiac surgical patients.

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Discussion

Dr. Elliot T. Gelfand (*Edmonton, Alberta, Canada*). Dr. John Hallett, a vascular surgeon at Mayo Clinic, in his presidential address to the Midwestern Vascular Society in September of 1996 commented on the ethics of change in surgery¹; to paraphrase him, he said that if a new procedure were going to be introduced, where an effective, durable therapy of reasonable cost already existed, it must provide superior results at lower cost. If that were not the case, he went on to say, particularly if a learning curve were involved, it probably ethically and morally would not be in the best interest of patients. If the potential benefits were merely debatable or unproven, the only course of action before widespread application of this new technology occurred was to embark on a scientifically impeccable, carefully monitored clinical study. Dr. Ribakove and his colleagues have described the feasibility of performing coronary surgery through a limited surgical exposure, aided by endovascular CPB and cardioplegic arrest. They have shown that in carefully selected patients, the immediate postoperative results including operative deaths and early graft patency are good, and perhaps comparable to results attainable via standard techniques. In the introductory remarks to the manuscript, anticipated advantages of this procedure include less pain, shorter hospital stay and recovery time, and a decrease in overall cost. In this study, none of these issues have been addressed, and clearly as mentioned by the authors in the manuscript and mentioned here as well, a randomized, prospective study to address these matters as well as longer term issues is mandatory. I would respectfully submit that until such time as valid data from prospective studies is available, this procedure should be viewed as experimental and widespread application should be undertaken with caution, and I would appreciate comment on that by Dr. Ribakove.

REFERENCE

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Dr. Ribakove. The cardiac surgery department at NYU participated in a Food and Drug Administration protocol that showed the safety of this system. Furthermore, we have undertaken prospective studies of both the valve and

CABG in patients undergoing these procedures. Careful follow-up is essential to eventually show equivalence of these less-invasive procedures to the gold standard of open sternum CPB.

Dr. Gelfand. The avoidance of CPB has been a major focus of many proponents of minimal access coronary surgery. They would make two points, I think today: first, that one of the primary reasons to do these kinds of procedures is to avoid bypass; and second, that precise and complete revascularization is possible on the beating heart. How would you counter these arguments?

Dr. Ribakove. Avoidance of CPB as a goal remains controversial. There is preliminary evidence that less inflammatory response occurs during these minimally invasive procedures despite somewhat longer bypass times. This would implicate the sternotomy as a major factor for the inflammatory cascade. Further study is indicated.

The concept that precise and complete revascularization can be performed on the beating heart has no scientific substantiation at this point. Early results of MIDCAB indicate between a 5% and 20% rate of either acute closure or problems with the anastomosis. This, of course, is for single-vessel bypass to the LAD coronary artery.

Dr. Gelfand. In this highly selected group of patients who would be considered by most of us to be the most straightforward candidates for surgical revascularization, are the described complication rates and lengths of hospital stay justified? Do you feel that a mean CPB time of 81 minutes and a mean clamp time of 44 minutes to do an average of 1.6 grafts per patient is appropriate? And, if in fact, there is a learning curve, would you want to be on one?

Dr. Ribakove. As with any new procedure, there is a learning curve. Although I might not want to be a patient on this learning curve, I also probably would not have wanted to be an early patient for standard CABG, valve operations, and a whole host of other procedures. However, we should not use learning curves as an excuse to stop potential advances in surgery or medicine.

As we move along the learning curve, our operative times continue to shorten. Overall complication rates are low and continue to improve.

Dr. Gelfand. Where do you anticipate that the cost savings will be? Is it in the cost of disposables or lengths of stay, or is there added anesthesia or operating room time in view of the fact that double-lumen tubes need to be placed? If you are using retrograde cardioplegia, percutaneous coronary sinus catheters need to be placed. Where are the cost savings anticipated?

Dr. Ribakove. As I mentioned during my talk, we are beginning to undertake a cost analysis of these procedures. Cost savings may come in the form of shorter hospital stay, but this remains to be seen. One bit of optimistic data is that in uncomplicated cases, the mean time back to work is 14 days, which could represent a significant overall cost savings.

Dr. Fabrizio M. Follis (Albuquerque, N.M.). The patient who was explored for bleeding, did you go back through the minithoracotomy or through a median sternotomy?

Dr. Ribakove. Through the thoracotomy.

Dr. Thomas A. Pfeffer (Los Angeles, Calif.). One of the reported benefits of the so-called minimally invasive procedures is the shortened hospital length of stay. Certainly even with conventional CPB with the single ITA to the LAD coronary artery, one could anticipate a hospital stay of 4 days or under; your mean hospital stay was 8 days. Can you share with us what the reason for the longer hospital stay in these patients?

Dr. Ribakove. Median hospital stay was 6 days. For our last 10 patients it is about 4 days. Hospitalizations are lengthened by repeat cardiac catheterization. In addition, there have been several extended hospital stays for unrelated problems.

Dr. Pfeffer. My second question relates to your 30% incidence of radial artery spasm. Was this a clinical manifestation with electrocardiographic changes or angina or a radiographic finding? Did you have a protocol of calcium channel blockers for these patients?

Dr. Ribakove. No patients in this study had postoperative ischemia. These findings were purely on an angiographic basis. All patients with radial artery grafts are kept on a protocol of intraoperative and postoperative intravenous and oral calcium blockers.

Presently, we do not know if there will be any clinical manifestations of this problem. We will, however, continue to closely follow these patients.

Dr. William I. Brenner (Hackensack, N.J.). We have heard, as we stand on the brink of possibly starting to use this technology, that the patient is in the operating room at 7 am and that the surgeon does not come into the operating room until 10:30 am. I am concerned, if this is correct, about our anesthesia colleagues in cardiac anesthesia. With declining reimbursement, how do we get people to go along, come on board, and stay in an operating room so many hours to do basically a two-bypass procedure?

Dr. Ribakove. Those estimates of starting times are completely false. The placement of the coronary sinus catheter is the only anesthesia procedure that adds significant time, and usually it is not used for CABG. Additionally, as the anesthesiologist gains experience, the catheter placement time shortens.

Finally, opening and closing times in these procedures are faster, which also helps to reduce operating room time.

Dr. Edward D. Verrier (Seattle, Wash.). A few years ago, the Cleveland Clinic showed that the use of an ITA, particularly in redos to supply blood to the entire anterior wall of the myocardium sometimes was not an adequate conduit in terms of the delivery of coronary blood flow. In this approach to multivessel disease, you are taking all of your grafts off of the ITA pedicle. Do you have concern or do you have data that would suggest that you can completely revascularize the myocardium based on one ITA proximal?

Dr. Ribakove. This was our first approach to multivessel revascularization and initial data from stress testing indicate these grafts are adequate. However, we have had the same concerns and more recently are adapting techniques to take proximals off the ascending aorta. Also, vascular stapling devices may enable us to do this even more easily in the future.