Intraoperative and intermediate-term angiographic results of coronary artery bypass surgery with Symmetry proximal anastomotic device

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Objective: The objective of this study was to investigate the patency in saphenous vein coronary bypass grafts in which the proximal anastomoses were performed with automatic connector devices or with a traditional suture technique.

Methods: Forty-six patients underwent coronary artery bypass grafting without cardiopulmonary bypass by using one thoracic graft and one or more saphenous vein grafts. Grafts were attached to the aorta with a Symmetry connector (St Jude Medical, Inc, St Paul, Minn) in 23 patients, and partial occlusion of the aorta and sutured anastomoses were used in 23 other patients. Grafts were studied intraoperatively with transit time flowmetry and angiography and revised if necessary. Angiography was repeated after 3 to 5 months.

Results: Intraoperative graft patency did not differ between the 2 groups. Follow-up angiography demonstrated excellent thoracic graft patency. Vein graft patency decreased to 50% in the Symmetry group, whereas it was 90% in the suture group ($P = .01$). Twenty-five percent of the Symmetry grafts had significant stenosis in the connector.

Conclusion: Saphenous vein grafts anastomosed to aorta with the Symmetry proximal connector have low intermediate patency compared with those with traditionally sutured anastomoses. We do not recommend the routine use of this device in coronary artery bypass operations.

Cerebrovascular accident is a serious complication of coronary artery bypass grafting (CABG).¹ CABG performed without cardiopulmonary bypass (CPB; ie, OPCAB) appeared to cause fewer neurologic disturbances than CABG with CPB (ONCAB).²⁻⁴ Cerebrovascular accidents might be caused by embolization on application of the partial occlusion clamp during construction of the proximal anastomosis.⁵ An automatic connector not requiring clamping of the aorta might be an important tool in preventing embolization in addition to shortening operating time.⁶

The purpose of this study was to evaluate graft patency and clinical outcomes in patients operated on with the Symmetry proximal anastomotic connector (St Jude Medical, Inc, St Paul, Minn).

Materials and Methods

The study was approved by the regional ethics board and planned with 10 to 15 pilot patients, followed by a randomized trial. After the first postoperative angiograms showed occlusion rates that were higher than expected, the pilot phase was extended to 23 patients, and 23 patients were included as control subjects. Forty-six patients referred for OPCAB who required at least one saphenous vein graft were included. In the first 23 patients the Symmetry connector was used, whereas in the control group proximal anastomoses were sutured with a partial occlusion clamp.

Operations

Patients underwent surgical intervention in a combined operation and angiography suite allowing intraoperative angiography. Surgeons had been certified after St Jude Medical Inc's course for the Symmetry device and had extensive experience with both ONCAB and OPCAB surgery.⁷ Procedures were performed through a median sternotomy. The left internal thoracic artery (LITA) was harvested, and the patient was heparinized. The saphenous vein was harvested with an open technique by a trained surgeon. The LITA was anastomosed to the left anterior descending artery first. Proximal anastomoses of the vein grafts were performed before the distal arteries in both groups. The veins were mounted on the device by the main surgeon. A correct-sized device was used according to vein diameter. The grafts were attached laterally on the aorta to prevent kinking. In control patients partial occlusion clamps and standard sutured anastomoses (6-0 polypropylene sutures) were used. Distal anastomoses were performed with 7-0 polypropylene sutures by using Octopus mechanical stabilization (Medtronic Inc, Minneapolis, Minn). The heart was positioned with a deep pericardial stitch⁸ and suction cup-type positioners.⁹ Proximal and occasionally distal occlusion of the native vessel were used to improve visibility. Intracoronary shunts were occasionally used.

Anticoagulation and Platelet-active Drugs

Patients received aspirin preoperatively and postoperatively. The heparin dose was 1 to 2 mg/kg to maintain the activated clotting time at greater than 250 seconds. Additional heparin was given as needed. Heparin was reversed with a protamine dose calculated to reverse 50% of administered heparin.

Intraoperative Graft Evaluation

Grafts were examined with transit time flow measurement by using the Butterfly Flowmeter (Medistim A/S, Oslo, Norway). Criteria described by D'Ancona and colleagues¹⁰ were used for determining graft quality. These criteria require that a well-functioning graft demonstrates a significant diastolic flow component and a pulsatility index of less than 5. Occluded grafts were revised. After closure of the chest, on-table coronary angiography was performed. In the case of nonfunctioning grafts, the chest was reopened, and the grafts were revised.

Postoperative Follow-up and Angiography

Postoperative complications and mortality were monitored. Coronary angiography was repeated at least 3 months after the operation. After studying the LITA grafts, each vein graft was selectively cannulated. Grafts were evaluated and graded as open or

Table 1. Patient characteristics

	Symmetry group	Control group	<i>P</i> value
N	23	23	
Age (y)	64.9 ± 12	64.7 ± 8.7	.61
Female sex	3	2	.63
LVEF	66 ± 14	63 ± 15	.75
Diabetes	3	3	1.00
Hypertension	10	13	.295
Previous PCI	2	1	.34
COPD	2	2	.8922

LVEF, Left ventricular ejection fraction; *PCI*, percutaneous coronary intervention; *COPD*, chronic obstructive pulmonary disease.

occluded. The proximal anastomoses were graded as normal or with less than 50% stenosis (grade 0), with more than 50% stenosis (grade 1), or occluded (grade 2).

Statistical Analysis

Data were entered in the SPSS software program (SPSS Inc, Chicago, Ill), and numeric data were analyzed with the Mann-Whitney test and the *t* test. Categorical data were analyzed by using χ^2 analysis.

Results

Clinical Outcomes

There were no significant differences demographically between the 2 groups (Table 1). There was no operative mortality. Two patients in the Symmetry group died after 3 months: one died from mediastinitis, and another died suddenly at home. None of them underwent postoperative angiography. There were no deaths in the control group. No perioperative infarctions or cerebrovascular accidents were recorded in either group, nor did any patients report typical anginal symptoms at the time of follow-up.

Intraoperative Graft Patency

All grafts were patent, as determined by means of flow measurement, before chest closure. Five grafts were revised on the basis of flow (2 Symmetry and 3 control grafts). The reason for revision was the distal anastomosis (*n* = 3), an overly long graft (*n* = 1), and stenosis in the vein body (*n* = 1).

Angiographic patency of the LITA grafts intraoperatively was 100%. Three vein grafts were revised on the basis of intraoperative angiography. One Symmetry and one control graft were corrected because of kinking, and one control graft was corrected because of occlusion of the distal anastomosis. One Symmetry graft was occluded distally but not corrected because of a poor distal vessel. Therefore after revision, all control grafts studied by means of angiography were open, whereas one vein graft in the Symmetry group remained occluded.

Table 2. Summary of postoperative angiography findings

	Symmetry group	Control group	P value
LITA total	22	23	NS
LITA studied	19	22	NS
LITA occluded	1	0	NS
Patent LITA	94.5%	100%	NS
Vein graft total	43	41	NS
Vein graft studied	32	40	<.09
Patent	16	36	<.01
Grade 0	8	35	<.01
Grade 1	8	1	<.05
Grade 2	16	4	<.01

LITA, Left internal thoracic artery.

Postoperative Graft Patency

Patency results are shown in Table 2 as the number of grafts and as a percentage of studied grafts. Mean time between the operation and angiography was 4.8 ± 2.4 months in the Symmetry group and 3.8 ± 0.9 months in the control group. The difference was not statistically significant. The LITA had excellent patency at both time points. Vein grafts had similar patency intraoperatively in both groups, but half of the Symmetry grafts were occluded postoperatively, and an additional 25% had intraconnector stenosis. In the control group 11% of the grafts were occluded at follow-up angiography, and only a single graft had stenosis in the proximal anastomosis.

Five patients receiving Symmetry grafts have subsequently undergone reintervention as a result of the angiographic findings of critical stenosis in the connector. One control patient underwent reintervention.

Discussion

CABG continues to be a major treatment modality for patients with coronary artery disease. The interest for making the procedure less invasive is intense, and efforts are made to eliminate CPB and minimize surgical incisions in the hope of reducing stroke rates and other complications.¹¹

Embolization of atherosclerotic debris during manipulation and partial occlusion of the ascending aorta is an important cause of cerebrovascular accidents.^{12,13} No-clamp techniques for construction of the proximal anastomoses have been described by Robicsek.¹⁴ The Symmetry connector appeared to be an ideal solution for the construction of no-clamp proximal anastomoses requiring minimal manipulation of the aorta, making the construction safe, quick, and simple. Early reports were encouraging.⁶ Unfortunately, the clinical testing has been limited and sometimes without angiographic follow-up.¹⁵ Clinical follow-up is not adequate because patients with occluded vein grafts might be asymptomatic. In other reports angiographic studies were performed in symptomatic patients.¹⁶⁻¹⁸ Traverse and co-

workers¹⁶ studied 19 connectors and found severe stenosis in 12 and occlusion in 6. Cavendish and associates¹⁷ and Reutebuch and colleagues¹⁸ found a high incidence of stenosis in symptomatic patients. Antona and coworkers¹⁹ described early angiographic patency of 94.7%, but these angiograms were performed early postoperatively and might correspond better with intraoperative than with postoperative angiographic patency. Katariya and associates²⁰ studied 32.6% of their patients after 3 months, showing 11% occlusions and 5% stenosis in the connector.

In previous studies from our center, both intraoperative and postoperative angiography were performed,⁷ demonstrating excellent on-table vein graft patency, with a decrease of 10% to 15% by 3 months. In the present study vein grafts in the control subjects behaved similarly, whereas in the Symmetry group grafts showed occlusion and stenosis at a much higher rate.

We have no definite explanation for the high occlusion rate in patients receiving Symmetry grafts. Because the connector is produced from a nitinol alloy directly exposed to blood, both acute thrombosis and stenosis from neointimal hyperplasia²¹ might be possible, as in coronary stents. Autopsy reports by Katariya and associates²⁰ and Donsky and colleagues²² demonstrated acute thrombosis within the device. We cannot determine whether total occlusions were caused by primary thrombosis or thrombosis in an already stenosed graft. The findings in the connectors with grade 1 stenosis might well be explained by neointimal hyperplasia. Traverse and coworkers¹⁶ observed that connector stenosis treated with stenting had a 64% recurrence rate, indicating an active process in the anastomoses. Cavendish and associates¹⁷ demonstrated evidence of neointimal hyperplasia by means of intracoronary ultrasonography. Mechanical factors might be of importance because the vein graft connected with Symmetry takes off from the aorta at a 90° angle,²³ although studies have indicated that a 90° takeoff might be hemodynamically beneficial. However, this angle predisposes to kinking if placement on the aorta or length of the conduit is not perfect. With the present model, proximal anastomosis is performed first, whereas most surgeons prefer to do distal anastomoses first to more easily assess graft length. This variable was eliminated in our study because the proximal anastomoses were always performed first.

OPCAB might require a different approach to anticoagulation, platelet-active drugs, or both.^{24,25} Our study⁷ comparing OPCAB and ONCAB did not demonstrate different graft patency, whereas Khan and associates²⁶ showed lower patency in OPCAB. Wiklund and colleagues²⁷ reported patency of 90% with Symmetry connectors in a small study using CPB. Carrell and coworkers²⁸ had no occlusions in a group of patients undergoing ONCAB studied prospectively but found 38% stenosis in the connector after 3 months. Platelet damage caused by CPB might prevent acute throm-

bosis in the connector but not the neointimal hyperplasia. In our series aspirin was used routinely. Introduction of clopidogrel^{17,23} might improve patency but could cause bleeding or other complications.²⁹ Further controlled studies should be conducted before introducing clopidogrel or similar drugs in CABG.

In conclusion, we agree that the development of connectors for both proximal and distal coronary anastomosis is warranted. Such devices might significantly decrease invasiveness and improve the results of CABG. More controlled studies must be performed before the introduction of new anastomotic devices on the market.

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Discussion

Dr John D. Puskas (Atlanta, Ga). Jacob, I enjoyed your presentation very much. Congratulations on addressing an important subject. We share—I think all of us share—your goal of reducing aortic manipulation, and we, like you, had an initial enthusiasm for the Symmetry device, which has waned because of problems similar to those you have described. But not all studies have reached these same conclusions.

There have been a total of 5 randomized studies that have not suggested significant decreases in patency, and the St Jude manufacturer will be quick to point out that they had US Food and Drug Administration (FDA) approval and it went through the entire approval process before getting to your hands for this study.

Therefore my question to you is as follows: What went wrong with the post-FDA process to have this device perform as poorly

in your hands as it did, and do you think that there is any difference in the way it has performed in your study compared with in some of the other studies on which FDA approval was based?

Dr Bergsland. This is a very good question, obviously, and my comment, after reviewing the literature, would be that the majority of the studies that have been performed included only clinical data, such as absence of angina.

In some cases angiography was performed in symptomatic patients, such as in the study by Bob Emery's group from Minneapolis. When they studied the symptomatic patients, they found an extremely high rate of occlusion and stenosis. Some of the other studies that have shown better patency rates with Symmetry connectors than we have shown have been performed after operations with CPB. It might well be that the connectors behave differently in CPB and in off-pump surgery because there is an element of metal that is exposed to the blood. I think that this is a possible mechanism. Wiklund from Sweden, for example, has performed a controlled study with the connector, but he used CPB. The main benefit of these devices would be in off-pump surgery.

I think that it is important that we do the right studies. I certainly appreciate St Jude Medical's big investment in connector technology, but I believe we just have to design the studies a bit differently and closer to how we are planning to use the method clinically.

Dr Puskas. Jacob, perhaps you would comment for us about those grafts with the Symmetry device that were open and those that were closed. Was there any difference in terms of the particular region of the heart to which those grafts were sewn distally, and did the size of the device used—the gray-, green-, or blue-sized Symmetry device—have any effect on the patency? Was there, for instance, a disproportionate number of the smaller-size connectors that closed?

Dr Bergsland. We did not find any such evidence, but our numbers are relatively small. We could not demonstrate any difference between the bigger and smaller devices or between grafts to different territories.

Dr Terrence M. Yau (*Toronto, Ontario, Canada*). Congratulations on a very provocative study. I think all of us recognize that there are a host of technical considerations during deployment of the Symmetry device that are quite different than what we are used to. However, I believe that it is possible to have good results with this device. In fact, in November, we reported in *The Journal of Thoracic and Cardiovascular Surgery* a consecutive series of 27 patients in whom the patency of connector grafts constructed to the right coronary artery territory was 100% at 1 year. Those patients underwent on-pump operations and were maintained on no antiplatelet therapy except aspirin.

With results as dramatic as yours, it might have been possible, even during the course of your series, to note that things were not going right. Did you change your technique over the course of these 23 patients, and if so, how did you try and improve your results?

Dr Bergsland. Obviously we got quite worried when we started to see these results, but we discussed this at length, we had gone through this with the ethics committee and so forth, and we had decided that we should finish this study. I think that was justifiable ethically; we had only 23 patients, and these could be random changes. Therefore we did finish treating the number of

patients that we had decided that we were going to treat. We did not change anything during the study because it would not be scientifically correct, such as introducing clopidogrel or other major changes.

I want to mention one more fact that was disturbing and that we noted in the article. The process did not seem to stop at 3 months. Some of the grafts that were grade 1, which means 50% to 99% stenosed at the time of restudy, showed further stenosis or occlusion over the following months. Five patients in the Symmetry group have required reintervention, including stenting of the native vessels or stenting of the Symmetry device itself. These have been stented with drug-eluting stents. We are going to follow these patients further to see what will be the subsequent development.

Dr Randall K. Wolf (*Cincinnati, Ohio*). Jacob, I enjoyed your presentation. I have a question for you. Given the fact that this is a nitinol device, and, as best I can tell, it traverses the media of the aortic wall, is it possible that in some patients' aortas there is so much recoil in the aorta that it closes down on this nitinol graft? And the reason I thought of that is that there is another device that is made of stainless steel with which the results are apparently quite good, but that is a stronger device. What do you think about that?

Dr Bergsland. It has been pointed out in an article by Carrel that in the Symmetry procedure the vein is telescoped through the hole in the aorta, and this is a big difference, of course, from the hand-sewn anastomosis. As you point out, this device is not so strong. This might cause the type of reaction you describe instead of what is happening in the hand-sewn proximal anastomoses, where the hole will open up and get bigger over time.

Dr Kit Arom (*Bangkok, Thailand*). I have 2 quick questions. First, how did you bring the graft off the aorta? Second, did you use clopidogrel after the operation?

Dr Bergsland. We started this study after we had seen some of the preliminary reports about the Symmetry device, and we put the device laterally on the aorta in all cases, trying to avoid the well-known problem of kinking. Therefore we put the proximal on the right side when we were going to the right coronary artery, and for the other ones, we put it on the left side of the aorta.

We did not use clopidogrel in this study, except in a few patients after the study period was over, when we saw that they had stenosis in the connector. Otherwise, we did not use clopidogrel, although I think it would be a logical thing to do. We would have to study this issue in another controlled study before we could recommend it.

Dr Robert W. Emery (*St Paul, Minn*). Jacob, our article in *Circulation* represented the first 8 months of our experience with this, and I think that was our learning curve. Originally, the Symmetry device was released as a simple, quick-release, push-a-button-and-you-are-done device, but I think there is significant learning that goes along with this, and like you, we learned the hard way.

Things like double loading, overloading, skiving of the aorta, thickened aorta, and misplacement on the aorta can all lead to stenosis, which is not really the graft's fault. It is a technical issue that none of us were taught and had to learn.

Did you sort of go through the same thing? Have you developed indications and contraindications, which are most

important in medicine, as to when to use and when not to use this device?

Dr Bergsland. We have not developed such recommendations. At this time, I would only use the connector in cases in which we truly had a very bad aorta, and I would weigh the chance of embolization from the aorta versus the chance of losing the graft later on. I agree that there is obviously a learning curve involved. However, all these operations were performed by a group of 4

surgeons from our institution in Oslo. These surgeons actually have extensive experience in off-pump and on-pump operations and had gone through the course offered by St Jude Medical. They have shown their quality in many previous studies, and I think that we see from the results with the hand-sewn anastomosis that they know how to do these procedures. Therefore I am sorry to say that if it is so difficult to use the device, it should not be recommended. It should be easier to use, not more difficult.

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