Clinical, Angiographic, and Interventional Follow-Up of Patients With Aortic-Saphenous Vein Graft Connectors

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Background—The use of aortic connectors for proximal saphenous vein bypass graft anastomoses eliminates the need for aortic clamping during coronary artery bypass grafting (CABG) and may reduce the incidence of stroke in the elderly and in patients with severe aortic atherosclerosis.

Methods and Results—We studied 74 consecutive patients who received the Symmetry Bypass System aortic connector at the time of CABG. A total of 131 of 144 proximal vein graft anastomoses were performed with this device. The left internal mammary artery was used in 62 patients, and 61 patients had “off-pump” coronary revascularization. A total of 11 patients were readmitted with chest pain consistent with unstable angina 173±39 days after CABG. Five of the 11 patients had previous in-stent restenosis before CABG. At angiography, 20 saphenous vein bypass grafts containing 19 connectors were found to have severe stenosis (n=12) or occlusion (n=6) and were treated with angioplasty and stenting or medical therapy. Seven of 11 patients were readmitted 76±11 days later with recurrent chest pain and were found to have severe stenosis at the previously stented connector site. Six patients underwent angioplasty followed by brachytherapy. Three of these patients redeveloped chest pain and were readmitted 151±71 days later. Two patients were started on oral Rapamune, and one patient underwent redo-CABG.

Conclusion—Eleven of 74 patients who received aortic connectors at the time of CABG developed symptomatically significant stenosis or occlusion at the connector site shortly after CABG, requiring multiple repeat interventions, including brachytherapy. (Circulation. 2003;108:452-456.)

Key Words: bypass ■ stents ■ restenosis ■ coronary disease

Neurological complications are increased in the elderly and in patients with atheromatous or heavily calcified aortas who undergo coronary artery bypass grafting (CABG).1,2 Revascularization without the use of cardipulmonary bypass (“off-pump”) may be particularly beneficial in high-risk patients3 such as the elderly, and it may potentially reduce the incidence of stroke and other neurological complications by avoiding cannulation and cross-clamping of the aorta. Thus, in a retrospective study, Demaria et al1 observed a significant reduction in mortality and the incidence of stroke (6.3% versus 0%) in octogenarians who underwent off-pump CABG compared with revascularization with cardipulmonary bypass.

However, off-pump bypass surgery still requires the use of aortic side-biting clamps to perform each proximal anastomosis, which may lead to aortic injury4 and the occurrence of stroke in this population. The use of recently developed sutureless aortic-saphenous vein graft connectors may facilitate off-pump coronary revascularization5 and reduce the incidence of stroke and cerebral microemboli in patients by eliminating the need for partial aortic clamping.6 In the present article, we report the clinical, angiographic, and interventional follow-up in the first 74 patients who received aortic connectors at our institution at the time of CABG.

Methods

We investigated the clinical, angiographic, and interventional outcomes of 74 consecutive patients (58 men and 16 women aged 66±2 years) who received the Symmetry Bypass System aortic connector (St Jude Medical, Inc) at the time of CABG at our institution between June 13, 2001, and February 25, 2002. Patient risk factors included hyperlipidemia (n=57), hypertension (n=39), positive family history (n=17), diabetes (n=19), and current or former smoking (n=22). Thirteen of the 74 patients had previously under-
gone coronary stent implantation and were referred for surgical revascularization because of the development of in-stent restenosis. A total of 131 of 144 proximal vein graft anastomoses were performed with the aortic connector, and the left internal mammary artery was used in 62 patients. A total of 61 patients had their revascularization performed without the use of cardiopulmonary bypass, and 10 patients underwent adjunctive laser transmyocardial revascularization.

There were 10 device failures at the time of implantation in 7 patients. This included 8 instances of excessive bleeding at the connector site and 2 instances of connector thrombosis. There were no perioperative strokes in the group.

Results

Angiographic and Clinical Follow-Up

Of the 74 patients who received aortic connectors at the time of surgery, 11 were readmitted with chest pain consistent with unstable angina 173±39 days after CABG. Five of these 11 patients had previous in-stent restenosis before CABG. Three patients had elevations in serum troponin on admission consistent with small, non–Q-wave myocardial infarctions. All patients underwent coronary angiography.

A total of 20 vein grafts with 19 connectors were studied at angiography (Table); 12 had severe stenosis at the connector site, and 6 were occluded. Eight patients underwent coronary angioplasty (PTCA) and stenting at the connector site and/or 5 patients underwent PTCA/stenting of their native coronary arteries. One patient underwent stenting at the left internal mammary artery anastomosis. Two patients were treated medically, and one of them was started on oral Rapamune (Wyeth-Ayerst) at a dose of 2 mg/d for 4 weeks. One patient had a small, non–Q-wave myocardial infarction after the procedure (creatine kinase-MB of 15 U; Figure 1).

Seven of the 11 patients were readmitted with their second episode of chest pain 76±11 days after their first interventional procedure after CABG (Table). After angiography, 6 patients underwent angioplasty at the connector site followed by brachytherapy (Checkmate, Cordis) with gamma irradiation (Ir-92) and received 18 Gy at 2 mm from the source at 8 connector sites. Two patients underwent PTCA and brachytherapy of their native coronary arteries, and one patient was started on oral Rapamune. One patient had a non–Q-wave myocardial infarction after the procedure (creatine kinase-MB of 102 U; Figure 2).

Three of the 11 patients were readmitted with their third episode of chest pain 131±70 days after their second interventional procedure. One patient underwent PTCA of a diagonal branch and was started on Rapamune. A second patient underwent PTCA and brachytherapy at the left internal mammary artery anastomosis. The third patient underwent repeat CABG.

One patient who was managed medically after his first admission for chest pain died from the development of line sepsis after peripheral vascular surgery.

Discussion

To our knowledge, this is the largest single-center study to report clinical, angiographic, and interventional follow-up in patients who received aortic-saphenous vein graft connectors. Our findings demonstrate that a significant number of patients present with unstable angina in the first year after CABG secondary to occlusion or severe stenosis at the connector site. Despite successful treatment with PTCA and stenting, many patients required multiple repeat interventions, including brachytherapy, for recurrent in-stent restenosis at the connector site.

The successful long-term treatment of saphenous vein graft disease remains a significant challenge because of the recurrence of significant stenosis after percutaneous intervention or disease progression in other portions of the graft. Initial treatment of vein graft disease with stenting seems to result in initial lower rates of target vessel revascularization8 and major cardiac events9 compared with PTCA, although this benefit was not sustained at 3 years.10 The presence of aorto-ostial disease remains a subset of vein graft disease that is significantly problematic to treat, in part because of the high elastic recoil and external compression unique to that location.11 The use of stents in this location is still associated with significant target lesion revascularization at 1 year (approaching 20%) and may be associated with a significant incidence of periprocedural non–Q-wave myocardial infarction.12 In our cohort, we observed a 64% incidence of target lesion revascularization after stenting at the connector site, which is much higher than previously reported at the aorto-ostium in sutured vein grafts. These observations may suggest that the presence of a metallic foreign body at the aorto-ostium or the manipulation and attachment of the vein graft to the connector could result in endothelial injury13 and contribute to a more vigorous injury response after stenting.

The 8 connector sites in 6 patients that developed in-stent restenosis after stenting at the connector site were successfully treated with brachytherapy during their second interventional procedure. However, 4 of these sites in 3 patients redeveloped severe stenosis or occlusion leading to repeat bypass surgery in one patient and initiation of Rapamune in two patients. Previous studies in saphenous vein bypass grafts with in-stent restenosis have demonstrated a 70% reduction in target lesion revascularization with brachytherapy compared with repeat PTCA or stenting.14 The 57% repeat target vessel revascularization is higher than previously reported after brachytherapy in vein grafts, although the number of patients in our group was small and all sites were localized to the aorto-ostium.

We observed the development of symptomatic stenosis or occlusion at 18 connector sites in 11 patients at angiography during their initial on-average presentation of 6 months after CABG. This comprises an attrition rate of 13.7% of a total of 131 connectors placed at the time of surgery. It is possible that this represents a significant underestimation of the true incidence of stenosis or occlusion at the connector site because only symptomatic patients underwent angiography. Previous serial angiographic studies in patients after CABG have demonstrated a significant rate of vein graft attrition in the first month after surgery, with a rate of occlusion between
12% and 13% at 1 month, which increased to 19% to 21% at 1 year.15,16

There have been several preliminary reports describing proximal anastomotic connector systems such as the type used in this study, with angiographic follow-up available in a small group of patients. Wiklund et al17 presented the angiographic findings in the first 10 of 34 patients 4 to 6 months after CABG. There were a total of 10 proximal anastomoses performed with the connector and 14 performed with sutures. At angiographic follow-up, all the patients were asymptomatic, and there was a severe stenosis in one of the sutured vein grafts and one occlusion at the connector site.

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>In-Stent Restenosis</th>
<th>Age, y</th>
<th>Sex</th>
<th>CABG</th>
<th>First Interventional Procedure</th>
<th>Second Interventional Procedure</th>
<th>Third Interventional Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Yes</td>
<td>43</td>
<td>F</td>
<td>LIMA-LAD, SVG-Diag,* and SVG-OM*</td>
<td>60 days after CABG: SVG - Diag=90% at connector (STENT ×5); SVG-OM=100%</td>
<td>52 days after first: 90% in-stent restenosis at Diag connector (treatment: PTCA/brachy)</td>
<td>74 days after second: 90% in-stent restenosis at Diag connector site (treatment: PTCA/Rapamune)</td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
<td>66</td>
<td>F</td>
<td>LIMA-LAD, SVG-OM,* and SVG-RCA*</td>
<td>60 days after CABG: SVG to RCA=90% at connector; SVG to OM=90% at connector (STENT); Non-Q-wave MI after PTCA</td>
<td>83 days after first: PTCA of SVG to OM at connector (treatment: PTCA/Brachy); Rapamune</td>
<td>...</td>
</tr>
<tr>
<td>3</td>
<td>Yes</td>
<td>43</td>
<td>M</td>
<td>LIMA-LAD, SVG-RCA,* and SVG-Diag-OM*</td>
<td>136 days after CABG (non-Q-wave MI): SVG to RCA=60% at connector with 90% distal RCA (STENT ×2); SVG to Diag to OM=100% Stent of Diag, Stent LIMA anastomosis</td>
<td>85 days after first: 90% SVG to RCA at connector (PTCA/Brachy); 90% in-stent restenosis of Diag; STENT of OM</td>
<td>...</td>
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<tr>
<td>4</td>
<td>No</td>
<td>74</td>
<td>M</td>
<td>LIMA-LAD, SVG-Ramus,* and SVG-RCA*</td>
<td>59 days after CABG: SVG to RCA=70% at connector (STENT); SVG to Ramus=95% at connector (STENT); STENT of LAD</td>
<td>55 days after first: 80% SVG to RCA at connector. (PTCA/Brachy); 90% Ramus graft body (STENT); 80% Ramus at connector (PTCA/Brachy)</td>
<td>49 days after second: 90% in-stent restenosis at LAD (PTCA/brachy); SVG to Ramus=100%</td>
</tr>
<tr>
<td>5</td>
<td>No</td>
<td>61</td>
<td>F</td>
<td>LIMA-LAD, SVG-OM,* and SVG-RCA*</td>
<td>153 days after CABG (non-Q-wave MI): 70% SVG to RCA at connector (STENT); 90% distal anastomosis of RCA-SVG (STENT)</td>
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<td>...</td>
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<tr>
<td>6</td>
<td>Yes</td>
<td>66</td>
<td>F</td>
<td>LIMA-LAD, SVG-LAD,* and SVG-RCA</td>
<td>182 days after CABG: 100% SVG to LAD (Med Rx)</td>
<td>123 days after first: STENT to LM, LAD, CX; Rapamune</td>
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<td>7</td>
<td>Yes</td>
<td>64</td>
<td>M</td>
<td>LIMA-LAD, SVG-OM1-OM2,* and SVG-RCA*</td>
<td>76 days after CABG (non-Q-wave MI): 90% SVG to OM at connector (STENT); 90% SVG to RCA at connector (STENT)</td>
<td>60 days after first: 80% in-stent restenosis OM at connector (Rota/STENT/Brachy); 80% in-stent restenosis RCA at connector (Rota/STENT/Brachy)</td>
<td>300 days after second: repeat CABG</td>
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<td>8</td>
<td>No</td>
<td>67</td>
<td>M</td>
<td>LIMA-LAD, SVG-LAD-Diag, SVG-RCA*</td>
<td>279 days after CABG: 90% SVG to RCA at connector (STENT); 90% distal SVG to RCA (STENT)</td>
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<td>...</td>
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<td>9</td>
<td>No</td>
<td>69</td>
<td>M</td>
<td>LIMA-LAD, and SVG-OM*</td>
<td>164 days after CABG; SVG to OM=100% (Med Rx)</td>
<td>30 days after first: patient died from line sepsis after peripheral vascular surgery</td>
<td>...</td>
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<tr>
<td>10</td>
<td>No</td>
<td>55</td>
<td>M</td>
<td>LIMA-LAD, SVG-Ramus-OM,* and SVG-PDA-PLB*</td>
<td>392 days after CABG: SVG to PDA to PLB=100%; SVG to Ramus to OM=90% at connector site (STENT); STENT of native RCA (non-Q-wave MI after PTCA)</td>
<td>98 days after first: 90% in-stent restenosis at Ramus at connector (PTCA/STENT/Brachy); STent of LM/CX</td>
<td>...</td>
</tr>
<tr>
<td>11</td>
<td>No</td>
<td>70</td>
<td>M</td>
<td>LIMA-LAD and SVG-OM*</td>
<td>403 days after CABG: SVG to OM=100% (Med Rx)</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

M indicates male; F, female; *, connector; LIMA, left internal mammary artery; LAD, left anterior descending artery; SVG, saphenous vein graft; Diag, diagonal branch of LAD; OM, obtuse marginal branch of circumflex; Brachy, brachytherapy; RCA, right coronary artery; MI, myocardial infarction; Med Rx, medical treatment; LM, left main artery; CX, circumflex artery; Rota, rotational atherectomy; PDA, posterior descending artery of the RCA; PLB, posterior lateral branch of RCA.
Calafiore et al\textsuperscript{18} presented their initial clinical experience in 17 patients who received the aortic anastomotic device (AAD) proximal anastomotic device (Bypass Ltd). Follow-up angiograms in 6 patients performed 48±26 days after CABG revealed that all the proximal anastomoses were widely patent.

There are important technical limitations with these devices that may predispose the vein grafts to develop kinking, which may lead to occlusion of the graft and contribute to the observations reported in this study. Because the connector must deploy the vein graft at a 90-degree takeoff angle from the aorta, the proximal portion of the graft may kink as it courses inferiorly toward the heart. A second technical consideration involves selecting the proper length of vein to graft because the device requires that the proximal anastomosis be performed first.

A short segment of vein may be overly stretched when performing the distal anastomosis, whereas too long a segment may result in kinking of the graft.\textsuperscript{17}

Conclusions

In a group of 74 patients who received the Symmetry Bypass System aortic connector, 11 patients were readmitted with chest pain consistent with unstable angina on an average of 6 months after CABG because of severe stenosis or occlusion at the connector site. These patients required multiple repeat interventions to treat these sites, with the majority of patients requiring brachytherapy due to restenosis after stenting at the connector. Although these devices may prove to be invaluable in preventing periop-

Figure 1. Serial angiographic findings in a 74-year-old man without previous in-stent restenosis during his first readmission for chest pain 59 days after CABG. There was a severe stenosis at the connector site in his saphenous vein bypass graft to the ramus intermedius. The patient was treated with angioplasty and stenting. The patient was readmitted 2 months later with recurrent chest pain. Severe in-stent restenosis was present at the previously treated connector site and in the body of the vein graft. The patient was treated with PTCA and stenting at both sites followed by brachytherapy. The patient had a small, non-Q-wave myocardial infarction after the second interventional procedure.

Figure 2. Serial angiographic findings in a 66-year-old woman with previous in-stent restenosis before CABG during her first admission for chest pain 60 days after CABG. There was severe stenosis at both connector sites, including the saphenous vein graft to the circumflex marginal branch. The patient was treated with angioplasty and stenting and had a small non-Q-wave myocardial infarction after her procedure. The patient returned with recurrent chest pain 83 days later; she had developed severe in-stent restenosis at the connector site. This was successfully treated with PTCA and brachytherapy.
operative stroke in the elderly and in patients with severe atheromatous disease of the aorta, they seem to be associated with a relatively high rate of symptomatic stenosis in the first postoperative year.

References
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