Patency Outcomes of Aortic Connectors

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Objective: Controlled outcome analysis of mechanical aortic connectors for proximal saphenous vein bypass graft anastomosis is lacking. We report the clinical and angiographic outcome of patients receiving the Symmetry aortic connector (St. Jude Medical, Inc St. Paul, MN, US) within a multicenter, prospective, randomized study.

Methods: Twenty-five patients at 3 study sites received aortic connectors at the time of coronary artery bypass surgery. Protocol-defined angiographic follow-up was completed in 19 of 25 patients (76%) at time-points up to 14 months postoperatively; 32 connector anastomoses were evaluated in these 19 patients. Beating heart surgery was performed in 17 patients, and 2 were performed with cardiopulmonary bypass. Age was 69.7 ± 8.1 year; all patients were males.

Results: The connector anastomosis patency rate was 15.6% (5/32). There were no deaths during the follow-up period. Four patients (21%) suffered myocardial infarction and 2 additional patients (10.5%) required percutaneous coronary interventions; one of who required 3 percutaneous coronary interventions, the other received one percutaneous coronary intervention.

Conclusions: In this nonrandomized cohort of patients, occlusion rate with Symmetry connectors was significantly greater than anticipated. Patients who have received these connectors during coronary artery bypass surgery may require closer follow-up and evaluation. While the manufacturer has stopped producing this device, there has been no recall of the product, clinical support remains ongoing, and next generation connectors have now been marketed. Consideration should be given to discontinuation of the clinical use of Symmetry connectors.

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INTRODUCTION

Proximal anastomotic connectors have been developed to facilitate the anastomosis between the saphenous vein graft (SVG) and the ascending aorta without the use of a partially occluding clamp. The rationale for development of such technology was primarily to minimize the potential for embolization of aortic atheromatous debris. In addition, such devices promise to reduce the time required for the construction of the anastomosis (four to 5 minutes by manual suture technique) and potentially improve the quality of the resulting anastomosis by standardizing operator technique.[1]

At this time, there is scarce data from prospective, controlled trials in the literature detailing patency and clinical outcomes for patients receiving aortic connectors. The authors report angiographic and clinical outcomes in a subgroup of patients that received St. Jude Medical's Symmetry™ aortic connector device.

METHODS

The Symmetry connector consists of a nitinol device, an aortic cutter to create the aortotomy, and a delivery device to implant the SVG to the aortic wall. After choosing an appropriately sized device, the SVG is loaded onto the device and fastened by hooks. A hole is then made in the aortic wall using an aortic cutter that, at the same time, retrieves the aortic wall plug. The device is then deployed in the aortotomy by releasing the nitinol struts first in the internal aortic wall, and then the external wall whereby the device expands in a star appearance.

The principal study design is a five-year prospective, randomized, controlled, single-blinded, multicenter clinical trial evaluating surgical coronary artery bypass grafting (CABG) with or without the use of cardiopulmonary bypass. Both treatment arms of the study (on-pump versus off-pump groups) receive a median sternotomy incision approach to assure equivalent visualization of the operative field. At the 17 original cardiac surgery programs participating, the trial is actively enrolling veterans that require an elective or urgent CABG-only procedure. Patients who are emergent, hemodynamically unstable, in cardiogenic shock preoperatively, have moderate to severe valvular disease, diffusely diseased distal vessels, small target coronary arteries (<1.1 mm), and are

unwilling or unable to provide informed consent are excluded.

All participating surgeons must meet minimum experience criteria related to performing off-pump procedures. Patients are assessed at multiple time points including presurgery, postsurgery, discharge, 30 days postsurgery, and one-year postsurgery. Using a comparison of baseline, interim, and one-year coronary angiography results read by a blinded catheterization core laboratory, the study hypotheses concern the technical assessment of the 2 surgical techniques: the completeness of revascularization and the graft patency/stenosis rates. One-year follow-up angiography was performed between 10 and14 months, with some interim angiography performed for clinical concerns as well. The catheterization core laboratory assessments, which are evaluated by 2 cardiologists in a blinded and standardized manner, compare the baseline, interim, and one-year follow-up catheterization assessments.

As part of the data collection plan for this preplanned subanalysis, the method used to construct the proximal SVG anastomosis (S = suture or D = device) was recorded by the surgeon on a form at the end of the surgical procedure. The choice of anastomotic method was left to the discretion of the individual surgeon. Surgeons at 3 sites (17.6%) voluntarily elected to use a device, specifically the St. Jude Medical's Symmetry connector. All 3 surgeons had attended a training course organized by St. Jude Medical and had performed over 50 Symmetry anastomoses before utilizing it for patients enrolled in this trial.

The initial questions related to evaluating the impact of St. Jude Medical's Symmetry device were first raised by the Catheterization Core Laboratory Directors. On March 10, 2004, the study's Data and Safety Monitoring Board issued a recommendation disallowing the use of Symmetry connectors based on evidence from the literature and interim assessment of the catheterization results reported by the Catheterization Core Laboratory and Co-Chairperson's office, which indicated occlusion in a significant number of grafts that were completed using the Symmetry connector.

RESULTS

Twenty-five patients at 3 sites received Symmetry connectors at the time of CABG; 32 connector anastomoses in 19 patients with follow-up angiography were assessed (19/25 = 76%). These 19 patients are the focus of the present analysis.

Age was 69.7 ± 8.1 year and all patients were males; comorbidities are listed in Table 1. Revascularization was performed using cardiopulmonary bypass, or "on pump" technique, in 2 patients (2/19 = 11%). Severe atherosclerotic disease of the aorta was documented in 2 patients (2/19 = 11%). There were no intraoperative complications except for excessive bleeding in 2 patients (2/19 = 11%). One patient suffered from a cardiac arrest in the perioperative period (1/19 = 5.2%).

A total of 60 grafts were performed in these 19 patients (mean 3.1 grafts/patient); 32 proximal SVGs were connected to the ascending aorta using the Symmetry connector device (32/60 = 53%). Two Symmetry connectors were used in 9 patients each (9/19 = 47%), while 3 Symmetry connectors were used in 2 patients each (2/19 = 10%).

The SVG connector occlusion rate was 84% (27/32). The graft patency rate was 15.6% (5/32) with Fitzgibbon class A patency (patent or nonflow limiting stenosis) present in 12.5% (4/32) and >50% stenosis (Fitzgibbon class B with patent but flow-limiting stenosis) present in 3% (1/32). Of the 4 class A patent devices, only 2 were completely free of stenosis by angiography; the other 2 had 40–50% stenosis of the ostium within the device. Occlusions of graft territories are detailed in Table 2. By contrast, the patency rate of left internal thoracic artery to LAD anastomoses was 94.7% (18/19). Four patients (21%) suffered from myocardial infarction and 2 additional patients (10.5%) required percutaneous coronary interventions (PCIs); one of who required 3 PCIs, the other received one PCI. For the 6 patients not having follow-up angiographies, 2 completed the study but declined angiography, one subject died of metastatic cancer, one moved out of the country, and 2 were lost to follow-up.

DISCUSSION

Vascular connections in CABG surgery require running or interrupted sutures, a technique described by Alexis Carrel in 1902.[2] Fitzgibbon and associates documented the patency of hand-sewn vein graft proximal anastomosis on the arrested heart and found an early occlusion rate of 12% and one-year occlusion rate of 19%.[3] Anastomotic devices were first introduced in vascular surgery to achieve reproducible, anastomotic quality and to facilitate surgical procedures.[4] In 2001, Eckstein and associates presented clinical results with the Symmetry aortic connector (St Jude Medical, St Paul, MN) postulating a clinical as well as technical benefit through reduced aortic manipulation with connector devices.[5] This device obtained European Certification in May 2000 and U.S. Food and Drug Administration (FDA) approval in May 2001 based on clinical data obtained from a European trial. The same group from Berne, Switzerland that reported the initial

TABLE 1. Co-morbidities

Chronic Obstructive Pulmonary Disease	6 (31.6%)
Cerebral Vascular Accident	2 (10.5%)
Peripheral Vascular Disease	1 (5.3%)
Diabetes	8 (42.1%)
Hypertension	16 (84.2%)
Left Ventricular Ejection Fraction less than 35 percent	1 (5.3%)
Smoking history	15 (79%)
Hyperlipidemia	9 (47.4%)

TABLE 2. Occluded (Fitzgibbon Class 0) Symmetry Connector Grafts by Territory

Territory	# Grafts	# Occluded Grafts (%)
Diagonal	9	7 (78%)
Circumflex	12	10 (83%)
Right	11	10 (91%)
Total	32	27 (84%)

clinical results in 2001 published a report in 2003 indicating a 38% incidence of critical stenosis at 6 months in the proximal vein graft segment for patients with connectors.[6] In 2002, Donsky and associates reported on 2 patients who had complete thrombotic occlusions of the aortic ostia of SVGs early postoperatively after use of the Symmetry device.[7] Cavendish and associates also reported in early 2004 on 5 patients presenting with an acute coronary syndrome 2 to 5 months following placement of this device. In all patients, SVGs were occluded or severely compromised by ostial stenosis.[8] Diegeler and associates reported a prospective evaluation of St. Jude Medical's second-generation aortic connector (Symmetry G2) and found early and midterm patency rates comparable to conventional sutured anastomoses at 6 month follow-up angiography.[9] At the March 18th 2004 meeting of the FDA's Circulatory System Devices Panel, a total of 213 adverse event reports related to the Symmetry aortic anastomotic device were retrieved from the FDA's Medical Device Reporting System (MDR) database. There were 23 reports of death, 185 reports of injury, and 5 reports of malfunction. The FDA concluded that these serious adverse outcomes related to aortic anastomotic devices raises a signal for potential public health concern.

No long-term angiographic evaluation of aortic connectors is available from controlled prospective studies. As part of the trial, 19 patients that received aortic connectors had protocol mandated follow-up control angiography. The connector anastomosis patency rate was a dismal 15.6% (5/32). Four patients (21%) suffered myocardial infarction and 2 additional patients (10.5%) required PCI; one of who required 3 PCIs, the other received one PCI. On March 10, 2004, the trial's Data and Safety Monitoring Board issued a recommendation disallowing the use of Symmetry connectors as unsafe.

In conclusion, higher than expected occlusion rates for SVGs connected to the ascending aorta using St Jude Medical's Symmetry aortic connector device are reported and form the basis of a recommendation for discontinuation of clinical use. While the company has announced they no longer manufacture the device, there has been no recall of the product, clinical support remains ongoing, and newer generation connectors are now being manufactured. Dual antiplatelet agents, evaluation for ischemia, and close follow-up are warranted in patients that have already received the device.

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