

Total Dislodgement of St. Jude Symmetry Proximal Aortic Connector after OPCAB

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INTRODUCTION

We have noted the informative report of Maisano et al [2002] concerning the use of St. Jude "symmetry" devices for proximal aorto-saphenous vein anastomoses (St. Jude Medical, St. Paul, MN, USA). We wish to report a lethal complication following application of this device.

DISCUSSION

A 57-year-old man underwent an urgent off-pump coronary artery bypass (OPCAB) operation for peri-infarction angina due to multivessel in-stent restenoses. This surgical procedure included the placement of an internal mammary artery graft to the left anterior descending coronary artery and 2 reversed saphenous vein bypass grafts to the diagonal and distal right coronary arteries. The proximal graft to the aorta for the right coronary artery (RCA) bypass was done without incident using a St. Jude Symmetry device. Satisfactory graft flows were indicated by low PI (pulsatility index) measurement values.

The patient's immediate postoperative course was complicated by the slow accumulation of a left hemothorax. Approximately 8 hours postoperatively, the patient underwent re sternotomy and evacuation of the left hemothorax. Exploration of all areas of dissection, anastomoses, and grafts was unremarkable. The patient's left hemothorax was attributed to thrombocytopenia (platelet count, approximately 49,000) prior to platelet transfusion.

The patient's course was then unremarkable except for transient hypertension (systolic blood pressure, approximately 180 mm Hg) that responded to treatment with nitroglycerine and sedation. No evidence of further bleeding was noted. The following morning after a satisfactory chest x-ray, unremarkable hemodynamic measurements, and normal respiratory parameters were obtained, the patient was extubated without incident. Approximately 15 minutes later, the patient suffered a sudden cardiopulmonary arrest; after a few seconds

of severe bradycardia, his condition progressed to ventricular fibrillation.

Reintubation and closed-chest cardiac massage were carried out with continuous cardiopulmonary resuscitation, and the patient was returned to the operating room. After femoral-femoral bypass was established, closed-chest massage was discontinued and the sternal incision reopened. It was immediately noted that the saphenous vein graft to the RCA was collapsed, and the proximal part of the aorta was covered with a hematoma containing an ongoing oozing site. Removal of this hematoma revealed that the aortotomy for the RCA graft was intact but freely bleeding.

The symmetry device connector with the attached proximal end of the right coronary vein graft was found within the hematoma approximately 2 cm from its aortotomy. Although satisfactory regrafting was done, and the patient was separated from bypass with use of an intra-aortic balloon assist, the patient had shown no signs of awakening. He developed severe hypoxic encephalopathy and subsequently died.

Because we saw no obvious indication that aortic tissue failure had occurred nor signs of device malfunction at the initial operation, sudden device failure at approximately 20 hours postinsertion was unexpected and remains unexplained. As was noted by Maisano et al [2002], bleeding from the symmetry anastomotic site can be due to subtle mismatch of device versus aortotomy site, although in our case, the aortotomy and color-coded connector matched. After this incident, we found a similar report at the FDA internet site [US FDA 2002] of symmetry device detachment 40 hours postoperatively, as well as reports of additional complications of this device [Wiklund 1993, Donsky 2002, Eckstein 2002a, Eckstein 2002b, Eckstein 2002c]. This event has also been reported to St. Jude Medical.

Until the mechanism(s) of these device failures are determined and preventative measures developed, we would urge caution in the use of these devices.

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REVIEW AND COMMENTARY

1. Editorial Board Member KN11 writes:

This report addresses an important clinical problem of tremendous concern to the readership, especially as it relates to the evaluation and use of new technology in the operating room.

- a) I question why they selected to place only one device, namely only for the graft to the RCA, and did not use the device for the saphenous vein grafted to the diagonal. What is the reasoning? They probably had technical difficulty or thought the aortic tissue was thin, etc. They must explain their reasoning for using one but not two aortic connectors in this case.
- b) Plus, what is their stepwise technique for determining whether or not there was a problem with this proximal graft at the time of first exploration? Did they manipulate it? How did they assure themselves that the connector was properly attached and not leaking?
- c) Finally, it is important to relay to the readership if this was their first case using the device, the 100th, or the 500th. This information would give us a basis to evaluate whether or not the authors have experience deploying the device or whether it is a true potential problem with

the device. Also, it would give us an idea of incidence for problems of this type.

Author's Response by Rick Bernstein, MD:

- a) Because we believe in versatility for the best geometric course of proximals, we used the Novare (Enclose) device for our diagonal graft; however, the St. Jude device appeared to allow the best and safest placement for the RCA graft, ie, just distal to the natural takeoff of the RCA. There was no technical difficulty, and the aortic tissue looked and felt grossly normal.
- b) At the time of the first exploration for bleeding, all anastomotic sites were inspected after evacuation of blood and clots from the mediastinum. All anastomotic sites were intact, the area of mechanical connection was not leaking, and it was not manipulated.
- c) This was the 49th in terms of number of previous applications of the St. Jude device in our practice, including twice on the descending aorta.

2. Editorial Board Member IG23 writes:

The patient died, so I would expect an autopsy report describing the status of the aortic wall with a detailed description of macroscopic and microscopic characteristics of the aortic wall, as well as some description or image of the proximal end of the graft with the connected device.

Author's Response by Rick Bernstein, MD:

The family refused our request for autopsy. The connector was misshapen following dislodgment, thus we can only speculate that dislodgment occurred by one or more of the following mechanisms:

- a) Packaging error, if the cutting device was not precise and somehow too large for the connector supplied with it.
- b) The aortic hole enlarged with elevated and pulsatile aortic pressure sufficiently to allow gradual extrusion of the device until the point of dislodgment.
- c) The mechanical strength of the material components of the connector was inadequate to prevent ejection under physiologic pressures, which can be encountered following bypass surgery and patient emergence from anesthesia.