Case report - Coronary

A case of ostial stenosis with the PAS-Port proximal anastomosis system in off-pump coronary artery bypass grafting

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Abstract

The use of an automatic aortic connector device for proximal saphenous vein graft anastomoses eliminates the need for aortic clamping during off-pump coronary artery bypass grafting and may reduce the incidence of stroke in the elderly and in patients with severe aortic atherosclerosis. The PAS-Port proximal anastomotic system is a recently developed sutureless automatic saphenous vein graft anastomosis device. We used the system in thirteen patients. Overall handling, feasibility and safety of the device were satisfactory in our limited experience. However, one patient developed severe ostial and proximal graft stenosis in four months postoperative angiogram.

Keywords: Off-pump; Coronary artery bypass surgery; Device; Saphenous vein

1. Introduction

Recent progress in off-pump coronary artery bypass grafting (OPCABG) toward reducing neurologic morbidity has led to interest in elimination of aortic manipulation. The ability to perform OPCAB without aortic clamping is desirable in order to lower neurologic morbidity [1]. The use of an automatic aortic connector device for proximal saphenous vein graft anastomoses eliminates the need for aortic clamping during OPCABG and may reduce the incidence of stroke in the elderly and in patients with severe aortic atherosclerosis. The PAS-Port proximal anastomotic system (Cardica Inc., Menlo Park, CA) was recently developed to facilitate a sutureless automatic end-to-side anastomosis of a saphenous vein graft to the aorta. The system consists of an implantable connector, an aortic cutter without the need of an aortic partial occlusion clamp, and a delivery system used to deploy the implant in the target vessel. A saphenous vein with a diameter of 4–6 mm fits for this system. A vein graft loaded delivery system has a mechanism that performs an arteriotomy and an implant deployment with a single turn of a knob.

2. Cases

We used the PAS-Port system in performing proximal anastomosis of a saphenous vein graft during OPCABG. Sixteen devices were used for saphenous vein grafting to the circumflex artery and the right coronary artery in thirteen patients who underwent OPCABG since April 2004. Their mean age was 78.2 years ranging from 61–91 years.

Fig. 1. Loading a saphenous vein graft by evertng the vessel wall on the connector (A). Addressing the assembled delivery system on the target ascending aorta (B). Removing the system following the implant deployment (C). Completion of the anastomosis during off-pump coronary artery bypass grafting (D).

An in-situ left internal mammary artery graft to the left anterior descending artery was used in all patients. The surgeon experienced the device operation in preclinical wet laboratory training. Atherosclerosis of the ascending aorta was evaluated preoperatively by chest CT and intraoperative assessment. Severe atherosclerotic or calcified ascending aorta was excluded for use of this device. A saphenous vein was explanted in a conventional fashion; small side branches were ligated without any clipping materials. The time taken to load the vein graft and assemble the device was about a minute and deployment was performed in a few seconds (Fig. 1). Fifteen out of
the sixteen vein grafts were successfully deployed on the aorta. One graft was not deployed into the aortic hole and the implant was dislodged outside the aorta in the first case. The aorta was partially clamped and the implant was removed. Then the graft was manually sutured safely. Presumably the device sliding on the aorta occurred during deployment process between cutting the aorta and delivering the implant. The surgeon needs to hold the lower part of device in order not to slide the device with caution during deploying the implant with a single turn of the knob. There was no major leakage at the anastomoses in successful fifteen deployments. Most minor leakage stopped within a minute spontaneously. Two minor leakage required placement of a purse-string suture around the implant for secure hemostasis. There was no other delayed leakage once hemostasis was achieved. All patients were treated with oral low-dose aspirin postoperatively. Early postoperative angiogram before discharge showed no stenosis or occlusion of the graft anastomosis. There was no long-term follow-up angiogram at this point. In one case that underwent angiogram four months postoperatively for percutaneous coronary intervention of a residual coronary lesion, there was moderate ostial and proximal stenosis of the saphenous vein graft with the patent graft (Fig. 2). The patient had been anticoagulated with ticlopidine postoperatively for scheduled percutaneous coronary intervention. There were no cardiac or thromboembolic events in all patients postoperatively.

3. Comment

Overall handling, feasibility and safety of the device were satisfactory in our experience. The device requires less time in loading a vein graft and minimum training than the Symmetry Bypass System (St. Jude Medical Inc., St. Paul, Minnesota) [2]. Although the surgeon failed implant deployment in the first case, there was a minimum learning curve and the surgeon succeeded in following cases confidently. There was no complication or adverse effect of the device usage postoperatively except one case of ostial stenosis of the graft in four months. There are several reports regarding early graft stenosis or occlusion in cases with the use of the Symmetry aortic connector [3–5]. One of the differences between the PAS-Port connector and the Symmetry connector is the amount of metal exposure in the bloodstream. The PAS-Port connector is designed to minimize metal exposure for possible thromboembolism. These types of graft connectors might behave like an intra-coronary stent and promote intimal hyperplasia of the vessel causing in-device stenosis [5]. Therefore minimum metal exposure seems to be favorable for prevention of possible graft failure. Another difference is that the PAS-Port connector has lower profile than the Symmetry, which is presumably better for prevention of graft kinking because the vein takeoff is at a 90 degree angle.

There is no doubt that the use of an aortic connector avoids the significant manipulation of the ascending aorta associated with cerebral vascular accidents in OPCABG. In our initial clinical experience, this device was reliable and easy to handle to produce reproducible anastomoses. However, there is a concern about the critical issue of early graft failure reported in the use of the Symmetry connector. Long-term follow up and further clinical experience are needed for safe application of this type of device.

References


Appendix A. ICVTS on-line discussion

Author: Stefanos Demertzis (Cardiocentro Ticino, Switzerland)

EComment: This is a very brief and rather too simplified experience report based on a small initial series of 16 device deployments. In order to evaluate the real cause of the moderate stenosis depicted in this report (the angiographic image does not at all look like a focal stenosis but more like venous graft remodeling / adaptation to the flow necessities of the venous coronary intervention of a residual coronary lesion, there was moderate ostial and proximal stenosis of the saphenous vein graft anastomosis (Fig. 2). The temptation to attribute these kind of angiographic appearances to one ‘trendy usual suspect’ is perhaps
understandable. However, the data presented in this report are, by far, not sufficient enough to sustain the suspicion.

In my opinion, it is not correct to address mechanical connectors as stents only because both are made of metal. Stents are placed in the most severely diseased segment of a vessel and are exposed to a hostile environment (after balloon dilatation, local plaque dissection and the resulting inflammatory reaction). When everybody is concerned about aliens, it is tempting to attribute to them every possible phenomenon, but this far from proves their existence.

In order to give the readers another perspective: my personal experience with the PAS-Port device includes at the moment 71 implants in 60 patients, all of them patency controlled either by coronary angiography (n=22) or multislice cardiac CT (49) at 6 months postop. We have documented 3 occlusions, 2 vein remodelings but no graft with a focal stenosis pattern which could be attributed to endothelial hyperplasia at or not far from the connection site.

All "early adopters" of new technology within the cardiac surgical community should be very prudent and very objective in the analysis of their results and pitfalls. The Symmetry disaster has consequences for the whole segment of innovation we all are waiting for i.e. the development of products which could enable us to offer the best revascularization procedure (CABG) with less trauma and endoscopically. If we want to promote real evolution we should stick to the rules of thorough scientific analysis and avoid provoking negative reflexes based on "trendy" similarities only.