

Initial Experience With the Aortic Connector Device for Sutureless Proximal Vein Graft Anastomoses Without Aortic Clamping

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ABSTRACT

Background: The aortic connector system(Q-CAB®, Symmetry®) enables a sutureless anastomosis between a vein graft and the ascending aorta for aorto-coronary bypass grafting without the need for side clamping of the aorta. This prospective study describes our initial experience with this novel system.

Methods: Ten patients requiring coronary artery bypass grafting were included in this clinical study. All proximal anastomoses performed with the aortic connector device were controlled by means of intraoperative angiography.

Results: A total of 12 connectors were deployed in 10 patients (9 males and 1 female, mean age 67 ± 9 years). There was no mortality and no device associated morbidity. There was no mechanical failure. All anastomoses were angiographically patent. Significant anastomotic bleeding occurred in 1 case, one proximal anastomosis had to be relocated on the ascending aorta because of graft kinking and one graft had to be shortened following completion of the distal anastomosis.

Conclusions: Sutureless proximal anastomoses can be performed easily, safely and reliably with the aortic connector device. The adaptation to the imposed limitations in the surgical technique is fast. The long-term fate of grafts connected using this technique should be followed in great detail. The aortic connector device could be a helpful option in situations when side clamping of the aorta should be avoided.

INTRODUCTION

The aortic connector (Q-CAB®, Symmetry®) is the first commercially available medical device designed to enable a sutureless anastomosis between a vein graft and the ascending aorta for aorto-coronary bypass grafting.

The device is made out of nitinol and is approved as a "suture replacement" in Europe and recently in the United States as well. Acknowledging the potential for future developments we introduced this novel technique in our practice following a specific prospective protocol. Our experience is summarized in this report.

MATERIALS AND METHODS

Ten patients (n = 10) scheduled to undergo a coronary artery bypass grafting procedure were enrolled in this protocol. Inclusion and exclusion criteria are shown in Tables 1 and 2.

The evaluation of the aortic connector's introduction into our clinical practice consisted of tracking technical difficulties, particularities, potential pitfalls or failures. This was aided by the use of intraoperative angiography to determine immediate patency. The surgeon documented his subjective assessment of the ease of use and technical difficulties at the end of the procedure. Patient, surgical and postoperative data were collected and reported. Averages of continuous variables are shown with standard deviation.

Surgical technique

Both responsible surgeons (SD, FS) completed the training required by the St. Jude Medical, Inc. prior to the clinical use of the device. The saphenous vein was harvested through multiple skin incisions. The branches were ligated using 4-0 Mersilene sutures (Ethicon, Hamburg, Germany). The left internal mammary artery was taken down simultaneously in a skeletonized fashion and treated externally with heparinized blood and papaverine.

The outer diameter of the harvested vein was measured, using a sizing bench supplied by the manufacturer that allows the surgeon to determine the outer diameter of the vein graft in 0.5 mm increments. The system has three different sizes: the smallest connector, which was only available at the end of the study, is suitable for vein grafts with an inflated outer diameter of 4.5 to 5.0 mm. The medium size implant is suitable for vein grafts with an inflated outer diameter of 5.0 to 5.5 mm and the largest available connector is designed for vein grafts with an outer diameter of 5.5 to 6.0 mm. The loading procedure requires the surgeon to first draw the vein graft over a metal tube and then attach the proximal end of the vein graft to the implant, by penetrating 7 individual hooks through the vein using a special tool. The implant was then everted and as a final step the surgeon was required to attach a nose cone to protect the 7 hooks from catching the aortic tissue during implant insertion.

After full systemic heparinization (activated clotting time more than 500 seconds) and once the location for the proximal anastomosis was chosen, a hole was created in the ascending aorta using a patented cutter device, which is part of the aortic connector system. The hole was then covered with a finger to prevent blood from freely flowing into the thoracic cavity and subsequently the applicator was positioned in this opening and the anastomosis was created by pressing a button located at the end of the applicator.

The ascending aorta and the right atrium were cannulated and cardiopulmonary bypass was instituted. In mild systemic hypothermia (32°C) the ascending aorta was cross clamped and cardiac arrest was induced by antegrade infusion of blood cardioplegia in the aortic root. The distal anastomoses were performed using a running suture technique (Prolene 7-0, Ethicon, Hamburg, Germany).

The angiographic control was performed by means of intraoperative digital coronary angiography using the Siemens Powermobil (Siemens AG Medical Engineering, Erlangen, Germany). For the purpose of the study this system was used in two ways: the transfemoral catheterization and dye injection (Ultravist 370, Schering AG, Schlieren, Switzerland) in the ascending aorta just in front of the aortic connector but without entering the graft or by means of retrograde dye injection through the graft prior to construction of the distal anastomoses.

RESULTS

Ten patients (9 males and 1 female, mean age 67 ± 9 years) underwent an aortocoronary bypass grafting procedure with at least one venous graft. Patient characteristics, as well as relevant surgical data are summarized in Table 3.

A total of 12 facilitated anastomoses using the aortic connector device have been performed. Data on the type of connectors used, as well as an analysis of the target vessels to which the vein grafts had been connected, are depicted in Table 4.

Three complications occurred. In one patient a significant bleeding around the anastomotic device was noted and based on the recommendations of the manufacturer, the device was removed, which requires only a gentle tug on the vein. The surgeon initially desired to use the same hole created for the implant for the hand-sewn anastomosis, but due to the fact that this hole was very close to the aortic root, placement of a side-biting clamp was difficult and the decision was made to oversew this hole and create a new hole further distal on the ascending aorta using conventional techniques. In another patient, one proximal anastomosis had to be redone manually due to an unfavorable course and kinking in the first third of the vein graft, which was connected to the posterior descending artery. In the third patient the vein graft to one marginal branch of the circumflex artery had to be shortened following reperfusion of the heart and completion of both the proximal and distal anastomosis. This was accomplished by segmental resection of the vein graft.

There were no other complications attributable to the new technique described in this study. The intraaortic balloon pump was placed in one patient with suspected postoperative diastolic dysfunction of the left ventricle (surgery after subacute anterior myocardial infarction). There were no reexploration for bleeding, no neurologic morbidity, no other major postoperative morbidity, no perioperative myocardial infarction and no in-hospital mortality.

DISCUSSION

The introduction of less invasive surgery techniques has clearly been the most significant innovation in the field of cardiac surgery in the last decade. There is evidence that by avoiding the use of extracorporeal circulation clinically relevant morbidity can be significantly reduced, especially with regards to neurological sequelae [Barbut 1997]. Coronary bypass surgery on the beating heart continued to become less technically demanding for the surgeon due to a close cooperation of medical device engineers, the relevant medical device industry and the early adopting cardiac surgeons. However, one critical issue has still to be resolved in a definitive way: the quality of the vascular anastomoses. The quality of sutured anastomosis are dependent on the surgeons skill set, training, variation of day-to-day performance, surgical access, patient morphology and anatomy and motion of the distal target. One approach to reduce variability in vascular anastomosis could be to abandon the traditional suturing technique in favor of mechanically performed anastomoses. This would, at least theoretically, guarantee standardized geometry and fluid dynamics and thus perhaps have a beneficial impact on immediate and long-term graft patency [Shennib 2001].

The aortic connector device (Q-CAB®, Symmetry®) is the first commercial release out of many innovative developments, currently in clinical evaluation [Calafiore 2001], which address this topic. It was initially launched and approved in Europe, but recently became approved by the U.S. Food and Drug Administration as well.

The device is made out of nitinol, an alloy of nickel and titanium, which is well known in biotechnology. The design takes advantage of the superelasticity of nitinol, enabling extreme deformations without losing the definitive shape. After device deployment the inner and outer flanges of the implant do not penetrate the aortic wall and the vein graft is only attached to the aorta by means of a sandwiching effect of the nitinol implant. The fact that nitinol in its deployed configuration is not very stiff, allows the surgeon to easily remove the implant should he not be satisfied with the anastomotic quality .

As an initial step in the use of this novel system, the surgeon must first mount the vein graft to the device. This procedure is not automated and requires company training to be accomplished with reliable accuracy. Failure to accurately attach all 7 hooks to the vein graft could result in leakage, requiring removal of the implant. Unfortunately, the system requires passing a metal tube through the lumen of the graft vessel with potential injury of the endothelial surface.

The use of the aortic connector requires some restrictions in the surgical technique: With this system, the proximal anastomoses have to be done first and (most important) result in the graft departing from the ascending aorta at a 90 degree angle. Based on our limited experience this may result in a significantly higher potential for graft kinking. Measuring the graft length while the heart is beating and fully engorged would help assess the correct graft length and help reduce the likelihood of kinking. Of course, surgeons who always perform their proximal anastomoses first are less prone to this problem. The choice of the appropriate anastomotic site is therefore crucial. We found the safest place for grafts directed to the right coronary artery to be between the right atrial appendage and the pulmonary artery. Grafts directed to the marginal branches of the circumflex artery can be connected safely with the ascending aorta slightly more laterally oriented than in the conventional technique. The two cases in which we had to correct the graft's length or change the anastomotic site are surely part of our learning curve. It is, however, our impression that the described change in the surgical routine resulted in longer bypass- and aortic cross-clamp-times.

An interesting observation was that we experienced only one bleeding complication. It remained unclear, if this occurred due to a possible lesion to the vein during the mounting procedure or due to an asymmetrically created hole.

Obviously and despite the non-penetrating nature of the connection between the device and the aorta, the connection seems to hold sufficiently. This confirms the recently presented results of other groups [Eckstein 2001].

We feel that the visualization of the anastomoses by means of intraoperative angiography added to our confidence in the device, which is why this form evaluation was added to our protocol. The quality resulting from dye injection just in front of the ostium enables only a limited evaluation of the graft and the distal anastomoses, allows however for assessment of the patency and symmetry of the proximal anastomosis. We did not feel comfortable with passing the proximal anastomosis and intubating the graft with the angiography catheter. The retrograde injection of dye yielded sufficient image quality (Figure 1).

The mechanical performance of the aortic connector system was reliable and repeatable and was felt to be safe for the patient. There was no mechanical malfunction or failed deployment. The two-step approach (with one hand controlling the bleeding from the hole in the ascending aorta and the other manipulating the applicator) will be certainly reevaluated by the engineers in the future.

The long-term fate of these anastomoses and grafts should be the subject of future close observations for several reasons: the loading procedure could be potentially harmful. The interface between vein, device and aortic endothelium

could also induce endothelial hyperplasia in man. To our knowledge the preclinical experience has not been published so far with special emphasis on changes of the aorta and vein graft in close proximity to the implant. Conceivably this could negatively affect long-term patency.

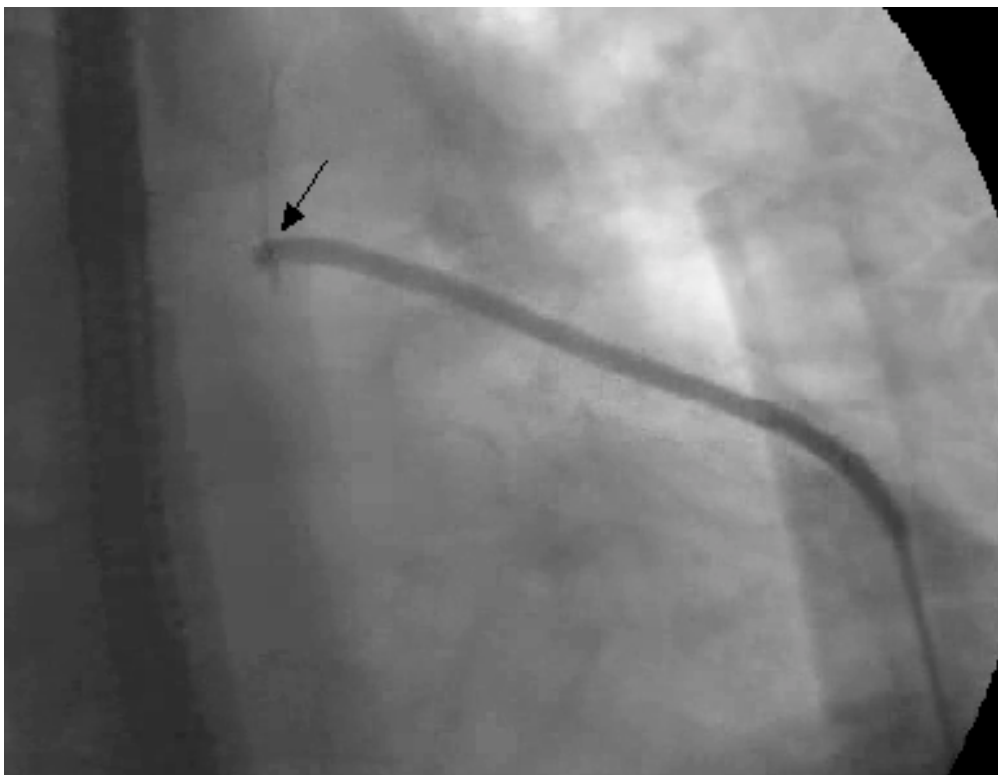
Despite these words of caution, we consider the aortic connector as a very useful tool in our armamentarium, especially in cases where side clamping of the aorta could eventually harm the patient. We adopted this technique in our practice for patients operated off- or on-pump who are not good candidates for total arterial revascularization and in whom manipulation of the ascending aorta should be avoided.

REFERENCES

1. Barbut D, Lo Y-W, Gold JP, Barbut D, Lo YW, Gold JP, Trifiletti RR, Yao FS, Hager DN, Hinton RB, Isom OW. Impact of embolization during coronary artery bypass grafting on outcome and length of stay. *Ann Thorac Surg*, 63: 998-1002, 1997.
2. Calafiore AM, Bar-El Y, Vitolla G, Di Giammarco G, Teodori G, IacÃ AL, D'Alessandro S, Di Mauro M. Early clinical experience with a new sutureless anastomotic device for proximal anastomosis of the saphenous vein to the aorta. *J Thorac Cardiovasc Surg*, 121: 854-8, 2001.
3. Eckstein FS, Bonilla LF, Englberger L, Stauffer E, Berg TA, Schmidli J, Carrel TP. Minimizing aortic manipulation during OPCAB using the symmetry aortic connector system for proximal vein graft anastomoses. *Ann Thorac Surg*, 72: S995-8, 2001.
4. Shennib H. Enter the era of facilitated anastomotic devices for coronary bypass surgery. *J Thorac Cardiovasc Surg*, 121: 833-4, 2001.

Figure Legends

Figure 1. Intraoperative angiography (retrograde dye injection directly through the graft) for patency and configuration control of the automated sutureless



anastomosis (marked
with the arrow)

Tables

Table 1: Inclusion criteria

1. Elective, hemodynamically stable patient
2. CABG with at least one venous graft indicated (concomitant procedures accepted)
3. EF > 35 %

Table 2: Exclusion criteria

1. Hemodynamic instability
2. Reported anaphylactic reaction to radiopaque dye
3. Renal failure (serum creatinine > 200 µg/l)

Table 3: Patient characteristics and surgical data

Patients (n)	10
males	9
females	1
Mean age (yrs)	67 ± 9
Diabetes mellitus (n)	7
Mean EF (%)	57 ± 14
LIMA (n)	10
RIMA (n)	2
RA (n)	3
Mean ECC-time (min)	112 ± 43
Mean X-clamp-time (min)	56 ± 34
Mean distal anastomoses/pt	3,9 ± 1,4
Mean drain loss (ml)	550 ± 260
Mean time to extubation (hrs)	2,6 ± 2,2
Mean CK (U/l - 1 hr postop)	480 ± 144
Mean CK-MB (U/l - 1 hr postop)	36 ± 11

Table 4: Characteristics of the devices and the target vessels of the vein grafts.

Connectors	12
1 per patient	10
2 per patient	2
Connector dimensions	
Grey (4,5 – 5,0 mm)	4
Green (5,0 – 5,5 mm)	7
Blue (5,5 – 6,0 mm)	1
Single grafts (n)	8
Sequential grafts (n)	4
Target vessels	
PDA / RCA	7
PLA / Marginal	5
RIM / Diagonal	3