A Multicenter Initial Clinical Experience with Right Heart Support and Beating Heart Coronary Surgery

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ABSTRACT

Background: During coronary surgery without CPB, exposure of posterior vessel via sternotomy can cause deterioration of cardiac hemodynamics requiring inotrope drugs support. Recent animal experiments demonstrate hemodynamic benefit of right heart support (RHS) with the AMED system.

The purpose of this study was to evaluate the hemodynamic effects during cardiac manipulation to expose the posterior coronary arteries, and determine the effect of RHS in restoring hemodynamics, increasing anastomotic exposure and reducing inotropic requirements.

Material and Methods: From July 28 to December 29, 32 patients (25 men/ 7 women), mean age of 63.4 (± 6.2 years, ages: 49 – 78) received coronary revascularization with the A-Med RHS device. They were divided into two groups of 16 patients, A and B. Group A patients had at least one circumflex branch bypassed. The anterior wall was systematically bypassed off-pump without RHS. The right coronary artery (RCA) and the obtuse coronary artery (OM) were completed utilizing RHS. In group B patients, all vessels including anterior vessels were bypassed with the RHS.

Mean arterial pressure (MAP), mean pulmonary arterial pressure (PAP), cardiac output (CO) and the average pump flow (APF) were recorded during the OM and RCA bypass for group A, and for group B LAD data was also recorded.

Results: Elective beating heart coronary artery bypass graft (CABG) was successfully accomplished in 32 patients with RHS. Data measurements recorded in Group A showed the improved hemodynamic recovery for OM and RCA bypass with RHS. The MAP increased from 44 to 68mmHg (OM) and from 63 to 81mmHg (RCA); the CO from 2.1 to 4.4 L/min (OM) and from 3.3 to 4.7 L/min (RCA). In group B, the data recorded showed the stability of the MAP in all vessels bypassed (LAD, OM and RCA). No device-related patient incidents ocurred. All 32 patients were discharged to their homes.

Conclusons: The AMED system, as RHS support, facilitated coronary bypass without CPB to posterior vessels, restoring hemodynamics, providing better exposure to anastomotic sites and apparently reducing inotropes need. Prospective randomize trials are necessary to confirm this initial experience.

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Table 1. Preoperative patients data

GENDER	Male 25 Female 7
AGE	63.4 ± 6.2 (49-78)
NYHA	3-4
Reoperation cases	1 patient
Unstable angina	5 patients
N. of diseased vessels	95
LMCA	8 patients
LVEF	28 patients> 50%, 3 patient 30-40%, 1 patient<25%

LMCA = Left main coronary artery diseased
LVEF = Left ventricular ejection fraction

INTRODUCTION

Myocardial revascularization without cardiopulmonary bypass (CPB) through a sternotomy has been used since the beginning of coronary artery bypass graft (CABG). The advantages of performing CABG without CPB have been well documented in the literature and include lower morbidity and mortality, reduced cost, and decreased need for blood transfusions [Benetti 1991, Westaby 1995, Buffolo 1996].Recently this surgical strategy has gained renewed interest for multivessel revascularization [Benetti 1991, Calafiori 1994, Buffolo 1996] and has been performed worldwide. In our hospitals in Brazil, 90% of the CABG cases were performed without CPB during 1999. However, we still have 10% of the cases done with CPB because of hemodynamic deterioration and bad target area visualization for posterior vessels.

Recently we studied the hemodynamic changes during CABG without CPB and found that even the left anterior descending coronary artery (LAD) exposition causes a decrease in cardiac output (CO). This tends to decrease considerably when the heart is displaced for posterior vessel bypass, for example, OM and posterior descending artery (PDA) many times cause hemodynamic instability during beating heart CABG. Futhermore, Grundeman et al. [Gründeman 1999] and Jansen et al. [Jansen 1998] reported in both animal and in patients that exposing posterior vessels by displacing the beating heart tends to decrease arterial pressure caused by right ventricular dysfunction as a result of mechanical interference with diastolic expansion. In animals, right- heart bypass normalized stroke volume and MAP by increasing left ventricular preload.

The objectives of this study are to evaluate the hemodynamic modifications during cardiac manipulation to expose the posterior coronary arteries, and determine the effects of RHS in restoring hemodynamics, increasing anastomotic exposure, and reducing inotropic requirements.

MATERIALS AND METHODS

Patients

From July 29 to December 30, 1999, 32 patients underwent beating heart CBG with RHS. The operations were performed by 16 surgeons (working in different institutions participating on this initial experience). The patients were all candidates for beating heart CABG, in which at least one of the target vessels was an OM. Patients who had electric instability were excluded. Preoperative patient data is shown in Table 1 (◎).

Surgical Technique

In group A, anesthesia was induced with sufentanyl and propofol and maintaned with sufentanyl and propofol and a mixture of nitrous oxide and oxygen. Muscular relaxation was obtained with pancuronium bromide. At the beginning of the procedure, a continuous infusion of nitroglycerin and papaverin is administered; volume is added if necessary. The mammary and radial arteries are harvested semiskeletonized.

After total heparinization (3mg/Kg/body weight), the arterial grafts are prepared as reported by Calafiori et al. [Calafiori 1994]. The target areas are exposed using the strategy proposed by Bergsland et al. [Bergsland1999]. The anterior vessels (LAD and diagonals) were bypassed on beating heart (without RHS) using a mechanical suture stabilizer. The deep vessels (OM and PDA) were exposed once the RHS was placed. The patient was placed in the Trendelenburg position and rotated rightward. The stabilizer was placed in the best position without taking care of the MAP depression or CO. No inotropic drugs were used out of two patients that were on inotropes before surgery. Once the best MAP and CO were recorded 3 to 5 minutes after stabilization, the pump was started and the flow increased progressively until the highest MAP and CO were obtained or restored. At the end of the anastomosis, the pump was stopped and the heart was put in anatomical position.

In group B, anesthesia and target area exposure was done according to each center's standard. After total heparinization, the RHS was placed, the pump was started with 2.0 L/min of flow, the arteries were bypassed during the assistance, and the flow was increased depending on the target area exposed keeping the MAP stable. At the end of the anastomosis , the pump was stopped and the heart was put in anatomical position.

All anastomosis were performed with a single suture.

Blood lost during the procedure was reinfused in the patient using a cell saver (Dideco, Mirandola, Modena, Italy). Protamine was reversed 1:1, and the patient closed in the usual manner.

A-Med System

The pump system includes the A-Med Coaxial ® Cannula, a cable driven A-syst centrifugal pump , a remote motor and the console. The coaxial cannula is placed across the tricuspid valve.The inner cannula is advanced to 10-15 cm and positioned in the main pulmonary artery, proximal to the pulmonary bifurcation. The correct cannula placement is verified by direct cardiac palpation. The miniature centrifugal pump is positioned in the surgical field and connected to the cannula. The remote motor and console are positioned outside the surgical field (see Figure 1, ◎).

Figure 1. The A-Med system RHS.

Hemodynamic Data

To evaluate the hemodynamic changes related to cardiac manipulation, MAP, PAP and CO, measured by a transesophageal doppler, (Cardio Q‘, Deltex Medical Limited, Chischester, West Sussex, UK) were recorded during sugery. Perioperative and post-operative outcomes and complications were collected until the patients were discharged (see Figure 2, ◎).

RESULTS

The operation was a success in all patients. In all cases, the deep vessels were better visualized and the stabilizer repositioned, increasing the exposition during RHS.

In group A, most patients had total arterial myocardial revascularization (89% of arterial grafts). A total of 48 anastomoses were performed, and the mean anastomoses per patient was 3.0. In group B, a total of 47 anastomoses were performed with a mean of 2.9 amastonmoses per patient. Table 2 (◎) shows the evolution of MAP, PAP, and CO during the heart manipulation, and the average flow necessary to reach or restore or maintain the hemodynamics in group A and B.

ICU stay was 26 (± 8 hours); hospital length of stay was 6 (± 1) days. The mean chest tube drainage was 350 (± 123) ml. Only two patients required a transfusion. There were no myocardial infarcts, acute renal failures or pulmonary complications.

Only two patients required inotropic medication after surgery greater than six hours, and those patients were on inotropes before surgery.

No device-related incidents occurred. All 32 patients were discharged to their homes.

DISCUSSION

The development of mechanical stabilization devices have enabled surgeons to perform more and more challenging revascularization procedures. However, in some cases the difficulty remains in accessing the posterior vessels of the heart while maintaining hemodynamic stability with a good anastomotic view .

This miniaturized circulatory bypass system seems to provide the hemodynamic stability necessary during beating heart surgery. In some cases, we felt that it would not be possible to do without this support system. Two of these patients had unstable angina and were on inotropes before surgery.

The beating heart approach has several advantages, such as 1) less inflammatory system activation, and 2) no con-

Table 2. Evolution of MAP, PAP, CO and average pump flow (APF)

GROUP A	1 BASELINE	2 OM pump off	3 OM pump on	4 RCA pump off	5 RCA pump on
MAP	66mmHg	44mmHg	68mmHg	63mmHg	81mmHg
CO	5.6 l/min	2.1 l/min	4.4 l/min	3.3 l/min	4.7 l /min
APF	–	–	2.1 l/min	–	1.5 l/min
PAP	18mmHg	18mmHg	17mmHg	19mmHg	18mmHg

GROUP B	1 BASELINE	2 LAD pump on	3 OM pump on	4 RCA pump on
MAP	71mmHg	71mmHg	70mmHg	72mmhg
PAP	17mmHg	17mmHg	18.4 mmHg	17.5mmHg
APF	0.0 l/min	2.0 l/min	2.3 l/min	2.1 l/min

For group A data measurements were recorded as : 1- Baseline, anatomical position ; 2 – OM position, pump off ; 3- OM position , pump on ; 4 – RCA position, pump off ; 5- RCA position , pump on. For group B data measurements were recorded as : 1- Baseline, anatomical position, 2-LAD position pump on, 3- OM position pump on, 4- RCA position pump on.

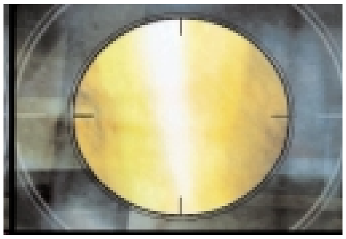

Figure 2. Patient of 57 years old, that had a hypertrophic left ventricle and two grafts (LIMA-LAD on beating heart and Vein to OM with RHS). FILM with A-Med system RHS.

sumption of clotting factors, all of which occur during standard CPB. This new system seems to minimize the blood contact area, but still needs more evaluation to prove the possibility of a reduction in the inflammatory response.

The principal finding of the study was the restoration of the CO associated with the increasing pump flow (group A), and the majority of the cases not requiring inotropic support. In this study for group A, the traditional Trendelenburg position, volume load and exposition strategy were used with the intention of restoring MAP and CO even though the hemodynamics were only restored with the the pump on. We know that in some cases the use of inotropic drugs can restores the hemodynamics. In these instances, however, we are not certain that inotropic drugs are more beneficial than the RHS. In group B, we saw that the highest pump flows were during the OMs bypass, confirming that this is the artery that causes the bigger hemodynamics modifications.

We can still comment on the necessity of doing left , right or bi-ventricular support during beating heart CABG. Grundeman et al. [Grundeman 1999] showed that left heart bypass failed to restore systemic circulation and Lönn et al. [Lönn 1999] showed that left heart assist was most effective for patients who have impaired left ventricular function. In our study, one patient had less than 25% of EF and had 2 OM's bypassed with no need for inotropic agents.

If we follow the evolution of the MAP on group A (see Table 2, ◎) while using the RHS, we notice that the hemodynamics were restored 100%, but regarding CO, only 90% was restored. This can probably be explained by a certain degree of left ventricular disturbance, caused by the application of the mechanical stabilizer and the heart displacement itself. The mini-centrifugal pump used as RHS was intuitive to set-up and to use. The coaxial cannula was inserted easily on the first attempt with 16 different surgeons.

We conclude that the A-Med System, as RHS facilitated coronary bypass without CPB to posterior vessels, restored hemodynamics, provided improved anastomotic view anastomotic to sites and, apparently reduced the need for inotropic support. Only a small number of cases were done with this device, therefore more cases need to be studied to confirm this initial experience.

REFERENCES

1. Benetti FJ, Naselli G, Wood M, Geffner L. Direct myocardial revascularization without extracorporeal circulation.Experience in 700 patients. Chest 100:312–6, 1991.
2. Bergsland J, Karamanoukian HL, Soltoski PR, Salerno TA. “Single Suture” for cincumflex exposure in off-pump coronary artery bypass grafting. Ann Thorac Surg 68:1428–30, 1999.
3. Buffolo E, Silva de Andrade JC, Rodrigues Branco JN, et al. Coronary artery bypass sugery without cardiopulmonary bypass. Ann Thorac Surg 61:63–6, 1996.
4. Calafiori AM, Di Giammarco G, Luciani N, et al. Composite arterial conduits for a wider arterial myocardial revascularization. Ann Thorac Surg 58:185–90, 1994.
5. Calafiori AM, Teodori G, Di Giammarco G, et al. Multiple arterial conduits without cardiopulmoary bypass: early angiographic results. Ann Thorac Surg 67:450–456, 1999.
6. Gründeman PF, Borst C, Verlaan CWJ, Meijburg H, Mouës CM, Jansen EWL. Exposure of circumflex branches in the tilted, beating porcine heart: echographic evidence of right ventricular deformation and the effect of right or left heart bypass . J Thorac Cardiovasc Surg 118:316–23, 1999.
7. Jansen EWL, Borst C, Laphor JR, et al. Coronary artery bypass grafting without cardiopulmonary bypass using the Octopus method: results in the first 100 patients. J Thorac Cardiovasc Surg 116:60–7, 1998.
8. Lönn U, Peterzén B, Carnstam B, Casimir-Ahn H. Beating heart coronary surgery supported by an axial blood flow pump. Ann Thorac Surg 67:99–104, 1999.
9. Westaby S. Coronary surgery without cardiopulmonary bypass (editorial). Br Heart J 73:203–5, 1995.