The Heart Surgery Forum #2008-1024
11 (5), 2008 [Epub October 2008]
doi: 10.1532/HSF98.20081024

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Beating-Heart Coronary Artery Bypass Grafting Using a Miniaturized Extracorporeal Circulation System

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ABSTRACT

Background. Experience with miniaturized coronary artery bypass (CAB) systems in coronary artery bypass graft (CABG) surgery on the beating heart is limited. We used a relatively new miniaturized cardiopulmonary bypass (CPB) system, which we termed assisted CAB (ACAB), to perform CABG on the beating heart in 110 patients, and we analyzed clinical outcomes in this patient group.

Methods. Between January 2004 and September 2006, we used ACAB to perform CABG on the beating heart in 110 patients. The mean patient age was 73 ± 8.1 years.

The ACAB system uses a small prime volume of only 500 mL, and the circuit is shorter than that used in conventional CPB. In addition, the tubing and oxygenator systems were surface-coated with phosphorylcholine. The initial heparin dose was 150 IU/kg, with a target activated clotting time of >250 seconds. With this management, none of the patients experienced system thrombosis. We did not use cardioplegia or aortic crossclamping and did not routinely retransfuse cardiotomy blood. Observational data for the 110 patients were analyzed.

Results. The mean number of anastomoses performed was 2.67. The rate of perioperative infarction was 1.8% (2 patients). Perioperative mortality was 7% (8 patients). The mean EuroSCORE for all patients was 6.4 ± 4, whereas it was 13.75 ± 6.18 for the patients who died. Mean CPB time was 64.96 ± 16.66 minutes.

Conclusion. In our experience, beating heart CABG supported by a miniaturized CPB is a safe procedure with acceptable perioperative results.

INTRODUCTION

The development of cardiopulmonary bypass (CPB) permitted coronary artery bypass grafting (CABG) and allowed surgeons to complete perfect anastomoses on the motionless heart in a bloodless field [Gibbon 1953]. Nevertheless, CPB has potential adverse effects on several organs and can lead to renal, pulmonary, and neurological dysfunction. Additionally, it triggers the body's inflammatory response, and aortic cannulation can lead to thromboembolic complications [Butler 1993; Beghi 2006].

With the aim of eliminating risk factors associated with CPB, off-pump coronary artery bypass (OPCAB) surgery was developed in the mid-1980s. However, this technique had certain limitations, including hemodynamic instability from displacement of the heart, particularly in patients with poor left ventricular function. It remains unclear which technique should be used for a specific patient, and the patient population has changed over the past years.

A novel miniaturized CPB system was developed that provides circulatory support with fewer adverse effects than standard CPB [Ohata 2007; Perthel 2007; Gerriaten 2007]. We modified a miniaturized CPB system for use in beating-heart CABG and investigated safety, morbidity, and mortality in 110 patients who underwent CABG surgery on the beating heart with this new system.

MATERIALS AND METHODS

From January 2004 through September 2006, 110 patients were supported with the assisted coronary artery bypass (ACAB) system while undergoing beating-heart CABG. Mean patient age was 73 ± 8.1 years; 82 patients (75%) were male. Two patients (2%) had 1-vessel disease, 20 (18%) had 2-vessel disease, and 88 (80%) had 3-vessel disease. Nine procedures (8%) were redos. The mean patient EuroSCORE was 6.4 ± 4. Eight cases (7.3%) were emergencies. The left ventricular ejection fraction was >50% in 65 patients (59%), 30%-50% in 33 (30%), and <30% in 12 patients (11%). Preoperative patient characteristics are listed in Table 1.

The ACAB System

The ACAB system we used was based on the centrifugal pump console SCP (Stöckert, Sorin Group, Munich, Germany) and the ECC.O-perfusion system (Sorin Group, Mirandola, Italy). The system was an integral combination of a venous bubble trap, an oxygenator with a gas exchange

Received March 7, 2008; accepted April 6, 2008.

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Table 1. Preoperative Patient Characteristics*

Male/female	82/28 (75/25)
Mean age, y	73
Mean body mass index	27.4
Diabetes mellitus	38 (34.54)
Hypertension	105 (96)
Peripheral arterial vascular disease	16
EuroSCORE	6.4 ± 4
Preoperative infarction	
≤48 h	4 (3.64)
≥48 h	58 (52.73)
Cardiogenic shock	7 (6.36)
History of shock: ≥48 hours and <3 weeks	6 (5.45)
History of cardiopulmonary resuscitation	5 (4.55)
Left ventricular ejection fraction	
>50%	65 (59)
30%-50%	33 (30)
<30%	12 (11)
Left main stenosis	40 (36)
Status post cardiological intervention	31 (28)
Redo surgery	9 (8)
Chronic obstructive pulmonary disease	23 (21)
Carotid artery stenosis	20 (18)
Cerebrovascular disease	8 (7)
Vessel disease (VD)	
1 VD	2 (1.8)
2 VD	20 (18)
3 VD	88 (80)

*Data are presented as n (%) or mean ± SD unless otherwise indicated.

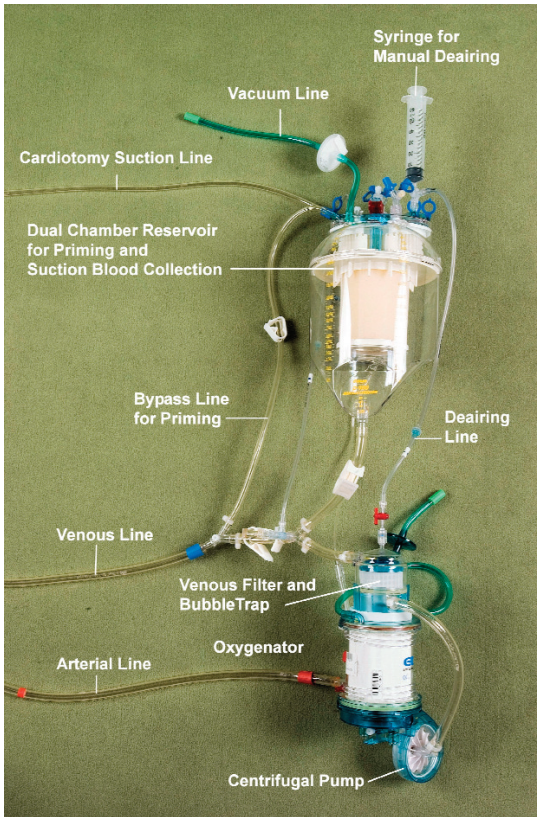

Figure 1. Miniaturized cardiopulmonary bypass: tubing system.

surface of 1.1 m^2, a heat exchanger, and a Revolution® centrifugal pump (COBE Cardiovascular, Sorin Group). No arterial filter was used. The SCP bubble detector, which controls an electronic clamp on the arterial line, was placed on the venous line. This placement permits early detection of air in the venous blood, before it reaches the venous bubble trap (Figure 1, Figure 2).

We developed a custom-made tubing system for this unit with a Dual Avant D970 cardiotomy reservoir (Sorin Group), which has 2 independent chambers. The priming fluid circulated through the reservoir while the system was deaired, leading to fast and effective removal of air during priming. During perfusion, the lower chamber of the reservoir served as a volume reservoir so that colloids were administered to the patient as needed.

The upper chamber was connected to the cardiotomy suction. For this purpose, a –40 mmHg vacuum source was hooked up to the reservoir, allowing suctioning of blood from the operating field at any time, with no need for an additional suction pump. According to our protocol, this blood was not retransfused unless a total volume of 800 mL was exceeded, which did not occur in any of our patients.

The perfusion system was completely coated with phosporylcholine. We administered an initial heparin dose of 150 IU/kg; the target activated clotting time (ACT) was >250 seconds.

The aorta was cannulated with a 24-Fr Soft-Flow cannula (Terumo, Ann Arbor, MI, USA); for venous cannulation, we used a 28/32-Fr 2-stage cannula (Maquet Cardiopulmonary, Hirrlingen, Germany).

The rate of blood flow through the extracorporeal circuit was adjusted as needed. The oxygenator was designed for flow rates up to 5 L/min. The heart was beating throughout the entire operation, and total flow, the sum of the endogenous cardiac output and circuit flow, was completely adequate.

The circuit flow rate was adjusted on the basis of the arterial blood pressure. If the heart pumped sufficient blood on its own and produced a mean arterial pressure of >60 mmHg, the blood flow rate in the extracorporeal circuit was reduced to 1.5 L/min. Optimal perfusion required close coordination among all team members, and blood gas analyses were performed at 20-minute intervals. Urine volume could not be less than 100 mL/h during the ACAB, and acidosis could not occur.

If cardiac pump function was compromised, eg, by cardiac luxation, extracorporeal blood flow was increased to a maximum of 5 L/min. For this reason, only patients with a body surface area of up to approximately 2 m^2 are candidates for this procedure. In smaller patients it is not possible to provide a flow index of 2.4 L/min per m^2 body surface area without exceeding the maximum flow rate permissible for the oxygenator. In the study patients who underwent the procedure, diminished venous return seldom occurred even with strong dislocation of the heart. When venous return is

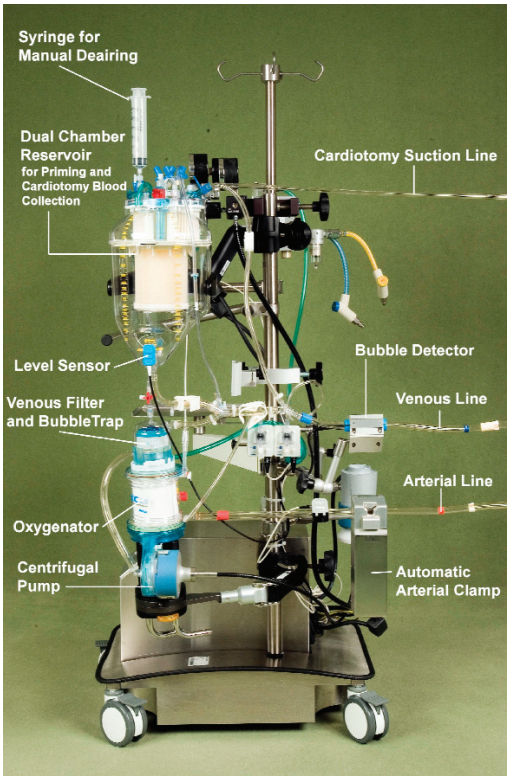

Figure 2. Miniaturized cardiopulmonary bypass: complete setup.

insufficient, it is important to place the heart back into in its original position before reattempting gentle luxation the heart. This approach is used in OPCAB surgery, and the surgeon who performed the procedure in our study patients was familiar with OPCAB surgery.

Because of the short tubing and compact design of the oxygenator/pump unit, the total priming volume amounted to 500 mL. Perfusion took place under normothermia at 37°C, ie, the patients were actively warmed.

Operative Management and Surgical Technique

All patients were thoroughly briefed about the procedure and gave informed consent.

Up to the time of surgery, previous medications, such as nitrates, β-blockers, angiotensin-converting enzyme inhibitors, and diuretics, were continued. Prior to the operation, central venous and pulmonary artery catheters were inserted, and electrocardiogram, arterial blood pressure, and bladder temperature were continuously monitored.

The surgical approach was via median sternotomy. The saphenous vein and left internal mammary artery (LIMA) grafts were harvested. Heparin was administered at a dose of 150 IU/kg, and the ACT was kept at >250 seconds. The average ACT was 373 ± 68 seconds (range 263-500 seconds). The ACT was measured with kaolin tubes and the Hemochron® jr system (International Technidyn Corporation, Edison, NJ USA). At the end of the ACAB procedure, heparin was neutralized with protamine at a reversal ratio of 1:1.

The ascending aorta was cannulated with a standard arterial cannula; a 2-stage cannula was inserted through the right atrium. No cardioplegia was given, and the ascending aorta was not cross-clamped. The procedure was performed on the beating heart. Because the lungs were ventilated throughout the operation, close coordination between the perfusionist and anesthesiologist was mandatory. Holding sutures were used to suspend the pericardium from the sternum, effectively retracting the lungs and creating space to perform the anastomoses.

Aprotinin was infused at 1,000,000 KIU during the operation. A deep pericardial traction suture (LIMA stitch) was placed between the inferior vena cava and the left inferior pulmonary vein to facilitate elevation of the apex of the heart and exposure of the posterior wall. The same techniques were used to perform all operations. The LIMA was harvested in a skeletonized fashion. Stabilization of the coronary arteries was accomplished with a commercially available stabilization system, the OPVAC® Synergy™ (Estech, San Ramon, CA, USA). Intraluminal coronary shunts were inserted whenever possible to keep the surgical field bloodless, and atrial pacing was established in case of bradycardia. Distal anastomoses were performed with continuous running 7-0 monofilament sutures for venous and 8-0 sutures for arterial grafts. Proximal anastomoses were constructed with a 6-0 running suture after aortic sideclamping.

According to the principle of functional revascularization, the anterior wall was first bypassed by anastomosing the LIMA to the left anterior descending coronary artery. Subsequently, the right coronary artery or its branches and the obtuse marginal branches were revascularized. During positioning and elevation of the heart, the ACAB flow rate was adjusted as dictated by blood pressure and cardiac output.

Definition of outcome parameters, data collection:

Myocardial infarction was defined as the occurrence of a new Q-wave on the electrocardiogram and/or an increase of the creatinine kinase -myocardial band fraction to more than 10% of the creatinine kinase. Neurological injury was defined as postoperative stroke. All data were entered into a database (Microsoft Access) and were retrospectively analyzed. Data are presented as mean ± SD.

RESULTS

From January 2004 to September 2006, a total of 110 patients underwent CABG on the beating heart while being supported with a new miniaturized CPB; 1 to 4 grafts (an average of 2.67 ± 0.71 peripheral anastomoses) were performed per patient. The LIMA was used in 103 patients (94%). Mean operative time was 160 ± 30.11 minutes. Four patients (3.6%) underwent a single bypass procedure, 39 patients (35%) received double bypasses, 56 (51%) had triple bypasses, and 11 patients (10%) had quadruple grafts (Table 2).

Hospital mortality and morbidity:

All patients were preoperatively in a high-risk group, EuroSCORE 6.4 ± 4. Perioperative mortality was 7% (8 patients). The primary cause of death was multiorgan

Table 2. Intraoperative Data*

Operative time, incision to closure	160.41 ± 30.11 min
Bypass time	64.96 ± 16.66 min
No. peripheral anastomoses	
Single bypass	4 (3.6)
Double bypass	39 (35)
Triple bypass	56 (51)
Quadruple bypass	11 (10)
Mean no. of grafts	2.67

*Data are presented as n (%) or mean ± SD.

failure in 3 patients, pneumonia in 2 patients, and sepsis in 2 patients. One patient died of severe pseudomembranous enterocolitis. Autopsies were performed in 2 patients and showed patent bypass grafts. All of the patients who died were in a high-risk group, with an average EuroSCORE of 13.75 ± 6.1.

Strokes occurred in 3 patients (2.7%), and 5 patients (4.5%) developed transient psychosyndrome. Postoperative myocardial infarction occurred in 2 patients (1.8%), and significant arrhythmias (atrial fibrillation) were observed in 33 patients (29%). Reexploration for bleeding was required in 3 patients (2.6%). Blood transfusions were not needed in 18 patients (16%). Wound infections requiring surgical intervention occurred in 3 patients (2.6%) (Table 3).

DISCUSSION

The complications related to CPB are well documented [Butler 1993; Kirklin 1997]. CPB was found to have adverse effects, such as initiation of the systemic inflammatory response because of complement activation and contact of patient blood with foreign surfaces [Ascione 2000]. In the past few years cardiac surgical patients have become older and increasingly multimorbid, leading to the investigation of less invasive cardiac surgical methods. Surgical, anesthesiological, and CPB techniques have improved significantly, resulting in better outcomes. Miniaturized extracorporeal circulation is one of these advances, clearly decreasing the morbidity in CABG patients compared to conventional CPB [Beghi 2006].

Table 3. Postoperative Complications*

Death	8 (7)
EuroSCORE	13.75 ± 6.1
Atrial fibrillation requiring therapy	33 (29)
Perioperative myocardial infarction	2 (1.8)
Low output syndrome requiring intraaortic balloon pump	2 (1.8)
Amount of postoperative bleeding, mL	957 ± 640
Reexploration for bleeding	3 (2.6)
No need for blood transfusion	18 (16)
Postoperative wound infection	3 (2.6)
Transient psychosyndrome	5 (4.5)
Stroke	3 (2.7)
Duration of artificial ventilation	
1-12 h	74 (67)
12-24 h	26 (23)
Duration of intensive care unit stay	
≥12 h	16 (14)
12-48 h	60 (55)
>48 h	24 (31)

*Data are presented as n (%) or mean ± SD.

There are some limitations to OPCAB surgery, such as incomplete revascularization and technical difficulties in constructing the coronary anastomoses, particularly in the inferior wall area and in cases with poor left ventricular function.

A study that compared CABG with conventional CPB and CABG with miniaturized CPB showed reduced global organ damage and preservation of alveolar function in the group of patients who underwent miniaturized CPB [Van Boven 2004]. This study also demonstrated reduced homologous blood product use in the mini-CPB group. In our patient group, no blood transfusions were necessary in 18 (16%) of patients, because we accepted hemoglobin values as low as 7 g/dL during ACAB. Because our patients were mostly elderly, with a mean age of 73 years, and high-risk cases, we tolerated postoperative hemoglobin values as low as 10 g/dL. In our study, the duration of ventilation was 1-12 hours in 74 patients (67%) and 12-24 hours in 26 patients (23%).

Another study of the use of mini-CPB [Beghi 2006] showed a decreased rate of perioperative nonfatal myocardial infarction (1 of 30 patients) and shorter intensive care unit stays. These results are in agreement with our results for 2 patients (1.8%) suffering postoperative myocardial infarctions (Table 3).

Another study reported a decreased rate of serum S 100B release during mini-CPB compared to conventional CPB, which translates to a reduced incidence of neurological complications [Fromes 2000; Remadi 2007]. In our series, 3 patients suffered a stroke (2.7%).

The EuroSCORE permits risk stratification and mortality prediction in cardiac surgical patients in Europe on the basis of objective risk factors. Based on EuroSCORE, all study patients were preoperatively in a high-risk group (EuroSCORE 6.4 ± 4). The patients who died (EuroSCORE 13.75 ± 6.1) were considered very high-risk patients; therefore, the mortality rate was acceptable [Nashef 1999].

The number of grafts performed (mean, 2.67) with this technique in our series is also comparable to those reported in the literature, either with miniaturized CPB or with the conventional method [Kamiya 2006].

Although the use of this mini-CPB system is beneficial for most patients, air entrapment resulting in air embolism remains a potential problem. Other authors have reported such technical complications. A study showed that air had entered the closed system in 2 of 15 patients. This finding led the group to abandon the use of this system [Nollert 2005]. In another study, air entered the pump in 3 patients but did not cause any detrimental effects [Remadi 2004].

Beghli et al [2006] reported no such adverse device-related complications in 30 patients in their series. We did not experience any such complications because we used measures to prevent them. To prevent atrial cannulation, the source of air entering the system, the cannulation site must be tightly closed

before CPB is commenced. If needed, the venous cannula is secured with a second purse-string suture. A microbubble detector in the venous line stops the pump when air is detected and clamps the arterial line. There is also a filter in the venous line that allows air to be aspirated with a syringe. The centrifugal pump and the oxygenator are additional barriers, trapping minor air bubbles.

Our experience has shown that this system has numerous advantages, eg, a small prime volume of 500 mL, which results in less hemodilution and decreased transfusion requirements [Shapira 1998]. The system also has a shorter circuit, which translates to a smaller foreign surface for blood contact, and results in less postoperative inflammatory response and reduced complement activation [Fromes 2000; Remadi 2004; Von Segesser 2003].

In our system, the tubing and centrifugal pump are coated with phosphorylcholine, which mimics characteristic features of biologic membranes. It is biocompatible, not heparin based, and is associated with low thrombogenicity and a reduced inflammatory response [Somer 2002; Ranucci 2002; Wiesenack 2004]. Because of these properties, we administered heparin at an initial dose of 150 IU/kg, maintaining an ACT of >250 seconds. With this type of management, none of our patients suffered any system thrombosis. To avoid thromboembolism when the ACT is low, however, the anticoagulant level in the collected blood should be increased before any retransfusion.

Although the miniaturized CPB circuit offers many advantages, some perfusionists regard this system to be unsafe and are reluctant to use it, which is why we modified the system to include a reservoir, as described above.

Although we widely perform OPCAB surgery, which allows complete revascularization, including revascularization of the inferior wall region, we believe that ACAB support would be more suited to permit complete revascularization without risk of hemodynamic deterioration, particularly in patients with severely reduced left ventricular function.

This study is limited by the fact that it is retrospective. We believe that a prospective randomized clinical study is required to compare CABG/ACAB to CABG/conventional CPB and/or to OPCAB.

CONCLUSION

Beating-heart CABG with the ACAB system is a reliable procedure in most patients. Our experience with miniaturized CPB shows satisfactory results. ACAB is intraoperatively safe, and it is our favored technique in multimorbid and/or elderly patients, and in patients with severely impaired left ventricular function.

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