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The CentriMag: A New Optimized Centrifugal Blood Pump with Levitating Impeller

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ABSTRACT

Purpose: Blood pumps are routinely used for circulatory and pulmonary support. However, blood trauma and pump failure remain severe drawbacks of currently available pump models. This study evaluated the first clinical application of a new, totally bearingless centrifugal blood pump (CentriMag).

Material and Methods: A centrifugal pump consisting of an electromagnetic suspended impeller was used as a blood pump during beating-heart coronary artery bypass grafting in 11 patients (mean weight, 77.4 kg). Heparin in a bolus of 150 IU/kg body weight was administered, and activated clotting time was maintained at approximately 180 to 250 seconds during extracorporeal circulation. Pump-induced blood trauma was evaluated by measurement of plasma free hemoglobin (PFH), lactate dehydrogenase (LDH), hematocrit, total bilirubin, and platelet levels.

Results: Mean pump flow was 3.3 ± 0.62 L/min, and mean pressure gradient through the oxygenator was 69 ± 4 mm Hg. No pump dysfunction occurred during a mean application time of 105 ± 26 minutes. Inspection of the pump housings showed no internal thrombus formation despite low-dose heparinization. Only slight hemolysis was observed with a mean PFH level of 1.96 µmol/L; LDH, 460 U/L; hematocrit, 33%; total bilirubin, 25 µmol/L; and platelets, 191×10^3/µL.

Conclusions: The bearingless CentriMag blood pump is a safe and reliable new device that produces only minimal hemolysis. It seems to be suited for long-term evaluation as a blood pump for extracorporeal membrane oxygenation or as ventricular assist device.

INTRODUCTION

Coronary bypass surgery with cardioplegic arrest has been the standard for more than 4 decades. Despite development of several enhanced cardioplegic solutions, ischemia and reperfusion injury, as shown by postoperative specific myocardial enzyme release, remains an issue, especially in patients with poor left ventricular function or unstable angina pectoris. Moreover, systemic inflammatory response syndrome induced by the foreign surface of the cardiopulmonary system can be poorly tolerated in older or polymorbid patients. Off-pump coronary bypass surgery has been shown to be a safer procedure in regard to that issue. Avoiding cardiopulmonary bypass (CPB) eliminates post-CPB systemic inflammatory response syndrome. However, off-pump coronary artery bypass grafting (CABG) is not always possible or reasonable, as in cases of dilated or hypertrophic left ventricle or extensive coronary disease. Beating-heart technique with extracorporeal circulatory support but without cardioplegia allows targeting of all the coronary territories and therefore performance of complete or extensive CABG procedures. The combination of unloading the left ventricle, which reduces end-diastolic left ventricular pressure, and the use of intracoronary shunts provides an excellent method of myocardial protection for CABG. Even though ischemia and reperfusion can be eliminated with the beating-heart method, pump-induced blood trauma and foreign body reaction remain drawbacks of that technique. Reducing the tubing and avoiding a cardiotomy reservoir minimize the foreign body surface and inflammatory response reaction. Blood trauma can be reduced by using a centrifugal blood pump instead of an occlusive roller pump. A bearingless design ideally would further minimize hemolysis, because there would be no friction in any suspension axis.

We report the first-time clinical application of such a bearingless centrifugal blood pump. The device was used in a series of 11 consecutive beating-heart CABG procedures.

PATIENTS AND METHODS

Eleven patients needing CABG were included in a prospective, nonrandomized study. The study design was approved by the ethics committee of University Hospital, Zurich, Switzerland. The mean age of the 11 patients was 67 ± 5.9 years (range, 51-81 years). The mean weight was 77 ± 11.62 kg (range, 55-93 kg), and the mean body surface area was 1.86 ± 0.15 m^2 (range, 1.6-2.05 m^2). In 1 patient, abdominal aortic aneurysm was treated by conventional open repair after completion of the CABG procedure. In another patient

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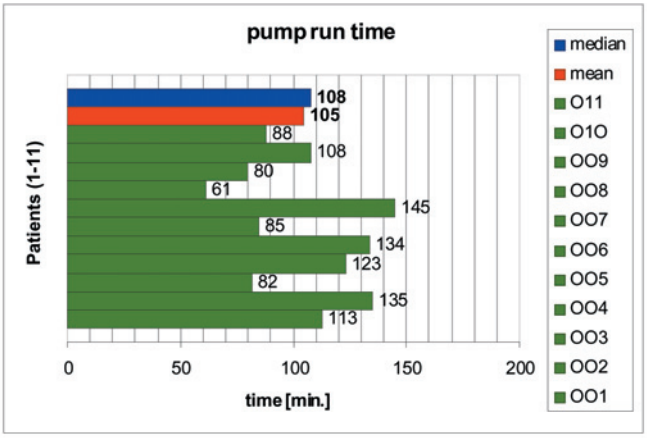

Figure 1. Extracorporeal pump run times for the 11 patient undergoing coronary artery bypass grafting procedures.

thrombendarterectomy of the right carotid artery was performed prior to the CABG procedure. Three patients with unstable angina pectoris received an intraaortic balloon pump preoperatively, and 1 patient with poor ejection fraction (<25%) received one intraoperatively.

Surgery

Takedown of the mammary artery and harvesting of the saphenous vein grafts were performed in a standard manner. Cannulation (right atrium to aortic arch) was performed after administration of heparin in a bolus of 150 IU/kg body weight. Extracorporeal circulation (ECC) was started after connection to the CPB system. Cannulas, tubing, and oxygenator were coated with heparin for reduction of blood activation potential during CPB. During ECC, heparinization was adapted to a target activated clotting time value of 180 to 250 seconds. Pump flow was adapted to the hemodynamics requirement during distal bypass grafting. Exposition and local stabilization were achieved with suction devices (OPVAC Synergy Plus off-pump system and Pyramid positioner; Estech, Danville, CA, USA). CABG was performed with endoluminal coronary shunts (1-1.5 mm; Guidant, Santa Clara, CA, USA). After completion of the distal anastomoses, the flow of the centrifugal pump was gradually reduced and finally stopped after completion of the proximal aortic anastomoses.

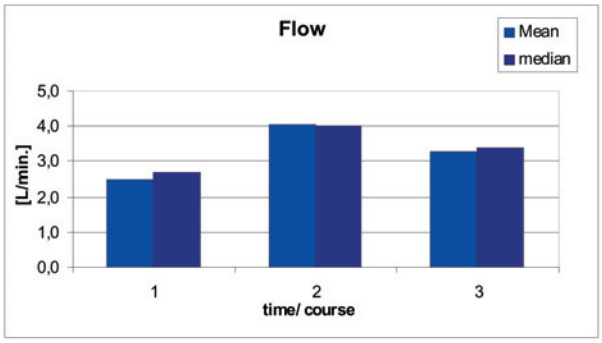

Figure 2. Flow produced by the CentriMag pump was between 2.5 and 4.0 L/min.

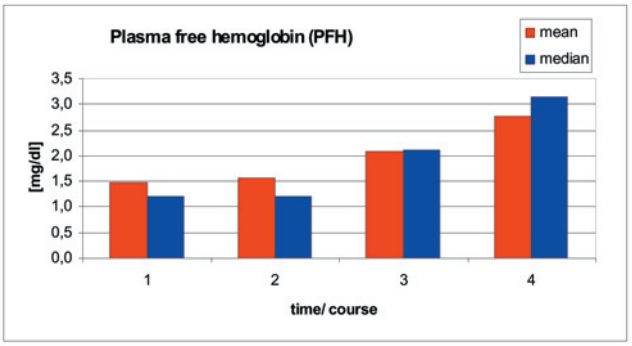

Figure 3. Course of the hemolysis parameter plasma free hemoglobin (PFH) (normal value, <5 mg/dL [normal reference value of the Clinical Laboratory, University Hospital, Zurich, Switzerland]). 1 indicates preoperative; 2, immediately postoperative (intensive care unit); 3, 2 to 3 days postoperatively; 4, day of discharge.

Study Parameters

In addition to the routine laboratory test battery, pump-induced blood trauma was evaluated specifically by measurement of plasma free hemoglobin (PFH), lactate dehydrogenase (LDH), hematocrit, total bilirubin, and platelet levels. Blood samples were taken on the day before surgery, on the first and second days in the intensive care unit (ICU) or general unit, and on the day of discharge. Pump function was assessed by registration of flow, speed, and pressure gradient. After weaning from ECC, the CPB system was gently flushed and examined for detection of macroscopic thrombus formation, especially in the pump housing.

CentriMag Blood Pump

The design of the pump is based on bearingless motor technology, which combines drive, magnetic bearing, and pump rotor functions into a single unit that has no valves, seals, mechanical bearings, or moving parts aside from the magnetically levitated rotor. The energy imparted by the motor serves to increase the velocity of blood in the direction of the axis of rotation out through the pump outlet. The system is capable of operating over a range of speeds up to 5000 rpm and generating a flow up to 9.99 L/min under normal physiologic pressure and conditions.

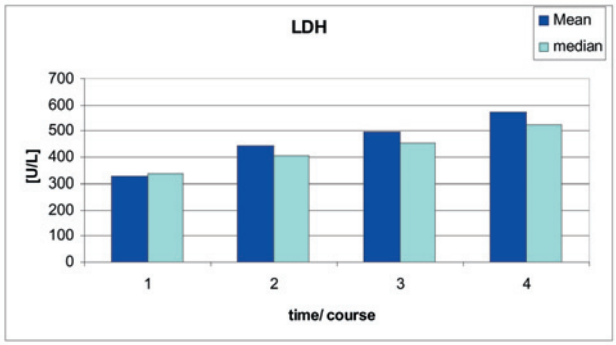

Figure 4. Hemolysis parameter lactate dehydrogenase (LDH) (normal value, 150-420 U/L [normal reference value of the Clinical Laboratory, University Hospital, Zurich, Switzerland]). 1 indicates preoperative; 2, immediately postoperative (intensive care unit); 3, 2 to 3 days postoperatively; 4, day of discharge.

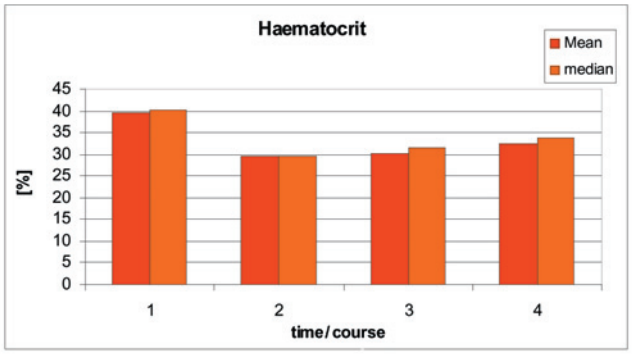

Figure 5. Hematocrit values show normal postoperative course and recovery (normal value, 40%-53% [normal reference value of the Clinical Laboratory, University Hospital, Zurich, Switzerland]). 1 indicates preoperative; 2, immediately postoperative (intensive care unit); 3, 2 to 3 days postoperatively; 4, day of discharge. 1 indicates preoperative; 2, immediately postoperative (intensive care unit); 3, 2 to 3 days postoperatively; 4, day of discharge.

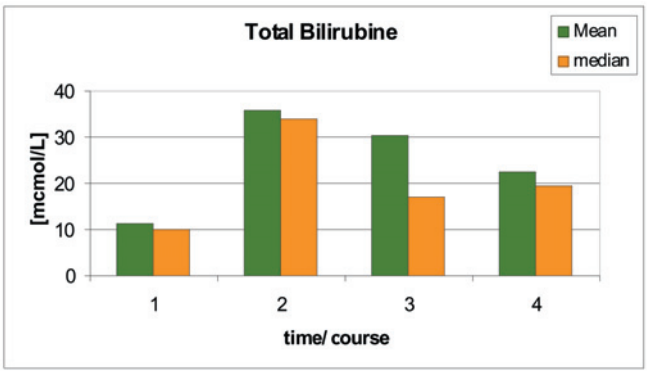

Figure 6. Total bilirubin, also a hemolysis parameter (normal value, <17 µmol/L [normal reference value of the Clinical Laboratory, University Hospital, Zurich, Switzerland]). 1 indicates preoperative; 2, immediately postoperative (intensive care unit); 3, 2 to 3 days postoperatively; 4, day of discharge.

Statistics

Mean values, standard derivation, and median, minimal, and maximal values were calculated with the Excel program (Microsoft, Redmond, WA, USA).

RESULTS

A mean of 3.6 ± 0.6 (median, 3.0; range, 2-3) coronary anastomoses per patient were performed. The left anterior descending coronary artery was revascularized in all 11 patients. Nine (81%) of the 11 patients needed triple revascularization. The mean duration of the operation was 304 ± 60 minutes (median, 285 minutes; range, 240-420 minutes). Extubation was preceded by a median intubation time of 17.35 hours (range, 11-52 hours). Ambulation was possible within an ICU duration of 2.5 ± 2 days (median, 2.5 days; range, 1-9 days). Mean hospital stay was 11 days (median, 11.5 days; range, 5-17 days). None of the patients needed a redo procedure or reexploration for bleeding.

Mean extracorporeal support time (Figure 1) was 105 ± 26.1 minutes (median, 108 minutes; range 61-135 minutes). Pump flow (Figure 2) was 3.28 ± 0.62 L/min (median, 3.4 L/min; range, 2-4 L/min) with a mean arterial perfusion gradient of 69 ± 4 mm Hg (range, 60-75 mm Hg). No pump dysfunction occurred at any time during surgery.

Hemolysis data are depicted in Figures 3 through 7. Only insignificant hemolysis was observed with mean levels of PFH of 1.48 to 2.75 µmol/L (Figure 3); LDH, 328 to 572 U/L (Figure 4); hematocrit, 30% to 39% (Figure 5); total bilirubin, 11 to 35 µmol/L (Figure 6); and platelets, 122 to 256 × 10^3/µL (Figure 7). A total of 6 ± 2 fresh frozen plasma (FFP) units, 2 ± 1 platelet concentrate units, and 3 ± 2 blood units were transfused intraoperatively and 2 ± 1 FFP units, 1 platelet concentrate unit, and 3 ± 1 blood units were transfused postoperatively.

Inspection of the 11 CentriMag blood pumps and the inlet and outlet tubes showed no internal thrombus formation on the pump housing or connectors.

DISCUSSION

The CentriMag blood pump is totally modular and independent of the motor unit. It has few parts: the rotor and an outer 2-piece shell. Consequently, the risk of thrombus formation usually associated with these components is eliminated. Under normal operating conditions, the electromotive force produced by the motor winding drives the levitated rotor. Rotation of the rotor with integral vanes creates a vortex that accelerates the blood by axial and centrifugal force. Platelet aggregation was significantly increased in roller pump compared with centrifugal pump patients, indicating higher susceptibility to postoperative thrombotic complications with the roller pump [Moen 1996]. The energy imparted by the motor serves to increase the velocity of blood along the direction of the axis of rotation out through the pump outlet. In our series, both safety and high biocom-

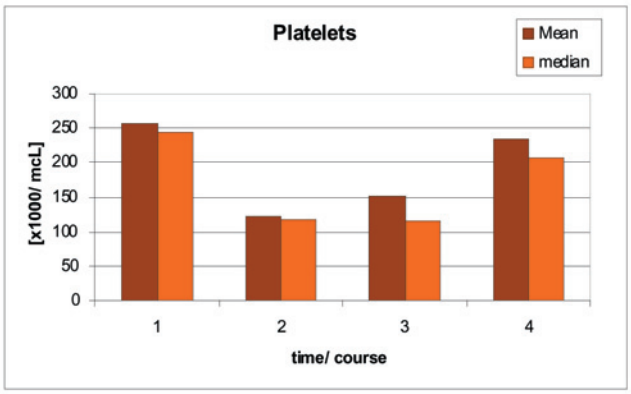

Figure 7. Course of platelet count (normal value, 143-400 × 10^3/µL [normal reference value of the Clinical Laboratory, University Hospital, Zurich, Switzerland]). 1 indicates preoperative; 2, immediately postoperative (intensive care unit); 3, 2 to 3 days postoperatively; 4, day of discharge.

patibility (low-grade hemolysis, no thrombogenicity) of the bearingless CentriMag centrifugal blood pump were well documented.

In vitro testing has been done in several studies [Naito 1996]. As of this writing a study comparing the clinical applications of different centrifugal blood pumps has not been conducted.

CONCLUSION

The results of this study of the first-time clinical application of the new bearingless CentriMag pump showed that the pump and drive unit are safe and that the pump produces only a very low level of blood trauma. Further evaluation, especially for long-term circulatory support as for extracorporeal membrane oxygenation (as in the management of acute respiratory distress syndrome or as a bridge to recovery or transplantation) is justified.

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