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PRECiSe (Priming Reduced Extracorporeal Circulation Setup): Results of a Safety Study

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ABSTRACT

Background: Different low-priming systems limited to coronary artery bypass grafting (CABG) have been introduced. We describe the priming reduced extracorporeal circulation setup (PRECiSe), a new low-priming system that supplies all of the features of cardiopulmonary bypass.

Methods: PRECiSe incorporates the DeltaStream diagonal pump, which pumps blood from the right atrium to the aorta via a membrane oxygenator and a filter. The system is placed beneath the patient's head, resulting in extremely short tubing lengths. A reservoir allows the use of suckers and vents. Autologous blood priming further reduces hemodilution.

Results: In the safety study, the system was used for extracorporeal circulation in 11 patients undergoing CABG without the occurrence of any adverse events. By using the PRECiSe system, we reduced the mean priming volume to 268.5 mL, resulting in minimal hemodilution and transfusion requirements.

Conclusion: The use of PRECiSe for extracorporeal circulation in CABG is safe and reduces priming volume as well as transfusion requirements. Further studies are necessary to investigate the clinical benefit for patients as well as the use of the system in open heart procedures.

INTRODUCTION

After the introduction of cardiopulmonary bypass (CPB) into clinical routines in the 1950s, the use of extracorporeal circulation (ECC) became the gold standard for cardiac surgery for several decades. Increasing knowledge about the negative effects of CPB and the description of the whole body inflammatory response led to the development of alternative approaches, especially for use in coronary bypass surgery. Extensive technical research, together with economic aspects and a strong demand by patients and cardiologists, led to the overwhelming application of off-pump surgery techniques, although the medium- and long-term results compared with those of the gold standard of grafting under CPB with cardioplegic arrest did not show beneficial results [Musleh 2003, Nathoe 2003]. Because of this situation and especially because of the limitation of off-pump procedures to coronary artery bypass operations, CPB is still used in the vast majority of cardiac surgery procedures.

Because the necessary priming of the extracorporeal circuit leads to substantial hemodilution in the patient, attempts have been made to reduce the system's size and thus reduce the need for transfusions in cardiac surgery. Besides intracardiac axial flow pumps for cardiac assistance during beating heart coronary artery bypass surgery, which may be beneficial in isolated subgroups, most of the so-called minimized bypass systems consist of a pump, an oxygenator, and, in most cases, an arterial filter. Some of these systems provide the possibility of cardiac arrest, and some use a vent with the blood returned to the patient via a cell-saving system.

We report the setup and the results of a safety study of the priming reduced extracorporeal circulation setup (PRECiSe) system, which provides full access to all cardiac structures with all of the features of a standard heart-lung machine but with an extremely reduced priming volume and therefore a minimal need for blood transfusions.

MATERIALS AND METHODS

The PRECiSe System

The PRECiSe system (Figure 1) is configured as a minimized ECC system for application in all fields of cardiac surgery and consists of the following existing and approved components (all CE-marked):

- Diagonal pump (DeltaStream; Medos AG, Stolberg, Germany),
- Membrane oxygenator (Hilite 7000; Medos AG),
- Arterial filter (Quart; Jostra AG, Hirrlingen, Germany).

In addition, flow sensor and continuous venous oxygen saturation measurement devices are integrated into the closed loop. Parallel to this loop, a hard-shell reservoir is connected with its inlet line to the outflow site of the diagonal pump and with its outlet line to the inlet site of the DeltaStream pump; thus, the blood volume of the patient can be easily reduced or increased via the reservoir to maintain adequate pressure management (Figure 2). Because only a small cable is necessary to control the pump, the system is placed beneath the patient's head, resulting in extremely short lengths of tubing to the venous and aortic cannulae.

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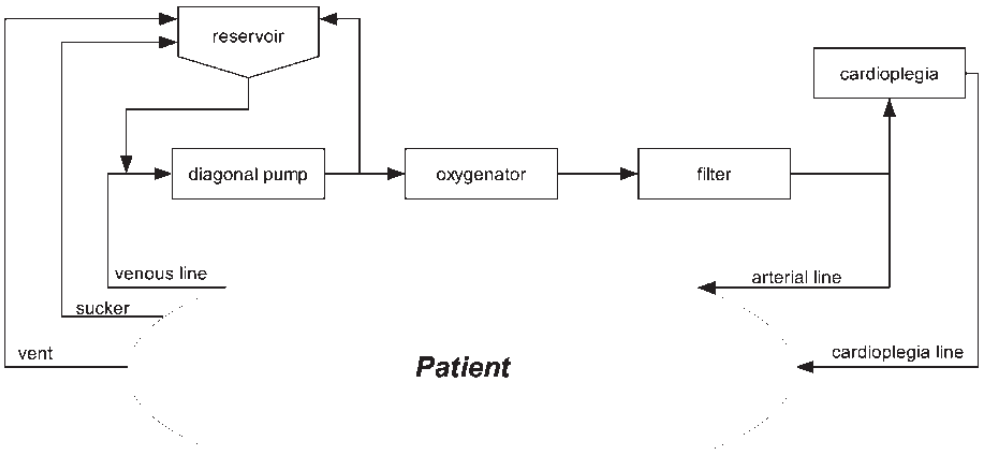

Figure 1. Schematic drawing of the priming reduced extracorporeal circulation setup (PRECiSe).

Cardioplegic arrest is performed by normothermic intermittent blood cardioplegia according to Calafiore et al [Calafiore 1995] by application to the aortic root. Additional suction lines and vents lead to the filter of the hard-shell reservoir, thus removing air and debris of the returning blood in the closed loop. The console of the DeltaStream pump and the additional pumps (cardioplegia, vent, sucker) are placed in the traditional position behind the surgeon for easy control by the perfusionist.

Priming

The priming of the PRECiSe system consists of modified crystalloid priming of 1250 mL total volume for convenient deairing of the system. Sufficient heparin (8000 IU) is added to cover the surfaces of the system components. All of the aprotinin (3 million IU total) is applied by the anesthesiologist [Royston 1987], because most of the priming will be removed from the system during autologous priming. Before connection to the patient's cannulae, approximately 500 mL of the initial priming volume is withdrawn from the hard-shell reservoir.

The activated coagulation time is held between 450 and 500 seconds during ECC [Gravlee 2000], and after the cannula is removed, full reversal with protamine is performed.

Cannulation

Routine cannulation may be performed for coronary artery bypass grafting and aortic valve replacement. In addition to the purse-string suture of the venous cannulation site at the right atrial appendage, a snare may be fixed over a cuff of atrial wall to prevent any air entrapment caused by the strong suction of the diagonal pump. This step is crucial because the venous blood is returned directly to the aorta via the oxygenator and the arterial filter. If a cardiac chamber is to be opened, bicaval cannulation with total bypass has to be performed, because the suction of the DeltaStream diagonal pump may entrap air via a patent foramen ovale. Because of the danger of injury to the right atrium and the possibility of air entrapment, we recommend not performing retrograde cardioplegia.

Autologous Blood Priming

After arterial and venous cannulation and connection of the cannulae to the tubes of the system, thorough deairing maneuvers are necessary to eliminate any air from both the arterial and the venous lines of the PRECiSe system. Before CPB is initiated, a major portion of the crystalloid priming volume can be replaced with venous blood and be pressed aside into a sterile bag, depending on the ability of the patient's hemodynamics to tolerate this maneuver.

Volume Management and Management of Blood Products

During ECC, volume management in the case of standard CPB was performed by the perfusionist by means of flow

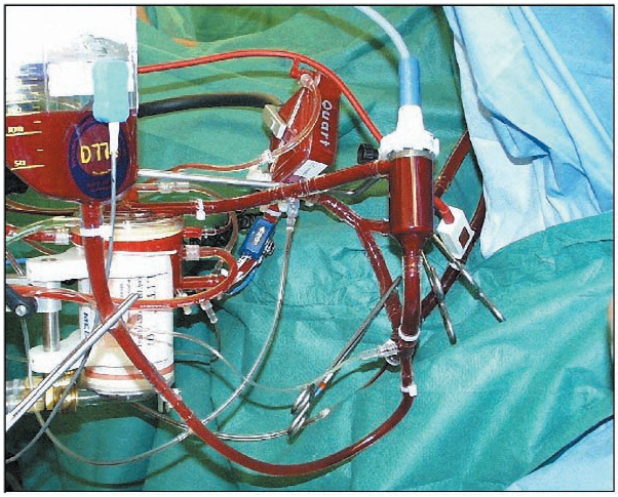

Figure 2. Pressure control by adding to or reducing the patient's circulation volume at the reservoir.

Table 1. Basic Patient Data, Extracorporeal Circulation, and Completeness of Revascularization Using PRECiSe (N = 11)*

Age, y	63.6 ± 5.0 (57-73)
Weight, kg	79.5 ± 8.8 (65-100)
Height, cm	170.0 ± 5.0 (160-177)
Operation time, min	172.7 ± 37.6 (140-240)
Extracorporeal circulation, min	61.9 ± 18.7 (36-94)
Cross-clamping time, min	37.1 ± 10.6 (21-54)
Planned bypasses, n	3.7 ± 0.9 (2-5)
Performed bypasses, n	3.3 ± 1.3 (1-5)
Ratio of performed to planned bypasses	0.88 ± 0.28 (0.33-1.25)

*Data are presented as the mean ± SD (range). PRECiSe indicates priming reduced extracorporeal circulation setup.

control and, if necessary, small amounts of vasopressors (noradrenaline). The addition of small amounts of crystalloid fluid are occasionally necessary to achieve adequate flow to prevent the inferior vena cava from collapsing around the venous return cannula and to avoid the danger of air entrapment.

Preoperative, intraoperative, and postoperative substitution of volume was performed by adding crystalloid solution or 6% hydroxyethyl starch. One unit of packed red blood cells was given if the patient's hematocrit dropped below the following levels:

- 25% after institution of anesthesia,
- 20% during ECC,
- 25% in the first 24 hours after surgery,
- 28% until patient discharge.

Before additional units of packed blood red cells were given, a new investigation of the red blood count was performed, and the fulfillment of transfusion criteria was checked.

Fluid management during the institution of anesthesia, during CPB, and during the first 2 postoperative days included monitoring of fluid balances, crystalloid and colloidal substitution, and transfusions of blood components, as well as the final priming as described above.

Study Protocol

This study was a safety and feasibility trial. Patients undergoing isolated and elective coronary artery bypass surgery and who were between 40 and 75 years of age were included in the study. The study protocol was approved by the local ethics committee. All patients gave written informed consent prior to their inclusion in the study.

Data Management

Besides the basic data of the patients (age, weight, height), procedure times (operation time, time of ECC, cross-clamping time), and planned and performed bypasses as well as their ratio as a marker of the completeness of revascularization, all data concerning fluid management during and after CPB were documented for statistical analysis. Hematocrits were measured preoperatively, after institution of anesthesia, after the institution and at the end of CPB, on patient admission to the intensive care unit, at 6 hours postoperatively, on postoperative days 1 and 2, and at discharge or 1 week postoperatively.

Statistical Analysis

All data are presented as the mean ± standard deviation.

RESULTS

Patients

Eleven patients undergoing coronary artery bypass grafting with the PRECiSe system were included in the study (Table 1). One to 5 distal anastomoses were performed in the patients with the left mammary artery anastomosed to the left anterior descending artery in all patients and with saphenous vein grafts anastomosed to the other coronary arteries. Revascularization was complete in 8 patients, and 3 patients with severe diffuse calcification of the coronary arteries received fewer grafts than planned.

An uneventful course of ECC was possible in all patients. The mean flow rate of the pump was 2.7 L/min. Because the flow of the pump is controlled by a limited negative pressure on the venous line, no significant flow drops due to the aspiration of the venous cannula to the atrial wall were observed. No air bubbles were detected by the bubble sensor, and no significant air was observed in the lines and in the pump by the perfusionist and the cardiac surgeon, respectively. No myocardial infarctions were observed. There was no need for inotropic support or intra-aortic balloon pumps. No postoperative reexplorations because of bleeding were necessary. There were no deaths and no system-related complications.

Final Priming Volume

Mean final priming volume after autologous blood priming during institution of CPB was 268.5 ± 218.7 mL.

Perioperative Transfusions

No transfusions of fresh frozen plasma, pooled platelets, or coagulation precipitates were necessary. Eight of 11 patients (72.3%) received no blood transfusions during their hospital stays. One patient received 1 packed unit of red blood cells during ECC and another 3 units postoperatively; one other patient received 1 unit postoperatively, and another received 2 units postoperatively. These results yielded a low mean transfusion rate of 0.09 ± 0.30 units intraoperatively, 0.55 ± 1.04 units postoperatively, and 0.64 ± 1.29 units total (Figure 3).

Perioperative Course of the Hematocrit

The hematocrit after institution of anesthesia showed a drop of 14% compared with the preoperative hematocrit and dropped an additional 11.1% after the beginning of ECC (Figure 4). The mean hematocrit after the institution of CPB was 29.7% ± 3.2%, with an increase to 30.8% ± 3.7% at the end of ECC. Mean urine output during CPB was 311.8 ± 271.2 mL, and there was no need for hemofiltration for any patient. The postoperative course of the hematocrit showed a slow increase up to 33.3% ± 4.9% at the time of patient discharge.

DISCUSSION

After the development and introduction of ECC systems nearly 50 years ago, cardiac surgery became routine [Kirklin

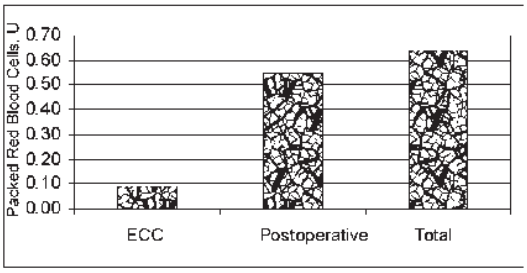

Figure 3. Intraoperative and postoperative need for transfusions of units of packed red blood cells. ECC indicates extracorporeal circulation.

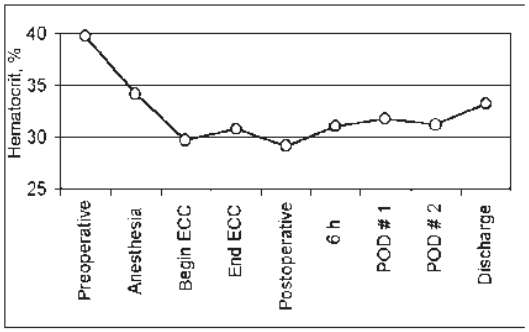

Figure 4. Course of mean hematocrit perioperatively. ECC indicates extracorporeal circulation; POD, postoperative day.

1993], and a variety of operations on acquired and congenital heart diseases became feasible. Although numerous technical modifications have been made during the past 5 decades, there are still negative effects of ECC that lead to a systemic inflammatory response [Kirklin 1983] with impacts on different organ systems. The additional transfusion of blood products is a frequent problem in cardiac surgery with special regard to patients who refuse any transfusions of blood or blood products and components [Beholz 2001].

To overcome these disadvantages at least in part and to reduce costs, especially in developing countries, off-pump coronary artery bypass procedures were developed in the late 1980s [Benetti 1991]. Besides the fact that these technologies were brought to clinical practice without valid data concerning the quality of the anastomoses and long-term results, these techniques remain difficult procedures for experienced surgeons [Beholz 2002] and may result in incomplete revascularization of the posterior wall [Amano 2001] because of hemodynamic changes that occur during exposition of marginal branches [Jurmann 1998, Mathison 2000]. In special subsets of patients, for example, those with temporary assisted circulation with intracardial axial pumps, [Meyns 2002] may help to overcome these hemodynamic changes, but because of the complexity of these systems and their high costs, they have not yet found wide acceptance in the clinical setting.

Recently, minimized ECC setups have been introduced; these setups mostly consist of a closed loop formed by tubes, a centrifugal pump, a membrane oxygenator, and, in most of the systems, an arterial filter. Initially designed for assisted circulation during beating heart surgery, these systems were modified later for cardioplegic arrest. Because there is only limited decompression of the heart during cross-clamping and the use of suckers or vents is possible only with a cell-saving device that enables the removal of plasma, there is still some concern about the benefits of these systems. Additionally, these systems are limited to coronary artery bypass procedures, as are off-pump procedures or procedures with assisted circulation.

Therefore, a concept of optimized ECC for universal application in coronary artery bypass surgery as well as in open heart surgery seems to be one possible solution to overcome the negative side effects of routine CBP (Table 2). A system that meets these criteria should include blood pumps with optimal biocompatibility, especially low thrombogenicity, reduced hemolysis, and reduced activation of leukocytes as well as mediators. The size of components should be minimized to reduce the priming volume and the hemodilution, thus leading to fewer blood transfusions. The system should provide access to all coronary regions as well as to intracardiac structures. Complete temperature management should be possible to provide for different forms of normothermia or hypothermia, depending on the patient's need. The use of modern concepts of myocardial protection such as blood cardioplegia must be easy to integrate. For open heart surgery, safe deairing procedures must be possible. Finally, the system should support modern concepts of fast-track anesthesia. Traditional ECC systems can meet these criteria only in part.

The PRECiSe system is designed to meet most of these demands on an optimized circulation setup. The DeltaStream was chosen as a mixed-flow pump [Goebel 2002] that combines the benefits of centrifugal and axial pumps. It has an extremely low priming volume of 30 mL and is flexible in its use, because the drive unit is a sterile part of the pump. It even can be mounted into the operation field because it needs only a small cable to control its flow. Flow can be maintained in a range of 0 to 8 L/min with a rotational speed of 100 to 10,000 rpm. Animal experiments have shown excellent hemodynamic properties with low hemolysis and a virtual absence of thrombogenicity [Goebel 2001], mainly caused by the washout effects between the impeller and the drive unit [Goebel 2002] due to the unique design of the impeller.

Our safety study demonstrates a safe perfusion in coronary bypass surgery without any side effects. Almost complete revascularization is achieved with acceptable times of operation, ECC, and cross-clamping. There was only a little hemodilution (11.1%) at the beginning of ECC, with only 1 packed unit of red blood cells needed in 1 patient during

Table 2. Desirable Features of Optimized Extracorporeal Circulation Systems

Increased biocompatibility of blood pumps
Reduced hemodilution by reduced priming volume
Full access to all cardiac structures
Temperature management
Physiologic cardiac arrest
Deairing procedures
Support of fast-track management of anesthesia

CPB. Most patients (72.3%) received no blood transfusions during their hospital stay.

In conclusion, the PRECiSe offers an alternative to routine CPB in coronary artery surgery with significant reductions in hemodilution and the need for blood transfusions. Total bypass will become possible with only a little modification of the venous cannulation to make the system applicable for open heart procedures. Further randomized studies will investigate the reduction in transfusion needs in coronary artery bypass grafting and valve surgery with the PRECiSe system compared with standard CPB.

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