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Right Heart Support During Off-Pump Coronary Artery Bypass Surgery—A Multi-Center Study

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Ram Sharony, MD,[1] Rudiger Autschbach, MD, PhD,[2] Eyal Porat, MD,[1] Martin Struber, MD,[3] Andreas Boening, MD,[4] Ralf Krakor, MD,[2] Axel Haverich, MD,[3] Jochen T Cremer, MD,[4] Nahum Nesher, MD,[1] Friedrich W. Mohr, MD, PhD[2] Gideon Uretzky, MD[1]

[1]Tel-Aviv Sourasky Medical Center, Israel
[2]Heart Center, Leipzig, Germany
[3]Hannover Medical School, Hannover, Germany
[4]University Hospital, Kiel, Germany

ABSTRACT

Background: Off-pump coronary artery bypass (OPCAB) surgery for posterior and inferior wall vessels requires heart displacement, which leads to hemodynamic instability. Based on results indicating that displacement primarily alters right heart function, this study evaluates the safety and efficacy of right heart support during OPCAB surgery to the posterior and inferior wall vessels.

Methods: In a multi-center, prospective study, 25 patients underwent multi-vessel OPCAB surgery. Right heart support was carried out using the Enabler™ circulatory support system (Hemodynamics Systems Ltd., Upper Yokneam, Israel). Hemodynamic measurements were recorded at baseline and during heart displacement with and without right heart support.

Results: No mortality was recorded. Mean graft number was 2.25 ± 0.36. Inability to position the Enabler™ system occurred in five cases. Once the Enabler™ was properly positioned, there was no case of conversion to cardiopulmonary bypass (CPB) due to failure of the Enabler™ to provide adequate support. Cardiac index (CI) declined from 2.4 ± 0.5 L/min./m^2 to 1.6 ± 0.6 L/min./m^2 ($p < 0.05$) during heart displacement and increased to 2.3 ± 0.6 L/min./m^2 ($p < 0.05$) following Enabler™ activation. Mean arterial blood pressure (MAP) dropped from 82 ± 18.6 mmHg to 53.1 ± 16.6 mmHg ($p < 0.001$) during heart displacement and was restored to 69.8 ± 19.4 mmHg ($p < 0.001$) with Enabler™ support.

Conclusions: Heart displacement caused a significant hemodynamic deterioration that was stabilized with right heart support. The Enabler™ system is safe and effective in facilitating multi-vessel OPCAB surgery. However, there are still serious technical problems during cannula insertion that cause an unacceptable failure rate of device utilization.

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Address correspondence and reprint requests to: Ram Sharony, MD, Department of Cardiothoracic Surgery, New York University, School Of Medicine, 28th Street & First Ave. New Bellevue, 15W16, New York, NY, Email: sharony@med.nyu.edu

INTRODUCTION

Off-pump coronary bypass (OPCAB) surgery was first introduced by Kolessov in 1967 [Kolessov 1967]. Recent improvements in surgical equipment and techniques [Westaby 1996] and the awareness of the adverse effect of cardiopulmonary bypass (CPB) [Kirklin 1983] have led an increasing number of surgeons to perform coronary artery bypass grafting (CABG) on the beating heart. In several centers, up to 94% of all surgical coronary revascularizations are performed on the beating heart [Cartier 2000].

Although the advantages of OPCAB are still a subject of debate, several reports indicate that avoidance of CPB during coronary revascularization has the advantage of reducing the following adverse effects: postoperative blood loss, need for transfusion, creatine phosphokinase (CPK) leakage [Arom 2000], incidence of neurocognitive disorders, length of hospital stay, and overall costs [Puskas 2000]. In other aspects, such as incidence of post-operative atrial fibrillation, major stroke, and mortality rate, OPCAB is at least comparable to revascularization with CPB. However, heart displacement for exposure of posterior and inferior vessels causes marked hemodynamic instability, manifested as reduction in both stroke volume and systemic arterial blood pressure [Grundeman 1997]. Previous studies have demonstrated that the major cause of these hemodynamic changes is impaired diastolic filling of the right heart during tilting, secondary to its distortion [Geskes 1999, Mathison 2000b]. Moreover, maneuvers that increased pre-load, such as the head-down (Trendelenburg) position and fluid administration, were found to improve hemodynamic parameters [Grundeman 1999].

Based on this evidence, we hypothesized that a right heart support device may stabilize hemodynamic parameters during OPCAB surgery. After demonstrating the effectiveness of a similar catheter pump in a heart failure model [Sharony 1999] and the beneficial effects of right heart support during posterior and inferior vessel exposure in an animal study [Porat 2000], we applied a support system in patients undergoing OPCAB surgery. The purpose of this study was to evaluate the safety and efficacy of right heart support with the Enabler™ circulatory support system during OPCAB surgery to posterior and inferior wall vessels.

Table 1. Patient Demographics

Characteristic	Value N(%)
Female/male (No.)	7/18
Mean Age (years) ± SD	67.3 ± 5.8
Diabetes (%)	11 (55)
Hypertension (%)	11 (55)
Mean Ejection Fraction ± SD	60.9 ± 8.1

MATERIALS AND METHODS

Twenty-five patients underwent elective OPCAB surgery in a multi-center prospective study. All patients required revascularization to posterior and/or inferior wall vessels. All had preserved left ventricular function and no evidence of exclusion criteria such as previous cardiac operation, presence of renal or pulmonary disease, documented arrhythmia, coagulopathy, or significant valvular disease. Patient demographic data is shown in Table 1 (◎). An informed consent was obtained from each patient, and the institutional review committee of each center approved the study.

Right heart support was established using the Enabler™ circulatory support system (Hemodynamics Systems Ltd., Upper Yokneam, Israel), a catheter pump designed to expel blood from the right atrium into the pulmonary artery in a pulsatile flow pattern.

The Enabler™ consists of an electrohydraulically driven piston [Rottenberg 1995] that, synchronized by ECG or arterial pressure, forces fluid into and out of a disposable head. The fluid displaces a polyurethane membrane, permitting pulsatile blood flow through a transvenous catheter. This catheter provides blood flow through a single lumen cannula by means of miniature valves located at inlet holes in the right atrium and at an ejection outlet in its tip, which is positioned in the main pulmonary artery (PA) (Figure 1, ◎).

After a median sternotomy was performed and the internal mammary artery (IMA) was harvested, heparin at a dose of 300 IU/kg was administered. Cardiac output monitoring was recorded using the Pico Flow Measurement System (Pulsion, Munich, Germany). Baseline hemodynamic measurements were recorded and the Enabler™ catheter was introduced through the appendage of the right atrium in stages: first a PA catheter was positioned in the main pulmonary artery, then the Enabler™ catheter was advanced over it, and finally the PA catheter was pulled back.

Arterial pressures, the system's flow rate, and continuous cardiac output were recorded before heart displacement (baseline), after the heart was tilted without activating the Enabler™, and following its activation at maximal support.

Statistical Analysis

Data is presented as mean ± standard deviation (absolute values) or as mean ± standard error of the mean (relative values). A value of $p < 0.05$ was considered significant. The hemodynamic changes were analyzed using a paired Student's t-test and sign test. All tests applied were two-tailed. The data was analyzed using SAS software (SAS Institute, Cary, North Carolina).

Table 2. Hemodynamic Changes During Heart Displacement and Enabler™ Activation

Variable	Baseline	Displacement w/o Pump*	Displacement with Pump#
CI	2.4 ± 0.5	1.6 ± 0.6[a]	2.3 ± 0.6[a]
Systolic ABP (mmHg)	114.7 ± 24.8	76.4 ± 18.4[a]	97.1 ± 17.4[a]
Diastolic ABP (mmHg)	65.7 ± 16.6	46.1 ± 10.4[a]	61.0 ± 10.9[a]
Mean ABP (mmHg)	82 ± 18.6	53.1 ± 16.6[a]	69.8 ± 19.4[a]

CI = cardiac index; ABP = arterial blood pressure. All values are presented as mean ± standard deviation. (*) p value is calculated for differences from baseline. (#) p value is calculated for difference from displacement w/o pump. [a]p <0.001.

RESULTS

Anastomoses were performed to the left anterior descending coronary artery (LAD) (n=19), the obtuse marginal branch (OM) (n=13), and the right coronary artery branch (RCA) (n=15), resulting in an average of 2.35 anastomoses per patient. Mean time of artery occlusion for anastomosis was 10.8 ± 5.5 min. Mean operation time was 2 hours, 57 min. ± 32 min.

Mean Enabler™ flow was 2.0 ± 0.3 L/min. Failure to properly position the Enabler™ occurred in five cases. Three of the positioning failures were observed during the insertion of the PA catheter and sliding of the cannula over it. In the other two cases, significant ventricular arrhythmia was recorded. Conversion to CABG with CPB was performed in four of these cases, and the remaining patient underwent OPCAB without the support system. Once the Enabler™ was properly positioned, there was no case of conversion to CPB due to failure of the Enabler™ to provide adequate support. In one case, a partial malfunction of the inflow valves in the catheter was noted. Hemodynamic parameters at baseline, during heart displacement without Enabler™ activation, and following its activation are summarized in Table 2 (◎). During the post-operative course, the peak level of plasma-free Hb was 19.9 mg/dL; four hours after return to the ICU, values had returned to baseline level. One patient had a myocardial infarction documented by elevated cardiac enzymes and new Q wave. Atrial fibrillation was recorded in four patients. Cerebrovascular accident, transient ischemic attack, and postoperative renal failure were not observed, and there was no mortality in the study group.

Hemodynamic Data

The hemodynamic data are summarized in Table 2 (◎). Cardiac index (CI), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) declined significantly during heart displacement. The Enabler™ stabilized both the systemic pressures and the cardiac index. Further analysis of the posterior and inferior vessel subgroups revealed that heart displacement caused similar CI and MAP deterioration in both: CI dropped to

1.72 ± 0.7 L/min. and 1.59 ± 0.58L/min., respectively (ns); and MAP declined to 47.8 ± 21.6mmHg and 53.3 ± 13mmHg, respectively (ns). In addition, the contribution of the support device was significant in both groups but without any significant differences between the groups (CI = 2.2 ± 0.7 and 2.36 ± 0.6, respectively (ns)).

DISCUSSION

Background

This study confirms our previous observation [Porat 2000] about the effectiveness of right heart support in maintaining a stable hemodynamic condition during heart displacement. Beating heart surgery has gained popularity in recent years, and many centers report an increasing number of patients undergoing OPCAB surgery. However, contradictory findings for beating heart surgery have been reported regarding cardiac output, perioperative myocardial infarction (MI), postoperative renal failure, intraaortic balloon pump (IABP) and inotropic agent requirements [Arom 2000, Cartier 2000b]. While OPCAB seems less deleterious to renal function than CPB-CABG [Ascione 1999], the precise advantage of OPCAB in a subgroup of patients with preoperative renal failure has not been clearly documented [Cartier 2000a]. The inability to demonstrate a prominent reduction in the morbidity associated with multi-vessel OPCAB relative to CPB-CABG has been described [Cartier 2000b]. This may be attributed, in part, to hemodynamic instability during heart displacement despite stabilizing attempts such as hemodynamic control by fluid administration, use of the Trendelenburg position, and vasoactive medications. Moreover, while these therapeutic modalities generally restore blood pressure, the CI, which is rarely recorded continuously, may remain low, an effect that can be harmful to the vital organs and could lead to disappointing OPCAB results [Kshettry 2000].

Additionally, certain comparative studies report a reduced number of grafts per patient for OPCAB as compared to CABG performed with CPB [Hart 2000], usually due to the difficulty of exposing the posterior vessels. The tendency to occasionally abandon grafting of the circumflex and PDA system during OPCAB surgery and to perform less than complete revascularization warrants concern. The importance of complete revascularization of the circumflex region for patient survival was recently emphasized [Tasdemir 1998, Scott 2000]. Thus, assuring hemodynamic control that would enable complete revascularization during OPCAB provides the impetus for pursuing assisted beating heart surgery.

Performance of the Enabler™

The maximal flow rate of the catheter pump, approximately 2.5 L/min., proved to be effective for maintaining adequate blood pressure and CI. Although higher flow may increase cardiac index and blood pressure, it may also result in excessive filling of the left ventricle [Mathison 2000a] and subsequent difficulties in exposing the posterior wall.

Levels of plasma-free Hb were lower than those reported in previous studies during roller or pulsatile CPB [Rottenberg 1995]. These findings establish the safety profile of the device.

Several problems of catheter insertion and positioning were observed that resulted in failure to establish heart support for 20 percent of the patients. The method used for this study, which required PA catheter insertion, positioning, and subsequent sliding of the device's catheter over it was often a time-consuming procedure that several times caused ventricular arrhythmia. A second-generation catheter, which was introduced into the market after the conclusion of this study, is inserted directly over a flexible stylet, providing a more effective means of placing the catheter.

Cannula insertion for the device required heparin administration at a dose of 300 IU/kg (activated clotting time (ACT) above 480 sec.), a much larger dose, with subsequent protamine, than is needed in regular OPCAB surgery. Although the amount of postoperative bleeding in our study was comparable to a previous report in OPCAB patients, the higher dose of heparin and later protamine-heparin complex may cause a more prominent inflammatory response than is observed in regular OPCAB.

Purpose and Limitations of Study

The aim of this study was to evaluate the safety and efficacy of the device. We did not compare different types of hemodynamic control during OPCAB. Therefore, no conclusion can be made as to whether assisted-heart OPCAB surgery is superior to other types of hemodynamic stabilization during OPCAB. Moreover, use of recently reported techniques such as pleural herniation, applying of a new exposure device, hemodynamic control by fluid replacement, and moderate pharmacological intervention has permitted routine bypassing of the OM and posterior descending (PDA) coronary arteries. This progression may limit the need for support devices only to high-risk patients for multi-vessel OPCAB surgery.

There are several limitations to this study. The small number of patients did not allow for further comprehensive analysis for identification of the specific patient subgroups most likely to benefit from a support device (e.g., posterior vs. inferior vessels, or hypertrophic or ischemic heart). Furthermore, limiting the study to patients with low preoperative risk made it impossible to determine the effectiveness of the support system in complicated cases. Additionally, the issue of cost effectiveness was not a focus of the study. Because the cannula was not introduced into the market at the time of the study, no cost accounting was available. It should also be observed that, in order to properly evaluate OPCAB surgery, several parameters of the postoperative course must be taken into consideration, such as the need for re-intervention and re-admission, but in our study no late follow-up was performed.

CONCLUSIONS

We are able to conclude that, despite the unacceptably high rate of support failure attributed to problems in the method of device insertion, the Enabler™ is safe and effective in facilitating multi-vessel OPCAB surgery to posterior and inferior vessels. This approach to supporting the beating heart can be used to maintain hemodynamic stability during

heart displacement in OPCAB surgery. Further comparative studies are necessary to identify the specific patient subgroups that would benefit most from using this method of assisted beating heart surgery instead of other contemporary methods of hemodynamic stabilization.

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REVIEW AND COMMENTARY

1. Editorial Board Member AX44 writes:

I wonder if this approach could be used as a boost from the RA into the RV and let the RV work. My feeling is that the problem is reduced filling of the RA because of positioning. Maybe a catheter in the SVC that moves blood to the RV would do the trick. I have been tempted to try a large cannula across the RA/IVC junction as an internal "stent" to prevent kinking at that level.

Authors' Response by Ram Sharony, MD:

Although the cannula pump reduces the filling of the right ventricle (RV), it also serves as an internal RV bypass and increases cardiac output. Both the right atrium (RA) and RV have an important role in the deterioration of cardiac output during heart displacement for grafting of the posterior vessels. Based on our experience and echocardiography studies, the RV (and RV outflow tract), as a low-pressure chamber, may be distorted during heart displacement. Therefore, the concept of right heart support must include the RV, and the outflow tip of the cannula pump system should be positioned distal to the right ventricular outflow tract, i.e., in the main pulmonary artery.

2. Editorial Board Member DB515 writes:

As the authors have explained, OPCAB methods have improved significantly and exposure of posterior and lateral vessels can not be routinely exposed in the vast majority of cases with Lima-stitch, or any of the new suction devices. This is probably more attractive than to use a modified pump. In our experience, we find that ischemia rather than right ventricular filling problems is the most common problem and in such cases the operation may be done with standard CPB on a beating heart. Whether this causes more problems than right heart assist should possibly be discussed. Maybe certain patients with calcified aorta may be candidates for the RVAD system.

Authors' Response by Ram Sharony, MD:

OPCAB methods have significantly improved in recent years and can be routinely applied in many cases. Although primary ischemia may cause hemodynamic instability, the reduction in blood pressure following heart displacement might compromise coronary perfusion. Standard CPB on a beating heart is a common alternative, but the right heart assist system increases blood pressure and cardiac index while it has the advantages of avoiding manipulation of the aorta. In addition, right heart bypass does not require an oxygenator that may be a source of morbidity. Based on our data, right heart support is another feasible tool in the surgeon's armamentarium to facilitate OPCAB surgery.