Off-Pump Coronary Artery Bypass Graft Surgery With a Pulsatile Catheter Pump for Left Ventricular Dysfunction

Massimo A. Mariani, Jan C. Diephuis, Martin J.H. Kuipers, Monica Gianoli and Jan G. Grandjean

Ann Thorac Surg 2007;84:690-692
DOI: 10.1016/j.athoracsur.2006.12.016

Off-Pump Coronary Artery Bypass Graft Surgery With a Pulsatile Catheter Pump for Left Ventricular Dysfunction

Massimo A. Mariani, MD, PhD, Jan C. Diephuis, MD, Martin J. H. Kuipers, Bsc, Monica Gianoli, MD, and Jan G. Grandjean, MD, PhD

Cardiothoracic Surgery, Thoraxcentrum Twente, Enschede, the Netherlands

We describe the use of a novel device, the pulsatile catheter pump, in patients with left ventricular dysfunction undergoing off-pump coronary surgery. During a 1-year period, 14 patients (mean ejection fraction 28% ± 8%) underwent off-pump coronary surgery using the pulsatile catheter pump. We recorded neither mortality nor major adverse cardiovascular and cerebral events. Mean support time was 55 ± 13 minutes. The average flow generated by the pulsatile catheter pump, as calculated per patient, was 2.4 ± 0.2 L/min (range, 2.2 to 2.8 L/min). Our results show that the pulsatile catheter pump is clinically safe and provides adequate mechanical circulatory support in patients with impaired left ventricular function undergoing off-pump coronary artery surgery.

(Ann Thorac Surg 2007;84:690–2)

The benefits of off-pump coronary surgery in patients with left ventricular dysfunction have been established [1, 2]. However, performing off-pump surgery on dilated hearts with a poor function can be technically demanding and lead to hemodynamic deterioration. In fact, when the heart is lifted, the hemodynamic performance may be compromised, resulting in decreased cardiac output. In this article, we report the use of a novel device, the pulsatile catheter pump (PulseCath; IntraVasc, Groningen, the Netherlands), in patients undergoing off-pump coronary surgery with left ventricular dysfunction.

The PulseCath is a disposable heart assist device with a counterpulsation effect. With a pump flow of 2 to 3 L per minute. The pulsatile pumping action is similar to the intra-aortic balloon pump (IABP), with aspiration during systole and ejection during diastole, close to the inflow openings of the coronary arteries. The main difference is that the PulseCath directly unloads the heart by active aspiration from the left ventricle, thus decreasing the oxygen demand. The PulseCath has been previously tested only in animal models as a temporary assist device [3, 4]. We report a clinical study using the Pulse-Cath for patients with left ventricular dysfunction undergoing off-pump coronary artery surgery.

From January 2005 to March 2006, 14 patients undergoing coronary artery bypass grafting surgery were supported by the PulseCath during off-pump coronary artery surgery. Patients with a predicted mortality of 6% or more according to the logarithmic EuroSCORE (European System for Cardiac Operative Risk Evaluation) and left ventricular dysfunction (below 40%) were included. The exclusion criteria were aortic wall disease, valve disease, previous cardiac surgery, and left ventricular thrombus. The 14 patients, 13 male and 1 female, had a mean age of 68.8 ± 7.0 years, mean length of 173 cm ± 10 cm, and mean weight of 79.9 kg ± 13.7 kg. The mean preoperative left ventricular ejection fraction was 28% ± 8%. The mean predicted mortality was 8.9% (EuroSCORE).

The PulseCath consists of a thin-walled catheter with a diameter of 21F, connected to a single port membrane pump [3–7]. The position of the PulseCath in the heart is schematically outlined in Figure 1. The tip of the catheter is positioned in the left ventricular cavity, the two-way valve is positioned in the aorta, and the membrane pump is located outside the body. The patented two-way valve is designed to guide the blood in the correct direction. The valve consists of a tubular housing and one moving part (leaflet) that pivots around an axis. The membrane pump has a blood chamber and an air chamber, divided by a flexible membrane. The membrane pump is activated by a standard IABP driver. During pump aspiration, the blood flows from the left ventricle to the membrane pump, and during pump ejection, the PulseCath valve guides the blood into the aorta, preventing backflow in the left ventricle.

Technique

Patients were prepared for beating-heart surgery as previously described [8]. For measuring blood flow, a Swan-Ganz catheter was inserted in the pulmonary artery. Activated clotting time was kept above 300 s [8], which is above the recommendation during use of the PulseCath (>200 s). All patients were operated on through a full sternotomy.

Accepted for publication Dec 11, 2006.

Address correspondence to Dr Mariani, Thoraxcentrum Twente, Haaksbergerstraat 55, PO Box 50 000, Enschede, 7500 KA, the Netherlands; e-mail: m.mariani@ziekenhuis-mst.nl.

Published by Elsevier Inc

0003-4975/07/$32.00
doi:10.1016/j.athoracsur.2006.12.016

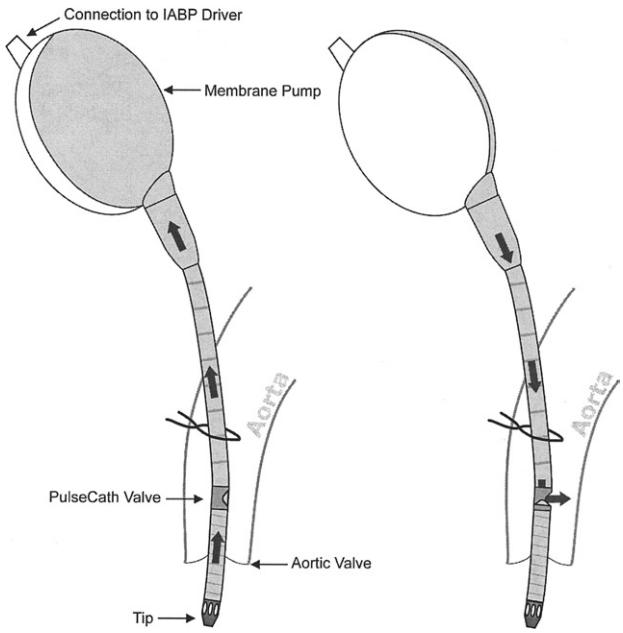

Fig 1. Position and functioning of the pulsatile catheter. The tip of the catheter is located in the left ventricle and the valve of the catheter in the aorta. (Left) During systole, blood is aspired from the left ventricle into the membrane pump (thick arrows); (right) during diastole, blood is ejected through the catheter valve into the aorta (thick arrows). (IABP = intra-aortic balloon pump.)

After exposure of the heart, a double pursestring suture was placed on the aorta, approximately 6 cm above the aortic valve. A guidewire was inserted in the aorta toward the aortic valve. An angled pigtail catheter was inserted over the guidewire, through the aortic valve, into the left ventricle. The PulseCath was then guided over the pigtail catheter, until the distal tip was in the left ventricle. The correct position of the catheter (tip in the ventricle and valve in the aorta) was determined using transesophageal echocardiography. After correct position was verified, the insertion set was removed, and a tube clamp was placed on the connector part on the proximal side of the catheter.

In the mean time, the membrane pump was filled with heparinized saline. The membrane pump was then connected to the connector of the catheter, using standard tubing methods. The catheter was fixed to the aortic wall with the pursestring sutures. One side of the drive line extension was connected to the air line of the membrane pump, the opposite end to a CS100 IABP driver (Datascope, New York, NY).

Electrocardiographic triggering and semiautomatic mode were applied in all patients. The timing of the IABP driver was the same as for the IABP. Correct timing was determined by observing the shape of the arterial pressure curvature. Inflation was set as soon as the slope of the arterial pressure curve was decreasing, deflation was set before the systole of the heart.

The flow generated by the PulseCath was measured using a Transonic HT110 flowmeter (Transonic Systems, Ithaca, New York). The sensor was placed around the connector at the proximal side of the catheter. Because the aspired and ejected blood flows through the same catheter, the determined average flow is zero. Therefore, the measured flow pattern was recalculated by a computer program, using the "pattern" output of the flowmeter.

After the anastomoses were completed, the IABP driver was switched off. The catheter was pulled backward, and the pursestring sutures were closed.

Comment

The number of bypass grafts was 3.8 ± 1.0. Mean support time was 55 ± 13 minutes. The average flow per patient generated by the PulseCath was 2.4 ± 0.2 L/min (range, 2.2 to 2.8 L/min). Introduction and positioning, fixation, functioning, and removal of the device was performed without any injury of valve or aortic structures. All patients were successfully weaned from the device. Inspection of all devices revealed no thrombus formation or any sign of damage. No specific blood cell trauma was observed. During normal functioning of the PulseCath, plasma free hemoglobin increased during operation to 17.3 ± 6.2 μmol/L (10.1 to 28.0 μmol/L) at end of weaning, and to 22.5 ± 20.0 μmol/L (10.0 to 70.8 μmol/L) at end of operation (Fig 2). In 1 patient, the valve of the PulseCath vibrated when the heart was lifted during anastomosis. In this patient, an increased level of free hemoglobin was found, which returned to normal level within 1 day. There were neither deaths nor major adverse cardiovascular and cerebral events.

Off-pump coronary surgery has proven to be effective in improving surgical results for patients with left ventricular dysfunction [1]. Our results show that the PulseCath is clinically safe and provides adequate mechanical circulatory support in patients with left ventricular dysfunction undergoing off-pump coronary artery surgery. The PulseCath is a useful tool for facilitating off-pump coronary revascularization in these patients. In addition, the PulseCath has been previously tested as a midterm left ventricular assist device in animal studies [3–4].

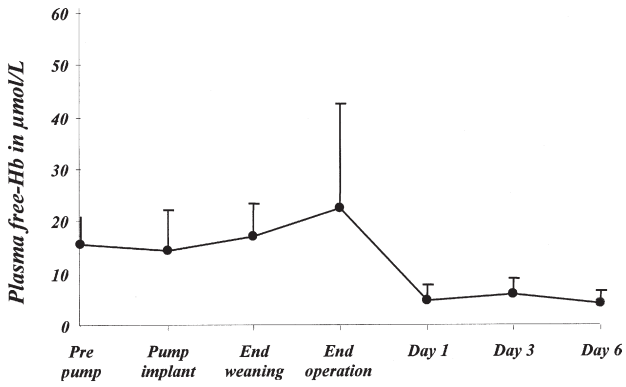

Fig 2. Plasma free hemoglobin (Hb [mean, SD]) in patients undergoing coronary artery bypass graft surgery on the beating heart with support of the pulsatile catheter.

FEATURE ARTICLES

Further studies are needed to confirm the efficacy of the PulseCath as a midterm left ventricular assist device in the clinical setting.

References

1. Puskas J, Cheng D, Knight J, et al. Off-pump versus conventional coronary artery bypass grafting: a meta-analysis and consensus statement from the 2004 IMICS consensus conference. Innovations 2005;1:3–27.
2. Dewey TM, Herbert MA, Prince SL, et al. Avoidance of cardiopulmonary bypass improves early survival in multivessel coronary artery bypass patients with poor ventricular function. Heart Surg Forum 2004;7:45–50.
3. Mihaylov D, Verkerke GJ, Blanksma PK, Elstrodt J, de Jong ED, Rakhorst G. Evaluation of the optimal driving mode during left ventricular assist with a pulsatile catheter pump in calves. Artif Organs 1999;23:1117–22.
4. Mihaylov D, Rakhorst G, van der Plaats A, et al. In vivo and in vitro experience with the PUCA-II, a single valved pulsatile catheter pump. Int J Artif Organs 2000;23:697–702.
5. Verkerke B, de Muinck ED, Rakhorst G, Blanksma PK. The PUCA-pump, a left ventricular assist device. Artif Organs 1993;17:365–8.
6. Verkerke GJ, Mihaylov D, Geertsema AAJ, Rakhorst G. Numerical simulation of the pulsating catheter pump: a left ventricular assist device. Artif Organs 1999;23:924–31.
7. Verkerke GJ, Geertsema AA, Mihaylov D, Blanksma PK, Rakhorst G. Numerical simulation of a left ventricular assist device on the cardiovascular system. Int J Artif Organs 2000; 23:765–73.
8. Mariani MA, D'Alfonso A, Grandjean JG. Total arterial off-pump coronary surgery: time to change our habits? Ann Thorac Surg 2005;78:1591–7.

Off-Pump Coronary Artery Bypass Graft Surgery With a Pulsatile Catheter Pump for Left Ventricular Dysfunction

Massimo A. Mariani, Jan C. Diephuis, Martin J.H. Kuipers, Monica Gianoli and Jan G. Grandjean

Ann Thorac Surg 2007;84:690-692
DOI: 10.1016/j.athoracsur.2006.12.016