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New ideas - Assisted circulation

PulseCath® as a right ventricular assist device

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Abstract

The PulseCath® is a pulsatile pump that offers a circulatory support up to 3 l/min. The PulseCath® is indicated for patients who require a higher degree of support than that offered by the intra-aortic balloon pump. We describe the first two cases of the use of the PulseCath® as a temporary support for the right ventricle after insertion through the pulmonary artery trunk. Two patients developed an acute right ventricular failure with severe hemodynamic instability after cardiac surgery. The PulseCath® was chosen to assist the right ventricle. An immediate improvement of hemodynamic parameters was observed in both cases. In the first patient an irreversible metabolic unbalance, already present prior to PulseCath® insertion, led to multi-organ failure and eventually to death. In the second case the early utilization of PulseCath® led to a complete recovery of the right ventricle and the patient was discharged in good clinical condition. Besides the technical feasibility, this report would suggest that a correct timing is the key to success for the PulseCath® as a right ventricular assist device.

Keywords: Right ventricle assist device; Right ventricle failure; Pulsatile catheter; Counterpulsation device

1. Introduction

The intra-aortic balloon pump (IABP) is the most widespread support device, but its ability to increase cardiac output is limited to approximately 0.5–1 l/min [1]. Moreover, the benefits of IABP in cases of right ventricular failure are not demonstrated. Ventricular assist devices (VADs) can actively pump over 5 l/min, but require open-chest surgery. The pulsatile catheter pump (PulseCath®, PulseCath B.V., Amsterdam, The Netherlands) offers a circulatory support of 2.5–3 l/min, therefore positioning itself between the IABP and the conventional VADs [2]. The PulseCath® consists of a 21-Fr (6.9 mm) flexible polyurethane catheter with a single pivoting leaflet at its tip. The PulseCath® actively aspires blood from the left ventricle and ejects it in the ascending aorta. The PulseCath® can be inserted closed-chest via the subclavian artery and it is operated by a standard IABP driver (Fig. 1) [3]. The PulseCath® is meant to assist those patients who do not receive with an IABP the amount of circulatory support that their clinical situation requires [4–6].

Despite being designed as a device for temporary support of the left ventricle, here we present the first two cases of the use of the PulseCath® as a temporary support for the right ventricle after insertion through the pulmonary artery trunk.

2. Patient 1

A 76-year-old male with severe aortic stenosis (peak gradient 88 mmHg, aortic valve area 0.63 cm^2) and a three-vessel coronary disease was planned for an aortic valve replacement with coronary revascularization.

Through a midline sternotomy, the left internal mammary artery (LIMA) was anastomosed to the left anterior descending artery. The saphenous vein was sequentially anastomosed to the diagonal branch and to the obtuse marginal branch. The right coronary artery was chronically closed and no suitable side branch was found for grafting. Aortic valve replacement was performed with a biological prosthesis (mitroflow 23 mm).

After weaning from cardiopulmonary bypass (CPB), the patient developed an acute right ventricular failure with hemodynamic instability. Therefore, the CPB was resumed and continued for one hour. During the second attempt of weaning from CPB, an IABP (CS300 Intra-Aortic Balloon Pump & Sensation IAB Catheter 2007, Datascope-Maquet Cardiovascular, Fairfield, NJ, USA) was inserted through the left femoral artery and inotropic support was optimized. The second weaning attempt was successful. The chest was closed and the patient was transferred to the intensive care (IC) unit.

After 2 h, the patient became instable and developed a cardiogenic shock. An emergency re-sternotomy was performed on the IC-unit and the extra-corporeal circulation was started again. Acute right ventricular failure was diagnosed by transesophageal echocardiography (TEE) and confirmed by visual inspection. Due to the patient's age

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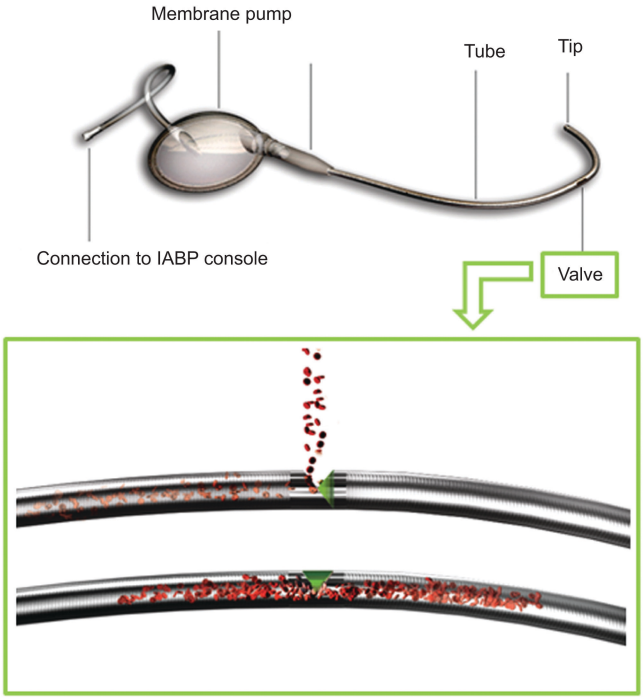

Fig. 1. PulseCath®: a patented rotating two-way valve is connected to an extracorporeal dual chamber membrane housing via a 21-Fr lumen catheter. It can be used with any standard IABP driver unit. During systole, blood flows from the ventricle through the catheter tip and is aspirated into the membrane housing. During diastole, the membrane pushes the blood back through the catheter subsequently opening the valve and delivering blood to the aorta through the side outflow port. IABP, intra-aortic balloon pump.

and co-morbidity, a right ventricular assist device (RVAD) was not indicated. As 'compassionate case' option, a PulseCath® device was chosen to assist the right ventricle. A guidewire was inserted into the pulmonary artery trunk using a double purse-string suture. The PulseCath® was routed into the chest through a supraclavicular incision at the left side. On the guidewire, the PulseCath® was then guided through the pulmonary valve into the right ventricle. A pressure line was inserted into the pulmonary artery, beside the PulseCath®, in order to monitor the pulmonary artery pressure (PAP). The system was connected to an IABP driver (Sensation and CS300 IABP system 2007, Datascope-Maquet Cardiovascular, Fairfield, NJ, USA) and 1:1 counterpulsation was started. Immediately after the PulseCath® was activated, an increase in systolic and mean arterial blood pressure was observed (arterial blood pressure 110/60 mmHg), with a complete recovery of the hemodynamics. We observed an immediate increase in cardiac output and a rapid recovery from metabolic acidosis (Fig. 2). Then the wound was closed (Fig. 3).

Although initially the hemodynamics were significantly improved by the PulseCath®, the metabolic picture did not recover during the following hours and the hemodynamics began to deteriorate as well (Fig. 2). On postoperative day (POD) 1, the hemodynamics became instable despite maximal inotropic support and 1:1 counterpulsation of both IABP and PulseCath®, as the decrease of mean arterial pressure shows (Fig. 2). The TEE did not show any residual contractility of the right ventricle and showed a seriously deteriorated left ventricular function. Progressive organ hypoperfusion occurred with oliguria (urine output 30 ml/h) and increased lactate by laboratory analysis (10.60 mmol/l). The patient died on POD 1 due to an irreversible metabolic unbalance with multi-organ failure.

3. Patient 2

A 73-year-old male with a recent STEMI, three-vessel disease, decreased ejection fraction (34%) e and a mild aortic valve stenosis (peak gradient 30 mmHg and aortic valve area 1.8 cm^2) was planned for a coronary artery bypass grafting (CABG).

The LIMA was anastomosed to the left anterior descending artery. Due to severe calcification of the aortic arch, the saphenous vein was Y-grafted to the LIMA and two sequential anastomoses were performed to the obtuse marginal branch and to the posterior descending artery. Weaning from the CPB was uneventful.

After 15 min from weaning the patient developed acute right ventricular failure with atrial fibrillation and episodes of ventricular fibrillation, for which DC-countershock was performed repeatedly. Despite maximal inotropic support, hypotension (mean arterial pressure 45 mmHg) and severe hypo-contractility of the right ventricle persisted, while left ventricle showed normal contractility. Due to the patient's age, and co-morbidity, an RVAD was not indicated. As 'compassionate case' option, a PulseCath® device was chosen as a right ventricular assist. The insertion procedure was carried out as described in Patient 1 (Fig. 3).

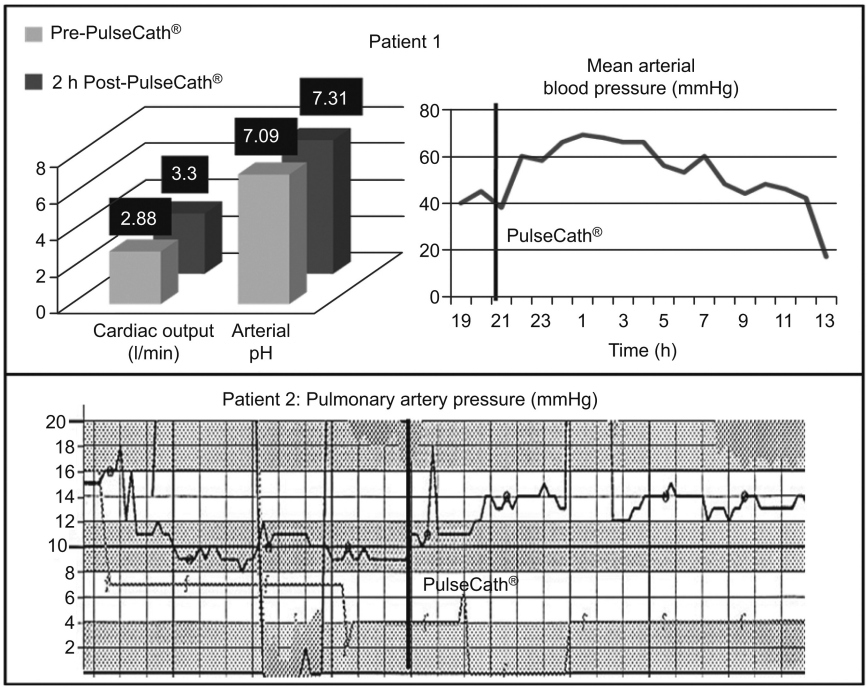

Fig. 2. Patient 1: the left diagram shows the improvement in cardic output and metabolic acidosis after two hours from PulseCath® insertion. The right graph shows the immediate improvement in blood pressure after the insertion of the PulseCath® and the progressive decrease due to metabolic unbalance and multi-organ failure. Patient 2: immediately after PulseCath® pulmonary artery pressure increased.

The system was connected to an IABP driver (Sensation and CS300 IABP System 2007, Datascope-Maquet Cardiovascular, Fairfield, NJ, USA) and 1:1 counterpulsation was started. Immediately after the start of PulseCath® utilization an increase in systolic and mean arterial blood pressure was observed as well in pulmonary artery pressure (Fig. 2), with an adequate organ perfusion.

To further support the heart, compromised by the hypoperfusion and right ventricle failure, an IABP (CS300 Intra-Aortic Balloon Pump & Sensation IAB Catheter 2007, Datascope-Maquet Cardiovascular, Fairfield, NJ, USA) was inserted in a retrograde way, through the ascending aorta. The wound was closed and the patient was transferred to the IC-unit.

Seven hours later, after a complete recovery of the right ventricular failure a re-sternotomy was performed due to persistent bleeding. Due to the recovery of the right ventricle documented by the TEE and confirmed by visual inspection, the PulseCath® was removed. Over the next 24 hours inotropic support was phased out. On POD 4, the IABP at the left side was removed and the sternum was closed. On POD 11, the patient was extubated. On POD 15, a mediastinitis by Enterococcus Faecium occurred, requiring curettage of the sternal wound, followed by a myoplasty using the major pectoral muscles on POD 25. On POD 49, the patient was discharged in good clinical condition.

4. Discussion

This is, to author's knowledge, the first report of the PulseCath® as a device for right ventricular support. Although IABP is a short-term device which is widely used to support the left ventricle failure, there is no comparable pulsatile device to assist the right ventricle.

As far as the technique of insertion is concerned, the PulseCath® can be easily inserted on a guidewire, using the Seldinger technique, into the right ventricle through the pulmonary artery. Moreover, the tiny wall of the pulmonary artery and of the right ventricle allows a precise assessment of the position of the PulseCath® by direct palpation.

The PulseCath® must be inserted under direct vision into the pulmonary artery, therefore with the sternum open. Nevertheless, when the PulseCath® is used as a postcardiotomy device for right ventricular support, it can be routed into the chest through a supra-clavicular skin incision on the left side allowing to close the wound at the end of the procedure.

As far as the efficacy of the PulseCath® is concerned, an immediate improvement of hemodynamics was observed in both cases.

In the first patient, the initial benefit was undermined in the following hours by the serious metabolic unbalance. It can be postulated that the efficacy of the PulseCath® might be insufficient when clinical and metabolic picture of the patient are irreversibly compromised. Therefore, to optimize the efficacy of the PulseCath®, the timing of insertion is a key factor.

In fact, in the second patient, the PulseCath® was inserted during the first operation immediately after the diagnosis of right ventricle failure. In this case, the patient could benefit from a complete recovery in a short while.

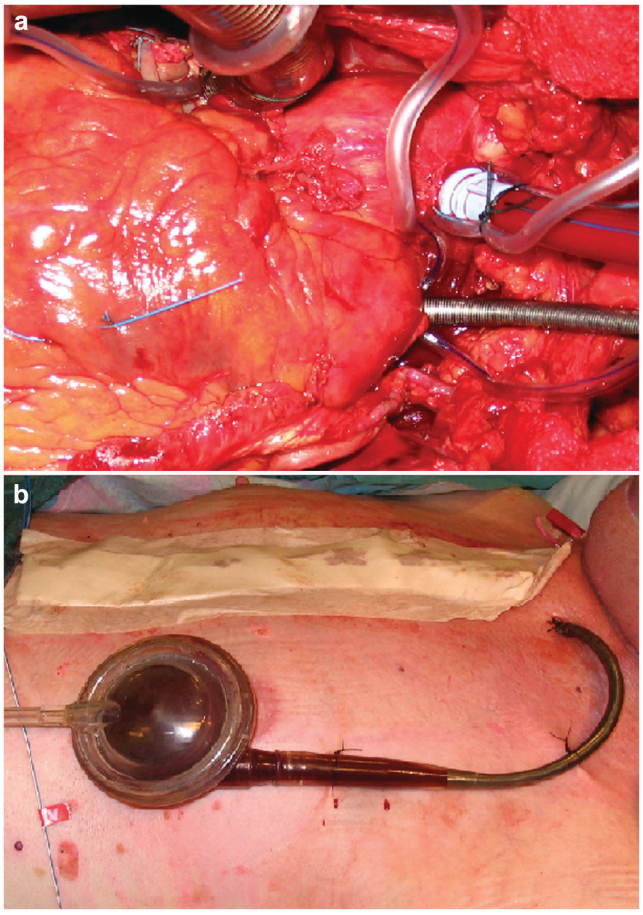

Fig. 3. Patient 1: (a) Through a supra-clavicular incision at the left side, the PulseCath® was inserted into the pulmonary artery trunk, by using a double purse-string suture. (b) At the end of procedure the wound was closed.

In both cases an IABP for coronary perfusion as well as left ventricular unloading was inserted. Even if the PulseCath® may offer only a partial support as a right VAD (in a previous study up to 2.8 l/min [5]), in case of postcardiotomy right ventricular failure the PulseCath® could offer a therapeutic benefit.

In conclusion, positioning of the PulseCath® in the right ventricle can be easily performed, by direct insertion in the pulmonary trunk.

Moreover, the supra-clavicular insertion of the PulseCath® makes it possible to close the wound.

A correct timing is probably the key of success for the PulseCath®, not differently from any other assist device.

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