doi:10.1510/icvts.2010.264051

INTERACTIVE CARDIOVASCULAR AND THORACIC SURGERY

Interactive CardioVascular and Thoracic Surgery 12 (2011) 912–913

www.icvts.org

Work in progress report - Assisted circulation

PulseCath iVAC 3L™ hemodynamic performance for simple assisted flow

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Received 15 December 2010; received in revised form 7 February 2011; accepted 8 February 2011

Abstract

The PulseCath iVAC 3L™ left ventricular assist device is an option to treat transitory left heart failure or dysfunction post-cardiac surgery. Assisted blood flow should reach up to 3 l/min. In the present in vitro model exact pump flow, depending on various frequencies and afterload was examined. Optimal flow was achieved with inflation/deflation frequencies of about 70–80/min. The maximal flow rate was achieved at about 2.5 l/min with a minimal afterload of 22 mmHg. Handling of the device was easy due to the connection to a standard intra-aortic balloon pump console. With increasing afterload (up to a simulated mean systemic pressure of 66 mmHg) flow rate and cardiac support are in some extent limited.

Keywords: PulseCath; Left ventricular assist device; Flow performance

1. Introduction

The PulseCath iVAC 3L™ (PulseCath) minimal heart circulatory left ventricular assist device is indicated in cases of left heart failure due to acute myocardial infarction, as well as transitory heart dysfunction post-cardiac surgery. Pulsatile blood flow (e.g. echocardiograph triggered) of up to 3 l/min should be obtained via an extracorporeal dual chamber membrane, with an unidirectional flow warranted by a two-way valve in a 21 French lumen catheter. CE marking of conformity was obtained in March 2009. The aim of this study is to evaluate performance of this device, depending on inflation frequency and various afterloads calibrations in an in vitro model.

2. Methods

The PulseCath was connected to an intra-aortic balloon pump console (Data scope 100CS; inflation, deflation timing 50/50) via the helium drive line. The blood chamber was filled with water. A silicone tube with a Y bifurcation was positioned across the two-way tilting disk valve and orifices were snared tightly proximal and distal to the valve. The 'tip of the device' was placed in a water reservoir, which simulates the left ventricle and pre-load. The ejection tube across the tilting disk valve was conducted to a second reservoir, which was positioned at variable levels above the first one, to simulate different after load situations (30, 60, 90 cmH_2O, respective 22, 44, 66 mmHg). Measuring the backflow from the second to the first reservoir by a flow-meter positioned on a connection tube in between, allowed, after a stabilization period, to determine effective maximal pump flow. Control of a steady water level in the upper reservoir was achieved by progressive snaring or opening of the backflow line (Fig. 1). The flow-meter was calibrated with a volumetric tank and timer.

3. Results

The measured flow rates are listed below (Fig. 2). Analyzing the performance curves for flow rates show optimal flow, independently from afterload, at inflation/deflation rates of about 70–80/min. Progressive increase of the afterload resulted in a general decrease of flow rate (Fig. 2). Flow reduction was more important at the first increase of afterload from 22 to 44 mmHg, than at the second step (elevation from 44 to 66 mmHg). The maximal achieved flow rate under 'optimal conditions' was about 2.5 l/min.

4. Discussion

The PulseCath minimal heart circulatory left ventricular assist device is a simple and cost-effective option for temporary circulatory support. Optimal flow rate (50/50 inflation/deflation timing; maximal balloon inflation volume) was achieved with an inflation/deflation rate of about 70–80/min. Increasing afterload provokes significant flow reduction. Maximal pump flow rate, under optimized conditions, was about 2.5 l/min in this in vitro model. Other factors, which would contribute to an elevation of the afterload, as may be observed in an in vivo application, were excluded. Large water reservoirs and continuous backflow allowed resistance-free aspiration and ejection by the

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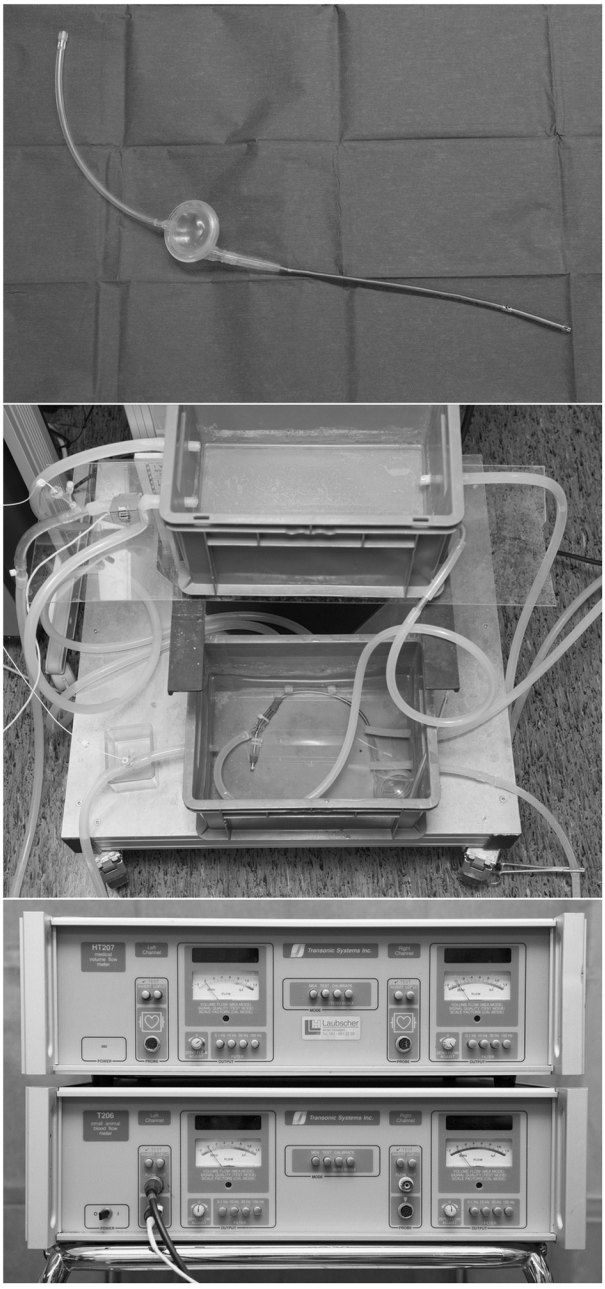

Fig. 1. Experimental set-up.

PulseCath. Simulated augmentation of the afterload leads to a rapid decrease of the flow rate. Maximal flow was 1.85 l/min and 1.64 l/min at 44 and 66 mmHg, respectively. Interestingly this decrease was more important with an afterload augmentation between 22 and 44 mmHg, than from 44 to 66 mmHg (Fig. 2).

Inflation/ deflation rate (bpm)	Flow rate (ml/min)		
	30 cmH_2O 22 mmHg	60 cmH_2O 44 mmHg	90 cmH_2O 66 mmHg
40	1330	1300	830
50	1750	1600	900
60	2290	1700	1500
70	2440	1800	1640
80	2500	1850	1600
90	2400	1700	1400
100	1720	1200	1100
110	1250	900	800

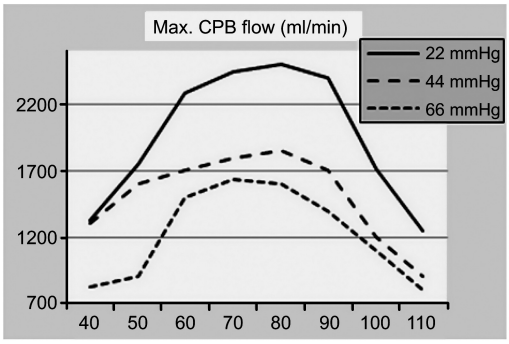

Fig. 2. Flow rate dependency from inflation pressure and afterload/flow rate performance curves. CPB, cardiopulmonary bypass.

The PulseCath assist device may be a simple and cost-effective therapeutic tool to support blood flow in post-operative cardiac failure. The main advantage is the simple handling with an already established control system. The in vitro test shows that technical handling is not an issue; however, flow rate and cardiac support are in some extent limited. Maximal achieved flow rate with a systemic pressure simulation of 66 mmHg was nearly 1.7 l/min and therefore below the suggested 3 l/min. Some previous experimental and clinical reports show encouraging results concerning assisted flow over a short period of time in particular setups [1, 2]. However, exact device related direct flow rates are difficult to determine and this experimental study may help to quantify potential flow in an afterload dependent simulation test. Further investigations will help to determine the exact indications for this device in humans.

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