Design, concept and first in-vitro results of the percutaneous, pulsatile left ventricular assist device-PERKAT LV

D. Kretzschmar[1], P.C. Schulze[1], M.W. Ferrari[2]

[1]University Hospital Jena, Department of Internal Medicine I, Jena, Germany; [2]HSK, Helios-Kliniken, Clinic of Internal Medicine I, Wiesbaden, Germany

Funding Acknowledgement: Type of funding source: Public grant(s) – National budget only. Main funding source(s): German Federal Ministry of Education and Research

Introduction: A very high morbidity and mortality is associated with cardiogenic shock due to left ventricular failure despite encouraging developments in interventional cardiology. Patients suffering from cardiogenic shock often require temporary mechanical circulatory support to stabilize organ perfusion. In addition, an increasing number of patients with complex multi-vessel diseases cannot undergo surgical myocardial revascularization as recommended by recent guidelines due to their comorbidities. Those patients could benefit from a protected PCI approach using a temporary mechanical assist device. The available LVAD systems have specific advantages and disadvantages.

Purpose: It was our aim to develop a percutaneous, pulsatile assist device that unloads the left ventricle in a physiologic way.

Methods: The PERKAT-LV ("PERkutane KATheterpumptechnologie") device consists of a self-expanding nitinol pump chamber which is covered by foils. Those foils carry multiple outflow valves at the proximal part of the pump chamber. A flexible suction tube with a pigtail-shaped tip and inflow holes are attached to its distal part. The system is designed for 16F percutaneous implantation via the femoral artery. Pulling back the outer sheath unfolds the nitinol chamber in the descending aorta while the flexible suction tube bypasses the aortic arch and ascending aorta with its tip in the left ventricle. In the second implantation step, a standard IABP balloon is placed into the pumping chamber and is connected to an external IABP console. Balloon deflation generates a blood flow from the left ventricle into PERKAT LV. During balloon inflation, blood leaves the system through the outflow foil valves in the descending aorta. Positioning and schematic drawing of PERKAT-LV is demonstrated in Figure 1.

Results: Preliminary in-vitro studies using a prototype of the PERKAT LV device were performed. It was tested in different afterload settings (0, 40, 80 and 120 mmHg) using a standard 30 ccl IABP balloon and varying inflation/deflations rates (70, 80, 90, 100, 110 and 120/min). We detected flow rates ranging from 2.0 to 3.0 L/min depending on the afterload setting and inflation/deflation rate.

Conclusion: The novel percutaneously implantable and pulsatile working PERKAT-LV device offers left ventricular unloading and circulatory support of up to 3.0 L/min in a first feasibility study. At the moment, the system is extensively studied under in vitro conditions. First in vivo evaluation will follow in the near future.

Based on the current results, we believe that the system is a promising novel approach for percutaneous application of temporary left ventricular mechanical support.

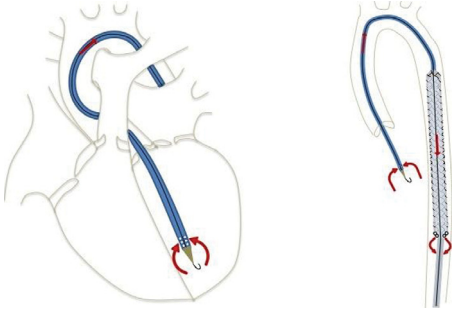

Figure 1