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Proposal for bail-out procedures - Assisted circulation

HeartWare third-generation implantable continuous flow pump as biventricular support: mid-term follow-up☆

Antonio Loforte*, Paola Lilla Della Monica, Andrea Montalto, Francesco Musumeci

Department of Cardiac Surgery and Transplantation, San Camillo Hospital, P.za C. Forlanini n. 1, 00151 Rome, Italy

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Abstract

A long-term mechanical biventricular support by HeartWare HVAS third-generation continuous flow pump (HeartWare, Inc, Miramar, FL, USA) was implanted in a Korean patient with a small chest size for treatment of a refractory end-stage heart failure due to an idiopathic dilative cardiomyopathy. We report our experience with a single patient and the early mid-term follow-up results with such a mechanical ventricular support.

Keywords: Heart failure; Magnetic-levitation; Biventricular assist device

1. Case report

Rotary blood pumps have been designed for increased reliability and smaller size for use in a broader population of patients than the first-generation pulsatile devices [1, 2].

A novel technology focusing on a magnetic-levitation (MAGLEV) system was first applied by the University of Virginia research group [1] and the application for rotary blood pumps was then reported by Hoshi et al. [1].

The core of the HeartWare HVAS third-generation rotary blood pump uses a 'hybrid' system to suspending the impeller. The suspension uses a combination of passive magnets and a hydrodynamic thrust bearing which operates by establishing a 'cushion' of blood between the impeller and the pump housing. Once power is applied to the device, there are no points of mechanical contact within the pump, ensuring a completely 'wearless' system [3].

We report our experience with a single patient, a 44-year-old Korean male with refractory end-stage biventricular heart failure, who received a HeartWare HVAS (HeartWare, Inc, Miramar, FL, USA) biventricular mechanical support at our institution as was similarly reported by Berlin [4] and Hannover [5].

Etiology at the time of the support was an idiopathic dilative cardiomyopathy and the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) level was 2. The Pennsylvania University score was 60 [6] and the Michigan University score was 7 [7] in terms of preoperative right ventricular function evaluation and right short/long axis ratio was >0.6 in terms of preoperative right ventricle geometry assessment [8]. The preoperative sequential organ failure assessment (SOFA) and the simplified acute physiology score (SAPS) II [8] were 10 and 30, respectively. The inotropic score as described by Potapov et al. [8] was 30.

The patient's body surface area was 1.6 m^2 associated with an extremely small chest size with A–P (anterior–posterior) distance from posterior sternum to anterior vertebral body at T-10 on computed tomography (CT)-scan <10 cm.

After median sternotomy during cardiopulmonary bypass, the left pump was implanted conventionally into the left ventricle apex and the outflow graft was connected to the ascending aorta. The second pump as a right ventricular assist device (VAD) was placed on the diaphragmatic surface of the right ventricle just below the acute margin by transesophageal echocardiography guide with the inflow cannula associated with two additional silicone rings placed under the fixation ring. The outflow graft was narrowed before surgery to 5 mm [4] and was sutured to the pulmonary artery. The narrowing was achieved by suturing a 3-cm long piece of graft with 6-0 Prolene (Ethicon, Sommerville, NJ, USA) just 2 cm from the outflow connector over a 5-mm Hegar dilator introduced into the graft.

Both pumps were intrapericardial (Fig. 1). The drivelines were tunneled and emerged in the lower abdominal quadrant on the left (left pump) and right (right pump) side.

The pump speeds were adjusted individually, depending on hemodynamics, to achieve a flow of approximately 5–6 l/min (left pump) and 3–4 l/min (right pump). Anticoagulation was targeted to an international normalized ratio (INR) 2.5–3. Aspirin was used as an antiplatelet agent.

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*Corresponding author. Tel.: +39 06 5870 4401; fax: +39 06 5870 4706.
E-mail address: antonioloforte@yahoo.it (A. Loforte).

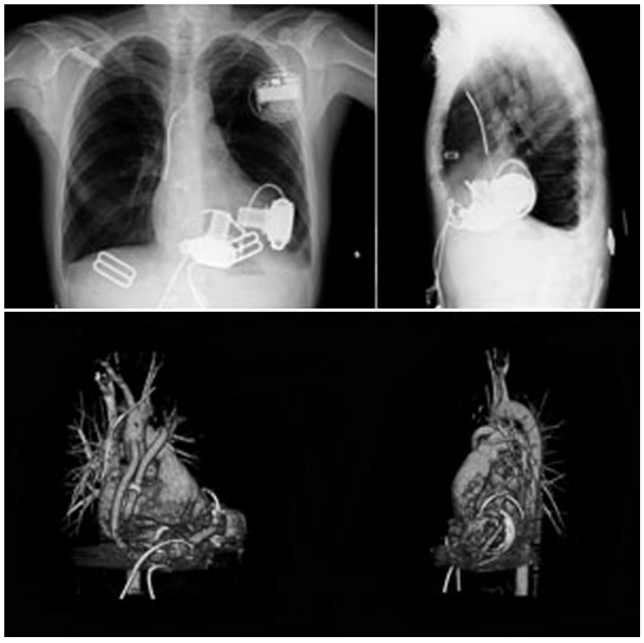

Fig. 1. HeartWare HVAS biventricular mechanical support position by chest X-ray imaging (upper part) and 3-D computed tomography (CT)-scan reconstruction (lower part).

Thromboelastometry analysis (ROTEM, Tem Intl GmbH, Munich, Germany) monitorings were adopted to manage the anticoagulation therapy.

The postoperative course was uneventful. The patient was discharged home with two controllers and four batteries on postoperative day (POD) 23. After discharge, the patient returned to our institution for routine monthly follow-ups.

The patient presented on POD 92 with fatigue and melena. At the time of admission, his hemoglobin was 6.7 g/dl, INR was 3.1, partial thromboplastin time (PTT) was 53 s, and platelet count was 204,000. Two previous evaluations for acquired-von Willebrand disease consisting of ristocetic cofactor and von Willebrand factor activity and multimeric analysis (as part of a separate ongoing screening activity in our patients with LVADs) were unremarkable. Platelet function testing was not performed.

The upper endoscopy was negative and the inferior endoscopy revealed active bleeding coming from the proximal part of the intestine. A CT-scan of the abdomen did not show any lesion precisely. His coagulopathy was corrected with multiple blood (six units), fresh frozen plasma (six units), and platelet transfusions (four units). Despite an INR of 1.2 and normal thromboelastography results, over the next seven hours, his hemoglobin count continued to decline.

Thus, he was taken for emergency surgical exploration. A midline laparotomy was performed. During the exploration part of the small intestine was bleeding thus it was opened and a 1.5-cm polyp mass was identified with continuous arterial bleeding. The mass was ligated, and the involved part of the small intestine was resected.

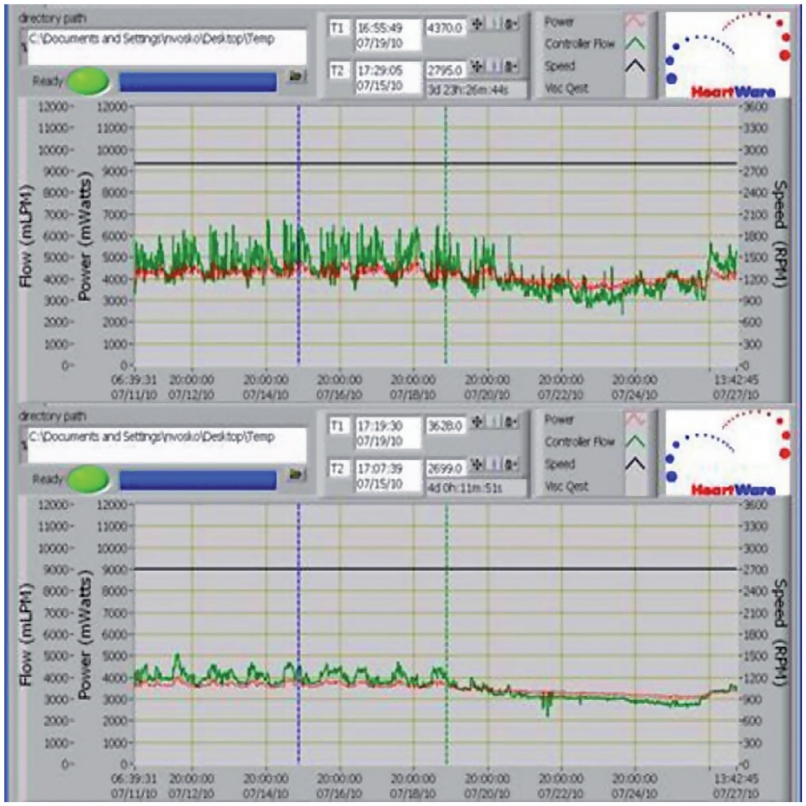

Fig. 2. Working data analysis of HeartWare HVAS devices (LVAD, left ventricular assist device, upper part; RVAD, right ventricular assist device, lower part) which documents a 'low flow' event for both pumps.

A heparin drip was started 24 hours postoperatively. By POD 6, the patient's diet was advanced and coumadin was restarted. He was discharged on POD 31. The final pathology of the mass documented a non-malignant lesion.

A retrospective analysis of HeartWare devices working data documented a 'low flow' event when he was still at home as a sign of the upcoming bleeding event which supports the high sensitivity of the device software system monitoring (Fig. 2).

Three months postsurgery, he is doing well, he is at home, his anticoagulation is back to baseline, and he has had no further bleeding episodes. There was no system malfunction. Neither minor nor major cerebrovascular events occurred. To date duration of support has been 189 days.

2. Discussion

Support with HeartWare HVAS biventricular assist device (BiVAD) may allow patients with terminal biventricular heart failure to be discharged home. The right pump placement on the diaphragmatic surface of the right ventricle provides a lower-risk of suction events. The technique may offer a solution for extremely small chest sizes if the unloading of both ventricles is not sufficient in terms of 'mechanical system fitting'.

Patients with gastro-intestinal (GI) bleeding should undergo prompt endoscopic evaluation and definitive therapy to prevent mortality from hemorrhage. GI bleeding after LVAD placement is a well-known, but poorly described problem occurring in 15% of patients [9]. Reliable management protocols are lacking and management is typically reduction in anticoagulation or antiplatelet intensity. More aggressive bleeding, such as in our patient, may require surgical treatment.

In summary further studies and longer times of follow-up with this novel type of mechanical biventricular support are necessary.

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