Current Technology: Devices Available for Destination Therapy

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KEYWORDS

• Destination therapy • HeartMate XVE • HeartMate II
• HeartWare

A new era of end-stage heart failure (HF) treatment with left ventricular assist device (LVAD) technology has emerged with 2 landmark randomized control trials. The first trial, the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial, validated the feasibility of a mechanical approach to the treatment of end-stage HF in 2001.[1] This trial led to the first approval by the US Food and Drug Administration (FDA) of an LVAD therapy for destination therapy (DT) with the HeartMate (HM) XVE. The second trial was completed recently and reported that the probability of survival free from stroke and device failure at 2 years was significantly improved on a continuous flow (CF) pump (HM II) compared with a pulsatile flow (PF) pump (HM XVE) in DT patients.[2] The FDA approved this CF LVAD for DT in 2010. The HM XVE and the HM II are the only 2 FDA-approved devices currently and have set the standards for LVAD use as DT. Several other devices are or will soon be undergoing clinical trials in the United States.

PF LVADs

LVADs are divided into PF and CF devices based on the characteristics of blood flow generated by the pump. The first-generation LVADs are characterized by a volume displacement pump that generates PF. In addition to the REMATCH trial, the Investigation of Nontransplant-Eligible Patients Who Are Inotrope Dependent (INTrEPID) trial and the European LionHeart Clinical Utility Baseline Study (CUBS) trial evaluated the use of the Novacor LVAD and the Arrow LionHeart LVAD, respectively.[3,4] All of these clinical trials revealed superior outcomes of PF LVADs over medical therapy for end-stage HF. However, widespread use of these LVADs for DT did not occur because of limitations highlighted by their high incidence of adverse events related to mechanical support, such as infection, device failure, and thromboembolic events, as well as their bulky and noisy design.

The HM XVE (Thoratec Corp. Pleasanton, CA, USA) (**Fig. 1**) was developed by Thermo Cardiosystems and is currently manufactured by Thoratec Corp. The original pump was operated with a pneumatic power source (the IP model). This model evolved into the vented electric (VE) model and then to the XVE model. The XVE model has improved strength of the percutaneous lead and an outflow graft with bend relief; also, the mounting of its biologic valve prosthesis is enhanced, as well as some other refinements. This device generates PF through a pusher plate situated in a relatively large housing, which precludes implantation in small patients (body surface area <1.5 kg/m^2). The unique textured inner surface of the titanium shell with a polyurethane diaphragm decreases the thrombogenic nature of the device, allowing patient

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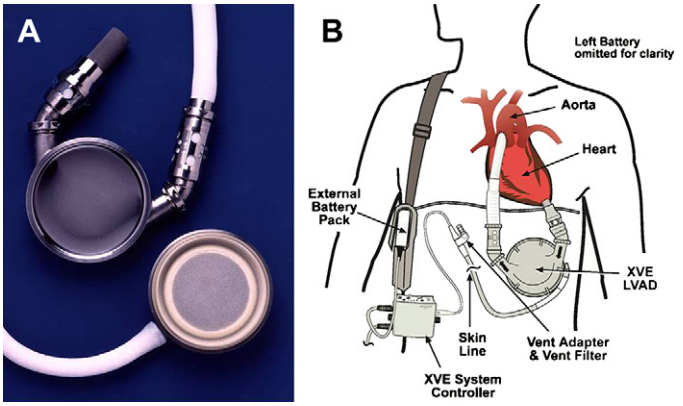

Fig. 1. (*A*) The pump of the HM XVE. The unique textured inner surface of the titanium shell with a polyurethane diaphragm decreases the thrombogenic nature of the device (*B*). (*Courtesy of* Thoratec Corp.)

management with no anticoagulation. A pusher-plate actuator produces mechanical energy converted from electrical energy. The inflow and outflow arms extend from the pump, and each arm contains a 25-mm porcine valve. The inflow cannula is placed into the left ventricular (LV) cavity through a plastic cuff sewn at the LV apex. The outflow arm is connected to a 20-mm Dacron graft, which is sewn to the ascending aorta in end-to-side fashion. The pump is placed in a large pocket in the anterior abdomen (in either the preperitoneal or the intraperitoneal space) and the percutaneous lead is brought out in the lower abdominal wall. Although the VE and the XVE models operate on electric energy, the percutaneous driveline contains a duct that allows access to the diaphragm and can be used for venting or pneumatic actuation of the device in emergent situations such as electrical driver failure. The driveline is connected to an external controller that weighs less than 300 g and to 2 batteries.

This device successfully pioneered a new era in HF therapy. The REMATCH trial randomly compared the HM VE with optimal medical management for patients with end-stage HF who were ineligible for heart transplantation (HTx).[1] It showed that survival at 1 and 2 years was 52% and 23% with the LVAD compared with 25% and 8%, respectively, with medical therapy. However, long-term use is limited by significant rate of device malfunction and infection. In the REMATCH study, the probability of device-related infection was reported to be 28% within 3 months, and that of device failure was 35% at 24 months. Although subsequent clinical studies have shown a better safety profile and greater reliability of the updated device (XVE), the average support that the pump can offer remains around 1.5 years.[5] Lietz and colleagues[6] reported the outcomes of this device in the post-REMATCH era. That study included 280 patients who underwent HM XVE LVAD implantation between November 2001 and December 2005 and reported that the probability of device exchange or fatal device failure was 72.9% at 2 years. Given these limitations and the recent approval of the HM II (Thoratec Corp, Pleasanton, CA, USA) for DT, the role for the HM XVE in DT is now minimal. A potential continued indication for its use remains in patients who have contraindications for anticoagulation; however, durability remains a major concern.

Another widely used PF device was the Novacor LVAS. Its basic mechanism is similar to that of the HM XVE but with a smoother inner surface, which anecdotally requires stringent anticoagulation. This device, although used worldwide for bridge to transplant (BTT), had a slightly higher incidence of stroke, This device was a durable workhorse for many years, and the stroke issue was improved with a new inflow cannula.[7] Nonetheless, sale of the Novacor was discontinued in 2008. No clinical trial using a PF device for DT is currently ongoing or being planned.

CF LVADs

Second-generation LVADs are characterized by CF driven by a rotary pump. This technology has proved more mechanically reliable and better tolerated by patients. In particular, the HM II (**Fig. 2**), was shown in a randomized control trial to be superior to the HM XVE for DT patients.[2] This device was the second to receive FDA approval for DT in January 2010, which led to rapid expansion of its clinical application. The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) LVAD registry reported 176 HM II implantations for DT during the first 6 months of 2010, a significant increase from 17 during the previous 6 months.[8]

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