

Advances in LVAD Patient Management: Clinical Strategies to Minimize Adverse Events



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When mechanical circulatory support devices first became available for clinical trial, a certain amount of courage was needed to implant these largely untested, but potentially life-lengthening, devices into our sickest patients. The earliest ventricular assist devices (VADs) were placed in patients needing immediate support while awaiting cardiac transplantation due to acute failure.¹

Twenty-five years later, the landscape is vastly different: the devices are greatly improved—more efficacious and more reliable. Clinical management strategies for LVAD recipients have been developed to guide the care of both bridge-to-transplant (BTT) and destination therapy (DT) patients.² We better understand appropriate patient referral and selection, optimal implantation techniques, and postimplantation management. These all coalesce to make LVAD implantation no longer a niche treatment modality, as evidenced by constantly improving outcomes and rapid adoption across many more cardiac centers of excellence.

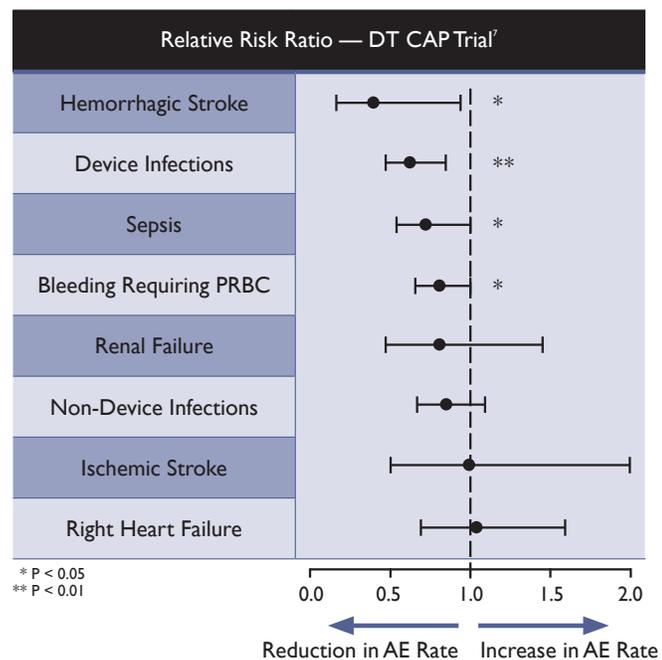
Thoratec developed the first LVAD approved as permanent treatment for end-stage heart failure, the HeartMate® XVE. The pulsatile-flow XVE was found to offer remarkably improved survival and quality of life when compared to optimal medical therapy.³ The HeartMate II®, a much more advanced continuous-flow LVAD, improves even further on the early outcomes. In the HeartMate II Destination Therapy trial (a randomized study of the HeartMate XVE and HeartMate II for advanced heart failure patients ineligible for transplantation), the HeartMate II was associated with significant improvements in terms of survival, device reliability, device-related infection, rehospitalization, and right-heart failure.⁴ Discussion of the superiority of the continuous-flow design has largely ceased, and the vast majority (98% or more) of LVADs being implanted in the United States are now continuous-flow devices.⁵

Clinical Management Guidelines

In early 2010, the HeartMate II Clinical Investigators group published state-of-the-art comprehensive guidelines for

the clinical management of advanced heart failure patients with continuous-flow LVADs.² These 39-page guidelines were based on the investigators' experience during the 1,300-patient HeartMate II BTT and DT studies and include evidence-based perspectives on patient selection, preoperative preparation, the timing of LVAD implantation, nutrition management, intraoperative considerations, patient education, and postoperative management.

Optimizing intraoperative and perioperative care has already yielded improved outcomes for both BTT and DT patients. In the HeartMate II BTT post-approval study (n=169), rates of ischemic stroke, hemorrhagic stroke, and RV failure were all lower when compared to the HeartMate II BTT trial (n=281), while survival to transplantation, recovery, or ongoing device support has continued to improve.⁶ In the BTT post-approval study, 90% of patients had successful outcomes at 6 months, and 85% at 1 year. Also, DT patients from the more contemporary HeartMate II Destination Therapy continuing access protocol (n=281) have shown superior outcomes to those enrolled in the primary cohort of the DT pivotal trial (n=133), with a trend toward improved survival (from 58% at 2 years in the DT trial to 64% in the DT CAP trial), a 50% reduction in hemorrhagic stroke, a 35% reduction in device-related infections, and a 25% reduction in sepsis.⁷



Patient Management Advances

Our management of patients with HeartMate II has evolved significantly in the past 2 years. We better understand effective anticoagulation and recognize that postoperative heparin is not always needed. Advances have also been made in blood pressure management and in the placement and postoperative care of percutaneous leads.

An evidence-based INR target has been established for LVAD recipients based on Boyle and colleagues' retrospective analysis of the pivotal BTT trial data.⁸ They determined that the anticoagulation protocols required for enrollment in the trial led to an unnecessarily high risk of bleeding. In response to these findings, INR recommendations for patients implanted with a HeartMate II have been reduced to between 1.5 and 2.5. Patients should also take 81 mg to 325 mg aspirin daily.²

With the use of early LVADs, percutaneous lead infections were relatively common. The HeartMate II percutaneous lead diameter has been minimized to reduce infection risk, and the lead is covered with woven polyester velour that encourages tissue ingrowth at the skin line. Over time, tissue bonds to the velour surface, anchoring the external surface of the lead to the surrounding tissue.¹⁰

We have found that the best way to prevent an infection is to protect the lead from movement at the exit site since the tissue ingrowth is delicate and easily damaged. Patients are taught how to carefully look after the lead site, and as a result, infection rates have dropped. We find, however, that most infections that do occur have a patient-compliance aspect to them. Constant vigilance is required.

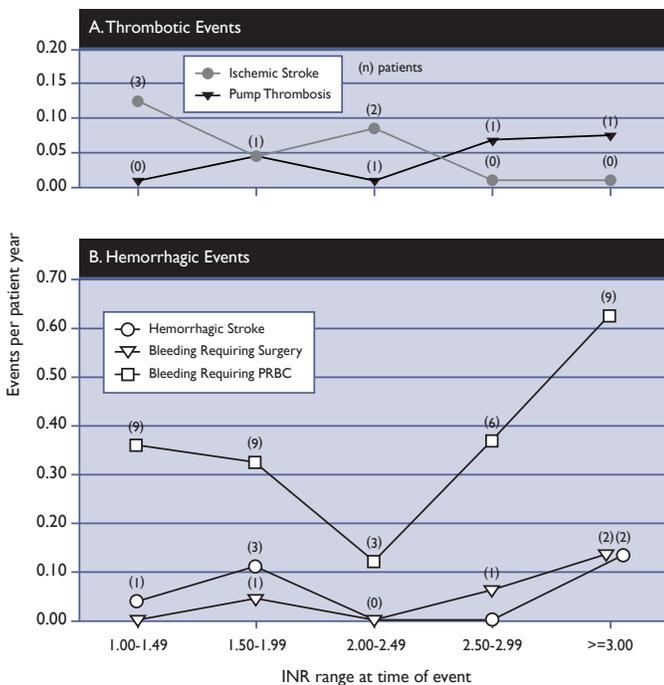
Tight blood pressure management has also been noted to be important for minimizing adverse events. The major hemodynamic effects of a continuous-flow LVAD are increases in diastolic pressure and flow.¹¹ Because these devices pump continuously throughout the entire cardiac cycle, aortic flow is also present during diastole when normal pulsatile flow is absent. When the pump speed of a HeartMate II is increased, diastolic pressure rises, systolic pressure remains fairly constant, and pulse pressure (systolic minus diastolic) is markedly reduced.

Because of this reduced pulse pressure during continuous-flow LVAD support, it is often difficult to palpate a pulse and measure blood pressure accurately using standard methods. Use of Doppler in the postoperative period has become a recommended approach to obtaining a regular blood pressure measurement.

Arterial blood pressure should be controlled with vasoactive and inotropic medications and intravascular fluid volume management, but not through adjustment of LVAD pump speed. The goal is to maintain the mean arterial blood pressure between 70 mmHg and 80 mmHg, but not to exceed 90 mmHg.²

Conclusions

Today, LVADs are advanced and sophisticated, but also more reliable and safe. Best practices have been developed using the combined experience of multidisciplinary teams of HeartMate II adopters to ensure that everything from patient referral and selection to long-term postoperative care is done using evidence-based guidelines and clearly established parameters. These elegant devices have moved from providing risky support for desperately ill patients to being safe and established options for a range of cardiac patients.



In a similar vein, we conducted a retrospective study to evaluate the effects of heparin use on thromboembolic and bleeding complications after HeartMate II implantation.⁹ Our findings indicated that patients who were directly transitioned to warfarin and aspirin without early postoperative intravenous heparin were at decreased risk for bleeding and did not appear to be at increased risk of pump thrombosis or ischemic stroke. Eliminating the routine use of postoperative heparin in patients at low risk of thrombotic events appears to be appropriate in most cases.

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