Left Ventricular Assist Device in Older Adults

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KEYWORDS

• Heart failure • Left ventricular assist device • Elderly patients

KEY POINTS

- Because of a limited donor pool for cardiac transplantation, use of a left ventricular assist device (LVAD) has been established as a life-prolonging treatment of patients with advanced heart failure who are ineligible for heart transplantation.
- Selecting the proper patient for an LVAD involves assessment of indications, risk factors, scores for overall outcomes, assessment for right ventricular failure, and optimal timing of implantation.
- LVAD complications remain an Achilles heel of LVAD implants with a 5% to 10% perioperative mortality and complications of bleeding, thrombosis, stroke, infection, right ventricular failure, and device failure.

INTRODUCTION

The population older than 65 years has experienced rapid growth, with census data showing an increase from 34.2 million in 2004 to 44.2 million in 2014. This is projected to more than double to 98 million by 2060.[1] The overall prevalence of heart failure (HF) in the United States and Europe is between 1% and 12% with the number of Medicare beneficiaries (≥65 years) with congestive HF (CHF) being estimated to be at the upper end of the scale at 9% to 12%.[2] The number of patients in New York Heart Association (NYHA) class IV and stage D HF is difficult to estimate, as data are scarce, but Olmstead County data estimate a prevalence of 0.2% in patients age 65 to 74, and 1.4% in those older than 75.[3] Applying a conservative estimate of 0.2% to the overall population older than 65 years, there are 88,400 affected individuals, which exceeds the overall left ventricular assist devices (LVADs) implanted so far of 13,286 between June 2006 and December 2014 reported to the US Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS).[4]

Identification of patients with stage D HF is important not only because of the limited resources on hand, but because the disease is generally progressive, mortality is high, and treatment options are limited. Treatments include home inotropy, mechanical circulatory support, cardiac transplantation, and palliative care/hospice.

Palliative inotropy may improve symptoms of HF, but has not been shown to prolong life. Orthotopic heart transplantation (OHT) has remained the gold standard for stage D HF. However, because of a limited donor pool, LVAD has been established as a life-prolonging treatment of patients with advanced HF and who are ineligible for heart transplantation.

The National Heart, Lung, and Blood Institute (NHLBI) initiated the artificial heart program in 1964 with the first temporary implantation in 1969 to support a patient awaiting a donor heart.[5] It has evolved to include pulsatile-flow LVADs as

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bridge to transplant (BTT) and as destination therapy (DT) in 2002. And with the subsequent approval of the continuous-flow LVAD (CF-LVAD) HeartMate II (HMII) as a BTT in 2008, the implantation of LVADs has rapidly risen to the point at which annual LVAD implantations exceeded the annual heart transplantations in 2012 (**Fig. 1**), coincidently the year the third-generation LVAD, HVAD (HeartWare International, Inc, Framingham, MA) was approved by the Food and Drug Administration (FDA).[6]

Life expectancy at birth in the general population is 78.8 years, which has been unchanged since 2012.[7] Age is an important factor in heart transplant patient selection. The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH)[8] trial in 2001 deemed patients older than 65 years as nontransplantable and studied them for LVAD DT. Recent studies show an age at transplantation of 70 being associated with lower survival,[9] whereas age of 72 is listed as a relative contraindication to heart transplantation.[10]

Careful patient selection for a ventricular assist device (VAD) is therefore critical. Only a few studies have evaluated age as a factor in the implantation of the second-generation LVADs. Small studies have shown no significant difference when evaluating the outcome in elderly individuals against their younger cohort.[11–13] This is contrary to other studies that show age related to higher risks in elderly individuals.[6,14,15] Although sample sizes are small, this discrepancy underscores the challenges in investigating elderly patients best suited for an LVAD. This article focuses on patient selection and timing of LVAD implantation in the elderly patient, to optimize the benefits over the risks and improve quality and quantity of life with the application of this new technology for advanced HF.

OUTCOME WITH HOME INOTROPY

In patients with HF with reduced ejection fraction stage D on home inotropes, the results are dismal. In the REMATCH trial, stage D patients on inotropes experienced a 75% mortality at 1 year and virtually no survival at 2 years. The Non-Transplant Eligible Patients who are Inotrope Dependent (INTrEPID) trial[16] showed an 11% 1-year survival. Similarly, the COSI trial[17] demonstrated a 6% 1-year survival (**Fig. 2**). However, in a study by Hashim and colleagues[18] published in 2015 involving 97 Class IV patients on inotropes, guideline-directed medical therapy with 82% of patients on cardiac resynchronization therapy (CRT)–implantable cardioverter defibrillator, the actuarial 1-year survival was reported as 47.6% (38.4% 2-year survival).[19]

HISTORY OF LEFT VENTRICULAR ASSIST DEVICES

The artificial heart program was developed by the NHLBI in 1964 as a heart replacement therapy,[6] which led the first cardiac assist device being successfully implanted in 1966 at the Texas Heart Institute. The HeartMate 1000 IP pneumatic implantable LVAD was then developed and first used by Texas Heart Institute in 1986.[20] Further technological development lead to FDA approval of HeartMate as a BTT in 1994. This BTT strategy was not borne out of evidence-based data, but out of necessity due to lack of available hearts. The updated version, the HeartMate XVE was subsequently approved in 1998 for BTT and as DT in 2002. However, because of the device's size and lack of reliability with malfunction or failure approaching nearly 73% after 2 years,[21] the second-generation LVAD systems, continuous axial-flow pumps, were developed.

The HMII, a second-generation LVAD, is the most widely implanted LVAD to date.[22] It is smaller, with only one moving part, the rotor, suspended in the blood flow path by ruby bearings. It resulted in lower rates of mechanical failure and other complications. The HeartMate II received BTT FDA approval in 2008. It subsequently received DT FDA approval in 2010 based on the trial published by Slaughter and colleagues,[23] in 2009. This trial

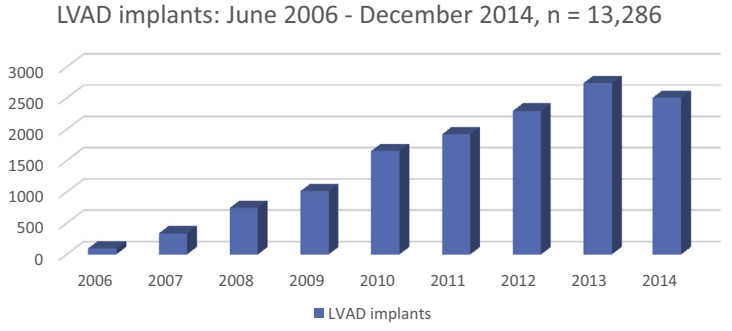

Fig. 1. Implants increasing over time, except for a dip in the total in 2014. (*Data from* Kirklin JK, Naftel DC, Pagani FD, et al. Seventh INTERMACS annual report: 15,000 patients and counting. J Heart Lung Transplant 2015;34(12):1495–504.)