# Orthotopic heart transplant versus left ventricular assist device: A national comparison of cost and survival

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**Objectives:** Orthotopic heart transplantation is the standard of care for end-stage heart disease. Left ventricular assist device implantation offers an alternative treatment approach. Left ventricular assist device practice has changed dramatically since the 2008 Food and Drug Administration approval of the HeartMate II (Thoratec, Pleasanton, Calif), but at what societal cost? The present study examined the cost and efficacy of both treatments over time.

**Methods:** All patients who underwent either orthotopic heart transplantation (n = 9369) or placement of an implantable left ventricular assist device (n = 6414) from 2005 to 2009 in the Nationwide Inpatient Sample were selected. The trends in treatment use, mortality, and cost were analyzed.

**Results:** The incidence of orthotopic heart transplantation increased marginally within a 5-year period. In contrast, the annual left ventricular assist device implantation rates nearly tripled. In-hospital mortality from left ventricular assist device implantation decreased precipitously, from 42% to 17%. In-hospital mortality for orthotopic heart transplantation remained relatively stable (range, 3.8%-6.5%). The mean cost per patient increased for both orthotopic heart transplantation and left ventricular assist device placement (40% and 17%, respectively). With the observed increase in both device usage and cost per patient, the cumulative Left ventricular assist device cost increased 232% within 5 years (from $143 million to $479 million). By 2009, Medicare and Medicaid were the primary payers for nearly one half of all patients (orthotopic heart transplantation, 45%; left ventricular assist device, 51%).

**Conclusions:** Since Food and Drug Administration approval of the HeartMate II, mortality after left ventricular assist device implantation has decreased rapidly, yet has remained greater than that after orthotopic heart transplantation. The left ventricular assist device costs have continued to increase and have been significantly greater than those for orthotopic heart transplantation. Because of the evolving healthcare economics climate, with increasing emphasis on the costs and comparative effectiveness, a concerted effort at LVAD cost containment and judicious usage is essential to preserve the viability of this invaluable treatment. (J Thorac Cardiovasc Surg 2013;145:566-74)

Nearly 6 million Americans have had congestive heart failure diagnosed.[1] Congestive heart failure causes more than 55,000 deaths in the United States each year, is responsible for 5% of all medical admissions, and accounts for direct costs of more than 35 billion dollars in the United States each year.[1,2] More federal funds are spent on congestive heart failure in the United States than any other diagnosis, and a disproportionate amount of these funds is spent on the treatment of advanced heart failure.[3] In patients with advanced disease, the options are limited, and orthotopic heart transplantation (OHT) is widely accepted as the therapy of choice, with 1-year post-transplant survival rates of roughly 85%.[4] Western societies have supported heart transplantation as an acceptable use of healthcare resources; however, the demand for this life-saving treatment far outstrips the availability of suitable donor organs. The OHT numbers in the United States have remained stable during the past decade at approximately 2000 patients treated annually, a mere fraction of the population who could benefit from this treatment.[4]

In 1964, the National Institutes of Health artificial heart program was created with the stated goal of putting a man-made heart into a human by the end of the decade. Despite the large investment of both public and private funds, little palpable progress was made until 2001 when the landmark Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial demonstrated a stark improvement in

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**Abbreviations and Acronyms**
LVAD = left ventricular assist device
OHT = orthotopic heart transplantation
NIS = Nationwide Inpatient Sample

survival when patients with advanced heart failure underwent HeartMate XVE (Thoratec, Pleasanton, Calif) left ventricular assist device (LVAD) implantation compared with those supported with conventional medical therapy.[5] In response to that trial, the Centers for Medicare and Medicaid Services authorized reimbursement for the use of Food and Drug Administration-approved LVADs as long-term destination therapy in October 2003.[6,7] More recently, a second leap forward occurred with the replacement of first-generation pulsatile LVADs with newer continuous-flow devices such as the HeartMate II LVAD (Thoratec), which was approved by the Food and Drug Administration for bridge-to-transplantation in April 2008 and for destination therapy in January 2010.[8,9]

Since the April 2008 approval, the HeartMate II has rapidly taken over market share as the most widely used implantable LVAD in the United States.[10] Additionally, patient outcomes have rapidly improved with this newer device, with 1-year survival rates now approximately 80%, a percentage almost equivalent to the reference standard of heart transplantation.[10] Although it took 4 decades longer than expected, the fruits of the 1964 investment have now been realized in the form of the HeartMate II, a man-made artificial blood pump that can be successfully implanted into a human, with resulting survival rates almost equivalent to transplantation. Despite this fantastic feat of modern medicine, the cost of this achievement and feasibility of widespread use must be carefully weighed. The purpose of the present study was to examine both OHT and LVAD usage and cost patterns in the years surrounding the initial HeartMate II bridge-to-transplant approval in April 2008—to shed light on current trends and possibly to help guide future use.

## METHODS

### Data Sources

Data were abstracted from the 2005 through 2009 Nationwide Inpatient Sample (NIS). The NIS is the largest Healthcare Cost and Utilization Project all-payer inpatient database, sponsored by the Agency for Healthcare Research and Quality. The NIS contains data from more than 8 million hospital discharges annually from 1050 hospitals located in 44 states, representing 95% of all US nonfederal hospital discharges.[11] The Agency for Healthcare Research and Quality has developed appropriately scaled discharge weights to generate national estimates of hospitalizations from the NIS.[12] These weights help compare hospitalization rates across years despite the varying number of states participating each year. The Healthcare Cost and Utilization Project validates the NIS for biases by comparing it with other population-based data sets.[13] In the present analysis, when more than 2% of the variables for a particular record had data missing at random, we excluded the record from the computations. No imputations were performed, and the data sets were reviewed for any systematically missing values and accordingly excluded from evaluation. Data reporting met the NIS data use agreement as established by the Healthcare Cost and Utilization Project. The NIS databases contain de-identified administrative level data and were not considered human subjects research and, hence, were exempted from review by the University of Virginia's human investigation committee.

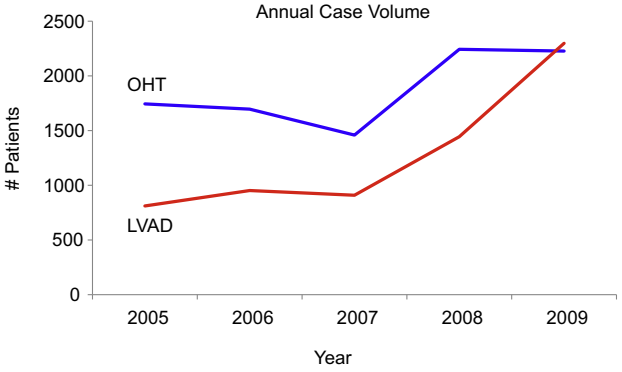


**FIGURE 1.** Treatment usage over time showing the number of patients undergoing either orthotopic heart transplantation (*OHT*) or left ventricular assist device (*LVAD*) implantation from 2005 to 2009.

### Patient Selection

Patients were identified based on whether they had been recipients of an OHT or an implantable LVAD. The patients were selected using the "International Statistical Classification of Diseases and Related Health Problems, 9th Revision, Clinical Modification" codes. All 15 procedure codes (PR1-PR15) were queried to identify patients having undergone operative procedures using the following "International Statistical Classification of Diseases and Related Health Problems, 9th Revision, Clinical Modification" codes: OHT, 37.5 (heart replacement procedures), 37.51 (heart transplantation), 33.6 (combined heart–lung transplantation); and LVAD, 37.66 (insertion of implantable heart assist system). Only patients older than 18 years of age were selected. Those with multiple procedural codes were assigned to the groups according to the first procedure code to avoid the possibility of double counting any patient record. The records were selected only once per any given group (according to the surgical procedure) and examined with the intent to perform a comprehensive analysis of the null hypothesis. Patient risk factors were assessed using 30 different Agency for Healthcare Research and Quality comorbidities.

### Total Charges and Cost-to-Charge

The total charges for each analyzed record were obtained from the Healthcare Cost and Utilization Project. Computations to calculate costs were completed by multiplying the total charges from the discharge record by the all-payer inpatient cost-to-charge ratio. These cost-to-charge ratios were calculated using annual reports by hospitals to the Centers for Medicare and Medicaid Services. The hospital-specific cost-to-charge was computed when available, and the weighted group average was used for calculations when the hospital-specific cost-to-charge was not available (approximately 11% of the time).

### Outcomes of Interest

Treatment usage, in-hospital mortality, cost, and discharge disposition after OHT and LVAD were our primary outcomes of interest. Complications were identified and limited to the hospital admission-recorded "International Statistical Classification of Diseases and Related Health Problems, 9th Revision, Clinical Modification" codes. Because the NIS contains