JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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PUBLISHED BY ELSEVIER

VOL. 67, NO. 16, 2016
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2016.02.025

ORIGINAL INVESTIGATIONS

Ventricular Assist Device in Acute Myocardial Infarction

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ABSTRACT

BACKGROUND Patients with acute myocardial infarction (AMI) complicated by acute heart failure or cardiogenic shock have high mortality with conventional management.

OBJECTIVES This study evaluated outcomes of patients with AMI who received durable ventricular assist devices (VAD).

METHODS Patients in the INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) registry who underwent VAD placement in the setting of AMI were included and compared with patients who received VAD for non-AMI indications.

RESULTS VAD were implanted in 502 patients with AMI: 443 left ventricular assist devices; 33 biventricular assist devices; and 26 total artificial hearts. Median age was 58.3 years, and 77.1% were male. At implantation, 66% were INTERMACS profile 1. A higher proportion of AMI than non-AMI patients had pre-operative intra-aortic balloon pumps (57.6% vs. 25.3%; $p < 0.01$), intubation (58% vs. 8.3%; $p < 0.01$), extracorporeal membrane oxygenation (17.9% vs. 1.7%, $p < 0.01$), cardiac arrest (33.5% vs. 3.3%, $p < 0.01$), and higher-acuity INTERMACS profiles. At 1 month post-VAD, 91.8% of AMI patients were alive with ongoing device support, 7.2% had died on device, and 1% had been transplanted. At 1-year post-VAD, 52% of AMI patients were alive with ongoing device support, 25.7% had been transplanted, 1.6% had left VAD explanted for recovery, and 20.7% had died on device. The AMI group had higher unadjusted early phase hazard (hazard ratio [HR]: 1.24; $p = 0.04$) and reduced late-phase hazard of death (HR: 0.57; $p = 0.04$) than the non-AMI group did. After accounting for established risk factors, the AMI group no longer had higher early mortality hazard (HR: 0.89; $p = 0.30$), but it had lower late mortality hazard (HR: 0.55; $p = 0.02$).

CONCLUSIONS Patients with AMI who receive VAD have outcomes similar to other VAD populations, despite being more critically ill pre-implantation. VAD therapy is an effective strategy for patients with AMI and acute heart failure or shock in whom medical therapy is failing. (J Am Coll Cardiol 2016;67:1871–80) © 2016 by the American College of Cardiology Foundation.

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Manuscript received February 8, 2016; accepted February 9, 2016.

ABBREVIATIONS AND ACRONYMS

AMI = acute myocardial infarction

AMI-CS = cardiogenic shock from acute myocardial infarction

BIVAD = biventricular assist device

ECMO = extracorporeal membrane oxygenation

HR = hazard ratio

IABP = intra-aortic balloon pump

LVAD = left ventricular assist device

MCS = mechanical circulatory support

MI = myocardial infarction

TAH = total artificial heart

TCS = temporary circulatory support

VAD = ventricular assist device

Acute myocardial infarction (AMI) is a common clinical problem with over a million cases annually in the United States alone (1). Improvements in management, particularly the paradigm of early revascularization, have improved the overall mortality after myocardial infarction (MI) to <5%. However, the most common cause of hospital mortality after MI, cardiogenic shock, complicates 8% to 12% of ST-segment elevation myocardial infarction and 5% of non-ST-segment elevation myocardial infarction and continues to have a high mortality of 40% to 50% (2,3). Most of these deaths are attributable to low cardiac output and end-organ dysfunction from left ventricular pump failure. Mechanical circulatory support has become an established therapy for end-stage chronic heart failure, but its role in shock or low-output states from AMI has not been well established. Patients with MI may not have sequelae of chronic heart failure, but may be more acutely ill, and the mode of deaths and complications in these patients after mechanical circulatory support (MCS) has not been evaluated in detail. The purpose of this study is to evaluate clinical characteristics and outcomes of patients who are supported with long-term ventricular assist devices (VAD) implanted in the setting of AMI.

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METHODS

DATA SOURCE. The INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) database is a prospective national registry of Food and Drug Administration-approved durable mechanical circulatory support devices implanted in the United States. Patient enrollment started on June 23, 2006, and, as of December 2014, there were 156 participating sites and 14,214 enrolled patients. INTERMACS is the only registry that satisfies the Joint Commission's requirement for a nationally audited registry for VAD and, until 2013, was the Center for Medicare Services-mandated registry for left ventricular assist device (LVAD) as destination therapy. Therefore, INTERMACS captures the vast majority of Food and Drug Administration-approved durable LVAD implants in the United States.

STUDY GROUP. All patients in the INTERMACS registry who received a durable continuous-flow LVAD with or without a right VAD, as well as patients who received a total artificial heart (TAH) were included in the study. Patients who had AMI as the admitting diagnosis or a major MI as a complication during hospitalization that resulted in VAD implantation (n = 502) were evaluated and compared with patients who underwent VAD implantation for non-AMI indications (n = 9,727).

DATA COLLECTION. Demographic, hemodynamic, severity of illness, and comorbidity data were collected at baseline. Routine follow-up data were collected at 1 week, 1 month, 3 months, 6 months, 12 months, 18 months, and every 6 months thereafter. Data on major adverse events was collected as the events occurred.

DEFINITIONS. The diagnosis of AMI was entered into the INTERMACS database on the basis of clinical and laboratory data at the implanting center. AMI was either the admitting diagnosis or a major complication during the hospitalization that resulted in VAD implantation. Adverse effects have been previously defined (4). The INTERMACS profiles 1 to 7 further characterize the severity of illness in advanced heart failure patients (5) (Online Table 1).

FOLLOW-UP. Follow-up for all study events was continued through March 31, 2014.

STATISTICAL ANALYSIS. Continuous variables were described with the median and interquartile range and compared using the nonparametric Mann-Whitney *U* test. Categorical variables were described with frequencies and compared using chi-square tests. Adverse event rates were calculated as events per 100 patient-months of follow-up and stratified as early (within 3 months of implantation) or late (>3 months post-implantation). Competing risk analysis was used to estimate the simultaneous time-related probabilities of patient outcomes. Parametric hazard modeling was used to evaluate the unadjusted and adjusted hazard ratios for early and late-phase mortality. The adjusted model contained risk factors identified in the 2014 INTERMACS annual report, including age, body mass index, mechanical ventilatory support, INTERMACS profile at the time of implantation, diabetes mellitus, dialysis at the time of implantation, creatinine level, right heart dysfunction, right VAD support, right atrial pressure, bilirubin, ascites, history of previous cardiac surgery, concomitant surgeries at the time of MCS, and destination therapy as implantation strategy (6). The INTERMACS Data Coordinating Center had access to primary data and performed all analyses. SAS