

Cryoablation during left ventricular assist device implantation reduces postoperative ventricular tachyarrhythmias

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Background: The number of patients undergoing implantation of a HeartMate II left ventricular assist device (LVAD; Thoratec Corporation, Pleasanton, Calif) is rising. Ventricular tachyarrhythmia (VA) after placement of the device is common, especially among patients with preoperative VA. We sought to determine whether intraoperative cryoablation in select patients reduces the incidence of postoperative VA.

Methods: From January 2009 through September 2010, 50 consecutive patients undergoing implantation of the HeartMate II LVAD were examined. Fourteen of these patients had recurrent preoperative VA. Of those patients with recurrent VA, half underwent intraoperative cryoablation (Cryo: n = 7) and half did not (NoCryo: n = 7). Intraoperatively, patients underwent localized epicardial and endocardial cryoablation via LVAD ventriculotomy. Cryothermal lesions were created to connect scar to fixed anatomic borders in the region of clinical VA. Demographics, risk factors, intraoperative features, and outcomes were analyzed to investigate the feasibility of cryoablation.

Results: Thirty-day mortality remained low (n = 1, 2%) among all LVAD recipients. There were no differences in risk factors between groups except that preoperative inotropes were less prevalent in Cryo patients ($P = .09$). Compared with NoCryo, the Cryo group had significantly decreased postoperative resource use and complications ($P < .05$). Recurrent postoperative VA did not develop in any of the Cryo patients ($P = .02$).

Conclusions: Postoperative VA can be minimized by preoperative risk assessment and intraoperative treatment. Localized cryoablation in select patients offers promising early feasibility when performed during HeartMate II LVAD implantation. Further prospective analysis is required to investigate this novel approach. (*J Thorac Cardiovasc Surg* 2013;145:1207-13)

Mechanical left ventricular assist devices (LVADs) have become accepted as an important therapeutic modality for patients with end-stage heart failure. Ventricular tachyarrhythmias (VAs) are common in patients supported with LVADs, with reported incidences ranging from 22% to 52%.¹⁻³ As LVAD technology, operative technique, and postoperative care improve, the duration of LVAD support is increasing in both bridge-to-transplant and destination therapy groups. Although tolerance of VAs in the LVAD population is improved compared with that of unsupported patients,⁴ VAs still contribute to mortality, hemodynamic instability, and prolonged hospitalization in LVAD recipients.¹ A standardized strategy for prevention and care of VAs is needed to maximize outcomes of patients supported by LVADs.

Given the high rate of postoperative VAs in LVAD-supported patients both at our institution and in the literature, we sought to develop a treatment strategy with the goal of limiting clinically significant postoperative VAs in LVAD recipients. A high failure rate was observed with attempts at catheter-based postoperative ablations; therefore, an intraoperative approach using cryoablation during LVAD placement was chosen. Patient selection for initial use of this novel treatment strategy focused on those deemed to be at highest risk for postoperative VAs. Patients with more than 1 episode of preoperative VA were selected to undergo targeted intraoperative epicardial and endocardial cryoablation at the time of LVAD placement. Initial results observed in several patients⁵ prompted further use of this approach and this study was performed as an early feasibility analysis of our novel technique.

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METHODS

Patients

This study was approved by the human investigation committee of the University of Virginia Health System (HSR 15225). All LVAD operations at our institution were entered prospectively into The Society of Thoracic Surgeons (STS) National Database. We retrospectively reviewed all patients at our institution undergoing placement of a HeartMate II LVAD (Thoratec Corporation, Pleasanton, Calif) from January 2009 to September 2010. Patient characteristics, demographics, risk factors, operative features, and postoperative outcomes were evaluated using a combination of

Abbreviations and Acronyms

Cryo	= cryoablation group
EP	= electrophysiology
ICU	= intensive care unit
LVAD	= left ventricular assist device
NoCryo	= no cryoablation group
STS	= The Society of Thoracic Surgeons
SVR	= surgical ventricular reconstruction
VA	= ventricular tachyarrhythmia

STS data and data obtained by review of inpatient and outpatient hospital records. With the exception of VA-related data points, we used known STS database definitions to describe all preoperative and operative variables as well as postoperative outcomes. VA was defined as more than 30 seconds of documented ventricular tachycardia or ventricular fibrillation as seen on a rhythm strip, electrocardiographic tracing, or implantable cardiac defibrillator readout. "Recurrent" preoperative or postoperative VA was defined as greater than 1 episode of documented VA present at any point before or after the LVAD operation. Of the 50 consecutive patients, 14 were identified as having recurrent preoperative VAs. These 14 patients, with multiple episodes of documented VA before LVAD placement, were separated for subgroup analysis to determine the early feasibility of intraoperative cryoablation in LVAD recipients with recurrent preoperative VA. In February 2010, the first patient in our series underwent intraoperative cryoablation at the time of LVAD implantation. All subsequent patients with a history of recurrent preoperative VA also underwent intraoperative cryoablation. Therefore, of the 14 patients with a history of recurrent VA, the latter 7 underwent intraoperative cryoablation (Cryo); the initial 7 did not (NoCryo). Subgroup analysis comparing these 2 groups of 7 patients was performed.

Operative Technique

Before LVAD implantation, an effort was made to identify the anatomic location of arrhythmogenic substrate in those patients selected for intraoperative cryoablation. Patients stable enough for transport to the electrophysiology (EP) laboratory ($n = 4$) underwent preoperative EP substrate mapping. In those patients not stable enough for transport ($n = 3$), electrocardiograms capturing ventricular tachycardia were systematically analyzed by a heart failure cardiologist, electrophysiologist, and cardiac surgeon to identify the approximate origin of arrhythmogenesis. Standard HeartMate II LVADs were then placed in all patients. After complete median sternotomy, the preperitoneal pocket was created to accommodate the LVAD pump and partial cardiopulmonary bypass was initiated. In patients undergoing intraoperative ablation, epicardial cryoablation was then performed using an AtriCure device (AtriCure, Inc, Cincinnati, Ohio) with a liquid nitrogen-cooled Cryo1 probe (AtriCure; Figure 1). Each preidentified site of arrhythmogenic substrate was ablated at -70°C for 2½ minutes. After epicardial ablation, full bypass was initiated, the aorta was crossclamped, and cardioplegic solution was administered. We opted to perform the endocardial ablation and LVAD placement on the arrested heart although these procedures can also be performed on the empty beating heart. The coring device was used to create a ventriculotomy for placement of the LVAD inflow cannula and the AtriCure device was again used with the Cryo1 probe for endocardial ablation via the previously performed ventriculotomy (Figure 1). For endocardial ablation in the arrested and nonperfused heart, we reduced cryoablation time to 2 minutes, again at -70°C . Appropriate loci for cryoablation were identified preoperatively after careful review of EP mapping studies and/or electrocardiograms by the heart failure cardiologist, electrophysiologist, and cardiac surgeon. To prevent

development of subsequent reentry circuits, we took care to ablate the previously identified arrhythmogenic site in addition to creating a surrounding ablation tract extending from the arrhythmogenic substrate to fixed anatomic sites such as the mitral valve and/or apical LVAD inflow cannula. Given the subsequent LVAD ventricular support, maximal ventricular preservation is not as vital and cryoablation was used liberally, especially when treating left ventricular lesions. In cases in which multiple or larger areas of arrhythmogenesis were identified preoperatively, large sections of ventricle underwent epicardial and endocardial cryoablation. No intraoperative or routine postoperative EP mapping was performed. After completion of the endocardial ablation, circumferential stitches were placed at the ventriculotomy, the LVAD inflow cannula was seated, and the remainder of the operation for standard LVAD placement proceeded as per usual.

Statistical Analysis

Our primary outcomes of interest were postoperative VA and recurrent postoperative VA. Secondary outcomes of interest included mortality and measures of resource use (ie, length of stay, intensive care unit (ICU) stay, and various complications). All group comparisons were unpaired. Bivariate comparisons with either the Pearson χ^2 or Fisher exact tests were used for all categorical variables. Analysis of variance was used for all continuous variables. Categorical variable comparisons are expressed as percentages of each group of origin. Continuous variables are reported as mean \pm standard error of the mean. Reported P values are 2-tailed. Data manipulation and analysis were performed with SPSS software (version 19; SPSS Inc, an IBM Company, Chicago, Ill).

RESULTS**Comparison of Patient Characteristics and Operative Features**

A total of 50 patients underwent HeartMate II LVAD placement between January 2009 and September 2010. Of these, 54% ($n = 27$) had the LVAD placed before the index intraoperative cryoablation case in February 2010 (Pre-Index) and 46% ($n = 23$) underwent LVAD implantation after that index case (Post-Index). Comparing the Pre-Index and Post-Index groups, there were minimal differences in patient demographics, risk factors, preoperative characteristics, or operative features (Table 1). Both groups were predominantly male, had a mean age in the 50s, had mainly nonischemic cardiomyopathy, and had similar preoperative risk factors. Pre-Index patients had a higher incidence of preoperative inotrope use (96% vs 70%; $P = .01$) but no other significant differences existed between groups. Notably, both groups had a high rate of documented preoperative ventricular arrhythmias (Pre-Index, 50.3%; Post-Index, 69.6%; $P = .45$). As previously mentioned, 14 of 50 total patients had a history of recurrent preoperative VA (multiple documented episodes of VA before LVAD placement) and were selected for subgroup analysis. Seven of these patients were seen before the index case and did not undergo cryoablation (NoCryo); 7 of these patients were seen after development of the protocol and thus underwent intraoperative cryoablation in conjunction with their LVAD implantation (Cryo).

Subgroup comparison of the NoCryo and Cryo groups revealed a similarly homogeneous population. No statistically significant differences were found between groups with

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