# Limited Utility of Tricuspid Valve Repair at the Time of Left Ventricular Assist Device Implantation

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*Background.* **The optimal management of tricuspid regurgitation (TR) in patients undergoing left ventricular assist device (LVAD) implantation is controversial. This study was undertaken to determine the impact of tricuspid valve repair (TVR) at the time of LVAD implantation on survival.**

*Methods.* **The Interagency Registry for Mechanically Assisted Circulatory Support was used to analyze the outcomes of patients undergoing LVAD implantation as destination therapy with or without concomitant TVR.**

*Results.* **Among 2,527 patients undergoing implant of a continuous flow LVAD as destination therapy during the study period, 989 (39%) had moderate or severe TR. The management of TR was not uniform among these patients. Patients with moderate and severe TR underwent TVR in 16.7% and 35.3% of cases, respectively. Moderate and severe TR at the time of LVAD implantation were associated with poorer survival over the entire follow-up period ($p = 0.009$). Interestingly, TVR at the time of LVAD implantation did not confer improved survival, even among patients with preimplant moderate or severe TR. A potential explanation for this finding is that patients with preimplant moderate or severe TR who underwent LVAD implant with concomitant TVR commonly experienced recurrent, late TR (21% to 27%).**

*Conclusions.* **Tricuspid valve repair is performed commonly at the time of LVAD implant despite the fact that it does not confer a clear survival benefit. For many patients, LVAD implant alone relieves preimplant TR as effectively as LVAD implant with TVR. Further study is necessary to determine what factors lead to recurrence of late TR in LVAD patients both with and without TVR.**

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Implantation of left ventricular assist devices (LVADs) is an established treatment for patients with end-stage heart failure. Smaller second- and third-generation LVADs have been associated with reduced complications, including bleeding and infections, as well as with improved quality of life [1–3]. The complication of right ventricular failure, however, continues to occur in a substantial proportion of LVAD recipients and is associated with reduced survival. Right ventricular failure persists as an important obstacle to long-term survival after LVAD implantation in these patients [4, 5].

Functional tricuspid regurgitation (TR) frequently accompanies right ventricular failure in LVAD patients as a result of structural changes that occur in the failing right ventricle [6–9]. The treatment of TR with tricuspid valve annuloplasty at the time of LVAD implantation has been identified as a potential means to reduce the frequency and implications of right ventricular failure after LVAD implantation [6, 10–12]. A number of single-center reports have demonstrated the safety of concomitant tricuspid valve annuloplasty at early follow-up [10–12]. The long-term effects of this procedure, however, are unknown, and a great deal of practice variation persists among heart failure centers. In this study, we examined the utilization of tricuspid valve repair (TVR) at the time of LVAD implantation in the United States and the effect of this concomitant procedure on TR and survival at long-term follow up.

## Material and Methods

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) was used. INTERMACS is a national registry for patients who have

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**Abbreviations and Acronyms**

INTERMACS = Interagency Registry for Mechanically Assisted Circulatory Support
LVAD = left ventricular assist device
TR = tricuspid regurgitation
TVR = tricuspid valve repair

received a durable mechanical circulatory support device that has been approved by the US Food and Drug Administration [13].

A total of 127 institutions were enrolled in INTERMACS from June 23, 2006, through March 31, 2013, and submitted data during this time frame. Each hospital had current approval from its institutional review board, and each patient signed an informed consent. This study analyzed data obtained from adult patients who received a primary continuous-flow LVAD with the device strategy of destination therapy at the time of implant.

Preimplant data were analyzed using basic summary statistics, and group comparisons were made using one-way analysis of variance, Student's $t$ test, and $\chi^2$ test of association. Time-related event data were analyzed using Kaplan-Meier methodology, and group comparisons were made with the log-rank test (note that the log-rank test is a univariate Cox proportional hazard test).

The effect of tricuspid valve regurgitation and tricuspid valve intervention on survival was made in both a univariate and multivariate fashion by a parametric hazard regression analysis. The adjusted effect of these variables was assessed after adjustment for significant preimplant variables. These variables are included in Appendix 1 (risk factors examined).

## Results

The INTERMACS was queried to identify subjects who had undergone primary implant of a continuous-flow LVAD during the study period. Patients 18 years and younger were excluded. Because the focus of the study was on the long-term outcomes of LVAD patients with TR, only patients receiving an LVAD as destination therapy at the time of surgery were included in the study. Among 8,609 INTERMACS patients undergoing primary implantation during the study period, there were 2,527 patients who fit the study criteria. Tables 1 and 2 show the categorical and continuous variables of the study population.

Figure 1 depicts the competing outcomes of survival on LVAD support, death, transplantation, and myocardial recovery. At 1-year follow-up, 71% of study patients were surviving on support, 24% were dead, 4% had undergone a transplantation, and 1% had an LVAD explant owing to native myocardial recovery. Our intent was to have a limited number of patients undergo transplantation during the follow-up period to assess the impact of TR on

*Table 1. Preimplant Characteristics of the Study Population for Categorical Variables*

| Preimplant Characteristic | Total N | Percent |
|---|---|---|
| Male | 2,527 | 81.76 |
| White | 2,527 | 74.32 |
| Married | 2,477 | 71.78 |
| College | 1,945 | 50.08 |
| Diabetes | 2,519 | 27.15 |
| Inotropic agents | 2,508 | 78.83 |
| Ascites | 2,292 | 6.81 |
| COPD | 2,476 | 11.35 |
| INTERMACS patient profile level 1: critical cardiogenic shock | 2,527 | 10.45 |
| INTERMACS patient profile level 2: progressive decline | 2,527 | 35.42 |
| INTERMACS patient profile level 3 | 2,527 | 31.86 |
| INTERMACS patient profile level 4 | 2,527 | 16.38 |
| INTERMACS patient profile level 5 | 2,527 | 3.60 |
| INTERMACS patient profile level 6 | 2,527 | 1.39 |
| INTERMACS patient profile level 7 | 2,527 | 0.91 |
| Destination therapy | 2,527 | 100.00 |
| NYHA functional class 4 | 2,358 | 81.47 |
| Coronary artery disease | 2,510 | 7.41 |
| Cerebrovascular accident | 2,470 | 5.30 |
| Transient ischemic attack | 2,470 | 2.96 |
| Cancer | 2,506 | 8.10 |
| Current smoker | 2,443 | 7.04 |
| Current drug abuse | 2,383 | 1.43 |
| Alcohol abuse | 2,446 | 9.65 |
| Blood type O | 2,471 | 44.88 |
| Rheumatologic disease | 1,424 | 3.93 |
| Hepatitis B | 1,341 | 1.34 |
| Hepatitis C | 1,339 | 2.91 |
| Dialysis | 2,527 | 1.42 |
| History of coronary artery bypass | 2,527 | 34.39 |
| History of valve surgery | 2,527 | 9.14 |
| Implantable cardioverter defibrillator | 2,503 | 84.26 |
| Intraaortic balloon pump | 2,527 | 22.83 |
| Ventilator | 2,527 | 4.51 |
| Peripheral vascular disease | 1,427 | 11.00 |
| Carotid artery disease | 1,377 | 13.80 |
| β-Blockers | 2,447 | 79.28 |
| Angiotensin-converting enzyme inhibitor | 2,356 | 47.11 |
| Mitral regurgitation (moderate/severe) | 2,194 | 59.25 |
| Tricuspid regurgitation (moderate/severe) | 2,160 | 45.79 |
| Aortic regurgitation (moderate/severe) | 2,057 | 5.69 |
| Left ventricular ejection fraction (<0.20) | 2,226 | 66.76 |
| Right ventricular ejection fraction (severely reduced) | 1,352 | 16.72 |
| Concomitant surgery | 2,527 | 40.48 |
| Failure to wean[a] | 2,527 | 0.83 |
| Extracorporeal membrane oxygenation | 2,527 | 1.35 |
| Patient profile modifier TCS | 1,964 | 19.60 |

[a] Failure to wean is defined as the inability to wean from cardiopulmonary bypass during other cardiac surgical procedure.

COPD = chronic obstructive pulmonary disease; INTERMACS = Interagency Registry for Mechanically Assisted Circulatory Support; NYHA = New York Heart Association; TCS = temporary circulatory support.