Published in final edited form as:

J Card Surg. 2019 December ; 34(12): 1511–1518. doi:10.1111/jocs.14275.

Hemodynamics of concomitant tricuspid valve procedures at LVAD implantation

Teruhiko Imamura, MD, PhD¹, Nikhil Narang, MD¹, Jerry Nnanabu, MD¹, Daniel Rodgers, BA¹, Jayant Raikhelkar, MD¹, Sara Kalantari, MD¹, Bryan Smith, MD¹, Ann Nguyen, MD¹, Ben Chung, MD¹, Takeyoshi Ota, MD, PhD², Tae Song, MD², Valluvan Jeevanandam, MD², Gene Kim, MD¹, Gabriel Sayer, MD¹, Nir Uriel, MD, MSc¹

¹Department of Medicine, University of Chicago Medical Center, Chicago, Illinois

²Department of Surgery, University of Chicago Medical Center, Chicago, Illinois

Abstract

Background—Tricuspid regurgitation (TR) is common in patients receiving left ventricular assist device (LVAD) implantation. The current literature is conflicting regarding the effects of concomitant tricuspid valve repair (TVR) at LVAD implantation. We investigated the hemodynamic effects of concomitant TVR at LVAD implantation.

Methods—Consecutive clinically stable LVAD outpatients who underwent hemodynamic ramp testings were enrolled in this study, and they were stratified by concomitant TVR. Results of hemodynamic ramp tests were compared between the TVR group and the non-TVR group.

Results—Among 65 LVAD patients undergoing ramp tests, 34 patients had received TVR, and 31 had not. There were no significant differences in baseline characteristics between two groups except for higher degree of TR and lower pulmonary artery pulsatility index in the TVR group ($P < .05$ for both). Following LVAD implantation, the degree of TR improved significantly in the TVR group down to the comparable level with the non-TVR group. During ramp tests, the TVR group had steeper cardiac index slope (0.14 ± 0.12 vs 0.07 ± 0.07 L/min/m²/step, $P = .002$) and higher cardiac index at set LVAD speed (2.99 ± 0.84 vs 2.52 ± 0.42 L/min/m², $P = .007$).

Conclusions—Concomitant TVR improves cardiac output and its response to LVAD speed change following LVAD implantation. Longitudinal clinical implications of such hemodynamic changes are unknown.

Keywords

heart failure; right ventricular failure; tricuspid regurgitation

Correspondence: Teruhiko Imamura, MD, PhD, FESC, FAHA, FACC, FJCC, Department of Medicine, University of Chicago Medical Center, 5841S Maryland Avenue, Chicago, IL 60637. te.imamu@gmail.com.

CONFLICT OF INTERESTS

G.S. is a consultant for Medtronic. Other authors declare that there are no conflict of interests.

1 | INTRODUCTION

Functional tricuspid regurgitation (TR) with a dilated annulus is often encountered in patients with advanced heart failure (HF).¹ Right ventricular (RV) dysfunction secondary to left ventricular (LV) failure results in RV cavity enlargement and tricuspid annulus dilation. Secondary pulmonary hypertension due to LV failure also contributes to worsening TR.¹ The presence of intracardiac pacing leads, often used in patients with advanced HF, inhibits the coaptation of tricuspid valve and worsens TR.² The worsening of TR subsequently results in progression of RV failure due to increased RV preload on.³

Recently, continuous-flow left ventricular assist devices (LVADs) have improved survival in adequately selected patients with advanced HF.⁴ However, preoperative moderate or greater TR still remains as an unsolved matter, and is a strong risk factor for postoperative mortality.^{5,6} Moderate or greater TR may not normalize following LVAD implantation and often contributes to postimplant RV dysfunction.⁷ It might therefore reasonable to consider interventions at LVAD implantation to address moderate or greater TR in hopes of improving postoperative clinical outcomes.

Prior reports have demonstrated an attenuation of early RV dysfunction with concomitant tricuspid valve repair (TVR) at the time of LVAD implantation.^{8,9} There have also been contrasting reports demonstrating no long-term benefits of concomitant TVR.¹⁰ Our team recently demonstrated that hemodynamics obtained during ramp studies have a considerable impact on clinical outcomes¹¹—it is unknown, however, if concomitant TVR is associated with a long-term hemodynamic benefit as determined through ramp studies. In this study, we investigated the relationship between concomitant TVR and post-LVAD hemodynamics obtained during hemodynamic ramp testing.

2 | METHODS

2.1 | Patient selection

Clinically stable LVAD outpatients underwent the previously described hemodynamic ramp study as part of our routine institutional follow-up protocol between May 2014 May and Feb 2017 and were followed for 1 year afterward.¹² Some of them had received concomitant TVR at time of LVAD implantation performed by either of two attending surgeons and were assigned to the TVR group whereas others were assigned to the non-TVR group. The indication of TVR was moderate or greater TR at time of LVAD implantation, which was determined by the attending surgeons. Most of TVRs were DeVega annuloplasty dictated by the surgeons' preference.¹³ In brief, a double-layer suture annuloplasty was performed using a pledged 2-0 polypropylene suture with the annuloplasty sized to a 26-mm size. Others were ring annuloplasty according to the standard procedure. Aorta was cross clamped at both surgeries. All patients received guideline-directed follow-up management.¹⁴ The study protocol was approved by the Institutional Review Board. All data were retrospectively collected from the electronic medical record.

2.2 | Ramp test protocol

Patients underwent a hemodynamic ramp study following LVAD implantation while clinically stable in the ambulatory setting.¹² Echocardiographic and hemodynamic variables were measured at first at baseline LVAD speed. Then, similar variables were measured at each incremental LVAD speed from the lowest LVAD speed to the highest LVAD speed. The attending cardiologists determined the set LVAD speed with a target of optimized hemodynamics: central venous pressure <12 mm Hg, pulmonary capillary wedge pressure <18 mm Hg, and cardiac index (CI) >2.2 L/min/m².¹² Speed-dependent changes in hemodynamic variables were expressed as slopes, which were defined as the change of variables per step over the entire range of LVAD speeds.¹⁵ All patients were followed at set LVAD speeds following the ramp tests.

2.3 | Variables evaluated

The grading of the valve regurgitation was conducted in accordance with the guidelines of American Society of Echocardiography: 0, none; 1, trace; 2, mild; 3, mild-to-moderate; 4, moderate; 5, moderate-to-severe; 6, severe.¹⁶ Transthoracic echocardiography was performed just before LVAD implantation and at 1 year following LVAD implantation as well as during ramp tests. Transesophageal echocardiography was performed intraoperatively (at the end of surgery) during LVAD implantation. During the ramp test, echocardiographic right ventricular function was additionally assessed. Death, HF, and other adverse events including gastrointestinal bleeding, according to the definition of International Society for Heart and Lung Transplantation, were counted during the 1-year observational period following the ramp test.

2.4 | Statistical analyses

Two-sided $P < .05$ were considered statistically significant. Continuous variables with normal distribution were compared between groups using unpaired t test, and those with non-normal distribution were compared between groups using the Mann-Whitney U test. Categorical variables were compared between groups using Fisher's exact test. Trends in the degree of TR were compared by using Friedman test as a whole and Wilcoxon signed-rank test as a pair. The slope was calculated as a change of variable per step of LVAD speed as detailed previously.¹⁵ Freedom from death or HF readmission were analyzed by Kaplan-Meier analyses and compared by using log-rank test.

3 | RESULTS

3.1 | Baseline characteristics at ramp test

Among 78 LVAD patients who received ramp tests, 13 were excluded due to the following reasons: one for the device malfunction; 10 for the lack of pre-LVAD hemodynamic data; two for the history of prior TVR. A total of 65 LVAD patients (60.3 ± 10.4 years old and 40 male) were enrolled (Table 1). Ramp tests were performed at a median of 205 (99, 653) days following LVAD implantation.

Of them, 31 (52%) patients had received concomitant TVR, whereas 34 had not. There were no significant differences in pre-LVAD baseline characteristics between two groups except

for higher degree of TR and lower pulmonary artery pulsatility index in the TVR group compared with the non-TVR group ($P < .05$ for both). Cardiopulmonary bypass time was significantly longer in the TVR group compared with the non-TVR group (184 ± 51 vs 129 ± 37 minutes, $P < .001$). Postoperative inotrope duration and rate of early right ventricular failure in the TVR group was not statistically different compared with the non-TVR group (9.3 ± 3.5 vs 8.2 ± 3.6 days, 25% vs 22%; $P > .05$ for both).

3.2 | Trends of TR before and after LVAD implantation

Among TVR group, 3/31 patients had moderate-to-severe TR and 28/31 had severe TR before LVAD implantation; whereas all non-TVR group patients had TR graded less than moderate before LVAD implantation (Table 2). Most of TVRs (88%) were DeVega annuloplasty,¹³ and others (12%) were ring annuloplasty. Nobody received a valve replacement. Of the four patients with DeVega annuloplasty, two were HeartMate II and other two were HVAD. Of 27 with ring annuloplasty, 19 were HeartMate II and other eight were HVAD.

The trends of TR grade are shown in Figure 1. Following concomitant TVR with LVAD implantation (red bars), TR grade decreased significantly ($P < .05$). After 1 year, TR grade worsened again up to 1.6 ± 1.4 ($P < .05$). There was no statistically significant difference in 1-year TR grade between the two TVR procedures (DeVega annuloplasty vs ring annuloplasty, $P = .14$). Among non-TVR group, TR grade remained unchanged following LVAD implantation alone ($P > .05$). After 1 year, TR grade increased up to 1.4 ± 1.5 , though did not reach statistical significance ($P = .081$). Although pre-LVAD TR grade was significantly higher in the TVR group ($P < .05$), TR grades at 1 year following LVAD implantation were statistically comparable to the non-TVR group ($P > .05$).

Overall, 7/65 patients (three in TVR group and four in non-TVR group) had TRs graded more than or equal to four (ie, moderate or greater) at 1 year following LVAD implantation (Figure 2). Particularly, 2/4 in the non-TVR group experienced de novo moderate TRs at 1 year despite both had no TR preoperatively.

3.3 | Hemodynamics and echocardiographic characteristics during ramp tests

At time of ramp testing, aspirin use and prothrombin time-international normalized ratio in the TVR group were not statistically different compared with the non-TVR group (75% vs 79% and 2.2 ± 0.3 vs 2.1 ± 0.3 ; $P > .05$ for both). During hemodynamic ramp testing, there were no significant differences in the slope parameters except for the higher CI slope in the TVR group compared with the non-TVR group (0.14 ± 0.12 vs 0.07 ± 0.07 L/min/m²/step; $P = .002$; Table 3). The post-ramp study set speed significantly increased from baseline ($P < .05$ for both). CI was significantly higher in the TVR group compared with the non-TVR group (2.99 ± 0.84 vs 2.52 ± 0.42 L/min/m², $P = .007$; Table 3).

Right ventricular function assessed by echocardiography did not significantly differ between the two groups ($P > .05$ for all; Appendix Table A1). Hemodynamic parameters of right ventricular function at set LVAD speed including central venous pressure/pulmonary capillary wedge pressure and pulmonary artery pulsatility index were also not statistically different between two groups ($P > .05$ for both).

3.4 | Clinical outcomes stratified by the concomitant TVR

Nine patients died and one patient received a heart transplantation during the 1-year observational period. One-year survival free from HF readmission in the TVR group comparable to the non-TVR group (56% vs 45%, $P = .30$; Figure 3). Event rates of comorbidities including gastrointestinal bleeding, stroke, ventricular tachyarrhythmia, driveline infection, and pump thrombosis were statistically comparable between two groups ($P > .05$ for all; Figure 4). Also, there were no statistically significant differences in the event rates of these comorbidities between the DeVega annuloplasty and ring annuloplasty group ($P > .05$ for all). No patients had atrial-ventricular block that required pacemaker implantation.

4 | DISCUSSION

We investigated the postoperative hemodynamic implications and 1-year clinical outcomes of concomitant TVR at LVAD compared with the non-TVR group. Our main findings are as follows: (a) Post-LVAD TR grade in the TVR group was statistically comparable with the non-TVR group, although TVR group had more severe TR preoperatively. (b) CI at set LVAD speed and its response to incremental LVAD speed were both higher in the TVR group. (c) Despite worse pre-implantation RV dysfunction with lower pulmonary artery pulsatility index, patients undergoing TVR had equivalent survival outcomes, and RV functional parameters postimplantation were approximately equivalent to those who did not undergo TVR.

4.1 | Natural history of TR following LVAD implantation without TVR

LVAD implantation alone does not improve pre-existing TR.⁷ Although secondary pulmonary hypertension improves following LVAD implantation in many cases,¹⁷ enhanced systemic flow and maladaptive RV geometric changes due to the leftward shift of the interventricular septum can worsen RV function and increase TR following LVAD implantation.¹⁸ In the non-TVR group, TR tended to worsen, albeit not reaching statistical significance, after LVAD implantation. It is known that significant TR has is intricately associated with the development of RV dysfunction and other comorbidities during LVAD support.^{5,7,19,20} This is a rationale why TVR is considered in patients with significant preoperative TR, although there has is definite evidence and guideline direction to support this strategy.

4.2 | Impact of concomitant TVR on hemodynamics

Most of the prior analyses of concomitant TVR have used large databases and focused on survival. To our knowledge, this is the first study to address the impact of concomitant TVR on hemodynamics and LVAD performance. Hemodynamic optimization following LVAD implantation is associated with improved patient quality of life and a reduction in comorbidities.¹¹ The hemodynamics of this study cohort improved significantly following LVAD implantation irrespective of concomitant TVR. Two important considerations, however, are worth noting:

1. RV function: RV dysfunction is both a cause and result of TR.³ Consistently, patients in the TVR group had TR graded as moderate or greater and lower pulmonary artery pulsatility index before LVAD implantation. Following concomitant TVR and LVAD implantation, echocardiographic RV functions and pulmonary artery pulsatility index improved to comparable level in the non-TVR group. Concomitant TVR may reduce preload of RV, prohibit inappropriate geometric change in RV, and terminate the vicious cycle of worsening of RV dysfunction and TR.
2. Cardiac output: Patients in the TVR group had higher CI and better augmentation of CI in response to LVAD speed changes, which may suggest that the TVR enhances the function of the LVAD. We do not have detailed echocardiographic data of TR and RV function during ramp testing, but TVR may prevent worsening of RV function and progression of TR at incremental LVAD speed and contribute to improving cardiac output. However, three-dimensional echocardiographic assessment recently demonstrated that RV function worsens and RV cavity enlarges following incremental LVAD speed changes, after reaching a patient-specific cross-point.²¹ More prospective studies with both simultaneous hemodynamics and RV-specific imaging are needed to better understand functional and structural changes in response to speed changes in patients with TVR following LVAD implant.

4.3 | Implication of concomitant TVR on long-term clinical outcomes

Incidence of comorbidities were statistically comparable between two groups, although the rates of gastrointestinal bleeding and pump thrombosis were numerically lower in the TVR group. More enhanced systemic circulation may suppress the activity of chronic inflammation associating with the formation of arteriovenous malformation.^{22,23} Also, enhanced cardiac output may enhance blood wash out in the pump, preventing the formation of clot.

4.4 | Future studies and study limitations

This study is not without limitations. This is a moderate-sized, single-center study which is retrospective in nature. The significant difference in pre-LVAD degree of TR, although there are no statistical differences in other background characteristics, makes comparing outcomes of TVR vs no TVR a challenge. Considering the current guidelines statement (Class IIa),¹⁴ it may be unethical to allow significant TR at the time of LVAD implantation untouched, making complete background matching between TVR vs non-TVR interventions very challenging. Recurrence of TR following TVR is a major concern. Song et al. hypothesized a recurrence of TR as a reason why concomitant TVR had no survival advantage.¹⁰ In this study, the degree of TR progressed at 1 year following concomitant TVR. However, most of the cases (27/31) remained mild or less. TR tended to worsen also in the non-TVR group although to non-significant levels. Furthermore, all patients in the TVR group except for one avoided recurrence of TR when their TRs diminished intraoperatively. Long-term echocardiographic observation is warranted. We used DeVega annuloplasty in most of cases

given our previous report demonstrating its durability, shorter operative time, and lower medical cost.¹³

Interestingly, 2/34 experienced de novo moderate TR following LVAD implantation alone despite they had no TR preoperatively. In other words, concomitant TVR might be required also for some specific patients without significant TR preoperatively. Optimal patient selection instead of just using the degree of TR may be warranted.

This study has several limitations similar to our previous ramp test studies.¹² Clinically stable LVAD outpatients received ramp test, but there may be selection bias. The timing of ramp test varied, which may affect the clinical outcome, although we previously demonstrated that the timing of ramp test did not affect clinical outcomes.²⁴ We do not have TR data during ramp test, whether TVR prevent worsening of TR at incremental LVAD speed remains unknown.

5 | CONCLUSION

The TVR group had higher CI at set LVAD speed and higher response of CI at incremental LVAD speed compared with the non-TVIR group. The clinical implications of this impact on hemodynamics warrants further investigation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ACKNOWLEDGMENT

N.U. receives grant support from Abbott and Medtronic; G.S. is a consultant for Medtronic.

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FIGURE 1.

The trend of tricuspid regurgitation (TR) grade following left ventricular assist device (LVAD) implantation in the tricuspid valve repair (TVR) group and non-TVR group. * $P < .05$ compared with the non-TVR group at the similar timing by using the Mann-Whitney U test; † $P < .05$ compared with the pre-LVAD variables by using Wilcoxon signed-rank test and Friedman test

FIGURE 2.

The trend of tricuspid regurgitation (TR) grade among those who experienced TR with moderate or greater degree at 1 year following left ventricular assist device (LVAD) implantation. A red dotted line indicates moderate degree of TR in the first year. *Two patients in the non-TVR group who experienced TR with moderate or greater degree despite no pre-LVAD TR

FIGURE 3.

Survivals free from heart failure (HF) readmission following ramp test in the tricuspid valve repair (TVR) group and the non-TVR group

FIGURE 4.

Event rate comparisons between the TVR group non the non-TVR group. * $P < .05$ between two groups by the Mann-Whitney U test. DLI, driveline infection; GIB, gastrointestinal bleeding; PT, pump thrombosis; TVR, tricuspid valve repair; VT, ventricular tachyarrhythmia

TABLE 1

Baseline characteristics

	Total (N = 65)	TVR group (N = 31)	Non-TVIR group (N = 34)	P value
Demographics				
Age, years	60.3 ± 10.4	58.0 ± 9.3	62.4 ± 11.0	.09
Male gender	40 (62%)	20 (65%)	20 (59%)	.42
Body mass index	30.1 ± 7.1	30.7 ± 7.7	29.6 ± 6.6	.52
Caucasian race	35 (54%)	15 (48%)	20 (59%)	.59
Ischemic etiology	43 (66%)	22 (71%)	21 (62%)	.30
Destination therapy	52 (80%)	26 (84%)	26 (76%)	.46
Devices				
HeartMate II	44 (68%)	21 (68%)	23 (68%)	.60
HVAD	21 (32%)	10 (32%)	11 (32%)	.60
Comorbidity				
Diabetes mellitus	24 (37%)	10 (32%)	14 (41%)	.31
Atrial fibrillation	24 (37%)	11 (35%)	13 (38%)	.51
History of stroke	12 (18%)	5 (16%)	7 (21%)	.45
Chronic obstructive pulmonary disease	11 (17%)	4 (13%)	7 (21%)	.31
Echocardiography				
Left ventricular diastolic diameter, cm	7.38 ± 1.21	7.39 ± 1.23	7.36 ± 1.21	.93
Tricuspid regurgitation degree	3.7 ± 2.3	5.9 ± 0.3	1.6 ± 1.1	<.001*
Diastolic tricuspid annular diameter, mm	38 ± 10	45 ± 12	33 ± 8	<.001*
Hemodynamics				
CVP, mm Hg	11.5 ± 6.9	12.6 ± 5.3	10.4 ± 8.2	.21
PCWP, mm Hg	23.7 ± 8.6	25.4 ± 7.5	22.1 ± 9.4	.12
CI, L/min/m ²	1.94 ± 0.68	1.85 ± 0.67	2.01 ± 0.69	.35
Pulmonary vascular resistance, WU	3.92 ± 3.03	4.51 ± 3.30	3.38 ± 2.69	.13
Pulmonary artery pulsatility index	3.96 ± 5.88	2.47 ± 1.28	5.37 ± 7.90	.045*
Ramp timing, days	205 (99, 654)	188 (76, 644)	214 (124, 698)	.22

Note: Continuous variables were compared by using unpaired *t* test or the Mann-Whitney U test as appropriate. Categorical variables were compared by using Fischer's exact test.

Abbreviations: CI, cardiac index; CVP, central venous pressure; PCWP, pulmonary capillary wedge pressure; TVR, tricuspid valve repair.

$P < .50$
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TABLE 2

Pre-LVAD degree of TR and performed valve procedure

	TVR group (N = 31)	Non-TV group (N = 34)
TR grade		
None	0 (0%)	7 (23%)
Trace	0 (0%)	6 (19%)
Mild	0 (0%)	18 (48%)
Mild-to-moderate	0 (0%)	3 (10%)
Moderate	0 (0%)	0 (0%)
Moderate-to-severe	3 (9%)	0 (0%)
Severe	28 (91%)	0 (0%)
Valve procedure		
DeVega annuloplasty	27 (88%)	—
Ring annuloplasty	4 (12%)	—
Replacement	0 (0%)	—

Abbreviations: LVAD, left ventricular assist device; TR, tricuspid regurgitation; TVR, tricuspid valve repair.

TABLE 3

Echocardiographic and hemodynamic variables during ramp test

	TVR group (N = 31)	Non-TVV group (N = 34)	P value
Slope parameters			
LVDd slope, cm/step	-0.18 ± 0.12	-0.14 ± 0.08	.069
CVP slope, mm Hg/step	-0.24 ± 0.22	-0.16 ± 0.58	.54
PCWP slope, mm Hg/step	-1.05 ± 0.68	-1.23 ± 0.96	.41
CI slope, L/min/m ² /step	0.14 ± 0.12	0.07 ± 0.07	.002*
Parameters at set LVAD speed			
HeartMate II LVAD speed	9379 ± 410	9348 ± 432	.81
HVAD LVAD speed	2714 ± 131	2696 ± 163	.79
LVDd, cm	5.93 ± 0.90	5.81 ± 1.45	.69
CVP, mm Hg	9.7 ± 5.5	7.7 ± 5.1	.12
PCWP, mm Hg	13.0 ± 5.1	12.7 ± 5.6	.81
CI, L/min/m ²	2.99 ± 0.84	2.52 ± 0.42	.007*
CVP/PCWP	0.95 ± 0.26	0.64 ± 0.37	.18
Pulmonary vascular resistance, WU	1.21 ± 1.30	1.13 ± 0.70	.74
Pulmonary artery pulsatility index	3.19 ± 3.52	4.52 ± 4.93	.18
Optimal hemodynamics	18 (58%)	20 (59%)	.58

Note: Continuous variables were compared by using unpaired *t* test or the Mann-Whitney *U* test as appropriate. Categorical variables were compared by using Fischer's exact test.

Abbreviations: CI, cardiac index; CVP, central venous pressure; LVAD, left ventricular assist device; LVDd, left ventricular diastolic diameter; PAP, pulmonary artery pressure; PCWP, pulmonary capillary wedge pressure.

* *P* < .05.