Utility of concomitant tricuspid valve procedures for patients undergoing implantation of a continuous-flow left ventricular device

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Objective: Patients referred for implantable continuous-flow left ventricular assist devices (cfLVAD) frequently have preoperative right heart failure and tricuspid regurgitation (TR). The objective of this report is to examine early clinical benefits of concomitant tricuspid surgery for these patients.

Methods: Sixty-one of 200 consecutive cfLVAD patients at our institution displayed preimplant right heart dysfunction and significant TR. Thirty-three underwent cfLVAD plus a tricuspid valve procedure (TVP), and 28 had cfLVAD alone. Preimplant characteristics and clinical outcomes were retrospectively studied. As previously described, post-LVAD right ventricular failure was defined as need for right ventricular assist device (RVAD) support or greater than 14 days of intravenous inotropic support.

Results: Preimplant characteristics were similar between the 2 groups. Cardiopulmonary bypass time was increased for the group that received concomitant TVPs. The most common TVP consisted of an undersizing ring annuloplasty. The cfLVAD-alone group had greater TR after implant relative to the cfLVAD+TVP group. The cfLVAD-alone group experienced greater postprocedure right ventricular failure relative to cfLVAD+TVP (46.4% vs 18.2%; $P < .05$). Furthermore, prolonged hospitalization was increased for the cfLVAD-alone group versus the cfLVAD+TVP. Survival was similar between the 2 groups.

Conclusions: Concomitant TVP appears to reduce postprocedure right ventricular failure for patients with significant TR undergoing cfLVAD implantation. (J Thorac Cardiovasc Surg 2012;144:1217-21)

Patients referred for support with an implantable left ventricular assist device (LVAD) frequently have right ventricular (RV) failure in addition to left heart failure. Some of these patients continue to manifest RV failure after LVAD implantation, which results in the need for RV assist device (RVAD) support or prolonged intravenous inotropic agent support. The advent of continuous-flow designs for LVAD pumps has resulted in reduced post-LVAD RV failure, but this complication continues to affect more than 20% of patients in recent LVAD trials.¹ Furthermore, the presence of post-LVAD RV failure, even in patients with continuous-flow LVADs (cfLVADs), is associated with reduced survival.² This complication may also affect duration of hospitalization, quality of life, and functional status for cfLVAD recipients.

Most patients with RV failure who undergo implantable LVAD surgery also have significant tricuspid valve

regurgitation (TR).³ Usually this TR is functional and reflects RV pressure or volume overload. The benefits of a concomitant tricuspid valve procedure (TVP) to correct TR at the time of LVAD implantation have not been rigorously examined. We previously reviewed the impact of concomitant tricuspid valve surgery in a cohort of patients that included many who received first-generation pulsatile LVADs.⁴ In this study, the role of concomitant tricuspid valve surgery is examined in a more modern experience consisting solely of patients having a cfLVAD.

In this study, a consecutive group of patients undergoing cfLVAD implantation with RV failure and significant TR are examined. The benefits of the concomitant TVP are studied as some of the patients received a concomitant TVP and others did not. This study focuses specifically on whether concomitant TVP is associated with reduced RV failure after the LVAD implantation. These results should provide insight for the clinical judgment of when concomitant tricuspid surgery should be attempted. Furthermore, it examines whether concomitant tricuspid surgery may be a strategy to avoid the need for mechanical RV support.

METHODS

Permission for this study was granted by the Institutional Review Board of Duke University Medical Center, and need for patient consent was waived. From 2005 to 2011, 200 consecutive cfLVADs were implanted at a single institution (Duke). Of the 200 patients, 61 had significant preimplant TR on preoperative echocardiography; these patients

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Abbreviations and Acronyms

cfLVAD	= continuous-flow left ventricular assist device
CPB	= cardiopulmonary bypass
LVAD	= left ventricular assist device
RV	= right ventricular
RVAD	= right ventricular assist device
TR	= tricuspid regurgitation
TVP	= tricuspid valve procedure

comprised the study group for this report. All transthoracic and transesophageal echocardiograms that were performed during the week before the LVAD implant were reviewed. Patients who met the American Society of Echocardiography's guidelines for moderate or severe TR defined the "significant TR" group. Patients with prior TVPs and those undergoing redo LVAD implants were excluded. Preimplant characteristics and hemodynamics were acquired for all 61 patients who met the definition for significant TR.

Of the 61 patients, 33 underwent concomitant TVPs (cfLVAD+TVP), while 28 underwent LVAD alone (cfLVAD-alone). None of the patients underwent planned RVAD support, and all were weaned from cardiopulmonary bypass (CPB). Use of RVAD support was based on clinical evidence of RV failure, including inability to fill the LVAD, inadequate systemic output (cardiac index or LVAD flow index < 2.0 L/min/m²), and elevated central venous pressure (> 20 mm Hg) despite multiple inotropes after weaning off CPB. All patients received inhaled nitric oxide at the time of weaning from CPB. During the postoperative recovery, inhaled nitric oxide was transitioned to inhaled prostaglandin or oral sildenafil, based on postoperative hemodynamics and clinical status.

Use of postoperative intravenous inotropes was based on hemodynamics, end organ function (ie, blood urea nitrogen, creatinine), and signs of right heart failure (weight gain, ascites, peripheral edema).

Postoperative outcomes were retrospectively extracted from the medical record. Postimplant RV failure was defined as need for RVAD or prolonged inotropes for greater than 14 days. Postoperative serum creatinine was recorded as a gauge of renal function. Postoperative length of intensive care unit stay and length of hospitalization were recorded and compared for the 2 groups. Echocardiograms with assessment of TR severity were performed on all patients during the implant hospitalization, before and after the procedure; TR grades were assigned according to the American Society of Echocardiography's guidelines. In addition, preoperative maximal tricuspid annular diameters were measured by transesophageal echocardiography in the midesophageal 4-chamber view and in the RV inflow/outflow view and compared between the 2 groups.

Preimplant characteristics that were normally distributed are expressed as mean values with standard deviations and are compared with an unpaired Student *t* test. Durations of postimplant inotropic support and hospitalization are reported as median days with the 25th and 75th percentiles and are compared with a Mann-Whitney test. Postoperative renal dysfunction is defined as a 50% increase in the serum creatinine relative to the immediate preimplant value; both postoperative renal dysfunction and RVAD use are presented as percentages and compared with the Fischer exact test.

RESULTS

Table 1 details the preoperative characteristics of the 2 groups. Patients within each group had similar ages and pulmonary artery catheter-based hemodynamics. Both groups had a small incidence of other procedures such as closure of a patent foramen ovale. The 2 groups consisted

of patients who underwent implantation during the same era, with similar surgeons, intensive care unit staffing, and treatment protocols. Tricuspid annular dimensions were similar between the cfLVAD-alone group and the group that received the concomitant TVPs. The total CPB time was increased for the group receiving the concomitant TVPs by approximately 1 hour.

Table 2 shows the type of TVPs for the cfLVAD and TVP groups. A minority of patients required replacement with a bioprosthesis; there were no mechanical replacements. The most common procedure consisted of an undersizing annuloplasty ring repair. We have recently begun using semirigid rings for tricuspid annuloplasty.

Figure 1 depicts echocardiographic TR grade before and after LVAD implantation in the cfLVAD-alone and cfLVAD+TVP groups. Almost 50% of the patients in the cfLVAD-alone group continued to demonstrate significant (moderate or severe) TR after LVAD implantation. This is similar to our earlier study on TR in LVAD patients receiving pulsatile devices.⁴ The majority of patients in the cfLVAD+TVP group had insignificant TR (less than moderate) at follow-up echocardiogram.

Table 3 describes post-LVAD outcomes between the 2 groups. Patients in the cfLVAD-alone group were more likely to experience postoperative RV failure ($P < .05$) and also more likely to require a postoperative RVAD ($P < .05$). Postimplant inotropic agent use also tended to be greater in the cfLVAD-alone group versus the cfLVAD+TVP group (12.1 vs 9.72 days; $P = .16$). Postimplant acute kidney injury tended to be less in the cfLVAD+TVP group versus the cfLVAD-alone group. Also, the cfLVAD-alone group had statistically more patients requiring prolonged hospitalization (> 30 days; $P < .05$) when compared with the cfLVAD+TVP group. Mortality rates were similar for the 2 groups.

RV failure is composed of the fraction of patients requiring postoperative RVADs or prolonged intravenous inotropic support. Figure 2 illustrates the incidence of RV failure in both groups after LVAD implantation. Forty-six percent of patients in the cfLVAD-alone group exhibited post-LVAD RV failure versus only 18% of the cfLVAD+TVP group; most of the difference resulted from greater RVAD requirement for the cfLVAD-alone group. The overall incidence of RV failure for the cfLVAD-alone group is greater than that of previous series, which is consistent with the fact that these patients represent a high risk group for RV failure.² This statement is supported by data from Table 1, which showed reduced RV systolic volume index and increased ratio of central venous pressure to pulmonary capillary wedge pressure for both groups.

DISCUSSION

Recent studies have suggested that use of cfLVADs versus older pulsatile LVADs is associated with a reduced

TABLE 1. Pre-cfLVAD patient characteristics

	cfLVAD-alone (n = 28)	cfLVAD+TVP (n = 33)	P value
Age (y)	59	56	.15
Sex (% male)	54	66	.45
Heart failure etiology (% NICM)	64	44	.12
BUN	32	40	.08
Creatinine (mg/dL)	1.7	1.6	.46
Heart rate (beats/min)	93	88	.27
CVP (mm Hg)	18	19	.16
Mean PAP (mm Hg)	38	38	.27
PCWP (mm Hg)	27	26	.44
Pulmonary vascular resistance (Wood units)	3.6	3.4	.30
CVP/PCWP	0.651	0.739	.10
Cardiac index (L/min/m ²)	1.8	1.78	.45
RVSWI (mL/min/m ²)	410	446	.32
Mixed venous oxygen saturation (%)	46	46	.37
Preoperative ventilator (%)	14	13	1.0
Year of most implantations	2008	2010	
Era of implantations	2005-2011	2005-2011	
CPB times (min)	111	179	<.001
Nontricuspid concomitant procedures (%)	19	18	.4
Preimplant TV annular diameter (4-chamber view) (cm)	4.35	4.38	NS
Preimplant TV annular diameter (RV inflow and outflow view) (cm)	4.66	4.58	NS

cfLVAD-alone, Continuous-flow left ventricular assist device alone; cfLVAD+TVP, continuous-flow left ventricular assist device plus tricuspid valve procedure; NICM, nonischemic cardiomyopathy; BUN, blood urea nitrogen; CVP, central venous pressure; PAP, pulmonary artery pressure; PCWP, pulmonary capillary wedge pressure; RVSWI, Right Ventricular Stroke Work Index; CPB, cardiopulmonary bypass; TV, tricuspid valve; RV, right ventricular; NS, not significant.

incidence of RV failure.¹ Nevertheless, even in an era of cfLVADs, RV failure remains an important postimplant complication that affects 20% of patients and negatively affects survival outcomes.^{1,2} While preimplant risk factors for this complication have been described, effective treatment or preventive measures are not well understood.^{1,2} We³ previously reported that TR is commonly encountered before LVAD implantation, does not resolve with mechanical left ventricular unloading, and is associated with postimplant RV failure. In this report, in a cohort of patients with

significant TR who received cfLVADs, we examine the benefits of concomitant TVPs to reduce postimplant RV failure.

Recently, Maltais and associates⁵ reported the echocardiographic changes associated with cfLVAD support and concomitant tricuspid valve annuloplasty. Repeat echocardiography at 1 month after implant demonstrated that the group that received concomitant TVP displayed reduced TR and decreased RV volume. The current report compliments this echocardiographic study by examining the clinical outcomes that define RV failure for a cohort of cfLVAD patients with significant TR who undergo either concomitant tricuspid valve surgery or LVAD implantation alone. Importantly, postimplant RV failure, defined by need for RVAD support or prolonged intravenous inotropic infusion (>14 days), is reduced in the group undergoing concomitant TVPs. This study suggests that concomitant tricuspid surgery may be a simple intraoperative strategy to help avoid RV failure.

Our earlier study of TVP during pulsatile or nonpulsatile LVAD implantation suggested a survival benefit for concomitant TVP, and a recent study from Atrache and colleagues⁶ also suggests a survival benefit of concomitant TVP and LVAD implantation.⁴ The current report and that of Maltais and coworkers⁵ do not demonstrate a survival benefit associated with concomitant TVPs. Several possible explanations can be offered for the equivalent survival outcomes found in this report and that of Maltais' group.⁵ First, this report examines a relatively small number of subjects and may be inadequately powered to show survival differences. Furthermore, this study does not randomize patients to receive concomitant TVPs, and the group that received the TVPs may have had worse RV performance before the LVAD implantation relative to those who were delegated to not undergo the concomitant procedure. For example, the group that underwent the concomitant TVPs shows a trend to have higher preoperative central venous pressure/pulmonary capillary wedge pressure ratios. The fact that patients were not randomized to either receive or not receive TVP is the single most important limitation to all conclusions. Also, a small fraction of the LVAD-alone group experienced improvement in their postimplant TR (even though they did not receive a procedure), which may have positively affected survival. Another explanation for the equivalent survival for the 2 groups is that the group undergoing LVAD alone may have received a variety of additional postimplant treatments for RV failure (eg, pulmonary vasodilators) that allowed for better hemodynamics and survival.

Although this study supports the use of concomitant TVPs for LVAD patients with significant TR, several important questions remain. First, the group undergoing concomitant TVPs included both moderate and severe preimplant grades of TR. It is unclear what preoperative

TABLE 2. Type of tricuspid valve procedures

Procedure	No.
Bioprosthetic replacement	4
Undersizing ring annuloplasty repair	29
Flexible ring	22
Semirigid ring	7
Total	33

FIGURE 1. Preoperative echocardiographic tricuspid regurgitation (TR) grade versus follow-up TR grade in cfLVAD-alone versus cfLVAD+TVP groups. *cfLVAD-alone*, Continuous-flow left ventricular assist device alone; *cfLVAD+TVP*, continuous-flow left ventricular assist device plus tricuspid valve procedure; *LVAD*, left ventricular assist device.

TR severity would warrant annuloplasty. Furthermore, Dreyfus and colleagues⁷ suggest that the decision for annuloplasty in the setting of functional TR should be based on annular size (dilation) rather than severity of regurgitation. This line of thought suggests that the surgical annuloplasty may have a positive impact on RV reverse remodeling independent of reducing the volume loading associated with TR. Therefore, it is unclear whether tricuspid annuloplasty should be deployed for annular dilation alone. Another

important question relates to the deployment of RVAD support in patients who undergo cfLVAD implantation. This study suggests that many patients who may be considered for RVAD support may benefit from tricuspid annuloplasty and that this strategy should be attempted first before committing the patient to biventricular support, which

TABLE 3. Clinical outcome measures post-cfLVAD implantation

	cfLVAD-alone	cfLVAD+TVP	P value
RV failure	13/28 (46.4%)	6/33 (18.2%)	<.05
Patients requiring > 30 days after LVAD hospitalization	12/28 (42.9%)	6/33 (18.2%)	<.05
Post-cfLVAD acute kidney injury	10/28 (32.14%)	7/33 (15.15%)	.21
Duration of hospitalization (d) (average, median, 25th, and 75th percentiles)	32 (20; 15, 37)	24 (19; 13, 27)	.21
Need for rehospitalization in first year	17/19 (89.47%)	22/26 (84.6%)	1.0
Thirty-day mortality	1/28 (3.5%)	1/32 (3.13%)	1.0
One-year mortality	5/22 (22.73%)	3/24 (12.5%)	.45

cfLVAD-alone, Continuous-flow left ventricular assist device alone; *cfLVAD+TVP*, continuous-flow left ventricular assist device plus tricuspid valve procedure;

FIGURE 2. Postoperative right ventricular (RV) failure for cfLVAD-alone versus cfLVAD+TVP. Bars represent the incidence of need for a right ventricular assist device (gray) or prolonged inotrope use (>14 days; black) for each group. * $P < .05$. *cfLVAD-alone*, Continuous-flow left ventricular assist device alone; *cfLVAD+TVP*, continuous-flow left ventricular assist device plus tricuspid valve procedure.

adds to the complexity and cost of the mechanical circulatory support. In addition, tricuspid annuloplasty may be complementary to temporary RVAD support and may facilitate later weaning from the RVAD.

CONCLUSIONS

This study examines a modern cohort of patients undergoing implantation of a cfLVAD who displayed preoperative RV failure and significant TR. Roughly half of the group underwent LVAD alone, whereas the other half had concomitant TVPs. The group that underwent concomitant TVP required more prolonged CPB times but, despite this, experienced reduced postimplant RV failure as described by less need for RVAD support and reduced inotropic infusion support. Furthermore, prolonged hospitalizations were less frequent for the group that underwent concomitant TVP. Therefore, patients undergoing implantable cfLVADs who have moderate or severe TR should be considered for concomitant TVP to reduce postimplant RV dysfunction.

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