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Tricuspid Valve Annuloplasty Reduces Weaning Time from Temporary Right Ventricular Assistance in Patients Implanted With a Left Ventricular Assist Device

Abstract

Introduction: Right ventricular (RV) failure is a serious complication after implantation of a left ventricular assist device (LVAD) and may require temporary mechanical assistance. We investigated the effectiveness of tricuspid valve annuloplasty in the presence of mild-to-moderate tricuspid valve regurgitation in reducing the weaning time from temporary RV support.

Methods: From 2002 to 2014, 48 patients (mean age 54 ± 7.3) underwent LVAD implantation. The intention to treat was bridge to transplantation in 40 patients and bridge to destination in eight patients. A magnetically levitated rotary pump, designed for temporary extracorporeal support, was implanted in 11 patients (group A) to support the right ventricle. In 9 patients (group B), temporary RV support was augmented by tricuspid valve annuloplasty. We compared the outcome of the two groups of patients.

Results: No significant differences were identified between the two groups regarding operative risk variables. Successful weaning from mechanical RV support occurred in nine patients in group A (81 %) and eight patients in group B (88%). Weaning time was significantly shorter for group B as compared to that of group A (9 ± 2.1 days versus 21.1 ± 8.1 days; $p<0.001$).

Conclusion: The presence of tricuspid valve regurgitation and moderate impairment of RV function may increase the risk of early complications following LVAD implantation. Our experience suggests that the associated procedure of tricuspid annuloplasty smooths the early postoperative course and may reduce the time of temporary RV support in patients with LVAD implantation.

Research Article

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Abbreviations: RV: Right Ventricular; LVAD: Left Ventricular Assist Device; RVADs: RV Assist Devices; LOS: Length of Stay; SD: Standard Deviation; ACT: Activated Clotting Time

Introduction

Right ventricular (RV) failure is a serious complication in patients implanted with a left ventricular assist device (LVAD). Approximately 20% of patients develop different forms of RV failure after LVAD placement. Previous studies have identified various factors predictive of RV failure. However, because many factors contribute to RV function after LVAD placement, RV failure often becomes clinically significant only after LVAD support is initiated. RV dysfunction is associated with tricuspid valve annular dilation and tricuspid regurgitation (TR) [1]. A high incidence of significant TR (approximately 50%) has been reported among patients referred for implantable LVAD procedures [2]. Significant TR leads to RV volume overload that distorts ventricular septal geometry, alters left ventricular (LV) filling, and impairs LV systolic function. Furthermore, the presence of significant pre-implant TR predicts greater utilization of temporary RV assist devices (RVADs), a prolonged need for inotropes, and a greater length of stay (LOS). We investigated the beneficial effect of tricuspid annuloplasty in patients implanted with an LVAD and temporary RV support.

Methods

We retrospectively reviewed our experience at San Camillo Hospital in Rome, Italy. From January 2002 to January 2016 a total of 73 patients with end-stage heart failure underwent implantation of an LVAD. The two most common LVADs were the HeartMate XVE and HeartMate II (Thoratec, Pleasanton, CA), followed by the HeartWare device (HeartWare, Framingham, MA). Preoperative and postoperative variables that correlated with survival were collected for each patient. Pre-implant characteristics, echocardiographic parameters, TR grade, laboratory values, and LOS are expressed as mean values ± standard deviation (SD). Echocardiographic data were retrospectively acquired for all patients. TR was graded on a scale from 1 to 4 for the following: none or trace (1), mild (2), moderate (3), and severe (4), as per international convention. Tricuspid valve annuloplasty with a rigid ring (Contour 3D® 690R Tricuspid Annuloplasty Ring; Medtronic, Minneapolis, MN), was routinely employed in patients implanted with an LVAD in the last 3 years. The Levitronix CentriMag (Levitronix Centrimag Extracorporeal Blood Pumping System and Primary & Backup Consoles - manufactured by levitronix, GmbH, Zurich, Switzerland) was used for temporary RV support. The RVAD was established with the right atrium and pulmonary artery or with femoral vein and pulmonary artery cannulation. The decision of RVAD insertion was justified in those

patients that could not be weaned from cardiopulmonary bypass after LVAD insertion. All procedures were performed at San Camillo Hospital and devices were placed with cardiopulmonary bypass support without cardioplegic arrest. Inhaled nitric oxide was administered during the early postoperative period for all LVAD patients who had increased pulmonary artery pressures or increased pulmonary vascular resistance. Weaning from the RVAD was conducted by decreasing the flow rate by 0.5 L/min every day until 1.5 L/min was reached. Transesophageal echocardiography was used continuously to assess ventricular function and to observe for ventricular dilation, septal shift, ejection fraction, and changes in inotropic drug requirements. Anticoagulation during weaning was increased until an activated clotting time (ACT) of 200 sec was obtained.

Final weaning and termination was preferentially done in the operating room. Weaning was continued until the flow rate was 0.5 L/min. Anticoagulation was increased by administering heparin 100 units/kg intravenously in order to obtain an ACT > 300 sec. The outflow tube was clamped and support terminated. After these patients were extubated they underwent treatment with intravenous milrinone or oral sildenafil. Postoperative inotropes were weaned providing that the patients displayed stable serum creatinine, blood pressure, and heart failure signs. Hospital records were reviewed to determine the duration of temporary RVAD support and hospital LOS. We identified two groups of patients: group A included 11 patients who received an LVAD and temporary RV, and group B included nine patients who received an LVAD, temporary RV support, and concomitant tricuspid valve annuloplasty.

Data are presented as frequency distribution and percentages. Continuous variable are expressed as mean ± SD and were compared using sample t-tests. Categorical variables were compared by means of $\chi 2$ tests. For all analyses, $p < 0.05$ was considered statistically significant. All data were analyzed using SPSS 20 (SPSS Inc, Chicago, IL).

Results

Table 1 shows baseline characteristics and hemodynamic data for the two groups. The two groups had equivalent baseline characteristics and hemodynamics. The groups both displayed evidence of advanced heart failure with poor hemodynamics and evidence of end-organ hypoperfusion with an elevated serum creatinine. Importantly, both groups also displayed pre-implant hemodynamics which are predictive of RV dysfunction, including increased central venous pressure (CVP), increased CVP-to-pulmonary capillary wedge pressure ratio, and reduced RV stroke work index (RVSWI). These findings emphasize the association between significant pre-implant TR and RV dysfunction.

We measured the duration of post-implant temporary RV support to understand the impact of tricuspid annuloplasty on post-implant RV function. The duration of RV support was significantly different between the two groups (21.1 ± 8.1 days for group A versus 9 ± 2.1 days for group B; p<0.001). Need for inotropic support was significantly longer for group A (p=0.002) (Table 2 & 3).

Table 4 shows postoperative complications. Patients that did not receive concomitant tricuspid valve annuloplasty had a significantly higher incidence of infection that required prolonged antibiotic treatment (p<0.005). No differences between the two groups were identified regarding in-hospital mortality (p=0.579), late RV failure (p=0.711), re-intervention for bleeding (p=0.038), or acute renal failure requiring dialysis (p=0.068). Length of hospitalization was increased for group A, 61,8 ± 1,8 days, compared to group B, 29,4 ± 4,5 days, (p=0.002). Survival appeared to be slightly decreased relative to other LVAD trials, but this was consistent with outcomes of LVAD patients who had complicating RV dysfunction. At 1-year follow-up, four patients from group A underwent heart transplantation. Two patients in group A died, one from LVAD thrombosis and the other from systemic infection. In group B, one patient was transplanted. In the same group one patient died after a cerebral hemorrhagic event.

Table 1: Preoperative characteristics.

Variables	Group (A)	Group (B)	p-value
AGE (y)	48,6 ± 7,1	51,2 ± 4,1	0,326
Intermacs Level	3,3 ± 0,4	3,2 ± 0,5	0,807
Intention to Treat			
- BD	3	2	0.604
- BTT	8	7	
Time Since First Diagnosis			
- < 1 month	2	2	0.933
- > 24 months	4	3	
- 1 month - 24 months	4	3	
- 12-24 months	1	1	
Etiology			
- idiopathic	2	2	0.899
- ischemic	6	5	
- myocarditis	2	1	

BD: Bridge to Destination; BTT: Bridge to Transplantation.

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Table 2: Preoperative echocardiographic and hemodynamic variables.

Variables	Group (A)	Group (B)	p-value
Mitral regurgitation	2.33 ± 0.7	2.45 ± 0.7	0.387
Tricuspid regurgitation	1.66 ± 0.6	1.72 ± 0.6	0.672
Ejection fraction (%)	21.4 ± 3.8	21.9 ± 3.7	0.143
LVEDD (mm)	74.6 ± 6.9	75.2 ± 7.5	0.152
LVESD (mm)	66.4 ± 7.9	67.3 ± 8.1	0.126
LVEDV (ml)	285 ± 106	275 ± 97	0.199
LVESV (ml)	230 ± 89	226 ± 80	0.122
TAPSE (mm)	15.3 ± 3.7	16.5 ± 3.4	0.084
CVP (mmHg)	7,5 ± 3,5	6,7 ± 3,3	0,826
RVSWI	5,2 ± 3,1	6,1 ± 3,5	0,767
Systolic PAP (mmHg)	50.8 ± 12.3	51 ± 13	0.05
PCWP (mmHg)	25.2 ± 5.2	24.4 ± 4.5	0.053
SVR (dyne/sec /cm-5/m^2)	1611 ± 295	1591 ± 270	0.159
PVR (dyne/sec /cm-5/m^2	244 ± 90	254 ± 110	0.114
Cardiac index (l/min/m^2)	2.5 ± 0.7	1.97 ± 0.4	0.115

CVP: Central Venous Pressure; CWP: Pulmonary Capillary Wedge Pressure; LVEDD: Left Ventricle End-Diastolic Diameter; LVEDV: Left Ventricle End-Diastolic Volume; LVESD: Left Ventricle End-Systolic Diameter; LVESV: Left Ventricle End-Systolic Volume; PVR: Pulmonary Vascular Resistance; RVSWI: Right Ventricle Stroke Work Index; SVR: Systemic Vascular Resistance; TAPSE: Tricuspid Annular Plane Systolic Excursion.

Table 3: Preoperative laboratory values.

Variables	Group (A)	Group (B)	p-value
BUN (mg/dl)	66 ± 37	68 ± 35	0.796
Creatinine (mg/dl)	1.3 ± 0.5	1.4 ± 0.3	0.663
ALT (IU/l)	29.5 ± 12	30.4 ± 16	0.899
AST (IU/l)	25.4 ± 5.7	24.8 ± 6.3	0.77
LDH	477 ± 83	487 ± 90	0.274
Total Bilirubin (mg/dl)	2.2 ± 0.4	2.1 ± 0.7	0.781
BNP (pg/ml)	1883 ± 830	2007 ± 955	0.577
WBC (×1000/ml)	5,6 ± 1,2	6,2 ± 1,4	0,956
HB (g/dl)	12,3 ± 1,5	13,2 ± 1,8	0,675
Platelets (×1000/ml)	220 ± 74	225 ± 67	0.605
INR	42 ± 23	38 ± 17	0.788

ALT: Alanine Aminotransferase; AST: Aspartate Aminotransferase; BNP: Brain Natriuretic Peptide; BUN: Blood Urea Nitrogen; HB: Hemoglobin; INR: International Normalized Ratio; LDH: Lactate Dehydrogenase; WBC: White Blood Cell.

Table 4: Postoperative outcomes.

Variables	Group (A)	Group (B)	p-value
Device type			
HeartMate II	10	8	0,711
Heartware	1	1	
Successful weaning	9/11 (81%)	8/9 (88 %)	0,656
Weaning time (days)	21.1 ± 8.1	9 ± 2.1	<0.001
Need for inotropic support	25 ± 2,6	7,8 ± 0.9	0.002
Postoperative Complications			
Dialysis	4/11 (36%)	0/9	0.068
Major infections	9 (81%)	1 (11%)	0.002
Redo for bleeding	5/11 (45%)	0/9	0.038
VAD dysfunction	2/11 (18%)	0/9	0.479
Late RV failure	1/11 (9%)	1/9 (11%)	0.711
Hospital stay(days)	61,8 ± 1,8	29,4 ± 4,5	P=0.004
In hospital mortality	2/11 (18%)	1/9 (11%)	0.579

RV: Right Ventricular; VAD: Ventricular Assist Device.

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Discussion

Piacentino et al. [2] reported a 50% incidence of significant tricuspid insufficiency among patients referred for implantable LVADs. Furthermore, they identified a very strong association between significant pre-implantation TR and worse post-implant outcomes, including a greater need for temporary RVAD, prolonged inotropic support, and longer overall hospitalization [2]. Also, significant TR does not appear to improve immediately after LVAD implantation alone. As TR increases, there is right ventricular volume overload leading to a distortion of right ventricular geometry, causing a higher incidence of RV failure.

These observations have led surgeons to perform tricuspid procedures concomitant with LVAD implantation, although there is not agreement about its effectiveness. Comas et al. [3] examined a cohort of LVAD patients with severe TR in which one group underwent LVAD alone versus another group undergoing LVAD plus tricuspid repair. While they found no effect on LOS or need for inotropic support, the group that received the tricuspid repair experienced less postoperative renal insufficiency. Saeed et al. [4] also reported a comparison of LVAD alone versus LVAD plus tricuspid repair for a cohort of patients with at least moderate TR. Again, there were no significant differences between the groups; however, the LVAD plus tricuspid repair group contained only eight patients. In addition, the majority of the tricuspid repairs consisted of a DeVega annuloplasty which may be a less effective repair strategy [4]. Robertson et al reported that performing a concomitant TV procedure for continuous-flow LVAD patients with moderate-to-severe TR did not reduce early death or RVAD requirement and was associated with worse early postoperative outcomes. Data from Robertson et al suggested to avoid routine concomitant TV procedures based solely on the degree of preoperative TR and suggested that additional selection criteria were needed to identify those patients in whom concomitant TV procedure may prevent postoperative RV failure [5]. Piacentino et al. [6] compared patients who underwent LVAD alone to those who underwent LVAD plus concomitant tricuspid procedures. They observed that the mean duration of postoperative inotrope utilization was increased for the LVAD alone group versus the group with concomitant tricuspid procedures (10.0 versus 8.0 days, respectively, p=0.04). The incidence of postoperative renal dysfunction was also increased for the LVAD alone group (39%) versus concomitant procedures (21%) (p=0.05). In addition, the LVAD alone group had a greater mean post-implant length of hospitalization versus the concomitant procedures group (26.0 versus 19.0 days, p=0.02). Finally, there was a trend toward improved survival for the group with concomitant tricuspid procedures versus LVAD alone. According to their data, Piacentino et al. [6] concluded that concomitant tricuspid procedures are associated with improved early clinical outcomes for patients with significant TR undergoing implantable LVAD procedures [6].

Currently no study has investigated the effects of tricuspid annuloplasty with rigid ring on the duration of weaning from RV support after LVAD implantation. In our current report, the group that received a concomitant tricuspid procedure demonstrated a reduced need for inotropes, shorter length of temporary RV support, lower incidence of postoperative infection, and shorter hospitalizations. Furthermore, there was a trend toward better survival. These data suggest that the addition of tricuspid procedures for mild-to-moderate tricuspid insufficiency improves early outcomes. Additionally, these outcomes are consistent with the review by Pal et al. [7], in which concomitant tricuspid procedures, unlike concomitant aortic procedures, were not associated with increased early mortality. However, in this study patients were not randomized to concomitant tricuspid procedures. A randomized study would provide greater evidence for the conclusion that concomitant tricuspid procedures provide a clinical benefit. Another limitation to this study and prior studies on this topic is the sample size. Unfortunately, there are no well-established guidelines for the application of RVAD support post-LVAD. One clinician may have a more aggressive approach to RVAD utilization and may even be committed to this approach prior to actual implantation of the LVAD. Other clinicians may always examine the hemodynamic status with the LVAD before turning to mechanical RV support.

Conclusion

In summary, our study compared two non-randomized groups of patients with significant TR undergoing implantable LVAD, of which one group received a concomitant tricuspid valve procedure. The group receiving a concomitant tricuspid procedure demonstrated improved early clinical outcomes. These observations support concomitant tricuspid procedures for patients with significant TR undergoing implantable LVAD.

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