Liberal use of tricuspid-valve annuloplasty during left-ventricular assist device implantation†

Kewal Krishan, Ajith Nair, Sean Pinney, David H. Adams and Anelechi C. Anyanwu*

Abstract

OBJECTIVE: The study aimed to determine whether liberal use of tricuspid-valve repair (TVr) is associated with adverse outcomes.

METHODS: The study was a retrospective review of 51 implantable left-ventricular assist devices (LVADs) performed in a single center between January 2008 and December 2009. TVr using Edwards MC 3 annuloplasty ring was performed if there was either documented moderate or greater tricuspid regurgitation or severe annular dilatation.

RESULTS: TVr was performed in 37 patients. One patient was converted to replacement intra-operatively. Compared with patients who did not have TVr, the age was similar (mean 52 vs 50 years, p = 0.62), as was frequency of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) level 1 or 2 (43% vs 50%, p = 0.13). Day 1 hemodynamics were also similar: mean central venous pressure (13.5 vs 14 mmHg; p = 0.10) and mean pulmonary artery pressure (25 vs 25.6 mmHg; p = 0.76), as was Day 1 bilirubin (3.1 vs 3.9 mg dl−1, p = 0.27). Median duration of mechanical ventilation (2 days) and inotropic support (5 days) and rates of bleeding were identical in both groups. Although there was a trend toward longer intensive care unit (ICU) stays in the TVr group (6 vs 5 days; p = 0.12), as a group these patients experienced less use of blood-product transfusion and less hospital length of stay. Hospital mortality was similar in both groups (TVr 18.9%, no TVr 21.4%, p = 0.7).

CONCLUSIONS: TVr can be applied during LVAD implantation without ‘obvious’ increase in perioperative risk. As there are theoretical benefits to eliminating tricuspid regurgitation, our data argue for a more liberal approach to TVr at the time of LVAD implantation.

Keywords: Tricuspid regurgitation • Tricuspid-valve repair • Left-ventricular assist device

INTRODUCTION

Tricuspid regurgitation is a common finding in patients with heart failure [1], and it occurs secondary to right-ventricular (RV) dilatation with tethering of the valve leaflets and dilatation of the tricuspid annulus and also, elevated pulmonary vascular resistance resulting from left-ventricular (LV) failure [2]. Traditionally, tricuspid regurgitation has not been treated in patients undergoing surgery for advanced cardiomyopathy because of concerns that acute increase in RV afterload which occurs when the tricuspid valve is made competent would precipitate worsening or intractable RV failure. The tricuspid valve has been described as a ‘pop-off’ valve and the regurgitation, even if severe, is deemed as a necessary consequence of advanced RV cardiomyopathy and one which should not be treated. This concept was extended to patients undergoing left-ventricular assist device (LVAD) therapy, such that the tricuspid regurgitation, regardless of severity, was generally left untreated in patients undergoing LVAD placement.

There are, however, theoretical short- and long-term benefits of treating tricuspid regurgitation in these patients. Elimination of tricuspid regurgitation may actually improve, rather than worsen, RV function and by reducing venous congestion may improve hepatic and renal perfusion. In addition, because many patients require LVAD support for prolonged periods (because of long waiting times for transplantation and increasing application of destination therapy), the presence of severe tricuspid regurgitation is likely associated with increased midterm morbidity and mortality, as has been demonstrated in other patient cohorts [3]. We have therefore adopted a liberal approach to tricuspid annuloplasty at time of LVAD placement and report our outcomes.

PATIENTS AND METHODS

We retrospectively reviewed clinical records of 50 consecutive patients who underwent 51 implantable LVAD placements at our institution from January 2008 to December 2009. Patient demographics are shown in Table 1. Tricuspid-valve surgery was performed concurrently in 37 of the implants.

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Surgical techniques

Criteria for tricuspid-valve intervention were either moderate-to-severe tricuspid regurgitation or severe annular dilatation (defined as any annular dimension >40 mm on transthoracic echocardiography). For patients undergoing TVr, LVAD implantation was performed with standard techniques. Choice of VAD was based on current approved devices and participation in clinical trials. Informed consent and Institutional Review Board approval were obtained prospectively for use of investigational devices. Procedures were done under cardiopulmonary bypass without aortic cross-clamping, unless cross-clamping was indicated for other reasons. After LVAD inflow and outflow cannula insertion, longitudinal right atriotomy was performed by a single surgeon. Atriotomy was sited close to the atrioventricular (AV) groove in an area that would not interfere with subsequent transplantation and also to allow for a sufficient ‘free’ area on the atrium, in case placement of an RVAD cannula is subsequently required. All the patients who underwent tricuspid annuloplasty received a ring annuloplasty using a true-sized MC3 tricuspid annuloplasty ring (Edwards Lifesciences, LLC, Irvine, CA, USA) [4]. It is a three-dimensional (3D) rigid ring anatomically designed for the tricuspid valve. Compared with conventional annuloplasty rings, this 3D ring may preserve atrioventricular dynamics [5, 6] and provides more normal stress distribution to the leaflets. Inspection of the tricuspid valve invariably shows severe annular dilatation and leaflet tethering, sometimes with additional tethering by transvalvular pacer electrodes. In one patient with extreme tethering, the tricuspid valve was replaced with a bioprosthesis. Following closure of right atriotomy, the VAD was deaired and cardiopulmonary bypass was weaned. For patients who did not have tricuspid annuloplasty, the use of cardiopulmonary bypass was dependent on patient factors, operative conditions, and surgeon preference. There were no differences in subsequent operative or perioperative management in patients who underwent tricuspid annuloplasty. Pulmonary vasodilators were used selectively, if there was evidence of persisting pulmonary hypertension and hemodynamically significant RV dysfunction ‘after’ LVAD support had been instituted. All operations were performed by a single surgeon.

Preoperative echocardiography

Each patient underwent standard preoperative transthoracic echocardiography in a single laboratory. The severity of tricuspid regurgitation was then graded according to recommendations of the American Society of Echocardiography [7].

Statistical analysis

Data are expressed as proportions, mean ± standard deviation or medians with interquartile range. Continuous variables were compared using the Student’s t-test or the Wilcoxon rank-sum test and categorical variables with the Fischer’s exact test. The p-values were calculated using the Wilcoxon rank-sum test. Differences were considered significant at a p value <0.05.

RESULTS

Baseline characteristics

Other than severity of tricuspid regurgitation, there were no substantial differences with respect to preoperative and perioperative characteristics in patients who underwent tricuspid annuloplasty compared with those who did not (Tables 1 and 2). Notably, the frequency of INTERMACS level 1 and 2 (cardiogenic shock or progressive decline) were similar in both groups (43% vs 50%; p = 0.13). Three out of 37 (8%) patients in the TVr group and 2/14 (14%) in the no TVr group underwent emergent device placement. Five patients (13%) in the TVr group had temporary RVAD support compared with one (7%) in the no TVr group. Median cardiopulmonary bypass time was longer in the TVr group than in the no TVr group (97 vs 74 min; p = 0.15). Concurrent other cardiac procedures were similar in both groups (18.9% vs 21.4%; p = 0.84). Three patients in the no TVr group underwent off-pump device placement. One patient in the TVr group was HIV (human immunodeficiency virus)-positive with no detectable viral load.

Outcomes

Postoperative data and outcomes are listed in Table 3. Hemodynamics on morning of Day 1 were similar in both groups: mean central venous pressure (13.5 vs 14 mmHg; p = 0.10); mean pulmonary artery pressure (25 ± 8.0 vs 25.6 ± 7.2 mmHg; p = 0.76); as were Day 1 laboratory data (Table 3). As a group, TVr patients experienced less use of blood-product transfusion than no TVr patients. One patient in each group was re-explored for bleeding. Median duration of mechanical ventilation (2 days) and inotropic support (5 days) were identical in both groups. The intensive care unit (ICU) stay and hospital stay were also similar. Hospital mortality was similar in both groups (TVr 18.9%, no TVr 14.2%; p = 0.7). There has been

Table 1: Preoperative patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>TVr (n = 37)</th>
<th>No TVr (n = 14)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Age (years)</td>
<td>52 ± 13.7</td>
<td>50 ± 13.4</td>
<td>0.62</td>
</tr>
<tr>
<td>Gender, male</td>
<td>31 (83.8)</td>
<td>14 (100)</td>
<td>0.38</td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td></td>
<td></td>
<td>0.87</td>
</tr>
<tr>
<td>Dilated</td>
<td>23 (62)</td>
<td>8 (57)</td>
<td></td>
</tr>
<tr>
<td>Ischemic</td>
<td>10 (27)</td>
<td>5 (36)</td>
<td></td>
</tr>
<tr>
<td>Valvular</td>
<td>4 (11)</td>
<td>1 (7)</td>
<td></td>
</tr>
<tr>
<td>Tricuspid regurgitation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>2</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>13</td>
<td>7</td>
<td></td>
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<tr>
<td>Moderate</td>
<td>18</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>4</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Indications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bridge to transplant</td>
<td>36 (97)</td>
<td>13 (93)</td>
<td></td>
</tr>
<tr>
<td>Destination therapy</td>
<td>1 (3)</td>
<td>1 (7)</td>
<td></td>
</tr>
<tr>
<td>INTERMACS level</td>
<td>2.5 ± 0.7</td>
<td>2.1 ± 0.9</td>
<td>0.13</td>
</tr>
<tr>
<td>Pre-existing coagulopathy</td>
<td>6 (19)</td>
<td>4 (28)</td>
<td>0.46</td>
</tr>
<tr>
<td>HIV positive</td>
<td>1 (3)</td>
<td>0 (0)</td>
<td>0.54</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD or No. (%). INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; HIV, human immunodeficiency virus; p-Values calculated using Wilcoxon rank-sum test.
one death on support after hospital discharge in the no TVr group due to pump failure (median days on support: 150 interquartile (IQ) ranges 90–228). Median follow-up on the device was similar in both groups (171 vs 182 days; p = 0.99): of 37 TVr patients, 10 (27%) were transplanted; in two patients, the device was explanted, one for recovery and one for pump thrombosis; and in another two patients, the device was exchanged. In the no-TVr group, eight (57.2%) were transplanted. Fifteen of 37 (40%) in the TVr group and 21.4% (3/14) in the no TVr group are alive on support, awaiting transplant. Cumulative death on support is similar in both groups (21.6% vs 21.4%; p = 0.99).

**COMMENTS**

We have found no incremental risk in undertaking TVr in patients with advanced cardiomyopathy undergoing LVAD placement. Notably, there was no increase in bleeding complications, RVAD use, morbidity, hospitalization, or mortality with TVr. The lack of increase in morbidity is significant in that patients with tricuspid regurgitation by definition have a higher degree of venous congestion in the abdominal organs and therefore might have been expected to have worse outcomes. Our data demonstrate the safety of tricuspid annuloplasty in the setting of LVAD placement and question the ‘pop-off’ valve hypothesis, which suggests tricuspid-valve regurgitation should not be corrected in this setting. TVr did not take more than 15–20 min; hence, it did not add substantially to duration of cardiopulmonary bypass. We did not experience any bleeding problems related to the right atriotomy or other direct surgical complications of TVr. The presence of pre-existing pacemakers in most patients removes concern for perioperative heart block and allows aggressive suture placement. Our data support observations in non-LVAD cohorts which suggest that incremental surgical risk of adding TVr to cardiac surgical procedures is negligible in most patients [8, 9].

Successes with newer-generation implantable LVADs have led to increased use of mechanical circulatory assistance [10]. Improvements in preoperative selection, perioperative techniques, and postoperative care have resulted in the reduction of mortality and morbidity after device implantation. In the immediate postoperative period, LVAD flows are often limited by output across the pulmonary vascular bed. LVAD patients may therefore require high-volume-loading conditions and frequently require blood-product transfusions. Both these factors exacerbate right-heart failure and predispose to tricuspid insufficiency. Increased flow after device placement in these patients can paradoxically exacerbate tricuspid regurgitation, presumably by mechanisms, such as distraction of the septal papillary muscle with systolic restriction of septal leaflet motion and distortion of the tricuspid valve hypothesis, which suggests tricuspid regurgitation should not be corrected in this setting. TVr did not take more than 15–20 min; hence, it did not add substantially to duration of cardiopulmonary bypass. We did not experience any bleeding problems related to the right atriotomy or other direct surgical complications of TVr. The presence of pre-existing pacemakers in most patients removes concern for perioperative heart block and allows aggressive suture placement. Our data support observations in non-LVAD cohorts which suggest that incremental surgical risk of adding TVr to cardiac surgical procedures is negligible in most patients [8, 9]. Successes with newer-generation implantable LVADs have led to increased use of mechanical circulatory assistance [10]. Improvements in preoperative selection, perioperative techniques, and postoperative care have resulted in the reduction of mortality and morbidity after device implantation. In the immediate postoperative period, LVAD flows are often limited by output across the pulmonary vascular bed. LVAD patients may therefore require high-volume-loading conditions and frequently require blood-product transfusions. Both these factors exacerbate right-heart failure and predispose to tricuspid insufficiency. Increased flow after device placement in these patients can paradoxically exacerbate tricuspid regurgitation, presumably by mechanisms, such as distraction of the septal papillary muscle with systolic restriction of septal leaflet motion and distortion of the tricuspid valve.
annulus [11]. Relative RV overload and increased pulmonary pressures can further contribute to worsened tricuspid regurgitation. It has been suggested that the absence of significant tricuspid regurgitation does not imply that the tricuspid orifice is free from abnormality, with significant tricuspid annular dilation representing a particularly important substrate for later tricuspid regurgitation [2]. Most patients who undergo LVAD placement have a defibrillator placed during medical management. Therefore, the presence of leads across the tricuspid valve significantly contributes to development and persistence of regurgitation. In our study, all patients received ring annuloplasty to reduce the chances of failure of the repair. In patients with cardiomyopathy, the right ventricle is usually dilated and tethering is quite severe; hence, ring annuloplasty is preferable to suture repair as incidence of failure of repair is very high with suture annuloplasty in this setting [12].

Aside from safety concerns, another counterargument in performing TVr in LVAD patients is that as LV failure resolves with ongoing device support, RV function can improve and tricuspid regurgitation may abate [13]. This has been found by some authors [14], but others reported an acute worsening in tricuspid regurgitation after LVAD insertion [15]. In another study, analysis of 36 cases of LVAD insertion showed that the performance of a tricuspid annuloplasty in those patients provided a consistent reduction in tricuspid regurgitation. By contrast, LVAD insertion per se, without tricuspid intervention, does not seem to produce uniform change in the degree of tricuspid regurgitation [16]. Concomitant tricuspid annuloplasty reduces the degree of tricuspid regurgitation in the setting of device implantation and may result in significant improvement in RV function and remodeling of the right ventricle, with reduction in size and enhanced ejection fraction [17].

Non-regression or progression of tricuspid regurgitation can have implications in terms of perioperative course, worsening symptoms, and functional outcome [18]. Due to prolonged back-pressure changes and congestive hepatomegaly, these patients tend to be more coagulopathic; therefore, relieving afterload on venous return improves hepatic function and thus coagulopathy. This in turn may reduce blood transfusion and its anticipated complications, such as infections, increased pulmonary vascular resistance, and allosensitization. Reduced transfusion-related volume requirements may also reduce chances of RV failure due to volume overload in the immediate postoperative period and, thus, the need for RV device placement, which in turn may reduce postoperative morbidity. In the long term, tricuspid regurgitation is associated with worsened survival [19], and persisting right-heart failure and hepatic or renal congestion could increase morbidity associated with subsequent transplantation. Finally, in patients receiving LVAD as destination therapy, persisting tricuspid regurgitation can mean patients persisting in heart failure, thus limiting the benefit of device therapy. We would therefore argue that, in patients with significant tricuspid regurgitation undergoing LVAD placement, who are expected to be supported for long periods, restoring annular size and geometry with tricuspid annuloplasty should be undertaken as, theoretically, it would improve the symptomatic and prognostic benefit of LVAD placement.

**Limitations**

Our data are limited by the relatively small sample size, retrospective design, and non-randomized allocation. However, we believe that if there exists a substantial detrimental effect of tricuspid annuloplasty, it should have been apparent in our series. Despite the fact that patients with tricuspid regurgitation are by definition sicker, with annuloplasty, we did achieve results comparable to patients who did not have significant tricuspid regurgitation. In addition, our group has a liberal approach to tricuspid annuloplasty in general for patients undergoing conventional cardiac operations [20] and therefore is well versed in its routine use. We do not know whether our results will be replicated by teams that do not perform tricuspid annuloplasty frequently in non-LVAD patients. Finally, our study focuses on in-hospital and short-term outcomes rather than long-term benefits.

**SUMMARY**

TVr does not appear to increase the early morbidity or mortality of LVAD insertion and may facilitate the perioperative management of these challenging patients. Future studies are required to confirm whether tricuspid annuloplasty does indeed transform to superior outcomes in this patient group.

**Conflict of interest:** D.H.A. has received honoraria, consultancy fees, and royalties from Edwards Lifesciences and Medtronic.

**REFERENCES**

A useful clinical report should convey a single important message. In this journal, Krishnan et al. [1] show that concomitant correction of tricuspid valve regurgitation does not increase operative mortality for patients receiving an implantable left ventricular assist device (LVAD). This confirms the previous report of Pal et al. [2] who defined the impact of concurrent cardiac procedures on mortality in HeartMate II LVAD patients in a bridge to transplant clinical trial. These authors recorded a 5.8% operative mortality rate for patients requiring uncomplicated LVAD implantation with no apparent increase in risk for concurrent mitral or tricuspid repair. By contrast, patients who underwent an aortic valve procedure manifest a 30-day mortality rate of 25%.

There is understandable reticence to complicate or prolong LVAD surgery in the high-risk heart failure patient. This begs the question ‘Is tricuspid annuloplasty really beneficial?’ In patients with left ventricular dysfunction or mitral valve disease, elevated left atrial pressure is transmitted backwards through the lungs as pulmonary hypertension [3]. This produces pressure overload and dilatation of the right ventricle with annular enlargement and secondary tricuspid regurgitation. The regurgitant fraction impairs forward flow through the lungs, thereby reducing LVAD filling and cardiac output overall. Elevated right atrial pressure and systolic reversal of flow in the vena cava are responsible for end-organ venous congestion and the signs and symptoms of tricuspid regurgitation.

When the tricuspid annulus dilates, it is the mural part that increases in length. The straight (septal) side retains its dimension [4]. The right ventricular papillary muscle attachments arise directly from the upper septum and from variable attachments to the trabecular septum or free wall, close to the septum. As such, they are little affected by remodelling and right ventricular dilatation of the free wall. Thus, stretching of the mural annulus is the dominant mechanism in functional tricuspid regurgitation.

In a classic angiographic study, Simon et al. [5] showed impaired contraction of the stretched tricuspid annulus to be the predominant mechanism of tricuspid regurgitation. Fukada et al. [6] demonstrated an asymmetric reduction in annular contraction, which does not resolve when pulmonary artery pressure falls. The annulus becomes dilated, flattened and circular. Uncorrected moderate or severe tricuspid regurgitation perpetuates right ventricular dysfunction and is associated with progressive heart failure and premature death [3].

Functional tricuspid regurgitation can be dynamic and responsive to medical therapy. It is possible to identify gross insufficiency, which weeks later has become mild in response to diuretics. It is important to adopt liberal indications for repair and regard previous episodes of moderate or severe regurgitation (or a substantially dilated annulus) as an indication for surgery, particularly for destination therapy patients. When the right ventricle fails, increased diastolic pressure can cause septal shift and compression of the left ventricle, which may impair LVAD filling. When the LVAD reduces left ventricular volume, tricuspid regurgitation may be exacerbated acutely because of leftward shift of the intraventricular septum and increased venous return in response to LVAD flow [7].

**Keywords:** Tricuspid • Circulatory support • Heart failure • Annuloplasty

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**EDITORIAL COMMENT**

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