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Impact of Tricuspid Valve Surgery at the Time of Left Ventricular Assist Device Insertion on Postoperative Outcomes

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Abstract

Tricuspid regurgitation (TR) is common in patients with heart failure undergoing left ventricular assist device (LVAD) implantation. Whether the TR should be surgically managed at the time of LVAD surgery is controversial.

We searched SCOPUS, Web of Science, Ovid EMBASE and Ovid MEDLINE (through May 10, 2014) for randomized controlled trials and observational studies comparing postoperative outcomes in patients treated with LVAD with concomitant tricuspid valve surgery (TVS) compared with LVAD alone.

Six observational studies including 3249 patients compared outcomes following LVAD+TVS vs. LVAD. Four studies were single-center and most did not adjust for potential confounders.

Addition of TVS prolonged cardiopulmonary bypass times by an average of 31 minutes (3 studies, 95% CI 20–42min). There was no difference in need for right ventricular assist device (6 studies, HR 1.42, 95% CI 0.54–3.76) acute renal failure (4 studies, HR 1.07, 95% CI 0.55–2.10), or early mortality (6 studies, HR 1.28, 95% CI 0.78–2.08) in patients treated with LVAD + TVS vs. LVAD alone.

TVS prolongs cardiopulmonary bypass times but available data demonstrate no significant association with early postoperative outcomes. However, differences in baseline risk of patients treated with TVS vs. not limits our ability to draw conclusions.

Keywords

heart valve; circulatory assist devices; heart failure; outcomes

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INTRODUCTION

Tricuspid regurgitation (TR) is common in patients with advanced heart failure (HF). Most often, TR in this setting is “functional” in nature, occurring as a result of progressive right ventricular (RV) and tricuspid annular dilatation in response to pulmonary venous hypertension from left-sided heart disease. Given its prevalence, significant TR is encountered in up to half of patients undergoing left ventricular assist device (LVAD) implantation¹. However, significant controversy exists regarding whether the TR should be surgically managed with valvular repair/ replacement at the time of LVAD implantation.

Postoperative RV failure is common following LVAD, occurring in up to 44% of patients². Patients with RV failure frequently require prolonged intensive care unit stays, implantation of RV assist devices (RVAD) and experience increased mortality^{2, 3}. The presence of significant pre-operative TR is associated with increased postoperative RV failure following LVAD¹. In the immediate postoperative period left ventricular (LV) offloading from the LVAD can contribute to leftward shift of the interventricular septum⁴ resulting in changes in RV geometry that may worsen TR and RV function. Furthermore, the regurgitant tricuspid flow can diminish forward flow through the pulmonary circulation thereby reducing LV preload and LVAD flow.

Accordingly, there has been interest in surgically correcting TR at the time of LVAD implantation in an effort to mitigate its potential effects on postoperative RV function. As there are no published guidelines to recommend for or against this practice, the choice has largely been operator-dependent, with some surgeons adopting an aggressive approach to repair. However, others have avoided concomitant tricuspid valve procedures at the time of LVAD to shorten cardiopulmonary bypass time.

To better inform this practice, we aimed to systematically review the available evidence comparing postoperative outcomes in patients treated with LVAD alone vs. LVAD with concomitant tricuspid valve surgery (TVS).

METHODS

The goals of this review were to systematically assess differences in early postoperative outcomes in patients with advanced heart failure and TR treated with LVAD compared with LVAD + TVS.

Eligibility Criteria

We included randomized controlled trials or observational studies which met the following criteria: 1) included adult human subjects, 2) compared a group of patients treated with LVAD alone vs. LVAD + concomitant TVS (tricuspid valve repair or replacement), 3) compared cardiopulmonary bypass time, early mortality, or postoperative RVAD use between groups, and 4) were published in the English language.

Search Strategy

On May 10, 2014, we searched SCOPUS, Web of Science, Ovid EMBASE and Ovid MEDLINE for articles containing the following terms: “LVAD” or “heart assist” or “left ventricular assist” or “heart mate” or “heartware” AND “tricuspid” or “tvr” or “tvpr” AND “procedure” or “repair” or “replace”. We restricted the search to articles published since the year 2000, given the rapid changes in device technology since that time. We did not restrict our criteria to studies solely analyzing patients with continuous-flow LVADs. The full search strategy is included as an Appendix.

Study Selection

Two reviewers (SMD and SVD) independently reviewed all abstracts identified using our search strategy. Abstracts that potentially met study criteria were identified and the full-text articles were then reviewed in duplicate to determine the final studies eligible for inclusion.

Study Outcomes

Outcomes of interest included cardiopulmonary bypass time, need for RVAD postoperatively, duration of inotropic support, post-LVAD hospital length of stay, development of postoperative acute renal failure, and early mortality. We used individual study definitions for postoperative acute renal failure occurring during the same hospitalization but after LVAD surgery. We defined early mortality as in-hospital or 30-day mortality as reported in the individual studies.

Study Quality

The quality of full-length articles was assessed using the Newcastle Ottawa Scale.

Author Contact

Three authors^{5–7} reported their continuous outcomes as median (interquartile range), a format which did not allow us to pool the data. We contacted them by email asking them to provide us with means (standard deviation), which only one of the authors⁵ was able to provide.

Statistical Analysis

We used the I^2 statistic, which estimates the percentage of total variation across studies that is due to heterogeneity rather than chance. Suggested thresholds for heterogeneity were used, with I^2 values of 25–49%, 50–74%, and 75% indicative of low, moderate, and high heterogeneity. Random effects models were used to pool data. Binary outcomes (RVAD, renal failure, mortality) are presented as risk ratios and continuous variables (cardiopulmonary bypass times,) are presented as estimated mean differences. The risk ratios for studies reporting the number of outcomes in each group, rather than an adjusted risk ratio, were calculated and pooled with the adjusted risk ratios reported by Robertson et al⁸. We performed sensitivity analyses including 1) restricting to studies that only included patients with continuous-flow LVADs, and 2) restricting to studies that accounted for baseline TR severity. Analysis was performed using Stata 13.0 (College Station, Texas) and Review Manager 5.1 (RevMan 5.1®, Nordic Cochrane Center and Copenhagen, Denmark).

RESULTS

Our search strategy identified 277 abstracts. From this group, 28 articles were reviewed, of which 6 met criteria for inclusion in this review. Five studies⁵⁻⁹ were observational in nature and one¹⁰ was a post-hoc analysis of clinical trial participants; there were no randomized controlled trials on this topic. In total, 4 studies^{5-7, 9} reflected the experience of a single-center. The remaining studies included data from the HeartMate II clinical trials¹⁰ and the Society of Thoracic Surgeons (STS) National Database⁸. The characteristics of the included studies are shown in Table 1. Only 3 studies limited their population to patients who would have an indication for TVR (at least moderate TR pre-LVAD⁶⁻⁸). Three studies only included patients with continuous flow devices⁸⁻¹⁰, while the remaining three each had a small proportion with pulsatile flow devices. The quality of the included studies as demonstrated by the Newcastle Ottawa Scale ranged from 6–9 stars (maximum score= 9 stars). Most studies lost stars for comparability of the patients treated with LVAD+TVS vs. LVAD alone, as patients treated with LVAD+TVS, on average, had more preoperative TR and worse RV function (Table 2), and those differences were not accounted for in many of the analyses.

Cardiopulmonary bypass time

Four studies including 2330 patients reported on cardiopulmonary bypass times^{5, 7-9}, though one reported only median times for each group and could not be included in pooled analysis⁷. In the remaining 3 studies, TVS at the time of LVAD prolonged cardiopulmonary bypass time by an average of 31 minutes per patient (Figure 1). Three⁷⁻⁹ out of 4 studies reported significantly longer bypass times with TVS.

Need for RVAD

All 6 studies including 3249 patients reported on the postoperative need for RVAD for RV failure. In pooled analyses, there was no difference in the need for RVAD in patients treated with LVAD + TVS vs. LVAD alone (RR 1.42, 95% CI 0.54–3.76, $I^2=71\%$, Figure 2). The study by John et al¹⁰, which analyzed data from the HeartMate II trials, was the sole study to find a significantly higher risk of RVAD insertion in patients treated with LVAD + TVS vs. LVAD alone (9.7% vs. 1.9%, $p<0.001$). However, this study did not account for differences in baseline risk or degree of TR. In a subgroup analysis including the 3 studies⁶⁻⁸ that exclusively compared patients with at least moderate TR who underwent LVAD + TVS vs. LVAD alone, there was still no difference in postoperative need for RVAD (RR 0.79, 95% CI 0.49–1.28, $I^2=5\%$, $p=0.34$). Results were also similar when limiting the analysis to the three studies that solely included patients with continuous flow devices⁸⁻¹⁰.

Duration of Inotropic Support

There were 3 studies representing 249 patients that reported on the postoperative duration of inotropic support^{5, 6, 9}. One study reported a significantly shorter duration of inotropic support in patients treated with LVAD+TVS⁶, where the median duration after LVAD + TVP was 8 days compared with 10 days after LVAD alone ($p=0.04$). The remaining two studies found no difference in inotrope duration in patients treated with LVAD + TVR vs. LVAD alone (mean 10.5 vs. 7.8 days, respectively⁵ and 8.6 vs. 8 days⁹).

Acute Renal Failure

Four studies reported on the risk of postoperative acute renal failure in patients treated with LVAD + TVS vs. LVAD alone, one of which reported a significantly higher risk in those with concomitant TVS. In pooled analyses including 2020 patients, there was no difference in the risk of postoperative acute renal failure in patients treated with LVAD + TVS vs. LVAD alone (RR 1.07, 95% CI 0.55–2.10, Figure 3). Between-study heterogeneity was moderate ($I^2=67\%$). The results from Saeed and Robertson showed more acute renal failure in those treated with TVS + LVAD compared with LVAD alone (pooled RR 1.56, 95% CI 1.16–2.11), which differed from the other 2 studies which demonstrated a trend toward lower risk of acute renal failure in patients treated with TVS (pooled RR 0.61, 95% CI 0.34–1.09). In reviewing the data from Saeed et al, while patients with TVS had a rise in creatinine postoperatively (from an average of 1.6 mg/dL preoperatively to 2.3 mg/dL on postoperative day 14) compared with a drop in creatinine in those treated with LVAD alone, but both groups had creatinine levels that were comparable to their preoperative values by postoperative day 30. It is notable that this group reported substantial prolongation in cardiopulmonary bypass times with addition of TVS (median 70 minutes longer than patients treated with LVAD alone). The study from the STS database reported increased risk of new onset renal failure and need for dialysis in patients treated with LVAD+TVS vs. LVAD alone, which persisted after accounting for propensity to perform a TVP.

Hospital Length of Stay

Four studies including 2401 patients reported on differences in hospital length of stay in patients treated with LVAD + TVS vs. LVAD alone^{5, 6, 8, 9}. The study pooling data from the STS database reported an adjusted 29% increased risk for prolonged hospital length of stay in patients treated with TVP compared with LVAD alone (RR 1.29, 95% CI 1.16–1.43, $p<0.001$)⁸. One study⁶ reported a significantly shorter length of stay in patients treated with LVAD + TVS compared with LVAD alone (median 19 vs. 26 days, $p=0.02$). Both of these studies, reporting disparate results, restricted their analyses to patients with at least moderate TR. The remaining 2 studies reported no differences in hospital length of stay in patients treated with LVAD + TVP vs. LVAD alone (mean 32 vs. 30 days, respectively⁵ and 23 vs. 20 days⁹).

Early mortality

In total, all 6 studies representing 3217 patients reported on early mortality, although none reported any difference in patients treated with LVAD + TVS vs. LVAD alone. There was no difference in early mortality in patients treated with TVS + LVAD vs. LVAD alone (Figure 4). There was no heterogeneity between studies. A subgroup analysis including the 3 studies that exclusively compared patients with at least moderate TR who underwent LVAD + TVS vs. LVAD alone^{6–8}, there was still no difference in early mortality (RR 0.93, 95% CI 0.67–1.29, $p=0.67$). Results were similar when limiting the analysis to the three studies that solely included patients with continuous flow devices^{8–10}.

There were very limited data provided in any of the studies on long-term outcomes. The exception was the report from the HeartMate II trials¹⁰, which reported no difference in 1-year (77% vs. 75%) and 2-year (63% vs. 64%) survival in patients treated with LVAD

+TVP vs. LVAD alone (John). Beyond that, three articles^{6, 7, 9} provided Kaplan Meier curves for mortality, though there were very few patients being followed beyond one year in any study.

DISCUSSION

Based on our review of the literature and synthesis of available data, while the addition of TVS prolongs cardiopulmonary bypass times, we did not find sufficient evidence to suggest that performance of TVS at the time of LVAD implantation has an effect on early postoperative outcomes. However, most existing studies are inadequately powered and fail to adequately adjust for potential confounders. The two largest studies, analyzing data from the HeartMate II trials¹⁰ and STS database⁸, found no difference in early mortality in patients treated with TVS at the time of LVAD, though one¹⁰ found a higher risk of RVAD and the other⁸ a higher risk of postoperative renal failure and prolonged length of stay.

TR is extremely common in patients with advanced heart failure, most often occurring as a result of progressive tricuspid annular enlargement and tricuspid valve leaflet tethering due to RV enlargement. The development of TR often leads to a difficult cycle of progressive RV enlargement, and in turn, worsening regurgitation. In patients undergoing valve surgery for mitral regurgitation, it is known that TR can progress after mitral valve surgery¹¹ and is associated with worse postoperative outcomes. This recognition has led to the most current guidelines from the European Society of Cardiology recommending that patients who have severe TR undergo surgical intervention at the time of left-sided valve surgery (class I), and such surgery should be considered in patients undergoing left sided heart valve surgery with at least mild TR and a dilated tricuspid annulus (class IIa)¹². However, similar guidelines do not exist in patients undergoing LVAD, though the prevalence of at least moderate TR has been estimated to be nearly 50% in recent studies^{1, 9}. Accordingly, whether TR is treated with tricuspid valve repair or replacement at the time of LVAD has largely been based on the preference of the individual surgeon. The tricuspid valve has often been viewed as a “pop-off” valve, and there is concern that fixing the TR may result in progressive RV dysfunction and failure in the early postoperative period. Furthermore, there has been some evidence that effective offloading of the left ventricle with the LVAD can result in improvement in the degree of TR^{13, 14}, though this has been inconsistent across studies with some showing no improvement without surgical repair¹⁵. As severe preoperative TR has been identified as a predictor of adverse postoperative outcomes¹⁶, other centers have taken the approach of surgically repairing the tricuspid valve in patients with significant TR at the time of LVAD implantation in the hopes of improving postoperative outcomes and potentially eliminating the need for future tricuspid procedures.

In this review, we found that patients treated with TVS at the time of LVAD consistently had longer cardiopulmonary bypass times across studies compared with patients who underwent LVAD alone, which is expected. However, we found no differences in postoperative outcomes including use of RVAD, renal dysfunction, inotrope duration, hospital length of stay, and early mortality in patients treated with LVAD+ TVS vs. LVAD alone. Only three studies compared the results from patients with at least moderate TR⁶⁻⁸, but there were still no differences in pooled analyses of outcomes when restricted to these

studies. In the remaining studies, patients treated with TVS had more TR and worse baseline RV function, and thus were at greater risk of adverse postoperative outcomes than those who underwent LVAD alone. However, differences in baseline risk were not adjusted for in their analyses. In many cases, the fact that postoperative outcomes were similar despite this difference in risk was interpreted as indication that TVS had a positive effect on postoperative outcomes in these patients. While there were no randomized trials on the topic to address this question, the sole study that adjusted for propensity to have TVS found a higher risk of renal failure and prolonged hospitalization in patients treated with TVS, though no difference in the need for RVAD or early mortality.⁸ Analyses of the impact of TVS on postoperative outcomes from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) and the Heartware trials were recently presented inter(national) meetings, though full-text results have not been published. However, neither reported differences in early mortality in their published abstracts^{17, 18}. In addition to the pooled results reported herein, Maltais et al reported evidence of reverse RV remodeling and improved RV function after LVAD+TVS⁹, though data are lacking to inform us as to whether these early changes translate into differences in long-term outcomes. As such, further work is also needed to better evaluate and understand the long-term implications of performing TVS at the time of LVAD. The increasing use of LVAD as destination therapy underscores the importance of examining this issue, as the LVAD remains in situ for the remainder of the patient's life and the impact of TR on long-term outcomes becomes of great importance.

There are limitations to acknowledge to aid in interpretation of these data. All included studies were observational, and patient selection for TVS may have contributed to results observed. Only 3 studies restricted their population to patients implanted with continuous flow LVADs, while others included older generation pulsatile flow pumps. Differences in physiology and surgical implantation requirements may contribute to variation in early postoperative outcomes. However, when we restricted our analysis for RVAD and early mortality to those studies using continuous flow devices, we found results to be similar. Some studies included patients who underwent both tricuspid valve repair and replacement. As we did not have access to the individual patient-level data from the various studies, we were unable to assess whether differences in outcomes may occur as a result of the type of TVP employed.

This is the first systematic review and meta-analysis to evaluate the impact of TVS performed at the time of LVAD implantation on cardiopulmonary bypass times and early postoperative outcomes. We found that there are limited observational data available on this topic. While cardiopulmonary bypass times appear to be longer in those treated with TVS at the time of LVAD implantation, there is insufficient information to draw definitive conclusions on the impact of TVS on early postoperative outcomes. As such, further data are needed in order to inform surgeons as to the best practice for these patients.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
 Cardiopulmonary Bypass Times in Patients Treated with LVAD+TVS Compared with
 LVAD Alone

Figure 2. RVAD Use in Patients Treated with LVAD + TVS Compared with LVAD Alone
 Risk ratios were calculated using the following [N(%) patients receiving RVAD in LVAD +TVS group/ LVAD alone]: 15(9.7%)/12(1.9%) (John), 5(14%)/1(7%) (Krishan), 2(36%)/2(26%) (Maltais), 1(3%)/8(10%) (Piacentino), 1(13%)/3(9%) (Saeed). For Robertson et al, reported risk ratios accounting for propensity to receive TVS were used.

Figure 3. Acute Renal Failure in Patients Treated with LVAD + TVS Compared with LVAD Alone

Risk ratios were calculated using the following [N(%) patients developing renal failure in LVAD+TVS group/ LVAD alone]: 5(15%)/8(16%) (Maltais), 7(21%)/32(39%) (Piacentino), 2(25%)/3(9%) (Saeed). For Robertson et al, reported risk ratios accounting for propensity to receive TVS were used.

Figure 4. Early Mortality in Patients Treated with LVAD + TVS Compared with LVAD Alone
 Risk ratios were calculated using the following [N(%) early mortality in LVAD+TVS group/
 LVAD alone]: 11(8.9%)/31(4.8%) (John), 7(19%)/2(14%) (Krishan), 6(18%)/2(4%)
 (Maltais), 1(3%)/8(10%) (Piacentino), 1(13%)/3(9%) (Saeed). For Robertson et al, reported
 risk ratios accounting for propensity to receive TVS were used.

Overview of Included Studies

Table 1

First Author	Year	Study Design	Study Population	LVAD Type	Outcomes Reported	Adjustment	* Newcastle Ottawa Scale Selection Comparability Outcome
Full-length articles							
John	2014	Post-hoc analysis of clinical trial	HM2 trials	HM2	RVAD, mortality	None	***
Krishnan	2012	Retrospective cohort	All LVAD	66% HM2, 6% HMXVE, 28% VentrAssist	CPBT, RVAD, hospital LOS, inotrope, mortality	None	***
Maltais	2012	Retrospective cohort	HM2 LVAD	HM2	CPBT, ARF, RVAD, hospital LOS, inotrope, mortality	None	***
Piacentino	2011	Retrospective cohort	>Moderate TR pre-LVAD	60% HM2	ARF, RVAD, hospital LOS, inotrope, mortality	None	***
Robertson	2014	Retrospective cohort (STS Database)	Moderate TR pre-LVAD	94% HM2 HeartWare, Heart Assist, Jarvik 2000, DuraHeart	CPBT, ARF, RVAD, hospital LOS, mortality	Yes, to account for propensity to receive TVS	***
Saeed	2011	Retrospective cohort	>3+TR pre-LVAD	43% HM2, 29% HMXVE, 12% VentrAssist, 10% Novacor, 7% HWHVAD	CPBT, ARF, RVAD, mortality	None	***

ARF= acute renal failure, CPBT= cardiopulmonary bypass time, LOS= length of stay, LVAD= left ventricular assist device, RVAD= right ventricular assist device, TR= tricuspid regurgitation, NR= not reported, HM= HeartMate, HW= HeartWare,

* The maximum stars are four for selection, 2 for comparability, and 3 for outcome.

Table 2

Patient Characteristics in Included Studies

First Author	N	Mean age (years)	Type of TVP	Preoperative TR Severity	Preoperative CVP/PCWP	† Preoperative renal function
John	LVAD+TVS	156	61	Repair, replace, % NR	NR	1.51 mg/dL
	LVAD	641	58			1.45 mg/dL
Krishan	LVAD+TVS	37	52	100% repair	NR	NR
	LVAD	14	50	11% severe 0% severe		
Maltais	LVAD+TVS	34	64	82% repair	TR VC 3.7 mm	1.3 mg/dL
	LVAD	49	62		1.6 mm	1.3 mg/dL
Piacentino	LVAD+TVS	34	53	85% repair	62% severe	2.0 mg/dL
	LVAD	81	56		33% severe	1.8 mg/dL
Robertson	LVAD+TVS	588	55	81% repair	NR	16% cr >2.0 mg/dL
	LVAD	1608	56			16% cr >2.0mg/dL
Saeed	LVAD+TVS	8	55	100% repair	*15 mmHg	Renal failure 25%
	LVAD	34	53		*11 mmHg	Renal failure 12%

Cr= creatinine, CVP= central venous pressure, HM2= HeartMate 2, LVAD= left ventricular assist device, PCWP= pulmonary capillary wedge pressure, TR= tricuspid regurgitation, TVR= tricuspid valve procedure, VC= vena contracta

* Mean CVP is shown as preoperative CVP/ PCWP was not reported

† Mean preoperative creatinine is shown if reported. Robertson reported the proportion who had creatinine >2.0mg/dL preoperatively and Saeed reported the proportion of patients with preoperative renal failure (undefined).