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Does Elective or Emergent Operative Status Influence Outcomes in Patients Undergoing Implantation of Left Ventricular Assist Devices?

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ABSTRACT

Background: Acuity models to predict survival after left ventricular assist device (LVAD) implantation do not include operative status as one of the calculated variables. The effect of elective versus emergent LVAD implantation on outcomes has not been examined.

Methods: Patients were stratified into 2 groups based on operative status (elective versus emergent). Variables were compared to determine whether there were differences in outcomes between elective versus emergent LVAD recipients

Results: Of the 130 patients, 59 underwent an elective procedure, whereas 71 had their LVAD implanted as an urgent/emergent operation. Patients in the urgent/emergent cohort had significantly worse preoperative hepatic and renal function and higher central venous pressures. Survival rates at 30 days, 6 months, 1 year, and 2 years were analogous for both cohorts. Patients in the emergent cohort had a higher incidence of postoperative right ventricular failure, with the requirement for short-term right ventricular support in 9.9% versus 1.7% ($P = 0.054$). The incidence of other LVAD-related complications, were similar in both groups. Emergency status did not predict postoperative mortality in univariate analysis.

Conclusions: Although patients who underwent emergent LVAD implantations had worse preoperative renal and liver function and a higher incidence of postoperative right ventricular failure, they exhibited similar midterm survival and a similar incidence of other postoperative complications.

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INTRODUCTION

Continuous-flow left ventricular devices (LVADs) have exhibited superior outcomes compared to the older generation pulsatile devices [Rose 2001; Barbone 2002; Miller 2007; John 2008; Pagani 2009; Slaughter 2009; Slaughter 2010]. As a result, mechanical circulatory support (MCS) has become a dominant technology for patients undergoing treatment both as a bridge to transplantation (BTT) and destination therapy (DT) [Kirklin 2013]. In the current era of surgical treatment of advanced heart failure, patient selection is paramount, as patients with worse preoperative clinical status have inferior outcomes [Boyle 2011]. In addition, quantifying risk prior to LVAD implantation is essential for patients and families in order to make informed decisions.

Previous studies have demonstrated an increase in postoperative morbidity and mortality following non-LVAD cardiac surgery, when the operation is performed on an urgent or emergent basis [Czer 1984; Christakis 1988; Stark 1990; Craver 1992; Thourani 2000; LaPar 2010]. Emergency operative status is included in most risk stratification models for cardiac surgery [Geissler 2000; Kolh 2006; Nilsson 2006; Granton 2008; Wendt 2009]. However, acuity models to predict survival after LVAD insertion, such as the HM (HeartMate) II score [Cowger 2013], the DTRS (Destination Therapy Risk Score) [Teuteberg 2012], and the screening scale published by the Columbia Group [Oz 1995], do not include emergent operative status as one of the calculated variables. Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) scores have provided a useful categorization of risk, with higher levels (1, 2, and 3) clearly demonstrating worse short- and long-term outcomes [Lietz 2007; Stevenson 2009; Boyle 2011]. Patients with higher INTERMACS scores would most likely receive an LVAD on an emergent basis, although this is not always the case. We therefore hypothesized that an analysis of outcomes for patients receiving an emergent LVAD would demonstrate inferior results compared to patients who underwent an elective implantation. The objective of our study was to analyze our single-institutional 6-year experience implanting 130 continuous flow LVADs and to determine the impact of procedure status (emergent versus elective).

METHODS

This retrospective study was approved by our health system's institutional review board. We reviewed our institution's LVAD dataset and analyzed patients who underwent continuous-flow LVAD implantation as a BTT or DT from March 2006 until June 2012. A total of 130 patients were identified and stratified into subgroups based on whether they underwent an emergent or elective LVAD implant. Implantations were considered urgent/emergent if patients met one of the following criteria: (a) experiencing cardiogenic shock; (b) on urgent preoperative MCS, such as intra-arterial balloon pump (IABP), Abiomed, CentriMag, Impella; (c) on inotropes and presenting with acute or chronic worsening in end-organ function.

PATIENT DATA

Patient demographics and preoperative characteristics included age, sex, race, body surface area, body mass index (BMI), previous sternotomy, preoperative creatinine, liver function tests, and associated comorbidities—hypertension (HTN), diabetes mellitus, chronic renal insufficiency (CRI), dialysis, chronic obstructive pulmonary disease (COPD), and peripheral vascular disease (PVD). Hemodynamic and echocardiographic data included pre- and post-LVAD (at 1 and 6 months) central venous pressure, pulmonary artery pressure (PAP), pulmonary capillary wedge pressure (PCWP), LV ejection fraction (LVEF), cardiac output (CO), cardiac index, LV end diastolic diameter (LVEDD), right ventricular end diastolic diameter (RVEDD), mitral regurgitation (MR), and tricuspid regurgitation (TR). Operative characteristics included type of device (HeartMate II or HeartWare), implantation for BTT or DT, cardiopulmonary bypass (CPB), and cross-clamp times. Outcome variables were complications, postoperative mortality, and survival at 30 days, 180 days, 1 year, and 2 years, as well as causes of death. Complications included reoperation for bleeding, driveline infections, pneumonia, RV failure, respiratory failure, tracheostomy, acute renal failure (ARF), ischemic stroke, hemorrhagic stroke, gastrointestinal bleeding (GIB), severe aortic insufficiency, and pump thrombosis. CRI was defined as glomerular filtration rate (GFR) < 60 mL/min/m2. RV failure was defined as (a) need for inotropic support for more than 2 weeks or (b) need for RVAD support. Ventilator-dependent respiratory failure was defined as inability to wean from the ventilator for at least 1 week.

STATISTICAL ANALYSIS

Patients were stratified into emergent versus elective implantation groups. Continuous variables were reported as mean, standard deviation (SD), minimum, median, and maximum, and were compared between groups using 2-sided 2-sample t-tests. Alternatively, a 2-sided Wilcoxon rank-sum test was used if severe departures from normality were observed in the distributions. Categorical variables were reported as count and percent and were compared between the groups using chi-square tests. Alternatively, Fisher's exact test was used if expected counts were not sufficiently large. Similar tests were used to compare postoperative complications. Preoperative and operative characteristics were evaluated using Cox proportional hazards models to test whether or not each individual characteristic was a significant predictor of postoperative survival. Hazard ratios and 95% confidence intervals (CIs) for hazard ratios were reported. Using a conservative cutoff of $P < 0.10$, predictors in the univariate analysis were then placed in a multiple Cox proportional hazards model predicting postoperative survival. Adjusted hazard ratios and 95% CIs for the adjusted hazard ratios were reported. Tests were performed using SAS 9.2. Tests were considered significant at $P < 0.05$.

RESULTS

Demographic Characteristics of Patients Who Underwent Elective versus Emergent LVAD

A total of 130 patients underwent LVAD implantation as a BTT or DT during the study period at our center and were included in our study. Of these 130 patients, 59 underwent an elective procedure, whereas 71 had their LVAD implanted on an emergent basis. Demographics and preoperative characteristics for each of these subgroups are summarized in Table 1.

There were no significant differences between the groups in age, sex, race, BMI, BSA, etiology of heart failure, incidence of HTN, previous sternotomy, chronic COPD, PVD, preoperative LVEF, PAP, PCWP, or preoperative RV function (P = not significant). Diabetes mellitus was more common in the elective group ($P = 0.0114$), whereas central venous pressure (CVP) was higher in the urgent/emergent group ($P = 0.0143$). Preoperative hepatic and renal function were worse in the emergent cohort. Within the emergent group, 22 patients were on preoperative MCS (22/71, 30.9%). Types of MCS included IAB*P* (17/22, 77.2%), HeartMate XVE (2/22, 9%), CentriMag (2/22, 9%), and Abiomed (1/22, 4.5%)

CPB Time and Cross-Clamp Time

Both CPB times (123.4 versus 90.5 min, $P < 0.0001$) and cross-clamp times (27 versus 6.1 min, $P < 0.0007$) were significantly longer in the emergent group.

Elective and Emergent Postimplant Survival

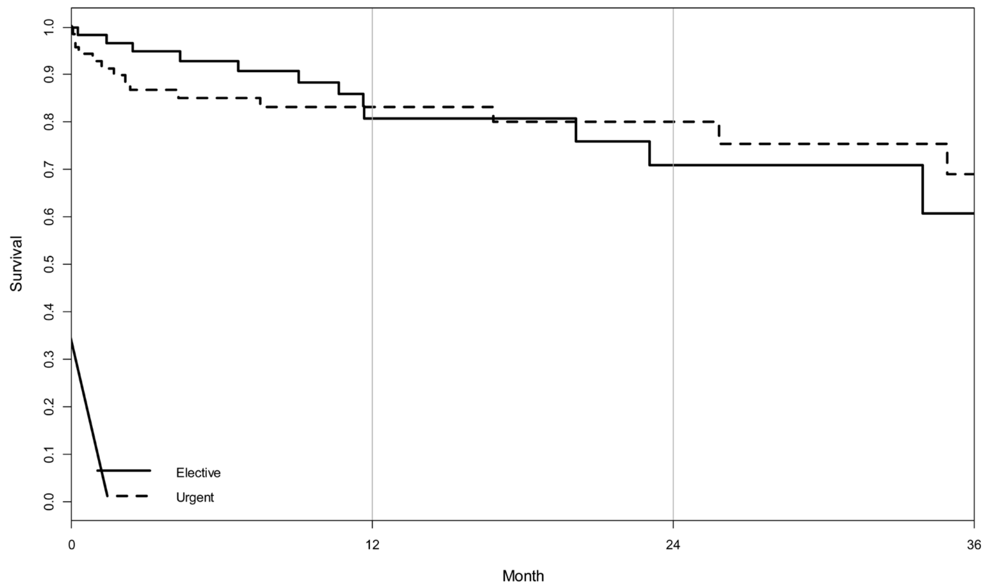
Survival rates were similar for both subgroups with 30-day, 6-month, 1-year, and 2-year survivals of 98%, 92%, 80%, and 70%, respectively, for elective patients versus 92%, 85%, 83%, and 80%, respectively, for emergent LVAD patients (Figure).

Transplantation Rates for Elective LVAD BTT Patients and Emergent LVAD BTT Patients

The indication for surgery was BTT in 52.5% (31/59) of elective cases versus 63.4% (45/71, $P = 0.2119$) of emergent cases. Among patients with an LVAD implanted for the indication of BTT, 13 (41.9%) elective LVAD patients underwent transplantation compared to 40% (18/45) of urgent/emergent LVAD patients.

Table 1. Demographic and Operative Characteristics of Patients Who Underwent Elective versus Emergent LVAD

Variable	Elective (n = 59)	Emergent (n = 71)	*P*
Age, mean (SD)	55.6 (10.2)	52.1 (13.1)	0.0934
Sex			0.4008
Female	18 (30.5%)	17 (23.9%)	
Male	41 (69.5%)	54 (76.1%)	
Race			0.7105
African American	26 (44.1%)	29 (40.8%)	
White	33 (55.9%)	42 (59.2%)	
BSA, mean (SD)	2.0 (0.3)	2.0 (0.3)	0.2825
BMI, mean (SD)	28.8 (5.4)	27.8 (5.5)	0.2891
Pre-VAD LVEF, mean (SD)	18.4 (9.1)	15.9 (7.0)	0.0813
Etiology of heart failure			0.9638
Ischemic cardiomyopathy	21 (35.6%)	25 (35.2%)	
No ischemic cardiomyopathy	38 (64.4%)	46 (64.8%)	
HTN	51 (86.4%)	58 (81.7%)	0.4637
Diabetes mellitus	33 (55.9%)	24 (33.8%)	0.0114
CRI	21 (35.6%)	28 (39.4%)	0.6526
Dialysis	1 (1.7%)	3 (4.2%)	0.4055
COPD	13 (22.0%)	12 (16.9%)	0.4598
PVD	8 (13.6%)	7 (9.9%)	0.5109
Previous sternotomy	18 (30.5%)	22 (31.0%)	0.9532
AST, mean (SD)	28.3 (13.6)	64.7 (124.9)	0.0279
ALT, mean (SD)	28.4 (20.1)	67.0 (120.8)	0.0166
Creatinine, mean (SD)	1.3 (0.4)	1.6 (0.7)	0.0049
Albumin, mean (SD)	3.4 (0.4)	5.1 (16.2)	0.4304
BTT or DT			0.2119
BTT	31 (52.5%)	45 (63.4%)	
DT	28 (47.5%)	26 (36.6%)	
Inotropes at time of implantation	44 (74.6%)	52 (74.3%)	0.9699
Concomitant cardiac procedure	9 (15.3%)	25 (35.2%)	0.0099
CPB time, mean (SD)	90.5 (36.9)	123.4 (50.5)	0.0001
Cross-clamp time, mean (SD)	6.1 (22.7)	27.0 (40.6)	0.0007



Kaplan-Meier curve comparing postoperative survival for elective and emergent LVAD implantations

Postoperative Complications, Hospital Length of Stay, and Readmission Rates

Postoperative complication rates were similar for elective and emergent LVAD patients as demonstrated in Table 2, except for postoperative RVAD support, which was more likely to occur in emergent LVADs (9.9% versus 1.7%, P = 0.05). Within the emergent group, 7 patients received RVAD, of which 4 died (57.1%). The only elective patient that received postoperative RVAD support, also died (100%). From the 3 emergent patients with postoperative RVAD support who survived, 2 patients had their RVAD implanted concomitantly with the LVAD, and 1 patient had the RVAD implanted on postoperative day 2. Of the 4 emergent RVAD patients who died, 3 received the RVAD after postoperative day 4 and 1 patient during the initial surgery. There were no significant differences in postoperative intensive care unit (ICU) stay (10.9 days for elective versus 11.8 days for emergent patients, P = 0.6571) and overall length of stay (LOS) (20.8 days for elective versus 22.5 days for emergent LVADs, P = 0.5418). Readmission rates within 30 days of hospital discharge were higher in the elective group (33.9% versus 18.3%, P = 0.0420). Pre- and postoperative (at 1 and 6 months) echocardiographic and hemodynamic data are presented in Table 3.

Causes of Death

Causes of death for elective LVAD implantation patients included septic shock (57.1%, 8/14), stroke (21.4%, 3/14), RV failure (7%, 1/14), multiorgan failure (MOF) (7%, 1/14), and refractory arrhythmias (7%, 1/14). Causes of death in the emergent group were RV failure (35.3%, 6/17), septic shock (17.6%, 3/17), stroke (17.6%, 3/17), MOF (11.8%, 2/17), bleeding (5.9%, 1/17), bowel perforation (5.9%, 1/17), and disconnection from power source (5.9%, 1/17).

Univariate Analysis

Univariate analysis demonstrated that preoperative CRI, alanine aminotransferase (ALT), and aspartate transaminase (AST) were significant predictors of survival. Emergency status did not predict postoperative mortality (odds ratio, 1.03; 95% CI, 0.49-2.13; P = 0.9470) (Table 4).

Cox Multivariate Logistic Regression Analysis

Variables that were significant in the univariate analysis ($P < 0.1$) were placed in a multiple Cox proportional hazards model with postoperative survival as the outcome. Stepwise logistic regression analysis demonstrated that preoperative AST and ALT remained significant predictors of post-LVAD survival (Table 5).

DISCUSSION

This study was undertaken to ascertain the effect of performing LVAD implantations on an emergent basis. One would certainly expect worse outcomes in patients receiving urgent/emergent LVADs, considering that higher morbidity and mortality after emergency procedures is a global phenomenon in every surgical specialty, including non-LVAD cardiac surgery. The primary finding in our analysis was that emergency status did not increase postoperative mortality or the incidence of postoperative complications. Surprisingly, there was a trend for improved midterm survival in emergent implantations. This occurred despite the fact that patients receiving LVADs on an emergent basis had significantly worse preoperative liver and renal function and increased CPB time. Aortic cross-clamp time with cardioplegic arrest, undertaken in order to perform a concomitant cardiac procedure (CCP), was also longer in the emergent group, although CCPs did

Table 2. Postoperative Complications*

Variable	Elective (n = 59)	Emergent (n = 71)	*P*
Resternotomy for bleeding	6 (10.2%)	8 (11.3%)	0.8406
DL infection	6 (10.2%)	7 (9.9%)	0.9532
Pocket infection	0 (0.0%)	1 (1.4%)	0.3601
Device infection	0 (0.0%)	2 (2.8%)	0.1939
Pneumonia	5 (8.5%)	6 (8.5%)	0.9961
Embolic stroke	3 (5.1%)	3 (4.2%)	0.8161
Hemorrhagic stroke	4 (6.8%)	6 (8.5%)	0.7219
Respiratory failure	5 (8.5%)	10 (14.1%)	0.3189
ARF	11 (18.6%)	23 (32.4%)	0.0757
Dialysis	3 (5.1%)	8 (11.3%)	0.2073
RHF	3 (5.1%)	13 (18.3%)	0.0223
RVAD	1 (1.7%)	7 (9.9%)	0.0538
GIB	17 (28.8%)	14 (19.7%)	0.2257
Reoperation for AI	2 (3.4%)	2 (2.9%)	0.8620
Tracheostomy	2 (3.4%)	2 (2.8%)	0.8506
Device exchange	2 (3.4%)	6 (8.6%)	0.2241
Overall postoperative stay, mean (SD) days	20.8 (13.4)	22.5 (16.7)	0.5418
Postoperative ICU stay, mean (SD) days	10.9 (11.2)	11.8 (11.2)	0.6571
Readmitted within 30 days	20 (33.9%)	13 (18.3%)	0.0420
Blood transfusion (2 or more units)	15 (25.4%)	19(26.7%)	0.4484
Duration of support, mean (SD) days	476.9 (359.4)	468.1 (430.2)	0.9002

*DL indicates driveline; RHF, right heart failure; AI, aortic insufficiency.

Table 3. Pre- and Postoperative (at 1 and 6 Months) Echocardiographic and Hemodynamic Data*

Variable	Elective (n = 59)	Emergent (n = 71)	*P*
Pre-VAD LVEF	18.4 (9.1)	15.9 (7.0)	0.0813
Post-VAD LVEF 1 month	19.6 (9.4)	19.1 (8.6)	0.7836
Post-VAD LVEF 6 months	25.1 (16.4)	26.5 (17.8)	0.7244
Pre-VAD LVEDD	73.6 (13.1)	69.4 (12.6)	0.0851
Post-VAD LVEDD 1 month	57.8 (17.2)	57.3 (13.6)	0.8634
Post-VAD LVEDD 6 months	62.3 (16.9)	59.8 (16.7)	0.5492
Pre-VAD CO	3.7 (1.2)	3.2 (1.3)	0.6477
Post-VAD CO 1 month	4.8 (1.2)	5.3 (1.3)	0.1029
Post-VAD CO 6 months	4.8 (1.3)	5.8 (5.5)	0.3403
Pre-VAD CI	1.8 (0.5)	1.5 (0.6)	0.6263
Post-VAD CI 1 month	2.4 (0.5)	2.7 (0.7)	0.1111
Post-VAD CI 6 months	2.4 (0.6)	2.4 (0.5)	0.6369
Pre-VAD PCWP	21.8 (8.6)	24.6 (10.4)	0.1211
Post-VAD PCWP 1 month	12.0 (8.8)	12.3 (6.4)	0.9182
Post-VAD PCWP 6 months	10.7 (6.0)	12.4 (7.1)	0.3316
Pre-VAD CVP	10.0 (5.3)	15.6 (7.4)	0.0143
Post-VAD CVP 1 month	7.8 (4.2)	9.7 (4.8)	0.0835
Pre-VAD PAPm	34.3 (10.5)	35.2 (10.9)	0.6599
Post-VAD PAPm 1 month	23.8 (8.4)	23.2 (8.1)	0.8114
Pre-VAD RVEDD	28.4 (12.3)	27.2 (9.6)	0.6234
Post-VAD RVEDD 1 month	29.6 (9.9)	29.5 (7.9)	0.9605
Post-VAD RVEDD 6 months	30.2 (9.7)	28.6 (8.1)	0.5099

*CI indicates, cardiac index, CPWP, capillary pulmonary wedge pressure; CVP, central venous pressure; PAPm, pulmonary artery mean pressure.

Table 4. Univariate Analysis: Predictors of Postoperative Survival

Variable	Hazard Ratio	95% CI	*P*
BTT or DT	1.60	0.78-3.30	0.1944
Sex	1.47	0.63-3.45	0.3669
Race	1.31	0.62-2.77	0.4807
Etiology of heart failure	0.61	0.30-1.27	0.1846
HTN	0.67	0.26-1.78	0.4214
Diabetes mellitus	1.10	0.54-2.26	0.7856
CRI	1.99	0.96-4.11	0.0577
COPD	0.93	0.36-2.46	0.8901
PVD	1.59	0.65-3.92	0.3081
Reoperation	1.45	0.69-3.05	0.3283
Inotropes at time of implantation	0.73	0.34-1.58	0.4222
Elective/emergent	1.03	0.49-2.13	0.9470
Concomitant cardiac procedure	0.80	0.30-2.11	0.6467
Pre-VAD LVEF	1.02	0.98-1.06	0.3453
Age	1.02	0.988-1.052	0.2244
CPB time	1.003	0.995-1.011	0.4165
Cross-clamp time	0.983	0.965-1.002	0.0628
Creatinine pre-VAD	1.73	1.02-2.95	0.0428
Albumin pre-VAD	0.81	0.40-1.62	0.7227
AST pre-VAD	1.005	1.002-1.008	<0.0001
ALT pre-VAD	1.0026	0.9992-1.0060	0.1309
BSA	1.52	0.41-5.60	0.5266
BMI	1.04	0.98-1.11	0.2094

Table 5. Cox Multivariate Logistic Regression Analysis

Variable	Hazard Ratio	95% CI	*P*
CRI	1.344	0.470-3.844	0.5812
Cross-clamp time	0.984	0.965-1.004	0.1077
Creatinine pre-VAD	1.363	0.569-3.262	0.4870
AST/ALT pre-VAD	1.004	1.000-1.008	0.0333

not increase operative risk on univariate analysis. Patient comorbidities, preoperative hemodynamic measurements, the need for preoperative inotropes, and the etiology of heart failure were analogous between the 2 groups. Additionally, outcomes were similar between the groups despite a significantly higher incidence of postoperative RV failure requiring RVAD support in the emergent cohort. This may be due to our aggressive approach in implanting an RVAD during the initial operation rather than returning to the operating room for a delayed RVAD after the patients has developed severe peripheral end-organ malperfusion, acidosis, and high pressor requirements. Early RVAD implantation is associated with decreased mortality compared to delayed RVAD insertion with end-organ dysfunction.

The implications of inserting an emergent LVAD are wide ranging and include more hemodynamic instability, more critically ill patients with multisystem organ failure, decreased ability to assess a patient's compliance and solidify access to postoperative care, and an abbreviated patient selection process. There are several potential ways to neutralize the surgical risk associated with emergent LVAD implantations, which include the following: (a) the artificial, complete maintenance of perfusion by the LVAD, which constitutes most of the systemic output; (b) the perioperative and long-term postoperative multidisciplinary approach to patient care, (c) the improved technology of newer continuous flow devices with less associated infectious and bleeding complications, (d) improvements in surgical implantation techniques; and (e) the "elective" LVAD patient is much sicker than the average surgical patient and is not too far in terms of acuity from patients receiving emergent LVADs.

There is only one study in the literature which examined the effect of emergency status on LVAD outcomes, which was published in 2009 by the Berlin group [Stepanenko 2010]. They reported that elective implantation, before the development of inotropic dependency, was associated with improved survival at 30, 180, and 360 days. Nonetheless, patients in this analysis were divided into 2 groups based on INTERMACS score (level I-III versus IV-V) and not emergent versus elective operative status. Studies of the influence of elective and emergency status on postoperative outcomes in non-LVAD cardiac surgery have been reported. Craver et al [Craver 1992] from Emory University reported 5-year survival rates of 91% and 83% (myocardial infarction (MI)-free survival) in 699 patients who underwent emergent coronary artery bypass graft (CABG) after failed percutaneous angioplasty. The same group showed significantly higher in-hospital mortality for emergent (41%) versus elective CABG with mitral valve replacement (MVR) (41% versus 14%) [Thourani 2000]. In the same study, postoperative mortality was 6% for elective isolated MVR versus 20% for emergent MVR. They also reported that urgent/emergent status correlated with lower long-term survival rates. Yang et al [Yang 2012] reported a trend toward higher in-hospital mortality in 141 octogenarians undergoing emergent AVR (10.2% versus 4.3%, $P = 0.1$). Song et al [Song 2012] analyzed 194 patients with Marfan syndrome who underwent proximal aortic replacement. These investigators showed that emergency status was associated with a higher incidence of chronic distal dissection and required more subsequent procedures, and that those patients had a worse associated postoperative quality of life. Survival rates were not reported in this study.

Our study has several limitations. First, our sample size was small and it is possible that the statistical tests were insufficiently powered. Second, our study was not a prospective, randomized trial and is subject to limitations inherent to any retrospective study. Third, our study was a single-institution study and selection bias may have been present.

In summary, our experience indicates that although patients undergoing emergent LVAD implantations have worse preoperative renal and liver function, have longer CPB times, and are more likely to develop postoperative RV failure requiring RVAD support, they still exhibit similar perioperative and midterm survival, LOS, and postoperative complications. The more sophisticated technology of newer generation devices and the dramatic improvement in systemic perfusion, albeit by an artificial mechanism, and advances in postoperative care may explain improved outcomes in patients receiving MCS on an emergent basis.

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