OUTCOMES WITH TEMPORARY MECHANICAL CIRCULATORY SUPPORT PRIOR TO MINIMALLY-INVASIVE CENTRIFUGAL LEFT VENTRICULAR ASSIST DEVICE

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Abstract

Background: Despite improved survival and morbidity after durable left ventricular assist device (dLVAD), outcomes for cardiogenic shock patients are suboptimal. Temporary mechanical circulatory support (tMCS) can permit optimization prior to dLVAD. Excellent outcomes have been observed using minimally-invasive dLVAD implantation. However, some feel tMCS contraindicates this approach. To evaluate whether left thoracotomy/hemisternotomy (LTHS) dLVAD placement is safe in this setting, we compared patients who did and did not require tMCS. Methods: Outcomes for patients receiving dLVADs via LTHS were compared among those bridged with ECMO, IABP, or no tMCS. We evaluated demographics, comorbidities, laboratory and hemodynamic data, and intra- and postoperative outcomes. Results: Eighty-three patients underwent LTHS dLVAD placement. Fifty did not require tMCS, while 22 (26%) required IABP, and 11 (13%) ECMO. Non-tMCS patients were primarily INTERMACS 3 (56%), while IABP recipients were mainly INTERMACS 2 (45%). All ECMO patients were INTERMACS 1. Patients with tMCS had worse end-organ function. Operative outcomes were similar except more concomitant procedures and red-cell transfusions in ECMO patients. ICU and hospital length of stay and inotrope duration were also similar. There were no differences in bleeding, stroke, and infection rates. Three- and twelve-month survival were: No tMCS: 94%, 86%; IABP: 100%, 88%; ECMO: 81%, 81% (p=0.45). Conclusions: Patients with cardiogenic shock can safely undergo LTHS dLVAD implantation after stabilization with ECMO or IABP. Outcomes and complications in these patients were comparable to a less severely ill cohort without tMCS.

INTRODUCTION

Despite continual improvements in durable left ventricular assist device (dLVAD) survival and morbidity, outcomes for patients in cardiogenic shock are inferior to those with less severe heart failure[1]. No consensus exists on the optimal method for stabilizing shock patients prior to dLVAD. Temporary mechanical circulatory support (tMCS), including extracorporeal membrane oxygenation (ECMO) and intra-aortic balloon pump (IABP), has been utilized, with highly variable results. A recent study of the INTERMACS registry, for instance, found worse survival and more early complications with ECMO bridging[2].

Our standard dLVAD technique is a minimally-invasive lateral thoracotomy/hemisternotomy (LTHS) using the Heartware HVAD (Medtronic, Minneapolis, MN)[3]. This technique yielded excellent perioperative outcomes and survival in the LATERAL trial, albeit in a highly selected cohort of mostly INTERMACS 3+ patients[4]. Utilizing this approach, our group has observed excellent outcomes in high-acuity patients as well. We hypothesized that patients requiring tMCS prior to LTHS HVAD would have similar outcomes to those without tMCS. Further, we propose that LTHS can be used safely for ECMO-bridged INTERMACS 1 patients without unacceptably high adverse event rates.

MATERIALS AND METHODS

Outcomes for patients receiving an HVAD via LTHS from 2013-2019 were compared among those bridged with ECMO, IABP, or no tMCS. We evaluated demographics, comorbidities, laboratory, echocardiographic, and hemodynamic data, and intra- and postoperative outcomes. These data were collected prospectively in an IRB-approved MCS program database.

Use of LTHS with the HVAD, as described by Schmitto[3], became our standard technique in April 2016. Prior to this, two patients underwent LTHS HVAD insertion. At the same time, we made VA ECMO our primary method of supporting patients in severe cardiogenic shock. In the preceding period, tMCS modality was dependent on surgeon preference, and could include ECMO or a percutaneous or surgical VAD.

IABP therapy was used for patients declining on inotropes, or who were inotrope-intolerant but not in severe shock (INTERMACS 2). Standard approach until 2019 was femoral insertion, which precludes ambulation. The goal was normalization of end-organ function and optimization of hemodynamics prior to dLVAD. Patients who continued to decline on IABP were converted to ECMO.

ECMO was initiated via peripheral cannulation. Distal perfusion cannulas were inserted routinely. The preferred strategy to relieve pulmonary edema was inotropes, followed by atrial septostomy[5,6]if necessary. Patients were managed in the cardiac surgery intensive care unit by a dedicated ECMO team. Patients were extubated and allowed to participate in physical therapy[7], including ambulation[8]. They were maintained on ECMO until resolution of end-organ dysfunction and vascular congestion, although dLVAD could be expedited in the face of ECMO complications.

Preoperative data were collected as near as possible to dLVAD implant. Exceptions were echocardiographic and hemodynamic data for ECMO patients, which were collected prior to ECMO. Pre-tMCS laboratory data were also collected. INTERMACS profile was determined by our multidisciplinary MCS team. Based on the analyses of Shah[9,10], it is our practice to assign all ECMO patients to INTERMACS 1, regardless of post-ECMO improvement. In patients supported with more >1 modality of tMCS, the final one prior to dLVAD was used for group assignment. Duration of tMCS was based on the final run prior to dLVAD. Patients were assigned to the tMCS groups if they had undergone support with either modality within a week of dLVAD. Complications were defined per INTERMACS criteria and included major and GI bleeding, device-related infection, and stroke (CVA). These were evaluated during the early (<3 month) and late (>3 month) postoperative periods. Patients were followed through death, transplant/explant, or February 29, 2020.

Statistical analysis was performed with Statistica 13 (Dell, Inc; Tulsa, OK). Normality was assessed with the Shapiro-Wilks and Kolmogorov-Smirnov tests. Normally distributed data are reported as mean±standard deviation, and non-normal data as median (interquartile range) (IQR). Continuous variables were compared between the three groups using one-way ANOVA for normally-distributed data, and the Kruskal-Wallis test for non-normal data. Comparison of pre- and post-tMCS variables between IABP and ECMO were made with a paired t-test or Mann-Whitney U test. Categorical variables were compared with the Pearson chi-squared test. Incidence rates for complications were compared using Poisson regression. Kaplan-Meier curves were used to depict survival by group, and were compared with the log-rank test. A p -value <0.05 was considered significant.

RESULTS

During the study period, 83 patients underwent LTHS dLVAD placement. Of these, 50 did not require tMCs, while 22 (26%) were bridged with IABP and 11 (13%) with ECMO. Preoperative data are summarized in Table 1.

Baseline demographics were similar among groups. Indication for dLVAD was primarily bridge to candidacy. Two ECMO patients (18%) and none in the other two groups required mechanical ventilation (p=0.001). All ECMO patients were INTERMACS 1, while IABP recipients were predominantly INTERMACS 2 (45%), and non-tMCS patients INTERMACS 3 (56%) (p<0.001). ECMO patients were hospitalized for median 14

days prior to dLVAD, versus 10 for IABP and 2.5 for no tMCS (p=0.002). Median ECMO duration was longer than for IABP (10 vs. 6 days, p=0.02).

Prior to dLVAD, ECMO patients had lower albumin and hemoglobin and higher AST, while IABP patients had higher creatinine. Echocardiographic variables were similar among the groups. Both tMCS groups displayed worse baseline hemodynamics (higher PCWP, CVP, and PAD; lower PA pulsatility index [PAPi]) compared to non-tMCS patients.

Table 2 compares pre- and post-tMCS end-organ function and net fluid balance during tMCS between IABP and ECMO recipients. Pre-tMCS ECMO patient values tended to be higher for all variables except BUN. Post-tMCS, IABP patients had significant decreases in BUN, creatinine, bilirubin, and MELD-XI, while ECMO patients had significantly decreased creatinine and MELD-XI. Decrease in creatinine was significantly greater for ECMO patients. Net fluid balance for the duration of tMCS and net fluid balance per day were not significantly different.

Operative data are presented in Table 3. Operative and cardiopulmonary bypass times did not differ among the groups. In addition to ECMO removal, 7 (64%) ECMO patients underwent concomitant procedures. These included: percutaneous septostomy closure in three; and septostomy closure with femoral artery repair, VT ablation, femoral thrombectomy, and veno-venous (VV) ECMO in one each. Fewer IABP (1 [5%]) and non-tMCS (4 [8%]) patients had concomitant procedures (p<0.001). In these patients, procedures were: VT ablation; splenectomy (for infarct) and femoral artery repair; surgical PFO closure with RVAD/VV ECMO; aortic valve plication; and left atrial appendage closure with VV ECMO.

One IABP and one non-tMCS patient required conversion to sternotomy, the former for coronary graft injury and the latter for hypoxemia and ventricular arrhythmias in the setting of an open PFO. That patient was one of two who required an RVAD. The other was an ECMO patient with intractable inotrope-dependent RV failure who underwent late RVAD insertion. ECMO patients more frequently required [?]4 units intraoperative red blood cells (64%, vs. 23% IABP and 4% no tMCS, p<0.001). No ECMO patient underwent transfusion-free implant. Despite this, no ECMO patient required reoperation for bleeding or delayed chest closure.

Post-dLVAD inotropic support duration did not differ among groups (median 7-10 days). Median ICU length of stay was slightly higher for ECMO (9 days vs. 6 in the other groups, p=0.08). Median hospital length of stay ranged from 16 days for no tMCS to 19 days for ECMO (p=0.21). Two operative deaths (18%) occurred in the ECMO group, one from multiorgan failure and one from a hemorrhagic CVA. There were no operative deaths in the IABP group and 2 (4%) in the no tMCS group (p=0.06).

Figure 1 compares rates (in events/100 patient-months [EPPM]) of postoperative adverse events. In the early phase (<3 months), major and GI bleeds were most common. Rates were similar in ECMO and non-tMCS groups. Device-related infections and CVAs were rare, and no ECMO patient suffered an early infection or ischemic CVA. One early hemorrhagic CVA occurred in an ECMO patient.

There were also no significant differences in rates of late (>3 months post-dLVAD) complications. In this phase, device-related infections were predominant. These occurred at a higher rate in IABP patients, although the trend is not significant (p=0.14). No late hemorrhagic CVAs occurred in ECMO or IABP patients, versus 0.93 EPPM in non-tMCS patients. Likewise, no ECMO patient had an ischemic CVA, compared to 0.62-0.71 EPPM in the other groups.

Figure 2 illustrates Kaplan-Meier survival and Figure 3 competing outcomes for the three groups. Overall survival curves are not different among groups (p=0.45). For ECMO patients, no late mortality occurred after two operative deaths, yielding 81% 3- and 12-month survival. By 12 months, 41% were transplanted. In IABP recipients 3- and 12-month survival were 100% and 88%. By 12 months, 36% were transplanted. In the no-tMCS cohort, 3- and 12-month survival were 94% and 86%, and 32% were transplanted by 12 months.

CONCLUSIONS

Our study examined outcomes of patients bridged to dLVAD with ECMO for severe cardiogenic shock, compared to less ill patients bridged with IABP or no tMCS. ECMO patients had a longer preoperative length of stay, more frequent mechanical ventilation, higher transaminases, lower albumin and hemoglobin, higher PCWP, lower PAPi, and more concomitant procedures. That said, operative and CPB times were similar amongst groups and reoperation rates were low. The postoperative length of stay in the ECMO group was slightly longer, though acceptable. We observed two perioperative ECMO deaths (18%), with exceptionally low early mortality in the other groups. Differences were not significant, but this highlights the greater severity of illness in ECMO recipients. Of note, longer-term outcomes of patients bridged with either form of tMCS were acceptable and comparable to those with no tMCS.

Use of ECMO as bridge to dLVAD remains controversial, as evidenced by the recent INTERMACS analysis of Ton et al.[2] They studied 2013-2017 registry data, which included 1138 patients bridged to dLVAD with ECMO and 3901 bridged with IABP. Their conclusion was that the exceptional acuity of ECMO-bridged dLVAD patients merits an even more severe profile ("INTERMACS 0").

Three-month survival in that study was 76% ECMO, 88% IABP, and 91% no tMCS, while 12-month survival was 67% ECMO, 79% IABP, and 82% no tMCS. We observed similar survival in our IABP and no tMCS cohorts (100% and 94% at 3 months; 88% and 86% at 12 months), but saw improved survival in the ECMO cohort (81% at 3 and 12 months). They observed increased early bleeding (19 EPPM) and ischemic CVA (2.8 EPPM) in ECMO patients. By contrast, our ECMO cohort had an early bleeding rate similar to that of non-tMCS patients (10.7 and 9.8 EPPM) and lower than the INTERMACS no tMCS cohort (13.2 EPPM). We observed more early bleeding (19.9 EPPM), driven by increased GI bleeding (10.7 EPPM), in the IABP cohort. No early ischemic CVA occurred in ECMO patients, compared to 2.8 EPPM in the INTERMACS analysis. One early hemorrhagic CVA occurred in an ECMO patient, for a rate of 3.55 EPPM. Late events were similarly rare in our analysis, with the exceptions of more infections in the IABP group and more hemorrhagic CVAs in the no tMCS group.

Poor ECMO survival in the INTERMACS series is likely driven by the high prevalence of biventricular support (22% of ECMO patients vs. 5% IABP and 3% no tMCS). Patients with biventricular support had reduced 3-month (61-69%) and 12-month (50-57%) survival. By comparison, none of our patients required durable BiVAD. Two patients (1.2%; 1 ECMO, 1 non-tMCS) required temporary RVAD, one of which expired in the perioperative period.

Similarly, Tsyganenko[11] reported a large single-center series (100 ECMO to dLVAD patients) with 38% operative and 57% 12-month mortality. One third required an RVAD. Shah[9]described 68 patients bridged with non-IABP tMCS, including 22 ECMO. They found that ECMO outcomes were similar to non-tMCS INTERMACS 1 patients despite improved hemodynamics and end-organ function in the ECMO group. In this series, 21% of tMCS and non-tMCS INTERMACS 1 patients required RVAD, vs. 2% of INTERMACS 2-3. Twelve-month survival was 70% tMCS, 77% non-tMCS INTERMACS 1, and 82% INTERMACS 2-3 ($p<0.001$).

In contrast, Han[2] showed very good 12 month survival for both ECMO-bridged (78%; N=18) and non-ECMO INTERMACS 1 (88%; N=17; 47% IABP), which they attribute to 46% of patients being transplanted within <12 months. Our 12-month transplantation rates were 32-41%.

ECMO is our primary tMCS for severe cardiogenic shock because we are a high-volume (˜200 cases/yr) center with protocolized management. Patients are routinely extubated and mobilized[7,8], allowing rehabilitation prior to dLVAD. We routinely await renal and hepatic recovery prior to dLVAD, even if it prolongs ECMO support. Our median ECMO duration was 10 days, and 4 patients (36%) were supported >14 days, all of which survived to discharge.

We acknowledge this may be contrary to current literature. Cheng[12] reported better early survival in patients transitioned to durable MCS after <4 days versus longer or not at all. Tsyganenko[11] found >7 days of ECMO was an independent risk factor for mortality. Durinka[13] reported using longer-duration support (mean 12.1 days) to await normalization of end-organ function before dLVAD. However, they found much poorer survival

for patients supported >14 days (25% vs. 92% <14 days).

We acknowledge that ECMO is not risk-free. Complications include bleeding, limb and spinal-cord ischemia, strokes, compartment syndrome, and cannulation site infection[14]. However, we believe some of the morbidity and mortality reported in the above-cited studies is due to prolonged intubation, which may impair RV function. In the studies that report mechanical ventilation for ECMO-bridged patients, the incidence ranges from 59-86% with RVAD usage ranging from 21-29%[10,11,15]. In our cohort, 2 patients (18%) were intubated at dLVAD insertion. One of these expired early from multiorgan failure, and the other required VV ECMO due to persistent hypoxemia. These patients were supported six and eight days, but may not have been sufficiently optimized. Finally, one ECMO patient (9%) required an RVAD. This patient was high risk due to prior chest radiation, three prior sternotomies, and biventricular dysfunction (pre-ECMO PAPi 1.2).

We also believe standardizing to the LTHS approach improved outcomes in ECMO-bridged dLVAD recipients. It has been postulated that leaving the heart in its natural position, avoiding RV compression, and leaving the pericardium intact reduce post-LVAD RV distention and failure[16]. We have previously shown that the LTHS approach improves outcomes in patients with RV failure[17].

Other studies evaluating minimally-invasive dLVAD for patients in cardiogenic shock include Wert[16], who compared LTHS HVAD placement to sternotomy in INTERMACS 1 patients. In this series, [?]90% of patients in both groups were on ECMO, and half had prior cardiac surgery. Seventy percent of LTHS patients remained on ECMO post-LVAD, for mean 3.5 days. In this very sick cohort, mean ICU stay was 16, and total hospital stay 31 days (p>0.05 vs. sternotomy). Significantly fewer LTHS patients required an RVAD (6% vs. 22%), and 3-month (27%) and 12-month (30%) mortality were significantly better than the 50% mortality at both timepoints in the sternotomy group.

Sagebin[15] compared outcomes for patients on ECMO who received a Heartmate 3 (Abbott, Abbott Park, IL) via a complete sternal-sparing (CSS) technique to those implanted via sternotomy. Median ECMO support was 8 days, and 59% were on mechanical ventilation. Eighteen percent of CSS patients required an RVAD, vs. 31% of sternotomy patients (p=0.08). Median ICU stay (12 vs. 11 days) and total stay (22 vs. 34 days) were similar. Six-month survival was 89% CSS and 68% sternotomy.

The same group[18] presented a large series comparing CSS to sternotomy for Heartmate 3. There was a high prevalence of INTERMACS 1 (41% CSS, 34% sternotomy) and ECMO (22% CSS, 13% sternotomy). They found a lower incidence of reoperation for bleeding (5% vs. 20%) and RVAD use (5% vs. 16%), and shorter median length of stay (15.5 vs. 21 days) for CSS. Six-month survival was 93% CSS and 77% sternotomy.

Our IABP patients tended toward worse renal and similarly poor RV function indices as ECMO patients. IABP has been shown not to improve survival in cardiogenic shock complicating myocardial infarction[19]. IABP also does not provide biventricular support. Our IABP patients had less improvement in creatinine during tMCS. Their higher incidence of early bleeding may have been partially due to ongoing congestion and renal dysfunction. However, their overall survival was excellent and none required an RVAD.

In summary, this report augments the growing body of evidence of improved outcomes with minimally-invasive dLVAD insertion. High-risk patients with cardiogenic shock were able to safely undergo LTHS dLVAD implantation after stabilization with ECMO or IABP, with acceptable short- and long-term outcomes. Perioperative outcomes and complication burden were also comparable to a less severely ill cohort who did not require tMCS.

Author Contributions: Sorensen: concept/design, data collection, data analysis/statistics, drafting manuscript; Griffith: concept/design, critical revision; Feller: concept/design, critical revision; Kaczorowski: concept/design, data analysis, critical revision, approval.

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FIGURE LEGENDS

Figure 1. A. Early (<3 months post-dLVAD) and B. Late (>3 months post-dLVAD) complications by presence of preoperative tMCS.

Figure 2. Kaplan-Meier survival by presence of pre-dLVAD tMCS. Patients were censored at transplant, explant for recovery, or end of follow-up (February 29, 2020).

Figure 3. Competing outcomes for patients bridged to dLVAD with A. ECMO; B. IABP; or C. No tMCS. Abbreviation: HTx: heart transplant

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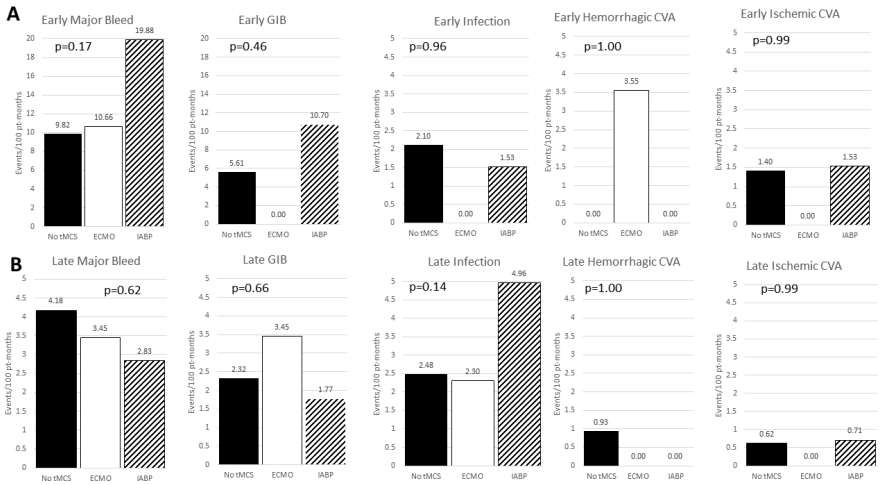

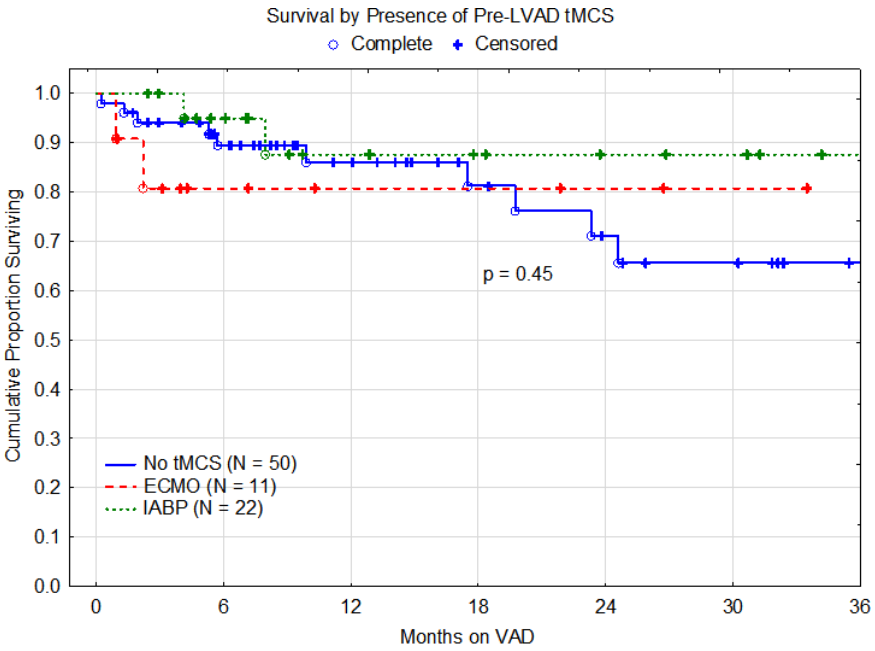

Group	Number at risk (Survival)			
	0 Months	3 Months	12 Months	24 Months
No tMCS	50 (100%)	44 (94%)	26 (86%)	13 (71%)
ECMO	11 (100%)	8 (81%)	3 (81%)	2 (81%)
IABP	22 (100%)	20 (100%)	10 (88%)	7 (88%)