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Article

Use of Intravascular Micro-Axial Left Ventricular Assist Devices as a Bridging Strategy for Cardiogenic Shock: Mid-Term Outcomes

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Abstract: Objectives: Cardiogenic shock [CS] is associated with a high-mortality. Suitable patients maybe successfully bridged using newer intravascular micro-axial left-ventricular assist devices [M-LVAD] for recovery or determination of definitive therapy. **Methods:** Between January-2020 and July-2024, 107 patients underwent placement of M-LVAD for CS. The cohort was divided into 4 groups based on their destination; group-1: 34 patients [32%] receiving transplant; group-2: 25 patients [23%] receiving durable LVAD; group-3: 42 patients [39%] bridging from post-cardiotomy CS [PCCS]; and group-4: 6 patients [5.6%] bridging decision/recovery [these were excluded from analysis]. Multivariable logistic-regression [MLR] and Cox-regression [MCR] models identified predictors of early-hospital and late mortality, with data reported as odds ratios [ORs], and hazard ratios [HRs], respectively. $P < 0.05$ was statistically significant. **Results:** Complications included device-malfunction [n=6, 6%], gastrointestinal bleed [n=9, 9%], stroke [n=11, 11%]; long-term hemodialysis [n=21, 21%]. Early-hospital mortality included 13 patients [13%]: 2 in group-1, 1 in group-2 and 10 in group-3 [p=0.02]. In the MLR model, the category of cardiogenic shock requiring M-LVAD placement was statistically significant [OR=4.7 (0.9-24), $P=0.05$]. Patients were followed for up to 4.5-years, and 23 deaths occurred; group-1: 3 patients, group-2: 5 patients, and group-3: 15 patients [p=0.019]. At 4.5-years, actuarial survival was $90.7 \pm 5.1\%$ in group-1, $79.2 \pm 8.3\%$ in group-2, and $62.8 \pm 7.7\%$ in group-3 [$P=0.01$]. In the MCR model, M-LVAD category [HR=3.63 (1.03-12.9) $P=0.04$], and long-term postoperative dialysis [HR=3.9 (1.6-9) $P=0.002$], emerged as statistically significant predictors of long-term mortality. **Conclusions:** In cardiogenic shock, our mid-term outcomes demonstrate good survival with M-LVADs as bridge to transplant and durable LVAD, and reasonable survival as bridge to recovery following cardiotomy, reduced ECMO usage and early ambulation/rehabilitation.

Keywords: ECMO; cardiogenic shock; micro-axial left ventricular assist device; temporary mechanical circulatory support; heart recovery; heart replacement

1. Introduction:

Cardiogenic shock [CS] in adults has a high mortality, especially when occurring post-cardiotomy [PCCS]. Previous studies have evaluated the role of ECMO in PCCS, and have described a high mortality of 42-44% [1,2]. A more contemporary series described better results with ECMO in PCCS of up to 67%, though that relied on the use of levosimendan, which is not FDA-approved in the USA [3]. Suitable patients in CS maybe successfully bridged to decision including transplant, durable left ventricular assist device [LVAD] or recovery using newer intravascular micro-axial ambulatory LVAD [M-LVAD] [4]. This approach can maintain or improve end-organ function and enables independent ambulation thereby preserving muscle mass, and potentially improving outcomes after operative therapy. We describe our single center experience with this device.

2. Methods:

Between January-2020 and May-2024, 107 patients underwent placement of M-LVAD for cardiogenic shock, and followed till September-2024. These included: Group-1-transplant: 34 patients [32%] patients underwent cardiac transplantation with one of these patients receiving a heart and kidney transplant; group-2-LVAD: 25 patients [23%] underwent placement of a durable LVAD; group-3-PCCS: 42 patients [39%] had placement of M-LVAD as bridge to recovery from PCCS, of which 16 patients had ECMO initially, and 20 patients had M-LVAD straightaway for weaning from cardiopulmonary bypass [CPB] following cardiotomy. In 6 patients [4.3%] it was implanted as a bridge to recovery/decision. Three patients were deemed to be ineligible for either transplantation or LVAD due to social circumstances [n=3] or metastatic cancer [n=1]. All these patients subsequently died following explantation of the M-LVAD. The fifth patient was a Jehovah's Witness and demanded transfer to a center experienced in implanting LVADs in Jehovah's Witnesses, and was lost to follow-up. The sixth patient had biopsy-proven giant-cell myocarditis that improved with immunosuppressive therapy and the device was explanted on the 28th day. These 6 patients were excluded from analysis.

The primary study end point was in-hospital mortality, and the secondary end points were overall survival, and device-related complications, including implantation site bleeding, device failure requiring exchange, haemolysis, dialysis or stroke anytime. Data was collected prospectively and entered into database maintained on secure hospital servers, and analyzed retrospectively [STUDY00017861]. This study was approved by the institutional review board of Penn State University, approval included a waiver of informed consent. All relevant data are within the manuscript and its supporting Information files. Normally distributed data was reported as means and standard deviations, using the analysis of variance test for differences between groups. Variables were then entered into a multivariable logistic-regression model to identify predictors of early hospital mortality, and the data was reported as odds ratios [OR]. Survival data was plotted by the Kaplan-Meier method, using the log-rank test for differences between the groups. Variables were then entered into a multivariable Cox-regression model to identify predictors of late mortality, and the data was reported as hazard ratios [HR]. $P < 0.05$ denoted statistical significance across all analyses.

2.1. Technique of M-LVAD Insertion:

A 7-cm transverse incision is made 2-cm inferior to the lateral half of the right clavicle. The pectoralis major and minor muscles are divided, and the axillary artery and vein are identified and mobilized, carefully avoiding the cords of the brachial plexus. Vessel loops are placed proximally and distally [Figure-1A]. Frequently, the subclavian vein overlies the artery and requires to be mobilized to one side with Vessel loops. The patient is then given 5000-units of heparin followed by the placement of a side-biting clamp on the subclavian artery. We prefer the subclavian artery to be >6.5 mm in size as measured by preoperative Doppler examination, for Impella-5.5 placement. A longitudinal arteriotomy is performed. An 8-mm Gelweave Dacron graft [Terumo Aortic US, Sunrise, FL] is then bevelled at a 45° angle and anastomosed end-to-side to the subclavian artery using continuous 5-0 Prolene suture [Figure-1B]. The obturator for the M-LVAD is then secured in place within the graft with the special plastic clips. A 0.035" Rosen J-wire [Cook Inc., Bloomington, IN] is used in conjunction with an AL-1 [Cordis Corporation, Miami Lakes, FL] catheter to reach the aortic root. With the AL-1 catheter pointing towards the aortic valve, the 0.035" J-wire is used to cross the aortic valve, followed by the AL-1 catheter. The J-wire is then removed and a 0.018" wire that is included with the M-LVAD is passed through the AL-1 catheter and positioned in the apex of the LV, and the AL-1 catheter is removed. The M-LVAD, is then flushed with heparinized saline, and backloaded onto the 0.018" wire. The M-LVAD is passed over the 0.018" wire under fluoroscopic and trans-esophageal echocardiographic [TEE] guidance with appropriate position in the left ventricle [Video-1].

The guidewire is then removed and the M-LVAD support is initiated at 1 L/min and then gradually increased to 5.5 L/min. Appropriate position of the device is confirmed on TEE and fluoroscopy, with the tip positioned 5.5-5.8 cm below the aortic valve and pointing in the cavity of

the LV, and away from the interventricular septum, lateral wall and the mitral valve [figure-1C]. The graft is then trimmed and secured to the obturator with multiple silk sutures, and brought out through the lateral aspect of the incision, and secured in that position once again with multiple silk sutures. After ensuring adequate hemostasis, the incision is closed in a standard manner with interrupted braided absorbable sutures and skin staples [figure-1D].

Anticoagulation while on M-LVAD support is sodium bicarbonate solution in the purge solution and systemic heparin titrated to maintained a Partial Thromboplastin time [PTT] of 40-50 seconds. Patients diagnosed with Heparin induced Thrombocytopenia [HIT] are treated with Argatroban infusion to maintained a PTT of 40-50 seconds.

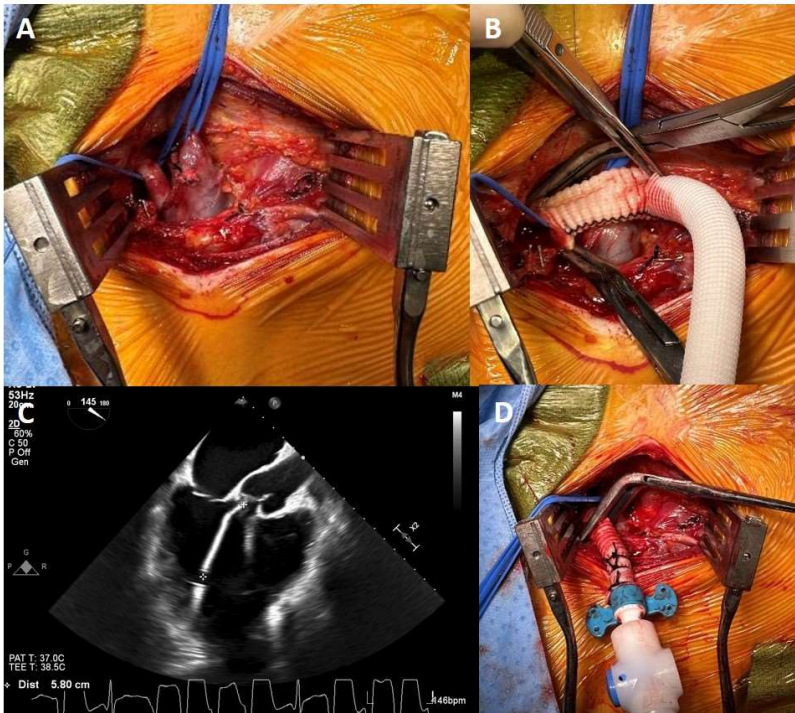


Figure 1. A: Exposure of the axillary vessels. B: Anastomosis of the graft to the axillary artery using 5-0 Prolene suture. C: TEE confirming length and position of Impella-5.5 inside the LV cavity. D: Completed Impella-5.5 insertion.

3. Results:

Median age was 58.4±13.2 years, and body mass index was 29.9±5.4 kg/m²; 14 patients were females [14%]. Percutaneous right ventricular assist device [p-RVAD] support was required in 15 patients [15%]: 5 patients [5%] after LVAD, 10 patients [10%] for PCCS, where it was used in conjunction with M-LVAD for LV support. No patients in the bridge to transplant group required p-RVAD support. Their preoperative characteristics outlined in Table 1. Twenty patients were transitioned from ECMO to M-LVAD: 3 patients [3%] in group 1, 6 patients [6%] in group 2, and 11 patients [11%] in group 3.

Table 1. Preoperative characteristics by groups:.

Variable	Group-1 [n=34]	Group-2 [n=25]	Group-3 [n=42]	P-value
	Means±SD	Means±SD	Means±SD	
Age [years]	53±12.4	57.5±13	63.3±12.4	0.002
Body mass index	28.5±3.9	29.1±5.3	31.4±6.1	0.045
	Number [%]	Number [%]	Number [%]	
Female	2 [5.9]	3 [12]	4 [9.5]	0.69
RVAD	0	5 [20]	10 [24]	0.009
ECMO to M-LVAD	3 [9]	6 [24]	11 [26]	0.043

SD: Standard-deviation.

3.1. Postoperative Results:

Complications are outlined in Table 2, and included device malfunction requiring exchange in 6 patients [6%], axillary hematoma re-exploration in 10 patients [10%], gastrointestinal bleed in 9 patients [9%], long-term hemodialysis in 21 patients [21%], heparin induced thrombocytopenia in 4 patients [4%] requiring cessation of heparin therapy and commencement of argatroban infusion, and central nervous system [CNS] ischemic stroke in 11 patients [11%]. For CNS strokes, we have an aggressive protocol in our hospital. The bedside nurse alerts a ‘brain-attack’ upon noticing any CNS symptoms/signs, triggering an immediate response from neurology and a CT-angiogram, and upon identification of thrombus involving a large cerebral vessel, promptly extracted by interventional team. With this aggressive protocol in place, we noticed that 8 patients had complete resolution of their neurological disabilities while 3 patients had residual deficits, isolated limb weakness [n=2] and dysphasia [n=1]. None of these CNS events were life-threatening. Perioperative mortality included 13 patients [13%]: 2 in group-1, 1 in group-2 and 10 in group-3 [p=0.02].

Table 2. Postoperative complications:.

	Group-1 [n=34]	Group-2 [n=25]	Group-3 [n=42]	P-value
	Means±SD	Means±SD	Means±SD	
Days on Impella support	27± 21	20± 14	14.5± 11	0.003
Intensive care unit days	38.7± 26	53±30.5	27.8± 25	0.002
	Number [%]	Number [%]	Number [%]	
Axillary hematoma	5 [14.7]	3 [12.5]	2 [4.8]	0.32
Device malfunction	2 [5.9]	2 [8]	2 [4.8]	0.87
Gastrointestinal bleed	2 [5.9]	1 [4]	6 [14.3]	0.3
Stroke	1 [2.9]	2 [8]	8 [19]	0.07
Right ventricular assist device	0	5 [20]	10 [27.8]	0.004
Dialysis	4 [11.8]	5 [20]	12 [28.6]	0.195
Hospital mortality	2 [5.9]	1 [4]	10 [23.8]	0.021

SD: Standard deviation.

3.2. Predictors of Perioperative Mortality:

We fitted a multi-variable logistic-regression [LR] model to explore the association between the independent variables and hospital mortality. The category of cardiogenic shock requiring M-LVAD placement was statistically significant [OR=4.7 (0.9-24), P=0.05] [Table 3].

Table 3. Logistic-Regression: Predictors of hospital-mortality.

	Odds Ratio [OR]	OR 95% confidence intervals	P-value
Right ventricular assist device	1.3	0.28-6	0.74
M-LVAD category	4.7	0.9-24	0.05

ECMO: Extracorporeal membrane oxygenator. M-LVAD: Microaxial left ventricular assist device.

3.3. Long-Term Results:

Patients were followed for up to 4.5-years. During the follow-up period 23 deaths occurred; group-1: 3 patients [8.8%], group-2: 5 patients [20%], and group-3: 15 patients [35.7%] [p=0.019]. At 4.5-years, actuarial survival was 90.7±5.1% in group-1, 79.2±8.3% in group-2, and 62.8%±7.7% in group-3 [P=0.01, figure-2].

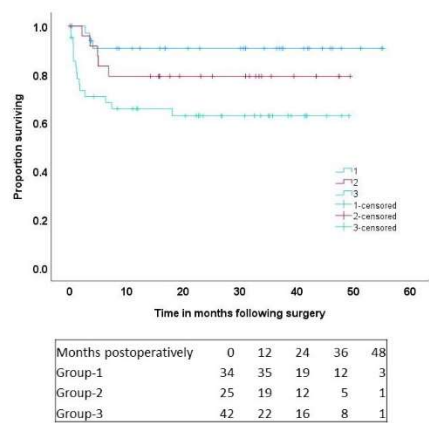


Figure 2. Survival by categories of Impella-5.5. Group-1 transplant. Group-2 durable left ventricular assist device. Group-3 post cardiectomy support.

3.4. Predictors of Long-Term Mortality:

3.4.1. Cox Regression:

Based on the univariate Kaplan Meier survival analysis which identified M-LVAD category, long-term postoperative dialysis and postoperative gastrointestinal bleeding as the predictors with $P < 0.1$, we conducted a Cox-regression analysis to assess the impact of various covariates, making the appropriate statistical adjustments [5]. Only M-LVAD category [HR=3.63 (1.03-12.9) $P=0.04$], and long-term postoperative dialysis [HR=3.9 (1.6-9) $P=0.002$], only emerged as statistically significant predictors of long-term mortality [Table 4]

Table 4. Cox aggression multivariable predictors of long-term mortality.

covariate	Hazard Ratios [HR]	HR 95% confidence interval	p-value
M-LVAD category	3.63	1.03-12.9	0.04
Postoperative long-term hemodialysis	3.9	1.6-9	0.002
Gastrointestinal bleeding	1.5	0.5-4.5	0.43

M-LVAD: Microaxial left ventricular assist device.

4. Discussion:

Cardiogenic shock [CS] in adults has a high mortality, especially when occurring following cardiectomy. Recent studies have evaluated the role of ECMO in PCCS, and have described a high mortality of up to 42-56% [1,2,6]. A more contemporary series described improved results with ECMO in PCCS, though that relied on the use of levosimendan, which is not available for use in the United States of America [3]. Presently, ECMO is an accepted strategy to prolong survival in these patients [7].

Newer intravascular micro-axial LVAD devices, appear to be suitable for bridging patients with CS to transplant or durable LVAD [4], with/without a p-RVAD [8]. Placement of these upper-body devices facilitates weaning from femoral venoarterial-ECMO and therefore early ambulation and prehabilitation, thereby preserving muscle mass, and making these patients better candidates for transplant or LVAD, and also reducing ECMO related hematological, neurological and limb complications. Assessment of RV-function is difficult in patients on ECMO even in the presence of a plethora of measurements [9]; poor RV-function adversely impacts post-LVAD survival. Similarly, assessment of pulmonary vascular resistance [PVR] is difficult in patients on ECMO [10]; high PVR

can adversely impact post-transplant survival. Assessment of RV-function and PVR can be easily accomplished with an M-LVAD, thereby greatly improving outcomes following transplant or LVAD implantation. Furthermore, ECMO has potentially deleterious effects on pulmonary, neurologic, coagulation systems, along with limb-ischemia and infective complications [11], all of which are improved by switching from ECMO to M-LVAD therapy.

Previously, Pawale et al. [12] described their results in 43 patients with refractory CS treated with direct implantation of durable LVAD without any bridging strategies. They described operative mortality of 14% and survival of 73.9% at 12-months, and concluded that this strategy provides good midterm outcomes and obviates the need for bridging strategies for CS, thereby avoiding associated complications including repeat surgeries for bleeding, requirement for LV-venting, limb-ischemia, temporary device and/or cannula exchanges. Our results have shown better actuarial survival of those bridged to LVAD with microaxial temporary devices of $79.2 \pm 8.3\%$ at 4.5-years. Furthermore, direct implantation without a bridging strategy does not allow for time to consider the implantation of such an expensive device; some patients may not be LVAD candidates due to lack of social support, disseminated malignancy, or active gastrointestinal lesions predisposing to profuse bleeding on anti-coagulation. In our series, we excluded 4 patients from advanced therapies due to aforementioned considerations. Some patients may be better served by cardiac transplantation; some patients may recover following percutaneous coronary intervention for acute MI and therefore not require a durable LVAD or transplant, and some patients may indeed have a potentially treatable condition [13]. The micro-axial temporary LVADs allow time to LV-recovery or develop the most suitable long-term treatment plan.

In our series of patients, we were able to demonstrate low rates of adverse events combined with good survival by utilizing these micro-axial temporary LVADs. Using these devices for bridging patients with cardiogenic shock, we were able to triage them into categories of transplantation, durable LVAD support or anticipated recovery, and also avoid complications described in previous studies with other more invasive temporary support devices [12,13]. Importantly, in patients who were eligible for cardiac transplantation, implantation of these M-LVADs enabled early mobilization and ambulation as status-2 on the waiting list, thereby preserving muscle mass. In the transplant cohort, we demonstrated an excellent actuarial survival of 90.7 ± 5.1 at 4.5 years.

Our study is also one of the larger ones to describe post-cardiotomy support in 42-patients using the M-LVAD device. In 16-patients, ECMO was used to wean from cardiopulmonary-bypass [CPB]; within 1-week, these patients were transitioned to microaxial-LVAD support as ECMO-weaning echocardiographic studies determined that longer duration of LV-support was required; p-RVAD support was also required in 4-patients. In 26-patients, microaxial-LVAD was used to wean from CPB; 6-patients also required percutaneous-RVAD. Actuarial survival was 62.8 ± 7.7 at 4.5-years in these 42 patients. Utilization of the microaxial-LVAD in PCCS, with/without p-RVAD, can facilitate weaning from ECMO or even avoid postoperative ECMO completely, with its inherent complications [11]. This strategy greatly improves outcomes following high-risk cardiac surgery.

In our series, p-RVAD support was required in 15-patients [15%]. In the LVAD-group, 5-patients required p-RVAD support. In the PCCS-group, in conjunction with microaxial-LVAD, 10-patients required p-RVAD+ECMO support not only for RV failure but also for oxygenation purposes. Interestingly, in the patients presenting with cardiogenic-shock and undergoing placement of microaxial-LVAD, either as a bridge to transplantation or as a bridge to durable LVAD, mechanical offloading of the LV and consequent reduction in the LVEDP, in conjunction with inotropes, was sufficient to maintain RV function, without requirement for p-RVAD.

Prior studies utilizing these micro-axial ambulatory temporary LVADs have corroborated our results in Group-1 and group-2 by demonstrating better unloading and recovery of LV function, shorter duration of ventilation, earlier ambulation, no ECMO-related complications, and therefore improved overall outcomes and survival [14-16].

Compared to previous studies [15], we were able to follow these patients for up to 4.5 years with good survival as outlined above. Furthermore, our study is probably the first to examine outcomes between patients undergoing placement of these devices in different categories of cardiogenic shock.

Multivariate analysis demonstrated statistically significant 3.6-4.7 fold worse survival in post cardiectomy support cardiogenic shock group compared to the group bridged to transplantation, utilizing the microaxial-LVAD as a bridging strategy to recovery from cardiogenic shock.

We found a higher incidence of stroke in our series compared to others [15]. However, due to our enhanced intensive-care protocols, we were able to limit the extent of disability. The increased numbers of strokes were found in the PCCS category, who have greater pre-existing incidence of atherosclerotic and cerebrovascular disease. We developed a protocol of cutting the shaft of the M-LVAD device following application of the aortic clamp during recipient cardiectomy during a transplant, or through the ventriculotomy during implantation of LVAD, and removing the device directly this way, thereby eliminating the risk of dragging any clots on the device through the innominate artery. In patients where the device was removed several weeks following cardiectomy, we employed bilateral carotid occlusion along with occlusion of the distal axillary artery during withdrawal of the M-LVAD through the Dacron graft, and performed proximal and distal embolectomies with an embolectomy catheter to flush out any residual clots. With these techniques, we were able to minimize the number of strokes [n=2] in the second half of our cohort.

4.1. Limitations:

The number of patients in the study was small. However, it represents a clean group of patients operated on by a limited number of surgeons, with a consistent practice of M-LVAD placement in terms of indications, surgical technique, and selection for the appropriate triage category.

5. Conclusions

These temporary microaxial intravascular LVADs have completely changed the way that cardiogenic shock has been managed over the last 3-years at our institution, with excellent mid-term outcomes. Larger studies and randomized controlled trials would be further required to corroborate these findings.

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Conflicts of Interest: No conflicts of interest to disclose for any of the authors

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