Comparative Study of Outcome of Axial Continuous-Flow HeartMate II LVAD Implantation with Fully Magnetically Levitated Centrifugal Continuous-Flow HeartMate 3 LVAD for the Treatment of Advanced Heart Failure

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ABSTRACT

Introduction: Left ventricular assist devices (LVAD) or assist systems, increase the rate of survival and improve quality of life among patients with advanced heart failure. So this study was done to compare the outcome and adverse events of our HeartMate II left ventricular assist device (HM II LVAD) implantation with recent published report of novel HeartMate 3 (HM 3) performance from CE Mark and MOMENTUM 3 trials.

Material and Methods: We retrospectively analysed our data of 44 eligible patients out of 58 who had HM II LVAD implantation. These data were compared with HM 3 cohort outcome from MOMENTUM 3 and CE mark trial.

Results: Our 44 HM II patients comprised of 23 (52%) Ischemic Cardiomyopathy (ICM) and 21(48%) non-Ischemic Cardiomyopathy (NICM). 78% of ICM and 67% of NICM group were male with average age of 63.7 ± 6.8 years and 53.9 ±16.3 respectively. 43.5% of ICM and 9.5% of NICM (p=0.012) had previous sternotomy. 78% of ICM and 67% of NICM (*p*=NS) were done as bridge to transplant; 22% of ICM and 33% of NICM (*p*=NS) were for destination therapy. 17% of ICM and 0% of NICM (*p* =0.06) were reported to have 30-day mortality.

Conclusion: ICM etiology was an independent predictor of mortality in our HM II cohorts. Our Pump thrombosis and mortality results were comparable to HM 3 cohort outcome results of the CE Mark trial and MOMENTUM 3 trial.

Keywords: HeartMate II LVAD, Magnetically Levitated, Flow HeartMate 3 LVAD

INTRODUCTION

Multiple trials and epidemiologic surveys have shown that Ischemic cardiomyopathy (ICM) have decreased survival compared to patients with nonischemic dilated cardiomyopathy (NICM).[1,2]

LVAD therapy leads to Left ventricular (LV) unloading and series of changes in myocardium. It brings changes in proteomic expression with subsequent improvement in contractile functions of cardiomyocytes. The process of reversal of remodeling starts leading to neuro-hormonal function and normalization of LV geometry. These changes are more likely to occur in the dysfunctional, yet viable, myocardium of patients with NIDCM.[3-5] Unfortunately, myocardial recovery at cellular and molecular level has not been associated with analogous bridge to recovery rates.[5] Further, there is a need to investigate the effect of heart failure etiology on patients with continuous-flow LVADs as a bridge to transplantation (BTT) or destination therapy (DT).

Recent reports suggested that there has been an increase in the risk of pump thrombosis associated with a currently approved axial continuous-flow pump, HM II and centrifugal continuous-flow pump, HeartWare.[1,2,6-8] The pump thrombosis leads to surgical pump exchange and increases the cost of care. HM 3, a novel magnetically levitated centrifugal continuous-flow pump, reduces shear stress on blood elements preventing pump thrombosis. The HM3 LVAD received its CE mark in October 2015. Compared to the HM II, the HM3 has the potential for higher overall efficiency [Figure 1A,B]. It is a new compact LVAD featuring fully magnetically levitated pump, artificial pulse, large pump gaps, and a modular driveline.[6-10]

We systematically compared outcomes of HM II LVAD implantation in patients with advanced heart failure secondary to ICM and NICM. We analyzed the outcomes following continuous-Axial-flow HM II LVAD implantation in these 2 cohorts of patients. Subsequently we compare our results with the HM3 cohort outcome from the CE mark trial (European Multicentre trial) and MOMENTUM 3 trial (USA Multicentre trial).

MATERIAL AND METHODS

Our Institutional Review Board approved this retrospective study. We retrospectively reviewed our institutions' LVAD dataset and analyzed 58 patients who underwent continuous-flow LVAD implantation as a BTT or a DT from September 2012 to August 2015. A total of 44 eligible patients were identified and formed the cohort of this study. We included all patients with advanced heart failure requiring LVAD as bridge to transplant or destination therapy.We excluded the patients who were planned for biventricular support, had evidence of active ongoing infection or irreversible end-organ dysfunction.

LVAD implantations at our institution are done for patients having BMI between 18 and 40 with end stage heart disease in New York Heart Association class 4 for 3 months. These patients have peak exercise oxygen consumption < 12 mls/kg/min or

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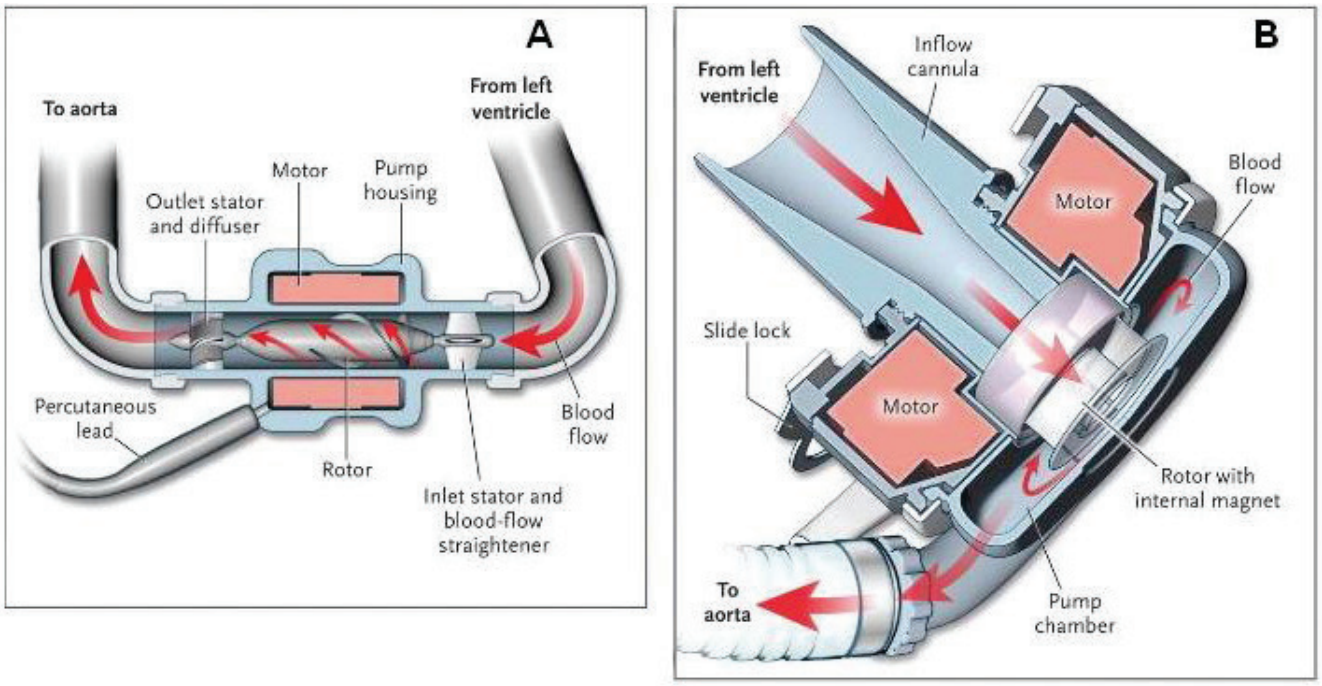

Figure-1: Diagrams of the Axial-Flow Pump and the Centrifugal-Flow Pump. Both pumps are considered to be continuous-flow pumps although the centrifugal-flow pump incorporates rapid changes in rotor speed to create an intrinsic artificial pulse. **Panel A** shows a diagram of the axial-flow pump; blood enters at one end of the rotor and is driven along the axis of the rotor to the outflow of the pump. **Panel B** shows a diagram of the fully magnetically levitated centrifugal-flow pump; blood enters at the central axis of the rotor and is driven outward centrifugally to the outflow of the pump. Courtesy Slaughter et al.[1]

ejection fraction < 25% or 30 days with inotrope dependence. Based on the etiology of heart failure these patients were stratified into two groups (ICM and NIDCM). This stratification was based on echocardiography/coronary angiography results or a history of angina or myocardial infarction.

58 patients had received Heartmate II LVAD implantation (Thoratec Corp., Pleasanton, CA) between September 2012 and August 2015. Data of 44 eligible patients were accumulated and statistically analyzed.

We studied patient demographics including age, gender, race, body surface area and body mass index (BMI). Their associated comorbidities e.g. diabetes mellitus, hypertension, peripheral vascular, chronic renal insufficiency (CRI), dialysis dependence and chronic obstructive pulmonary disease were studied. Other peri-operative data included preoperative creatinine, liver function tests, previous sternotomy and days in hospital prior to LVAD implantation. CRI criteria was glomerular filtration rate < 60 mls/min/m2.

Operative data included cardiopulmonary bypass time and indication (BTT or DT). The hemodynamic data studied were central venous pressure, pulmonary artery pressure, pulmonary capillary wedge pressure, LV ejection fraction, cardiac output and cardiac index. The echocardiographic data included pre- and post-LVAD (at 1 and 6 months) left ventricular end diastolic diameter, right ventricular end diastolic diameter, mitral regurgitation and tricuspid regurgitation.

We analysed outcome variables such as complications; intensive care unit and overall length of hospital stay; transplantation; reoperation for aortic insufficiency; readmission rates; postoperative survival at 1 month, 6 months, and 1 year and cause of death.

We studied complications including re-exploration for bleeding and gastrointestinal bleeding. Infective complications were driveline infections, pocket infections and wound infection. Other post-operative complications included pneumonia, right ventricular (RV) failure, postoperative right ventricular assist device implantation, dialysis, ventilator-dependent respiratory failure (VDRF), tracheostomy, hemorrhagic or ischemic stroke. VDRF was defined as inability to wean from the ventilator for at least 1 week. RV failure was defined as 1) more than 1 week of inotropic support, or 2) need for RVAD support. Every effort is made preoperatively to optimize the patient's condition diuresis, improve peripheral perfusion, protect against RV ischemia, and correct coagulopathy.

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) scores for our patients were as class 1: 7%, class 2: 40%, class 3: 26%, class 4: 20%, class 5: 5%, and class 6: 2%. Our BTT patients waited for 125 days ± 52 for heart transplantation after being listed as status 1B.

Recommended antithrombotic management in both groups included aspirin (at a dose of 81 to 100 mg daily for all patients) and warfarin (with dose adjustment to achieve a target international normalized ratio [INR] of 2.0 to 3.0.

STATISTICAL ANALYSIS

Statistical analysis were done using Statistical Analysis System (SAS version 9.2), a software suite developed by SAS Institute (developed at North Carolina State University).In an univariate analysis patient demographics, operative characteristics, postoperative complications, and hemodynamic data were compared between the two groups. Reporting of continuous variables was done as mean, standard deviation, minimum and maximum, and was compared using two-sided two-sample

t-tests. We used Wilcoxon rank-sum tests if normality could not be assumed.

We report categorical variables as count and percent and compared them using $\chi 2$ tests. Fisher's exact tests were used for small expected cell counts. We used log- rank test to compare survival at 30 days, 180 days, and 360 days between ICM and NICM. Following Transplantation patients were censored from the survival plot. [Figure 2A]

We placed variables were placed in a multiple Cox proportional hazards model with 30 day, 180 day, and 360 day survival as the outcome. A backward selection process was used to restrict each of the models to contain all significant predictors. Only variables with 95% non-missing values were included in the model. We reported adjusted hazard ratios and 95% confidence intervals for hazard ratios. Results were considered significant if p value was < 0.05.

Subsequent we looked at the outcome and adverse events in the HM 3 cohorts from published data at CE mark and MOMENTUM 3 trial at 6months and 1 year.

RESULTS

Out of 44 studied patients 23 (52%) presented with ICM with average age of 63.7± 6.8 years as opposed to 53.9± 16.3 in NICM (p= 0.017). The patients in ICM group tend to be older. ICM group also was male dominant comprising 78% males as compared to 67% in NICM group. (p=0.388). As expected there were more patients who underwent redo sternotomy in ICM group (43.5%) as opposed to 9.5% of NICM group (p=0.012). Indications for Implant was bridge to transplant in 78% of ICM and 67% of NICM; and destination therapy in 22% of ICM and 33% of NICM. [Table 1]

Post-LVAD complications and improvements in postoperative hemodynamic measurements were also similar for both groups. We found that 17% of ICM and 0% of NICM (p =0.06) were reported to have 30-day mortality. The mortality at the end of 1 year was 39% for ICM and 19% for NICM (p=0.14). [Figure 2A]

Bleeding requiring reoperation occurred in 4 cases (9.1%), two in each group.GI bleed occurred in 12(27.3%). Superficial wound infection occurred in 8(18.9%). There were no driveline infections and no device failure. Stroke occurred in none. Neurologicalc complications like TIA/Seizure occurred in 2(4.6%), Hemolysis occurred in 2(4.6%). [Table 2] The details of adverse events in HM3 cohorts in CE mark trial (n=50) and MOMENTUM 3 trial (n=151) are listed in Table 2. As per CE trial amongst the HM3 cohort at 1 year, 74% of the patients remained on LVAD support, 6% transplanted while 2% had the device explanted successfully. Other reported adverse events included gastrointestinal bleeding in 12% and stroke in 18%., 16% of the patients had infection of driveline while 2% of the patients

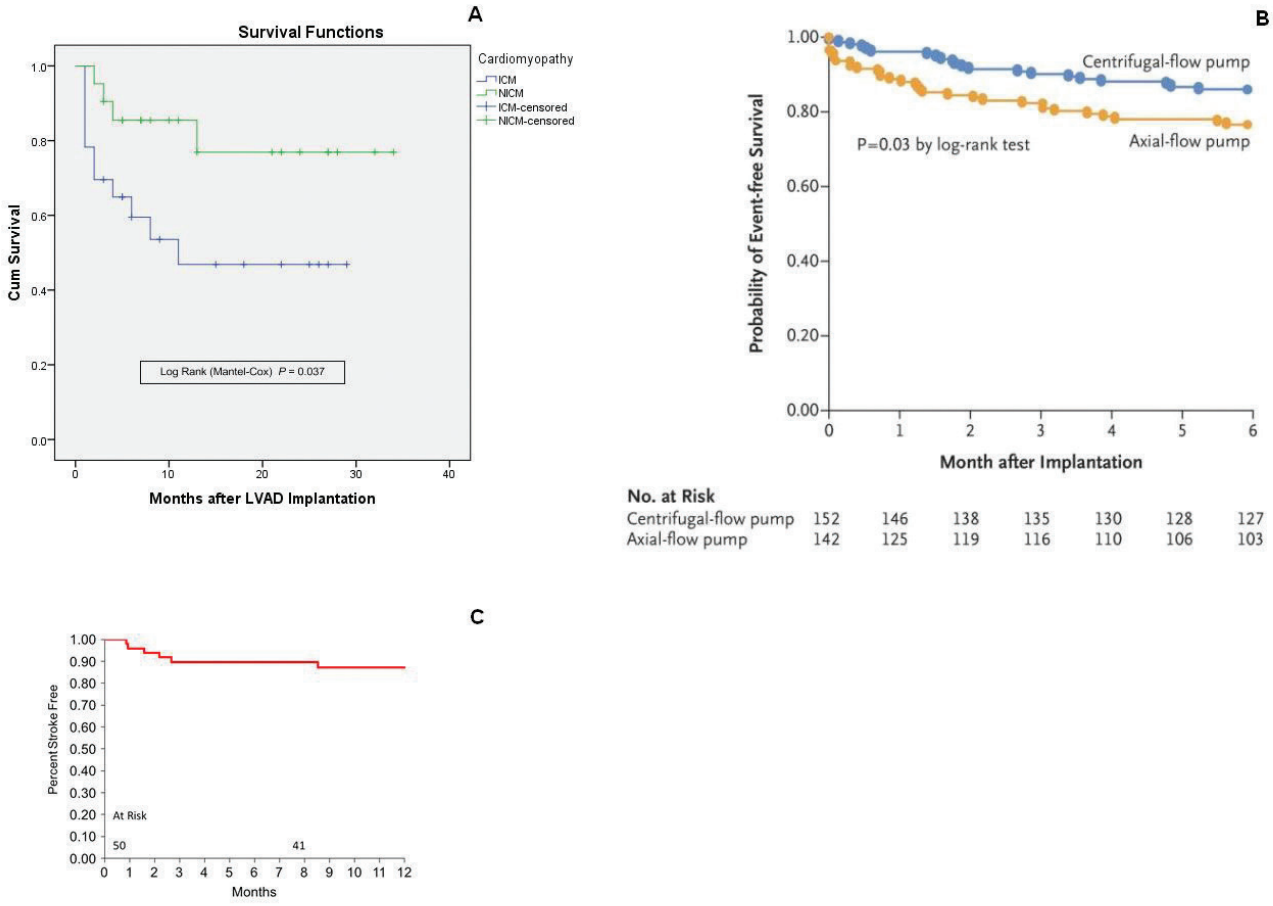

Figure-2: A. Kaplan–Meier survival analysis of our study patients with ischemic versus non-ischemic cardiomyopathy status post HM II left ventricular assist device placement. **B.** Kaplan–Meier estimates in the Intention-to-Treat randomized population in MOMENTUM 3 trial, of event-free survival, which included survival free of disabling stroke or survival free of reoperation to replace or remove the device at 6 months after implantation. **C.** Kaplan-Meier survival to 1 year after implantation in CE mark trial.

	Our study ICM(N=23)	Our study NICM(N=21)	CE mark trial (N=50)	Momentum 3 trial (N=152)
Age, years	63.7 ± 6.8	53.9 ± 16.3	59±13	60.3±12.3
Male	18 (78.3%)	14 (66.7%)	90%	80.3%
Indication, n (%)				
Bridge to transplantation	18(78%)	14(67%)	27 (54%)	41(27%)
Destination therapy	5(22%)	7(33%)	23(46%)	84(55.3%)
Intermacs profile				
Profile 2	2 (12.5%) (N=16)	0 (0%) (N=18)	5 (10%)	50(32.9)
Profile 3	9 (56.3%) (N=16)	6 (33.3%) (N=18)	21 (42%)	76(50)
Profile 4	1 (6.3%) (N=16)	1 (5.6%) (N=18)	20 (40%)	22(14.5)
Profile 5	4 (25.0%) (N=16)	4 (22.2%) (N=18)	3 (6%)	2(1.3)
Profile 6	0	0	1 (2%)	0
Inotropes	15(65.2%)	8(38.1%)	29 (58%)	132(86.8)
Previous sternotomy	10 (43.5%)	2 (9.5%)	10 (20%)	NA
ICM	23	-	NA	68(44.7)
NICM	-	21	NA	84(53.3)

Table-1: Compiles the patients demographics, Comorbidities, operative procedures and INTERMACS class

Events	Our study (N=44)			CE Mark trial (N=50)			Momentum 3 trial (N=151)		
	No. Pts	% Pts	No. Events	No. Pts	% Pts	No. Events	No. Pts	% Pts	No. Events
Bleeding	16	36.4%	18	22	44%	43	50	33.1%	100
Requiring surgery	4	9.1%	4	8	16%	11	15	9.9%	15
Gastrointestinal	12	27.3%	14	8	12%	9	24	15.9%	47
Sepsis	1	2.3%	1	10	20%	10	14	9.3%	19
superficial inf	8	18.9%	10	24	48%	38	46	30.5%	57
Driveline	0	0%	0	8	16%	8	18	11.9%	21
*Stroke	0	0%	0	9	18%	9	9	6%%	9
Ischemic	1	2.3%		5	10%	5	8	5.3%	8
Hemorrhagic	0	0%	0	4	8%	4	4	2.6%	4
**Neurologic dysfunction a	2	4.6%	2	4	8%	4	9	6%	9
Right heart failure	2	4.6%	2	5	10%	5	45	29.8%	49
Requiring RVAD	0	0%	0	2	4%	2	4	2.6%	4
Pump malfunctions	0	0%	0	0	0%	0	1	0.6%	1
Pump thrombosis	0	0%	0	0	0%	0	0	0%	0
Ouflow graft thrombosis	0	0%	0	1	2%	1	0	0%	0
Hemolysis	2	4.6%	3	0	0%	0	1	0.7%	1

*Disabling stroke; **Transient ischemic attack / seizure; RVAD: right ventricular assist device

Table-2: Outlines the adverse events in our patients and HeartMate 3 cohorts from CE Mark and MOMENTUM 3 trials

had outflow graft thrombosis. In 1 year follow up there was no incidence of hemolysis, pump thrombosis or pump malfunction. There was significant improvement in six-minute walk test distance from a mean of 273 m to 371 m (p<0.0001). EQ-5D (quality-of-life score) also showed a significant improvement from a mean of 52.7 to 70.8 (p=0.0006). In MOMENTUM 3, reoperation for pump malfunction was 1 (0.7%) but suspected or confirmed pump thrombosis occurred in no (0%) patients in the centrifugal-flow pump group.

On multivariate analysis ICM emerged as an independent predictor of mortality (OR: 3.19). [Figure 2A]. When we looked at other variables such as inotropic or vasopressor requirement, IABP use, serum creatinine level or complex operations involving aortic or tricuspid valves at the time of LVAD placement, we found that these variables did not have impact on mortality. The survival curve for our study [Fig 2A], MOMENTUM 3 trial [Fig 2B] and CE Mark trial at 1 year [Fig 2C] are shown in Figure 2.

DISCUSSION

Continuous-flow LVADs have become the standard of care for patients with advanced heart failure.[1,2] It has effect on the myocardium as shown by marked reduction in myocytolysis in the study of comparisons of tissue samples taken at the time of implantation and at the time of transplantation. It also leads to normalization of calcium uptake, calcium-binding rates, and lipid levels in myocardium and norepinephrine levels in plasma.[3]

Plasma BNP and ET-1 levels correlate with both LV function and myocardial morphological improvement following LVAD implantation. However, results showed comparable reduction in the DCM and ICM groups (both P < 0.03).[4]

Relative myocardial perfusion has been found to increase > 5% from baseline in only one of six patients when mechanical circulatory support was used. This suggests that the decreased metabolic requirements induced by ventricular unloading correspondingly decreased blood flow requirements to

physiologically inactive myocardium.[5]

The HM II device provides excellent hemodynamic support with low device-related thromboembolic events. Despite morbidity, use of the HM II LVAD as bridge-to-transplant therapy is associated with excellent survival and low mortality rates. However, there is an increased risk of increased mediastinal and gastrointestinal bleeding associated with anticoagulation therapy. The driveline infection remains a potential complication.[11-17]

Patients requiring VAD support for myocardial failure can undergo significant reverse remodelling. Explantation can lead to optimal outcome with minimal morbidity.[15]

Some study suggested that survival at 30, 180, and 360 days after LVAD implantation is similar between the re-sternotomy and primary sternotomy group. No major differences in complications or hemodynamic measurements were observed.[18]

The prognosis of patients with ischemic heart failure is worse than in patients with a non-ischemic etiology as per large-scale therapeutic trials and epidemiological surveys. The patients with hypertensive heart disease, myocarditis, alcoholic cardiomyopathy and cardiac dysfunction due to rapid atrial fibrillation comprise 'non-ischemic heart failure' subgroups. These causes are reversible. Hence the etiology of heart failure should be determined routinely in all patient in view of prognostic and possible therapeutic differences.[2]

There is a need to investigate the effect of heart failure etiology on outcomes after left ventricular assist device (LVAD) implantation.[18] Tsiouris et al found survival on 30 day, 6 month, and 1 year survivals as 94.1%, 85.3%, and 82.4%, respectively, for ICM patients versus 95.5%, 92.4%, and 89.4%, respectively, for NIDCM patients ($p = 0.743$). The multivariate logistic regression analysis did not show the etiology of heart failure as an independent predictor of survival ($p = 0.505$). The postoperative outcomes were not significantly affected by the etiology of heart failure. The improvements in postoperative hemodynamic measurements and post-LVAD complications were similar in both groups.[19]

The clinical use of mechanical circulatory support was developed by Thermo Cardiosystems, Inc. (TCI). TCI designed HeartMate family of implantable left ventricular assist devices (LVADs). The started with a pneumatic actuated pusher plate pump, called HM I in 1986. It is considered a standard of measurement and has been implanted in over 2,300 patients worldwide. Then a rotary-pump-based LVAD using an axial flow blood pump with blood immersed mechanical bearings formed next generation, the HM II. [Figure 1A] Clinical trials of the HM II were initiated in 2000. The HM III, representing TCI's next-generation LVAD, is structured around a centrifugal blood pump that uses a magnetically levitated rotating assembly.[20] The wide blood-flow passages without mechanical bearings makes pump frictionless. The pump is programmed to create an intrinsic artificial pulse by facilitating rapid changes in rotor speed. [Figure 1 B] The stasis in the pump and hence incidence of thrombosis is reduced due to fixed pulse asynchronous with the native heartbeat.[9,10,20] Since 1976, Thoratec Incorporation is based in Pleasanton, California. However, St. Jude Medical (Saint Paul, Minnesota) acquired Thoratec in 2015. In January 2017, Abbott Laboratories acquired St. Jude Medical.

The survival rate is acceptable in trials of patients with the HeartMate 3 LVAD.[6-8] In the second 6 months of follow-up, there was a decreasing trend in complications such as bleeding, infection, stroke and right heart failure. There was improvement in six-minute walk distance, NYHA class and Quality of life (QOL) measures.[6] Both trials demonstrated absence of hemolysis and pump thrombosis in 1-year follow-up. Both HM 3 studies indicate that there appears to be enhanced durability and hemocompatibility for long-term support with the HM 3.[6-8]

Limitations of our study include: A retrospective, single institutional analysis, an observational, non-randomized study subject to limitations inherent to any retrospective study. The small sample size makes study insufficiently powered. Duration of follow-up was relatively short. There is potential of inaccuracy of data retrieved retrospectively from medical records. A single institutional study leads to selection bias.

CE Mark trial: The limitations of this study was the non-randomized, non-controlled design with relatively small number of patients. Comparison to other clinical studies is not possible due to the mix of BTT and DT indications. The patient care practices varied due to different institutional preferences at 10 different centres as implantations took place in different parts of the world.[6]

MOMENTUM 3 trial has following limitations: not possible for the patients and investigators to be unaware of the treatment assignments leading to bias. The surgeons had long-term experience in the implantantion of axial-flow pumps, and thus the surgical and medical outcomes were potentially biased against the centrifugal-flow pump. The decision to remove or replace a pump for suspected or confirmed pump thrombosis was derived from the LDH level or evidence of pump dysfunction but was at the discretion of the local site investigators.[7,8]

CONCLUSIONS

Our study of cohort of 44 HM II LVAD patients, demonstrates ICM etiology as an independent predictor of mortality. These patients are older and are more likely to have previous sternotomy. These warrants larger scale investigation of LVAD implantation in ICM patients looking into INTERMACS and IMACS database.

The lower rate of reoperation for pump thrombosis led to better outcomes 6 months after the implantation of a fully magnetically levitated centrifugal-flow pump for patients with advanced heart failure in MOMENTUM 3 trial. With its shorter implantation time and reduced blood product requirement in the early postoperative period, the HM3 system was found to be safe and effective. However, The results observed in our study of HM II pump thrombosis and mortality results are comparable to post 1 year HM 3 LVAD cohort outcome results of the CE Mark trial and Momentum 3 trial. Our careful selection criterion, robust implantation technique and careful postoperative care/ anticoagulation protocol contributed to good results with HM II cohorts.

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