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Six-month outcomes in postapproval HeartMate3 patients: A single-center US experience

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Abstract

Background: The European CE Mark approval study and the MOMENTUM 3 trial demonstrated safety and a reduction in hemocompatibility-related adverse events with the use of HeartMate 3 (HM3) device. This single-center study investigated the real-world experience in HM3 patients since FDA approval.

Methods: This retrospective, observational study included patients implanted with the HM3 LVAD as a primary implant between October 2017 and March 2020. Patients were divided into trial group and postapproval group. The primary endpoint was survival at 6 months. Secondary endpoints were adverse events including pump thrombosis (requiring pump exchange), stroke, renal failure, acute limb ischemia, re-exploratory for bleeding, gastrointestinal bleeding, right ventricular failure, and driveline infection.

Results: A total of 189 patients were implanted with HM3 device during the study period. 174 patients met the inclusion criteria: 82 patients in the trial group and 92 patients in the postapproval group. The postapproval group had younger patients, higher preoperative mean international normalized ratio, and greater numbers of patients with bridge to transplant (BTT) indications, IINTERMACS profile 1, and use of mechanical assist devices (other than IABP) than the trial group. Other characteristics between the two groups were comparable. Overall survival at 6 months in the postapproval group was 93.3% versus 93.8% ($p = .88$). The postapproval group demonstrated a statistically significant lower incidence of re-explorative surgery for bleeding (10.9% vs. 46.3, $p = .01$) than the trial group.

Conclusion: In this single-center study, the real-world 6-month survival in the postapproval group was comparable to the trial results. Further studies are needed to monitor long-term outcomes.

KEYWORDS

cardiovascular pathology, cardiovascular research, clinical review, transplant

Abbreviations: CF-LVAD, continuous flow left ventricular assist device; FDA, US Food and Drug Administration; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; LVAD, left ventricular assist device; NYHA, New York Heart Association; RVF, right ventricular failure.

1 | INTRODUCTION

The use of left ventricular assist devices (LVADs) for advanced heart failure has become a standard of care either as a bridge to transplant (BTT) or as destination therapy (DT).[1,2] Older generation LVADs were associated with many device-related adverse events, such as pump thrombosis, bleeding, stroke, and infections.[2–5] The HeartMate 3 (HM3) (Abbott Laboratories), a new generation continuous-flow LVAD (CF-LVAD) with fully magnetically levitated rotors, demonstrated a reduction in the incidence of hemocompatibility-related adverse events during the 2-year follow-up in the MOMENTUM 3 trial.[6]

After the completion of the MOMENTUM 3 trial, the HM3 device received US Food and Drug Administration (FDA) approval in 2018. Long-term survival observed in both US and European (CE Mark trial) clinical trials was similar to that seen with the previously approved devices but with a significant reduction in hemocompatibility-related adverse events, such as freedom from pump thrombosis and pump failure and reduced incidence of stroke.[6–9] The only experience regarding outcomes during the postapproval phase comes from the European ELEVATE registry, which also supported the findings of reduced adverse events and a real-world survival of 92% at 6-month follow-up.[10]

However, no such real-world survival data exist for patients implanted in the United States during the postapproval phase, except for the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) data. The aim of this study was to provide real-world US data since FDA approval of the device.

2 | PATIENTS AND METHODS

2.1 | Study design

This single-center, retrospective, observational study included patients who underwent implantation of the HM3 LVAD between October 2017 and March 2020. Data were collected prospectively and entered into an institutional patient registry database. This study was approved by the Ochsner Institutional Review Board (IRB), and all patients consented or waived informed consent as per the IRB policy. To standardize our approach and better compare the findings with HM3 trial results and future studies, we used the standardized Mechanical Circulatory Support-Academic Research Consortium (MCS-ARC) Adverse Events for Outcomes and Adverse Events.[11]

2.2 | Study population

Inclusion criteria for this study were (1) primary implantation with the HM3 LVAD during the study period and (2) availability of 6-month follow-up after LVAD implantation.

A total of 189 patients were implanted with the HM3 at our institution from October 2017 to March 2020. Eighty-two patients were included in the trial group (MOMENTUM 3 and CAP trials) and formed the comparator group, while the remaining 107 patients were implanted after FDA approval of the device (postapproval group). Of these 107 patients, 102 patients met the primary HM3 implant criteria; the 5 excluded patients were implanted with the HM3 as a replacement device for previously placed durable mechanical devices. Of the 102 patients, 92 patients were selected for the final analysis because they had completed 6 months of follow-up (Figure 1).

2.3 | Data collection

Patient baseline information included demographic details, comorbidities, preoperative echocardiographic findings, preoperative right heart catheterization pressures, INTERMACS profile, New York Heart Association (NYHA) functional classification, indication for mechanical support, and preoperative laboratory values. Adverse events within the first 6 months of the implant were also collected.

2.4 | Endpoints

The primary endpoint was survival at 6 months. Secondary endpoints included freedom from pump thrombosis (requiring reoperation or pump exchange) and other adverse events such as re-exploration for bleeding, stroke, acute limb ischemia, gastrointestinal bleeding, driveline infection, renal dysfunction requiring renal replacement therapy, and right ventricular failure (RVF).

2.5 | Statistical analysis

Categorical data are reported as frequencies and percentages and were compared using the chi-square test. Continuous data are reported either as mean ± standard deviation (*SD*) or median with interquartile range (IQR) unless specified otherwise. Continuous data were compared using the two-sided Wilcoxon–Mann–Whitney test. The log-rank test was used for time-to-event analysis, with patient survival data presented as a Kaplan–Meier survival curve up to 6 months from an implant date. Patients were censored when they were transplanted. Statistical significance was defined as $p \leq .05$. The data were analyzed using SAS/STAT software version 14.2 (SAS Institute, Inc.).

3 | RESULTS

3.1 | Comparison between trial and postapproval group patients

Baseline characteristics between the trial and postapproval patients were comparable, except for age, preoperative international normalized

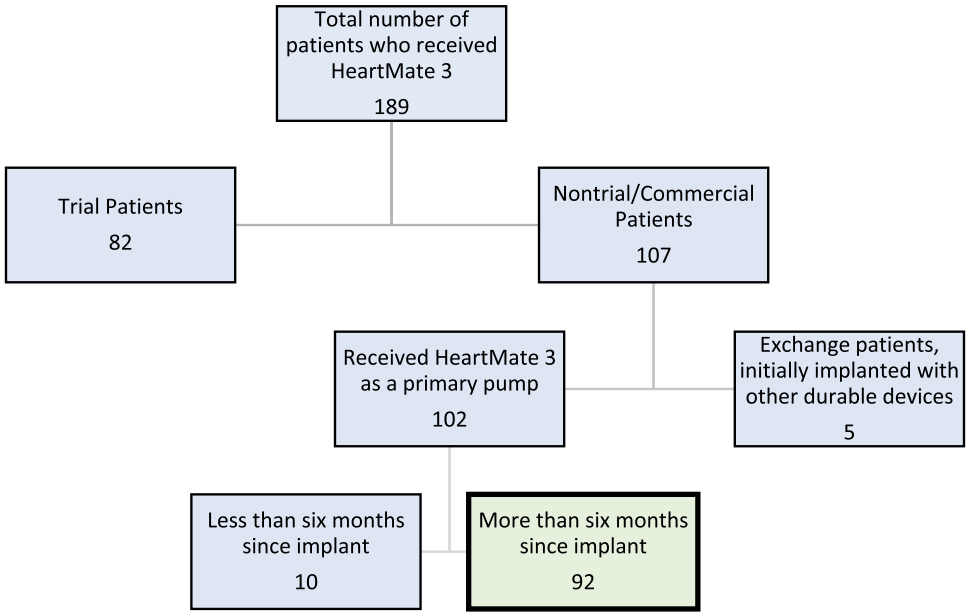

FIGURE 1 Patient selection

ratio (INR), indication for implantation (BTT vs. DT), and use of temporary assist device other than intra-aortic balloon pump (IABP) before the HM3 implantation (Table 1). The postapproval group had younger patients (49.60 ± 13.92 vs. 55.40 ± 11.54 years $p = .01$), a higher preoperative mean INR (1.13 ± 0.18 vs. 1.08 ± 0.16 $p = .04$), more BTT patients (25% vs. 13.4% $p = .05$) and more patients supported with Impella 5.0, Tandem, or extracorporeal membrane oxygenation (ECMO) (7.6% vs. 0% $p = .01$) than the trial group. Also, the postapproval group had more patients in INTERMACS profile 1 (18.5% vs. 7.3% $p = .04$) than the trial group.

3.2 | Characteristics of postapproval group patients

Baseline characteristics for the 92 patients in the postapproval group are provided in Table 1. The mean age at the time of an implant was 49.60 ± 13.92 years. The majority were African American (64.1%), male (81.5%), and implanted as DT (75%). Of the 92 patients, 68 (73.9%) had INTERMACS profile 1–2. Before receiving an LVAD, seven (7.6%) patients were upgraded from IABP to higher support temporary mechanical circulatory assist device (Tandem, Impella 5.0, or ECMO) for ongoing cardiogenic shock. As shown in Table 2, the median length of hospital stay after the surgery was 22 (IQR 17–28) days. The average pump speed at the time of discharge from the hospital was 5300 ± 260 rpm with an average pump flow of 4.29 ± 0.46 L/min.

3.3 | Six-month survival

In the postapproval group, 30-day survival was 97.8% and 6-month survival was 93.3% (Table 2 and Figure 2). Four patients underwent heart transplantation during the first 6 months of follow-up. Six deaths occurred during the first 6 months of HM3 support. Differentiating 6-month survival based on the indication of implantation, survival in the DT group was 88.9% versus 100% (0.12) in the BTT group. At 3-month follow-up after LVAD implant, 59 (71.1%) patients were NYHA class 2 (Table 2).

3.4 | Adverse events

In the postapproval group, two (2.2%) cases of pump thrombosis were seen due to outflow graft twist, requiring an emergent pump exchange. Four (4.4%) patients had strokes, and 3 (3.3%) patients required dialysis due to renal failure. There were two (2.2%) cases of acute limb ischemia secondary to the use of IABP. Thirty-two patients had RVF requiring inotropes >14 days (34.8%). These findings were comparable to those of the trial group (Table 3).

One statistically significant difference was observed in adverse events between the trial and the postapproval groups. Postoperative bleeding requiring re-exploration was statistically lower in the postapproval versus the trial group (10.9% vs. 46.3%; $p = .01$).

3.5 | Comment

The primary endpoint of this study was 6-month survival in postapproval (posttrial) patients who received the HM3 as a primary device in the United States. Our single-center 6-month survival for posttrial patients is 93.3%, which mirrors the 6-month survival in the trial group from our center (93.8%). Our postapproval patients were not selected based on strict inclusion criteria as set for the trial patients. As a result, younger acutely and critically ill patients

TABLE 1 Baseline characteristics

Characteristic	Trial group *n* = 82	Postapproval group *n* = 92	*p*
Age, years, mean ± *SD*	55.40 ± 11.54	49.60 ± 13.92	*.01*
Gender			.34
Male	62 (75.6)	75 (81.5)	
Female	20 (24.4)	17 (18.5)	
Race			.63
African American	54 (65.9)	59 (64.1)	
Caucasian	27 (32.9)	33 (35.9)	
Other	1 (1.2)	0	
Body mass index, kg/m^2, mean ± *SD*	28.20 ± 6.15	28.50 ± 5.74	.50
Comorbidities			
Diabetes	28 (34.1)	31 (33.7)	.86
Dyslipidemia	41 (50.0)	47 (51.1)	.89
Hypertension	71 (86.6)	73 (79.4)	.21
Chronic obstructive pulmonary disease	11 (13.4)	11 (12.0)	.77
Cerebrovascular disease	13 (15.9)	15 (16.3)	.96
Cardiac surgery before the implant			.23
None	71 (86.6)	85 (92.4)	
CABG	7 (8.5)	5 (5.4)	
Valvular repair	0 (0)	1 (1.1)	
Other	4 (4.9)	1 (1.1)	
Preoperative laboratory values, mean ± *SD*			
Total bilirubin, mg/dl	1.10 ± 0.61	1.20 ± 1.05	.65
Sodium, mEq/L	135 ± 3.10	135 ± 3.60	.38
Creatinine, mg/dl	1.30 ± 0.34	1.40 ± 0.55	.22
International normalized ratio	1.08 ± 0.16	1.13 ± 0.18	.04
Lactate dehydrogenase, U/L	284 ± 95.10	397 ± 310.70	.06
MELD score, mean ± *SD*	11.40 ± 4.55	12.80 ± 5.11	.09
Indication for implant			*.05*
Bridge to transplant	11 (13.4)	23 (25.0)	
Destination therapy	71 (86.6)	69 (75.0)	
Preoperative echocardiogram findings, mean ± *SD*			
Ejection fraction, %	15.80 ± 6.47	15.50 ± 6.09	.91
Left ventricular end-diastolic diameter, cm	7.30 ± 1.00	7.30 ± 0.87	.70
Left ventricular end-systolic diameter, cm	6.70 ± 1.04	6.70 ± 0.94	.91
TAPSE, cm	1.70 ± 0.41	1.70 ± 0.47	.38
S-prime, cm/s	10.60 ± 2.83	9.80 ± 2.29	.11
Preoperative right heart catheterization, mean ± *SD*			
CVP, mm Hg	9.10 ± 5.45	9.50 ± 5.80	.80
PAS, mm Hg	52.70 ± 17.14	52.30 ± 14.64	.99
PAD, mm Hg	23.80 ± 9.31	23.10 ± 8.19	.64
PAPi	4.90 ± 4.32	4.70 ± 3.94	.91

Characteristic	Trial group *n* = 82	Postapproval group *n* = 92	*p*
Tandem/Impella/ECMO as assist device	0 (0)	7 (7.6)	.01
INTERMACS profile			.17
1	6 (7.3)	17 (18.5)	.04
2	54 (65.9)	51 (55.4)	.17
3	21 (25.6)	23 (25.0)	.99
4	1 (1.2)	1 (1.1)	.99
New York Heart Association classification			.69
III	2 (2.4)	4 (4.4)	**
IV	80 (97.6)	88 (95.6)	**

Note: Data are presented as *n* (%) unless otherwise indicated. ***p* Values are not reported for the individual New York Heart Association classifications because, like the overall comparison, they were not significant.

Abbreviations: CABG, coronary artery bypass surgery; CVP, central venous pressure; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; MELD, Model for End-Stage Liver Disease; PAD, pulmonary artery diastolic pressure; PAPi, pulmonary artery pulsatility index; PAS, pulmonary artery systolic pressure; TAPSE, tricuspid annular plane systolic excursion.

TABLE 2 Outcomes by group

Outcome	Trial group *n* = 82	Postapproval group *n* = 92	*p*
Overall survival at 30 days	80 (97.6)	90 (97.8)	0.99
Heart Transplant within 6 months	2 (2.4)	4 (4.4)	0.49
Death at 6 months	5 (6.1)	6 (6.5)	0.91
Overall survival at 6 months	75 (93.8)[a]	82 (93.3)[a]	0.88
6-month survival by indication			0.88
DT group	67/71 (94.4)	61/67 (91)[b]	0.45
BTT group	8/9 (88.9)	21/21 (100)[b]	0.12
NYHA classification 3 months after LVAD Implant			0.77
1	1 (1.3)	0 (0)	
2	52 (69.3)	59 (71.1)	
3	19 (25.3)	22 (26.5)	
4	3 (4)	2 (2.4)	
Pump statistics			
Pump speed, rpm, mean ± *SD*	5,350 ± 270	5,300 ± 260	0.23
Flow, L/min, mean ± *SD*	4.35 ± 0.56	4.29 ± 0.46	0.39
Length of hospital stay, days, median [IQR]	24 [17–34]	22 [17–28]	0.93

Note: Data are presented as *n* (%) unless otherwise indicated.

Abbreviations: BTT, bridge to transplant; DT, destination therapy; IQR, interquartile range; NYHA, New York Heart Association.

[a]Postapproval survival difference between BTT and DT group was not statistically significant ($p = .16$).

[b]Two patients in the trial group and four patients in the postapproval group were transplanted before 6 months and are not included in the overall survival calculation. For the trial group, $n = 80$ (82–2); for the postapproval group, $n = 88$ (92–4).

underwent implantation of the HM3 who otherwise would not have qualified for the HM3 device during the trial phase. This population reflects real-world experience. Although our trial and postapproval patients were not statistically different based on overall baseline INTERMACS profile ($p = .17$), the postapproval group included more patients with INTERMACS profile 1 ($p = .04$) than the trial group, and these patients required a higher degree of hemodynamic support with Impella 5.0, Tandem, or ECMO devices ($p = .01$). At our center, we have historically seen higher percentages of INTERMACS 1 and 2 profile patients than reported in the MOMENTUM 3 and European postapproval ELEVATE registry (73.9% vs. 32.3% vs. 31%, respectively).[10,12] This difference in patient profiles can be attributed to differences in patient populations, referral patterns, and differences in access to health care facilities, insurance coverage for advanced therapies, and late transfers from outside institutions (our center is the only heart transplant and LVAD center for the state of Louisiana). Another explanation for this difference can be related to the fact that because the trial findings showed a significant improvement in the device hemocompatibility profile when compared with the previous generation devices, surgeons at our center had more confidence in implanting the HM3 in sicker patients vs other devices.

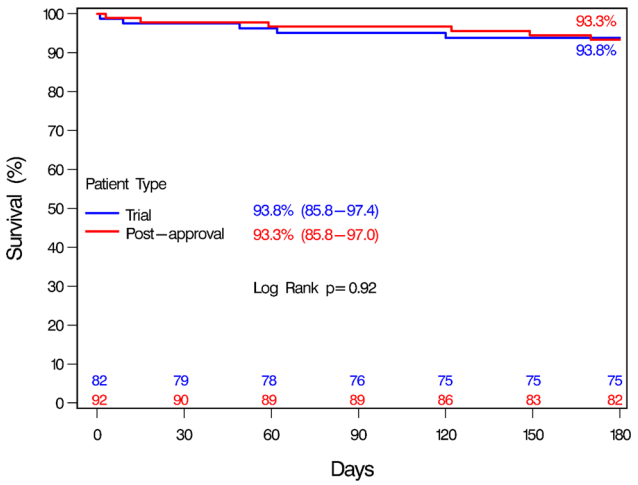

FIGURE 2 Kaplan–Meier survival curve—overall survival at 6-month trial patients: five deaths, two transplanted. Postapproval: six deaths, four transplanted

Our postapproval group patients were younger than the trial group patients because the HM 3 device was used in all comers, including patients who were upgraded from IABP to higher support devices (Tandem, Impella, and ECMO) due to ongoing cardiogenic shock while on IABP support (which was an exclusion for the trial patients). Due to postapproval group consisting of more young patients, a higher percentage of these patients were BTT candidates as compared to the trial group ($p = .05$). Also, the postapproval group had a statistically elevated preoperative INR (a decreased synthetic function of the liver) compared to the trial group, reflecting a higher degree of illness ($p = .04$).

Six deaths occurred in the postapproval group and five deaths in the trial group. Two patients in the trial group and four in the postapproval group were transplanted within the first 6 months of their LVAD implant. Six-month postapproval survival data are comparable with the results from the MOMENTUM 3 trial and the primary implants cohort of the ELEVATE registry (93.3% vs. 88% vs. 92%, respectively).[10,12] The observed long-term benefit of the HM3 versus the previous generation of CF-LVADS is a marked reduction in stroke rates.[13] Stroke rates 6 months after an implant at our center were comparable between the trial and postapproval groups (7.3% vs. 4.4%; $p = .52$). However, the stroke rate at our center is comparable to the 6-month MOMENTUM 3 and postapproval ELEVATE registry (4.4% vs. 7.9% vs. 5.4%, respectively).[7,10]

TABLE 3 Adverse events

Adverse Event	Trial group $n = 82$	Postapproval group $n = 92$	p
Re-exploratory surgery for postoperative bleeding	38 (46.3)	10 (10.9)	*.01*
Stroke	6 (7.3)	4 (4.4)	.52
Acute limb ischemia	1 (1.2)	2 (2.2)	.99
Gastrointestinal bleeding	17 (20.7)	12 (13)	.22
Pump thrombosis	3 (3.7)	2 (2.2)	.66
Driveline infection	13 (15.9)	14 (15.2)	.99
Renal dysfunction requiring RRT	8 (9.8)	3 (3.3)	.12
Severe RV failure requiring inotropes >14 days during initial implant hospitalization	34 (41.5)	32 (34.8)	*.36*
Severe RV failure requiring RVAD during implant	4 (4.9)	3 (3.3)	.71

Note: Data are presented as *n* (%) unless otherwise indicated.

Abbreviations: RRT, renal replacement therapy; RV, right ventricular; RVAD, right ventricular assist device.

The lower rate of stroke seen at our center could be attributed to our adherence to robust blood pressure and anticoagulation management protocols.[14,15]

A significant reduction in re-exploration rates was observed in the postapproval group. This observation can be explained by a series of changes made during the perioperative phase of the implant: modification in surgical technique (placing 16 vs. 12 pledgetted stitches around the sewing ring), preoperative administration of vitamin K (two doses 24 h before implantation), and use of thromboelastogram analysis for correction of coagulopathy before leaving the operating room. Lessons learned during the trial phase showed that the majority of patients who underwent re-exploration for bleeding had a bleeding site at the apical sewing ring. Increasing the number of pledgetted stitches from 12 to 16 eliminated bleeding from the sewing ring site. We have determined that administration of two doses of vitamin K 24 h before LVAD implantation reduces bleeding complications. Vitamin K administration has become a part of our routine and was used during the postapproval phase of device implantation.[16]

Pump thrombosis was comparable between the two groups, and all cases of pump thrombosis were related to outflow graft twist identified by computed tomography scan. All patients presented with acute onset low-flow alarms. At the time of pump exchange, thrombus was present in the outflow graft extending into the HM 3 device. All of these patients underwent successful pump exchange with full recovery. The incidence of outflow graft twist has now been completely eradicated with the changes in the spline cover of the HM3 pump.

The MCS-ARC definition of acute severe RVF was used for analysis.[11] A reduction in the incidence of severe RVF requiring inotropes >14 days was observed in the postapproval group (34.8% vs. 41.5%; $p = .36$) compared to the trial group patients. This finding can be explained by our incremental improvement in understanding the HM3 device, improved perioperative management, and a significant reduction in the incidence of postoperative bleeding requiring re-exploration (a well-established risk factor for the development of RVF).[17–23] Also, the incidence of right ventricular assist device (RVAD) use for severe RVF was similar between the two groups.

3.6 | Limitations

The study has all the inherent limitations of any retrospective analysis. Our findings are suggestive, rather than conclusive, and based on a small number of selected patients for this single-center experience. Long-term follow-up with larger cohorts in a multicenter US experience will project a better picture of the long-term efficacy of the device.

4 | CONCLUSION

Our postapproval, single-center 6-month survival of 93.3% is suggestive of comparable real-world findings when compared with the MOMENTUM 3 trial patients and the data from the ELEVATE registry. However, similar findings through multi-institutional studies are needed to confirm these results.

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CONFLICTS OF INTEREST

Aditya Bansal has received speaking honoraria from Abbott, Tandemlife, and Abiomed. Sapna Desai has received speaking honorarium from Abbott. The other authors declare no conflicts of interest.

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