4-19-2022

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0003-4975/$36.00
https://doi.org/10.1016/j.athoracsur.2022.03.071

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ABSTRACT

BACKGROUND Outcomes in patients with smaller body size after HeartMate 3 left ventricular assist device (HM3) implantation are not well characterized. We sought to evaluate outcomes in smaller vs larger body surface area (BSA) patients in the MOMENTUM 3 pivotal trial and its Continued Access Protocol cohort.

METHODS The analysis cohort included 1015 HM3 patients divided into 2 groups: BSA ≤1.70 m^2 (small patients, n = 82) and BSA >1.70 m^2 (large patients, n = 933). The composite primary end point was survival at 2 years free of disabling stroke or reoperation to replace or to remove a malfunctioning device. Adverse events were compared between groups.

RESULTS Smaller patients were more frequently women (56.1% vs 17.7%; $P < .001$) and had lower prevalence of diabetes (28.1% vs 43.9%; $P = .005$) and hypertension (51.2% vs 71.9%; $P < .001$), larger median indexed LVEDD (normalized by BSA, 40 vs 33 mm/m^2; $P < .001$), and lower median serum creatinine concentration (1.1 vs 1.3 mg/dL; $P < .001$). The proportion of patients achieving the composite end point at 2 years was 77% in both groups (adjusted hazard ratio, 1.14; 95% CI, 0.68-1.91; $P = .62$). Two-year adverse event rates were also similar between groups except for sepsis (6.1% vs 14.9%; $P = .029$) and cardiac arrhythmias (24.4% vs 35.3%; $P = .005$), which were higher in the larger patients.

CONCLUSIONS Outcomes after HM3 implantation were comparable between small and large patients. Smaller body size should not be used to deny HM3 implantation in patients who are otherwise suitable candidates for durable mechanical circulatory support.

(Ann Thorac Surg 2022;■:■-■)
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Durable mechanical circulatory support (MCS) devices have revolutionized the treatment of end-stage heart failure during the last 25 years. Small patients were initially deemed ineligible for the bulky first-generation volume displacement devices. The HeartMate XVE left ventricular assist device (LVAD), for example, required a minimum body surface area (BSA) of 1.5 m^2. The MCS field has since experienced dramatic LVAD technology improvements. Large, pulsatile devices have been replaced by miniaturized, intrapericardial, continuous flow pumps, allowing use in

The Supplemental Material can be viewed in the online version of this article [https://dx.doi.org/10.1016/j.athoracsur.2022.03.071] on http://www.annalsthoracicsurgery.org.

Accepted for publication Mar 28, 2022.

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Abbreviations and Acronyms

BSA = body surface area
CAP = Continued Access Protocol
HMII = HeartMate II LVAD
HM3 = HeartMate 3 LVAD
HR = hazard ratio
INTERMACS = Interagency Registry for Mechanically Assisted Circulatory Support
IQR = interquartile range
LV = left ventricle
LVAD = left ventricular assist device
LVEDD = left ventricular end-diastolic diameter (i, indexed)
MCS = mechanical circulatory support
QOL = quality of life

smaller adults and more recently in pediatric patients.[1] However, the safety and efficacy of LVADs in small patients have been understudied, and small adults are still frequently denied durable LVAD therapy on the basis of anatomic and physiologic concerns. For example, the perception that smaller patients have smaller left ventricle (LV) size may affect their LVAD candidacy as it has been shown that patients with smaller LV cavities have a differential outcome.[2] Furthermore, small adult patients have been significantly underrepresented in clinical trials and LVAD registries.[3-11] Analyses from The Society of Thoracic Surgeons Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database reported an average BSA of 2.07 m^2 in implanted patients[7]; however, only 2% of patients had a BSA $\leq$1.5 m^2.[9] In addition to anatomy, clinician concerns include a potential higher incidence of adverse events, such as stroke, pump thrombosis, infection, bleeding, and right ventricle failure,[9,12,13] and a perception that LVADs cause more pain in small patients.

The HeartMate 3 LVAD (HM3) is a fully magnetically levitated, intrapericardial pump with a short inlet cannula (Abbott).[14] This pump demonstrated superior results compared with the HeartMate II LVAD (HMII; Abbott), which required a preperitoneal pump pocket and was not designed for small patients.[15] Despite the successful use of HM3 in the general population of LVAD patients, there remains a lack of HM3 clinical data specific to small patients.

In this nonpowered, retrospective analysis, we evaluated outcomes of small patients who received the HM3 within the MOMENTUM 3 pivotal trial and its Continued Access Protocol (CAP) study. We hypothesized that "small" HM3 patients (BSA $\leq$1.70 m^2) have similar overall outcomes compared with "large" HM3 patients with (BSA >1.70 m^2).

TABLE 1 Baseline Demographics and Preoperative Characteristics

Demographic	BSA $\leq$1.70 m^2 (n = 82)	BSA >1.70 m^2 (n = 933)	*P* value[a]
BSA, m^2	1.63 (1.54-1.68)	2.08 (1.92-2.26)	<.001
BMI, kg/m^2	21 (19-24)	29 (25-33)	<.001
Age, y	64 (53-70)	62 (53-69)	.38
Female	46 (56.1)	165 (17.7)	<.001
Race			<.001
White	48 (58.5)	627 (67.4)	
Black	23 (28.1)	262 (28.1)	
Asian/Pacific Islander	7 (8.5)	9 (1.0)	
Other race	4 (4.9)	33 (3.5)	
Destination therapy	58 (70.7)	569 (61.0)	.08
Ischemic cause of heart failure	27 (32.9)	408 (43.7)	.06
History of diabetes	23 (28.1)	410 (43.9)	.005
History of hypertension	42 (51.2)	671 (71.9)	<.001
History of ICD insertion	51 (62.2)	659 (70.6)	0.11
IABP	14 (17.1)	129 (13.8)	.42
INTERMACS profile			.69
1	0 (0)	22 (2.4)	
2	25 (30.5)	274 (29.6)	
3	45 (54.9)	495 (53.5)	
4-7	12 (14.6)	135 (14.6)	
LVEDD, mm	63 (58-70)	68 (62-76)	<.001
LVEDDi, mm/m^2	40 (36-43)	33 (29-37)	<.001
Mean arterial pressure, mm Hg	73 (69-82)	79 (73-87)	<.001
Pulmonary capillary wedge pressure, mm Hg	22 (14-28)	24 (17-29)	.06
Central venous pressure, mm Hg	8 (4-13)	10 (6-15)	.009
Pulmonary vascular resistance, Wood units	3.4 (2.2-4.5)	2.8 (1.9-4.1)	.04
Total bilirubin, mg/dL	0.8 (0.6-1.3)	0.9 (0.6-1.3)	.61
Blood urea nitrogen, mg/dL	23 (18-29)	25 (19-35)	.036
Albumin, g/dL	3.6 (3.2-3.8)	3.6 (3.3-3.9)	.32
Creatinine, mg/dL	1.1 (0.9-1.4)	1.3 (1.0-1.6)	<.001

[a]Wilcoxon rank sum test or χ^2 or Fisher exact test as appropriate. Continuous variables are presented as median (interquartile range). Categorical variables are presented as counts (percentage). BMI, body mass index; BSA, body surface area; IABP, intra-aortic balloon pump; ICD, implantable cardioverter-defibrillator; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; LVEDD, left ventricular end-diastolic diameter; LVEDDi, indexed LVEDD.

PATIENTS AND METHODS

PATIENT COHORT. The analysis cohort includes 515 patients implanted with HM3 in the MOMENTUM 3 pivotal trial (NCT02224755) and the first 500 of 1685 patients implanted in the MOMENTUM 3 CAP cohort (NCT02892955). Patients were observed for 2 years with a data cutoff in February 2020. The MOMENTUM 3 pivotal trial was a multicenter, randomized study comparing the HM3 with the HMII.[16] MOMENTUM 3 CAP is a single-arm, prospective, multicenter study for continued evaluation of the HM3. Both studies were sponsored by Abbott. Protocols were approved by each Institutional Review Board, and written informed consent was obtained from all patients or their authorized representatives.

DEFINITION OF SMALL BSA. No consensus for small body size definition exists for adult LVAD recipients. Patients with BSA $\geq$1.2 m^2 were eligible for LVAD implantation in MOMENTUM 3 and CAP. Only 14 analysis cohort patients (1.4%) had BSA $\leq$1.50 m^2. For our analysis, the threshold

for small BSA was set at the 10th percentile (rounded down to the nearest tenth) of the available patient distribution (BSA $\leq$1.70 m^2).

END POINTS. We analyzed pump parameters, left ventricular end-diastolic diameter (LVEDD), and the index parameter of LVEDD normalized by BSA (LVEDDi) between groups. The MOMENTUM 3 composite primary end point, survival at 2 years free of disabling stroke (modified Rankin score >3) or reoperation to replace or to remove a malfunctioning pump, was evaluated. Death, disabling stroke, pump exchange, explantation for reason other than myocardial recovery, urgent transplantation for device malfunction, and withdrawal from the study were considered failures of the primary end point. Other end points included overall survival, adverse events, functional status and quality of life (QOL) by New York Heart Association class, 6-minute walk distance, and EuroQol 5-Dimension 5-Level (EQ-5D-5L) visual analog scale over time. Moderate to extreme pain or discomfort as reported by the patient in the EQ-5D-5L questionnaire was investigated. Finally, we examined whether readmission rates due to low flow alarms were higher in small patients.

STATISTICAL ANALYSIS. Continuous variables are presented as median and interquartile range (IQR) or mean $\pm$ standard deviation. Categorical variables are described as counts and percentages. Univariate comparisons of median values were performed with Wilcoxon rank sum test. Univariate comparisons of categorical variables were performed with χ^2 test or Fisher exact test as appropriate. The Kaplan-Meier method was used to calculate survival estimates for time-to event analyses. Cox proportional hazards models were used to calculate adjusted hazard ratios (HRs) for the composite primary end point and survival as described in Supplemental Tables 1 and 2. Adverse event rates are shown as percentage of patients experiencing events and events per patient-year compared between groups using Poisson regression. Rate differences are described as rate ratios and 95% CIs. Longitudinal changes in LV size, pump parameters, 6-minute walk test distance, and QOL were analyzed by repeated measures linear mixed effects modeling.

All reported P values are 2 tailed, and P values $< .05$ are considered statistically significant. Statistical analyses were performed with SAS software, version 9.4 (SAS Institute).

RESULTS

BASELINE CHARACTERISTICS. The analysis cohort included 1015 HM3 patients with average BSA of 2.07 $\pm$ 0.27 m^2. There were 82 small patients ($\leq$1.70 m^2) and 933 large patients (>1.70 m^2). Small patients were characterized by lower baseline blood urea nitrogen and creatinine concentrations but higher pulmonary vascular resistance. They were also more likely to be female or of Asian descent and were less likely to have a history of diabetes or hypertension compared with larger patients (Table 1).

In comparison to larger patients, the small patients had lower baseline LVEDD but higher LVEDDi. Figure 1 shows the relationship between LVEDD and LVEDDi vs BSA. Outcomes for patients stratified by LVEDD are provided for reference in Supplemental Figure 1.

INTRAOPERATIVE AND EARLY POSTOPERATIVE RESULTS. In smaller vs larger patients, median implant time (260 [IQR, 198-340] minutes vs 264 [IQR, 205-343] minutes; P = .97), cardiopulmonary bypass time (83 [IQR, 64-107] minutes vs 83 [IQR, 64-110] minutes; P=.97), and need for concomitant procedures (36.6% vs

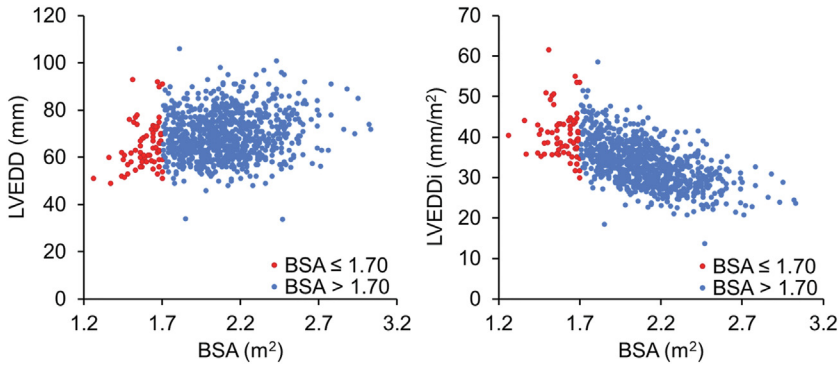

FIGURE 1 Scatter plots demonstrating the relationship between left ventricular end-diastolic diameter (LVEDD) vs body surface area (BSA) and LVEDD normalized by BSA (LVEDDi) vs BSA. The red and blue dots represent patients with BSA ≤1.70 m^2 and BSA >1.70 m^2, respectively, and demonstrate that smaller body size does not equate to smaller LVEDD.

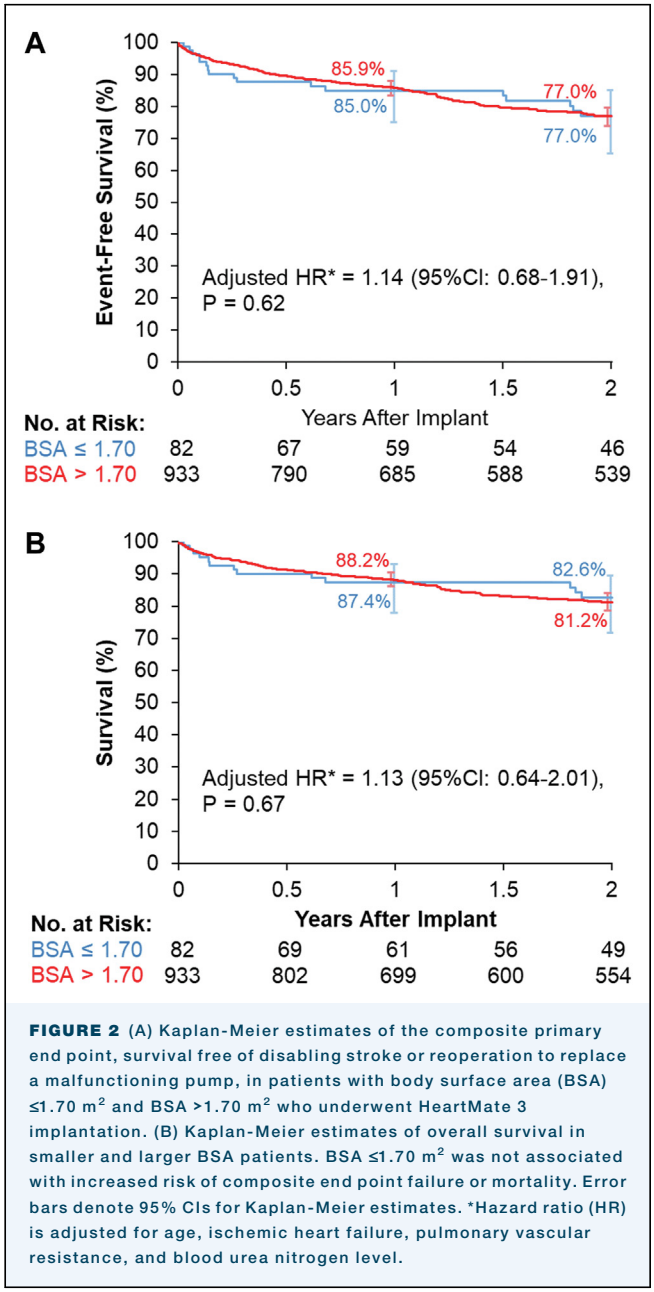

FIGURE 2 (A) Kaplan-Meier estimates of the composite primary end point, survival free of disabling stroke or reoperation to replace a malfunctioning pump, in patients with body surface area (BSA) ≤1.70 m^2 and BSA >1.70 m^2 who underwent HeartMate 3 implantation. (B) Kaplan-Meier estimates of overall survival in smaller and larger BSA patients. BSA ≤1.70 m^2 was not associated with increased risk of composite end point failure or mortality. Error bars denote 95% CIs for Kaplan-Meier estimates. *Hazard ratio (HR) is adjusted for age, ischemic heart failure, pulmonary vascular resistance, and blood urea nitrogen level.

36.4%; *P*=.98) were comparable. The rate of discharge on HM3 support from implant hospitalization was similar between groups (92.7% vs 94.9%; *P*=.40), but median length of stay was longer for smaller patients (21 [IQR, 17-29] days vs 19 [IQR, 14-25] days; *P* = .032).

PUMP PARAMETERS, CHANGES IN LVEDDI, AND MEAN ARTERIAL PRESSURE

Average HM3 pump speeds and estimated flows at different time points are shown in Supplemental Table 3. At all time points, small patients were supported at lower pump speeds and flows over time. However, indexed flows (flow normalized by BSA) were higher in smaller patients (*P* < .05). Compared with large patients, LVEDD in small patients continued to be lower with LVAD support but LVEDDi was higher (Supplemental Figure 2). Mean arterial pressure averages were not significantly different between groups over time (Supplemental Table 4).

PRIMARY COMPOSITE END POINT AND SURVIVAL. Kaplan-Meier estimates for the composite end point of survival free of disabling stroke or reoperation to replace a malfunctioning pump are shown in Figure 2A. The proportion of patients achieving the composite end point at 2 years was 77.0% in both groups (adjusted HR, 1.14; 95% CI, 0.68-1.91; *P* = .62). In Supplemental Figure 3, Kaplan-Meier estimates of the composite primary end point in additional substratifications of BSA ranges (≤1.50 m^2, 1.51-1.70 m^2, 1.71-2.00 m^2, 2.01-2.30 m^2, and >2.30 m^2) were also similar (log-rank, *P* = .97).

Kaplan-Meier estimates of overall survival at 2 years were 82.6% and 81.2% in small and large patients, respectively (adjusted HR, 1.13; 95% CI, 0.64-2.01; *P* = .67; Figure 2B). Causes of death for both groups are reported in Supplemental Tables 5 and 6. Competing outcomes for both cohorts are shown in Supplemental Figure 4.

ADVERSE EVENTS. The 2-year adverse event incidence and rates are shown in Table 2. There were no significant differences except for lower incidences of sepsis, cardiac arrhythmias, and ventricular arrhythmias in small patients. There was numerically but not statistically significantly more right ventricular assist device use in small patients (8.5% vs 5.1%; *P* = .19).

FUNCTIONAL STATUS AND QOL

Both groups experienced similar heart failure symptom improvements (Figure 3A) and significant increases in 6-minute walk test distances from baseline (Figure 3B). The cohort of small patients had slightly better QOL during the 2-year follow-up (*P* = .037; Figure 4), and the degree of moderate to extreme pain or discomfort was no different between groups (Supplemental Figure 5).

READMISSIONS ASSOCIATED WITH LOW FLOW ALARMS. Of the patients discharged from the implant hospitalization, 22.4% of small and 14.2% of large patients were later readmitted for low flow alarms (*P* = .06), detailed in Supplemental Table 7.

COMMENT

In this study, we report the baseline characteristics and clinical outcomes of small (BSA ≤1.70 m^2) compared with large HM3 patients enrolled in the MOMENTUM 3

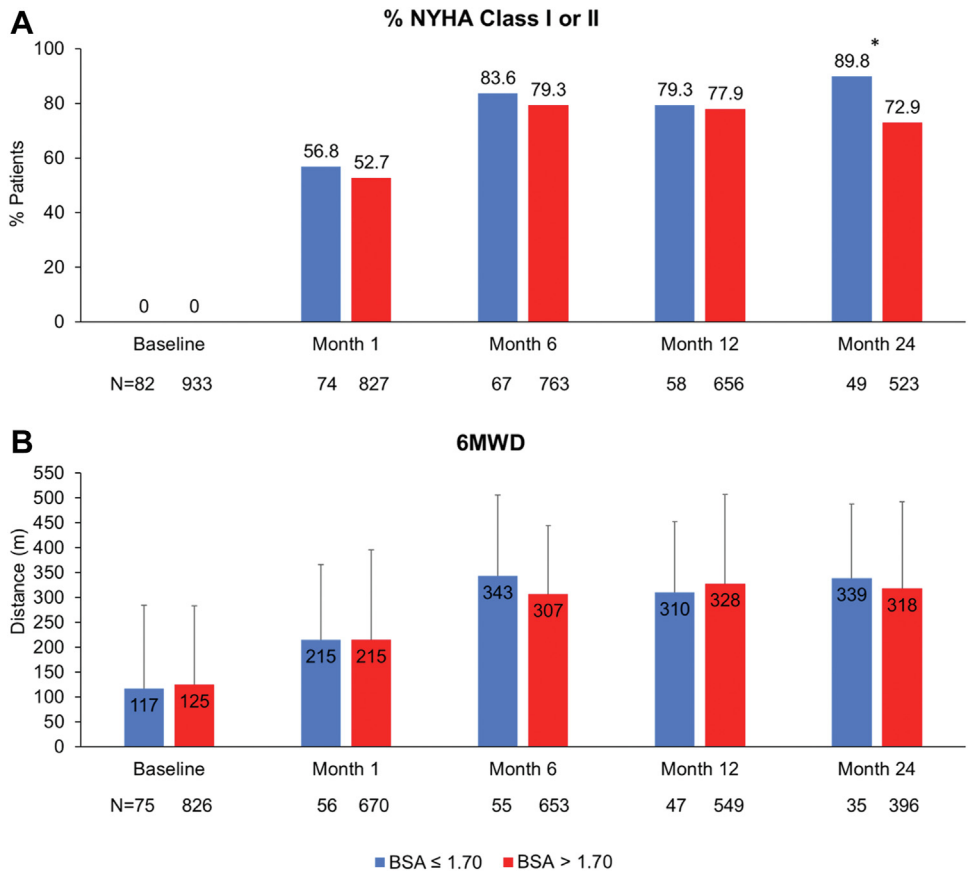

FIGURE 3 Functional status over time as measured by (A) New York Heart Association (NYHA) classification and (B) 6-minute walk distance (6MWD) in patients with body surface area (BSA) ≤1.70 m^2 and BSA >1.70 m^2. Both groups demonstrated improvements from baseline. *P < .05 for smaller vs larger BSA at the study time point by χ^2 test.

pivotal trial and CAP cohort. We found that small adult HM3 patients are more likely to be female, to have lower incidence of diabetes and hypertension, to have relatively large LVs, to have lower pump speeds but higher indexed flows, to achieve similar 2-year survival as large patients, to demonstrate a favorable adverse event profile including low rates of stroke and pump thrombosis, and to show comparable improvements in functional status and QOL.

The association between female sex and smaller body size in durable LVAD recipients has been previously demonstrated.[9,10,13,17,18] However, a more specific phenotype for this underserved population of patients has not been well characterized. As expected, smaller BSA patients in our analysis have high female representation and a lower body mass index. This smaller size cohort of patients also demonstrated lower incidence of diabetes and hypertension. INTERMACS profiles and implant strategy were comparable between groups, but there was a tendency toward use as destination therapy for the smaller patients (70.7% vs 61.0%).

Although it is unclear whether ventricular size plays a significant role in determining LVAD outcomes, at least 2 studies have shown potential importance. In a cohort of HMII recipients, an LVEDD smaller than 60 mm was associated with higher risk of stroke and mortality.[19] In an INTERMACS analysis, Shah and colleagues[20] found that survival improved with progressive increase in LV size. An important finding of this study is that small body size does not equate to small LV size. Analysis of LVEDD normalized by BSA may be an informative index. According to the American Society of Echocardiography and the European Association of Cardiovascular Imaging, normal LVEDDi ranges are 22 to 30 mm/m^2 for men and 23 to 31 mm/m^2 for women.[21] In our study, we found that LVEDDi was abnormally high in both groups. Furthermore, LVEDDi was higher in smaller patients and remained higher throughout the follow-up period. Although preimplantation LVEDD may represent a more important variable than BSA in many patients, we did not find differences in failure of the primary composite end point between patients with different LVEDD

TABLE 2 Adverse Events at 2 Years

Adverse event	BSA ≤1.70 m² (n = 82) No. (%)	BSA >1.70 m² (n = 933) No. (%)	*P* value[a]	EPPY BSA ≤1.70 m²	EPPY BSA> 1.70 m²	Rate ratio (95% CI)	*P* value[b]
Suspected device thrombosis	1 (1.2)	13 (1.4)	1.00	0.01	0.01	0.87 (0.11-6.65)	.89
Stroke	11 (13.4)	95 (10.2)	.36	0.10	0.08	1.26 (0.69-2.28)	.45
Disabling (MRS >3)	5 (6.1)	44 (4.7)	.58	0.04	0.04	1.13 (0.45-2.84)	.79
Bleeding	37 (45.1)	427 (45.8)	.91	0.76	0.66	1.16 (0.94-1.43)	.17
Gastrointestinal	19 (23.2)	243 (26.1)	.57	0.35	0.34	1.02 (0.75-1.40)	.89
Major infection	45 (54.9)	528 (56.6)	.76	0.78	0.77	1.01 (0.82-1.24)	.92
Driveline	24 (29.3)	218 (23.4)	.23	0.27	0.22	1.26 (0.88-1.80)	.20
Sepsis	5 (6.1)	139 (14.9)	.029	0.04	0.12	0.33 (0.13-0.80)	**.014**
Right-sided heart failure	25 (30.5)	319 (34.2)	.50	0.22	0.26	0.87 (0.59-1.27)	.47
RVAD or inotropes ≥14 days	19 (23.2)	171 (18.3)	.28	0.15	0.13	1.17 (0.73-1.87)	.52
RVAD	7 (8.5)	48 (5.1)	.19	0.06	0.03	1.62 (0.73-3.57)	.24
Cardiac arrhythmia	20 (24.4)	329 (35.3)	.047	0.18	0.35	0.50 (0.33-0.77)	**.002**
Ventricular	8 (9.8)	195 (20.9)	.016	0.07	0.21	0.35 (0.18-0.68)	**.002**
Renal dysfunction	7 (8.5)	132 (14.2)	.16	0.06	0.11	0.52 (0.24-1.11)	.09

[a]The χ^2 test or Fisher exact test as appropriate; [b]Poisson regression. Boldface *P* values represent statistical significance. BSA, body surface area; EPPY, events per patient-year; MRS, modified Rankin score; RVAD, right ventricular assist device.

ranges, including patients with LVEDD smaller than 50 mm. However, evaluation of the influence of LV size on outcomes was limited by the low number of patients with a small LVEDD in our study. A larger population of patients from large registries with more heterogeneous LVEDD is necessary to investigate the influence of a small LV cavity in LVAD outcomes. The relationships between body size, ventricular size, and clinical outcomes play an important role in patient selection and warrant further study.

Tailoring specific surgical implantation techniques to small patients may be necessary but has not been described to date. In this study, intraoperative findings were comparable between the groups with similar procedure length, cardiopulmonary bypass time, and incidence of concomitant procedures. Smaller patients were managed with lower pump speeds throughout follow-up and achieved lower pump flows compared with larger patients, which is indicative of allometric relationship between body size and cardiac output. However, the indexed pump flows were higher in the group of smaller patients, whereas mean arterial pressure was maintained at similar levels compared with the larger patients. As mean arterial pressure was not found to

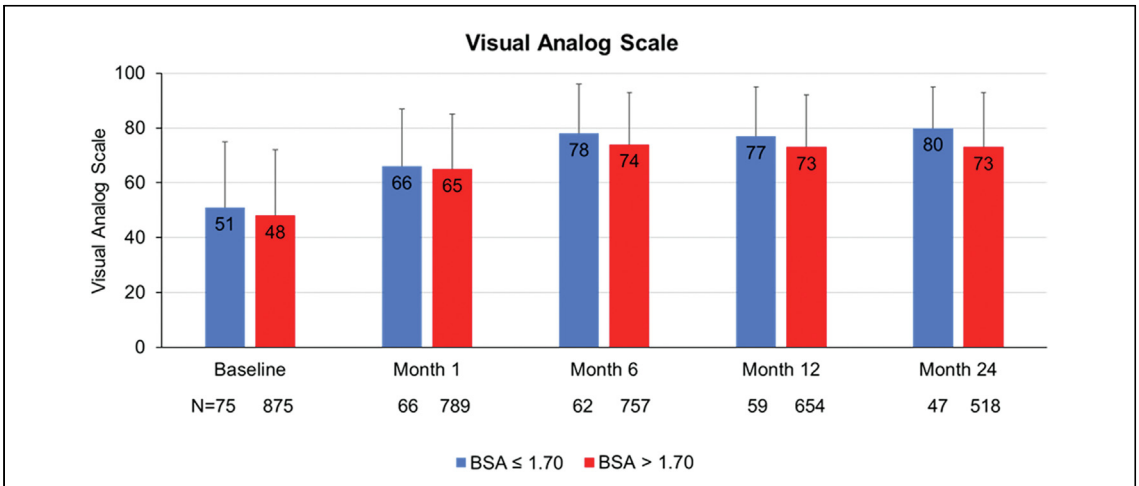

FIGURE 4 Quality of life over time as measured by the EuroQol 5-Dimension 5-Level (EQ-5D-5L) visual analog scale in patients with body surface area (BSA) ≤1.70 m² and BSA >1.70 m². Both groups demonstrated significant improvements from baseline. Overall, the smaller BSA cohort also had slightly better scores during the 2-year follow-up compared with larger patients (*P* = .037).

correlate with body size, this may suggest the presence of lower systemic vascular resistance index in smaller patients as well.

A main finding of our study is that survival free of disabling stroke and pump replacement and overall survival were similar between groups. A 2017 INTERMACS analysis showed similar overall survival between patients with BSA $\leq$1.5 m^2 and BSA >1.5 m^2.[9] A multicenter Japanese study also reported similar survival outcomes in 30 patients with BSA <1.5 m^2 compared with 74 patients with BSA $\geq$1.5 m^2 who received the HMII.[13]

Few studies have investigated whether small patients experience a different adverse event profile. Zafar and coworkers[9] reported higher incidence of bleeding and driveline infections and lower rates of late right-sided heart failure and renal dysfunction in patients with BSA $\leq$1.5 m^2. Ono and colleagues[13] also found a higher incidence of driveline infections in this population of small patients. A European study that investigated outcomes in 167 patients who received the Berlin Heart INCOR LVAD demonstrated that BSA <1.87 m^2 was an independent risk factor for death due to stroke or systemic bleeding.[12] In general, results from our analysis demonstrate similar adverse event rates between smaller and larger HM3 patients. It is reassuring that despite the lower pump speeds and lower flows demonstrated in smaller patients, the incidence of pump thrombosis and stroke was similar, perhaps because of full magnetic levitation technology, which has been associated with a lower incidence of hemocompatibility adverse events.[16,22] Driveline infections were comparable between groups. A lower incidence of ventricular arrhythmias was seen in smaller patients. Although this finding may be counterintuitive, it suggests that potential contact between the inflow cannula and the myocardial wall in smaller patients may no longer be a concern. It is possible that the higher incidence of ventricular arrhythmias in larger BSA patients in this study is related to a larger body size,[23] a larger preoperative LV size,[24] and a more frequent history of implantable cardioverter-defibrillator insertion. Right-sided heart failure is a complication believed to potentially affect smaller patients more than larger patients. In our analysis, right ventricle failure rates were similar between groups, but there was a numerically higher rate of right ventricular assist device use in smaller patients.

An interesting finding of this study is that despite demonstrating higher indexed pump flows (normalized by BSA), readmissions secondary to low flow alarms were numerically higher in the smaller BSA group. However, low flow alarms are triggered by absolute pump flows (2.5 L/min), not indexed flows. It is possible that conditions such as dehydration and hypertension more frequently expose smaller patients to the low flow alarm threshold compared with larger patients. Native heart contribution to the cardiac output through the aortic valve was not measured in the MOMENTUM 3 trial; therefore, we cannot conclusively explain these findings. Additional studies investigating the long-term safety of patients supported with lower pump flows are needed.

Finally, small patients enjoyed similar improvements in functional status and QOL compared with larger patients. As LVAD technology evolves and patients experience longer survival, improvements in these areas become increasingly important. Pain and discomfort were not more common in the smaller patients, reassuring because of a risk of more physical interactions between the device and the chest wall, a potential source of pain.

LIMITATIONS. This analysis has several key limitations. First, this was a nonpowered, retrospective evaluation of MOMENTUM 3 pivotal trial and CAP patients. The entry criteria restricted patients to BSA $\geq$1.2 m^2. Second, our cutoff of BSA $\leq$1.70 m^2 was chosen to achieve a sufficiently large sample that nevertheless represents the extreme low end of the size distribution (<10th percentile). Most of our small patients had a BSA between 1.50 and 1.70 m^2, and therefore our results mainly apply to patients in this more limited BSA range. Conducting the main comparative analysis with the historical cutoff BSA $\leq$1.50 m^2 was not possible because only 14 patients would have qualified. However, a supplemental analysis of the group with BSA $\leq$1.50 m^2 showed similar results to larger patients with respect to the primary end point at 2 years. It is possible that the observed outcomes may have differed if more patients with BSA $\leq$1.50 m^2 had been enrolled. Also, with only 82 patients in the group with BSA $\leq$1.70 m^2, the analyses are still somewhat underpowered and at risk of type II error. Despite these limitations, our study provides important long-term clinical evidence in a group of smaller patients who constitute a minority of the overall population of LVAD patients but may benefit from HM3 therapy.

CONCLUSION. Small body size (BSA $\leq$1.70 m^2) should not represent an exclusion criterion for HM3 implantation in patients with advanced heart failure who are otherwise candidates for durable MCS and exhibit a dilated LV. The relationship between body size, ventricle size, and postimplantation outcomes deserves further investigation.

The authors wish to acknowledge Gerald Heatley as a statistical contributor for this work.

FUNDING SOURCES

The authors have no funding sources to disclose.

DISCLOSURES

Ezequiel Molina has no conflicts to disclose. Jennifer Cowger: consultant/speaker for Abbott and Medtronic; on steering committee/study panels for Medtronic, Abbott, and Procyrion. Henry Ford: institutional funds from Abbott, Medtronic, and Procyrion. Sangjin Lee: consulting payments made to his institution from Medtronic. Douglas Horstmanshof: consultant and speaker's bureau fees from Abbott. Joseph Cleveland: grant support from Abbott. Daniel Goldstein: educator and surgical proctor for Abbott. Mandeep Mehra: payments made to his institution from Abbott for consulting; consulting fees from Portola, Bayer, Triple Gene, and Baim Institute for Clinical Research; advisory board member for Medtronic, Janssen, NuPulseCV, Leviticus, FineHeart, and Mesoblast. Nir Uriel: grant support and consultant fees from Abbott and Medtronic. Christopher Salerno: consultant fees from Abbott and Medtronic. Kevin Bourque and Joyce Chuang: Abbott employees. Yoshifumi Naka: consultant fees from Abbott.

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