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A Real Life Experience with HeartMate III

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ABSTRACT

Background

The HeartMate 3TM (HM3) left ventricular assist device (LVAD) is the most recent LVAD to receive CE mark and FDA approval. It is a fully magnetically levitated pump with no reported haemolysis, pump thrombosis or pump failure in the first in man study (1). It has now received market approval in the European Union, United States of America and Australia. We reviewed our real life experience with the device, to assess outcomes over the medium term.

Methods

We conducted a retrospective review of prospectively collected data for 33 consecutive patients implanted with a HM3 LVAD between November 2014 and October 2018 at The Alfred, Melbourne, Australia.

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Results

Of the 33 patients, 31 remained alive at the census date, with only two early deaths and 11 patients transplanted. There were no pump thromboses, but there were three cases of clot ingestion (two on the right and one on the left). Seven patients required permanent biventricular assist device (BiVAD) support. The duration of HM3 support at the time of census was a median of 196 (IQR, 118-386) days.

Conclusion

This series demonstrates excellent results of the HM3 LVAD in an uncensored, real life, consecutive group of patients in a single institution.

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Introduction

The HeartMate 3TM (HM3) left ventricular assist device (VAD) (Abbott, Chicago, IL, USA), is a relatively new bearingless magnetically levitated centrifugal VAD, which supersedes the axial flow HeartMate II VAD. The benefits of the HM3 are that it is a smaller, more compact pump designed to sit within the pericardium. It has a modular driveline designed to make the exchange of a damaged driveline easier and an artificial pulse built into the software, aimed at washing the rotor surfaces and eliminating stasis. The pump itself has wider gaps in the blood contact surfaces to reduce shear stress and thereby reduce thrombosis.

The first in man study of 50 patients, conducted in 10 centres across Europe, Kazakhstan, Canada and Australia, demonstrated excellent results up to 12-months with no haemolysis, pump thrombosis or pump failure (1-3). Survival was 92% at 6-months and 81% at 12-months.

More recently a review of 27 patients receiving the HM3 LVAD, outside of a clinical trial setting, also demonstrated excellent results with 6-month survival of 85.2% (4), 1-year survival of 85.2% (5) and the absence of pump thrombosis or stroke events at either time point (4,5). Although purporting to be a 'real-life' experience with the pump, the study excluded patients with biventricular support, other types of assist devices such as extra corporeal membrane oxygenation (ECMO), VAD exchanges and reoperative procedures. Furthermore, eight of the included patients were participants in the HM3 CE Mark trial.

The aim of our study was to present an uncensored, consecutive experience with the HM3 LVAD in our institution.

Materials and methods

We conducted a retrospective review of prospectively collected data. All patients who underwent HM3 LVAD implantation at The Alfred Hospital, Melbourne, Australia between November 2014 and October 2018 were included in the analysis. There were no planned 'Destination Therapy' patients as this indication is not funded in Australia. All patients were implanted with either a 'Bridge to Transplant' or 'Bridge to Candidacy' aim. Patients with pre-operative ECMO, right sided mechanical support, redo sternotomy, concomitant procedures and pump exchanges were all included. The census date was 28th December 2018.

All HM3 VADs were implanted via median sternotomy and on cardiopulmonary bypass support using standard techniques. Post-operatively heparin infusion was commenced at 12 hours provided there was no untoward bleeding risk. Warfarin [(targeted international normalized ratio (INR) of 2.0-3.0, and aspirin 100 mg day)] were commenced once the patient had started oral intake. Pump speed on the left side

was maintained within operating parameters of 5400 to 6000 rpm aimed for a mean blood pressure of 65-75mmHg. Regular echocardiographic assessment was used to adjust flows to ensure aortic valve opening.

Right sided support was provided by a temporary centrifugal circuit or by off label use of the HM3 VAD (6). Our operative technique for temporary (7) and permanent (8) RVAD implantation has been previously published. In brief, temporary RVAD support is provided by anastomosing an 8 mm Dacron graft to the main pulmonary artery and tunneling it through the anterior abdominal wall to the subcostal area where it is cannulated with a 21F or 23F wire-reinforced arterial cannula (Maquet Cardiovascular, LLC; Wayne, NJ). A 23F or 25F wire-reinforced venous cannula (Maquet) is placed percutaneously or through a cutdown over the right femoral vein, with its tip in the mid-right atrium. Both of the cannulae are connected to a Rotaflow centrifugal pump (Maquet) without an oxygenator. Flows are adjusted to maintain adequate filling of the LVAD and are monitored by echocardiographic assessment of interventricular septal position and ventricular cavity size.

Permanent RVAD support has utilised the off label application of the HM3 pump, which we insert into the right atrium using multiple layers of Teflon felt as a 'standoff' over the inflow cannula. Thus only about 10mm of inflow cannula is within the right atrium, and the pump sits away from the atrial wall, usually in the right pleural cavity. The outflow conduit is not banded but is kept fairly long by bringing it down along the diaphragm and then over the right ventricle beneath the left hemisternum and then anastomosed to the main pulmonary artery.

Use of ECMO to bridge patients to permanent VAD can stabilize patients in cardiogenic shock, improve end organ function and allow time for further assessment

of suitability for VAD therapy. All ECMO patients in this series were supported by peripheral ECMO prior to VAD implantation. Peripheral cannulation of the femoral vasculature by Seldinger technique under ultrasound guidance is typically performed. A distal perfusion catheter is placed percutaneously in the limb with arterial cannulation to provide antegrade limb perfusion in all cases. Support is provided by a centrifugal pump, Biomedicus Carmeda coated cannulae (Medtronic Inc., Minneapolis, MN, USA) and a Quadrox D membrane oxygenator (Maquet Cardiovascular LLC, San Jose, CA, USA). Patients are anti-coagulated with intravenous heparin in the absence of bleeding complications, aiming for an Activated Partial Thromboplastin Time of 55-75 seconds. Patients who were not able to wean went on to have VAD implantation, and are included in this study.

Statistical analysis

This data was analysed using SPSSTM software Version 25. Data was initially assessed for normality. Parametric data is reported as mean (standard deviation), non-parametric data is presented as median with an interquartile range, and categorical data presented as frequencies and percentages. Patient survival is reported as hazard ratios (95% CI) and presented using a Kaplan-Meier curve. Biochemical variables were assessed for normality and as all were found to be well approximated by a log-normal distribution they were log-transformed prior to analysis. Differences between time points were determined using post-hoc pairwise comparisons after fitting a main effect for time with each patient treated as a random effect. Results are presented as geometric means and ratios, both with 95% confidence intervals. To account for multiple comparisons, a reduced p-value of 0.01 (or maybe even 0.001) was used to reduce the chance of a type I error.

Results

Between November 2014 and October 2018, 71 VADs were implanted at The Alfred Hospital, Melbourne, Australia. Of these, 33 were HM3 LVADs and the remainder were Heartware HVADs (Heartware Inc., Framingham MA, USA). Only one patient (the first implant) was part of a study (the CE Mark trial) (1-3). The remainder were implanted under the Australian Special Access Scheme and with Therapeutic Goods Administration (TGA) approval from April 2018.

Demographics and pre-operative characteristics of the patient group are outlined in Table I. Peri-operative data is outlined in Table 2.

Six patients were bridged from ECMO to HM3 LVAD support. Fourteen patients required temporary mechanical RVAD support and seven patients required permanent HM3 RVAD support. Of the seven HM3 RVAD implants, five were performed at the time of the LVAD implant due to severe right heart failure considered not to be reversible by the treating surgeon and cardiology team. Two patients supported by a temporary RVAD failed weaning and were converted to a HM3 RVAD; one at 11 days and one at 21 days post LVAD implant. The remaining 12 temporary RVAD patients were successfully weaned from the RVAD and had it removed.

There was one LVAD exchange in the study cohort in a patient who had a HMII implanted 22 months earlier. Due to short to shield issues, the patient suffered a pump stop and had the HMII exchanged for a HM3. Two patients, (both with known internal jugular or superior vena cava thrombus) suffered clot ingestion into the right sided HM3. One required a pump exchange at seven months' post implant and one was successfully treated with heparinization. After three days of anticoagulation, that HM3 RVAD spontaneously recommenced operation without any obvious sequelae. The

patient had remained stable without significant right heart failure during the period of RVAD pump stop. Overall 41 HM3 devices were implanted in 33 patients. VAD operating parameters at discharge and follow up visits are outlined in Table 3. Biochemical parameters pre and post operatively are outlined in Figure 1. Repeated measures ANOVA performed on log transformed data demonstrated significant differences only between the peak post-operative values of alanine transferase, creatinine, bilirubin and lactate dehydrogenase and their measurements made at all other time points ($p < 0.001$). Otherwise the measurements did not significantly differ over time.

The duration of HM3 support at the time of census was a median of 196 (IQR, 118-386) days. This represents the equivalent of over 23.8 years of HM3 support analysed in the left position. The analysis also includes 1767 days (4.8 years) of support in the right atrial position. The longest supported (LVAD) patient is also the first implanted patient and has been supported for 1469 days (over 4 years) at the time of census (and remains supported at the time of submission).

Eleven patients have been transplanted. A competing risks analysis is shown in Figure 2 and Kaplan-Meier survival in Figure 3. Two patients died in the post-operative period. One died on day three post-operatively from a large embolic stroke which was thought to have occurred intraoperatively from left ventricular cavitory thrombus ingestion. The second death occurred on day 12 post-operatively from multi organ failure and sepsis, despite a temporary RVAD implanted at the time of the LVAD.

Bleeding complications were prominent. Twelve patients required return to the operating room for bleeding. These events tended to occur within the first few days after VAD implant. Five patients had gastrointestinal tract bleeding, all occurring in

the first three months post implant, and seven patients experienced recurrent epistaxis. One patient developed persistent intra-abdominal bleeding in the early post-operative period requiring repeat laparotomies, before eventually recovering.

Two patients required revision of their outflow graft in the early post-operative period, for kinking. One patient required resternotomy two years after LVAD implant with erosion of the outflow graft from the drive line within the pericardium. One patient required a pleurodesis for recurrent effusions.

In terms of infective complications, eight patients had driveline infections requiring localized treatment. One patient developed a deep sternal wound infection requiring multiple debridements and eventual closure.

Discussion

In this series of 33 consecutive HM3 patients, we have presented a truly 'real world' consecutive unfiltered experience. Previous reports have excluded many high risk patients in accounts of their HM3 experience and have included significant numbers of patients enrolled as part of the European CE Mark trial (4,5). Those reports excluded patients requiring concomitant procedures, mechanical right sided support, pre VAD mechanical support such as ECMO and redo sternotomies. All of these conditions are well known to increase mortality and morbidity in VAD recipients (9,10). A recent report from Germany found that redo sternotomy increased the risk of mortality, blood product transfusion, hepatic and renal dysfunction and ischaemic stroke after VAD implant compared to patients with no previous sternotomy (9). In a separate publication, the same authors found preoperative ECMO to be associated with worse survival, increased right heart failure, respiratory failure and renal failure (10). In our series, five (15%) patients were redo sternotomies, and six (18%) were

supported on ECMO leading up to the VAD implant. This significantly increases the potential perioperative risk of our cohort according to those previously published studies. However, we have previously analysed our own results for patients supported to VAD implant by ECMO, and found no significant reduction in survival (11). Indeed, all six of the patients bridged to VAD by ECMO in this current series were alive at the census date, as were all five patients who had redo sternotomies.

More recently, the ELEVATE registry data has been released, describing results in a prospective observational multi-national registry of 463 consecutive HM3 implants after commercial approval in Europe and Kazakhstan (12). In that cohort, 12% of patients had pre-operative mechanical circulatory support and 17% had previous sternotomy. These premorbid conditions are more in line with the cohort we have presented. However, the follow up period in that study was brief with a survival of 90% reported at 30 days, improving to 95% if only primary implant patients were included. In contrast our uncensored median follow up of 6 months demonstrated a survival of 95%.

The CE Mark study and the ELEVATE registry did not identify any pump thromboses (1-3,12). The much larger MOMENTUM study which compared the HM3 to the axial flow HMII, identified only seven cases of suspected or confirmed pump thrombosis in 516 patients implanted (13). This contrasted significantly with 70 suspected or confirmed cases of pump thrombosis in the 512 patients implanted with the axial flow device. This appears to be an important benefit of the HM3 in comparison to previous generation VADs. Other case reports of HM3 thrombosis do exist, with one occurring as early as day two. In that report no identifiable kink or technical reason and no manufacturer fault was identified (14). The proposed mechanism was inadequate anticoagulation soon after surgery and multiple low flow events. Another pump

thrombus occurring at day 8 has been reported, a possible mechanism in that instance being an off pump implantation (15). At reoperation, a left ventricular clot was identified and removed and the pump exchanged but clot ingestion into the second pump and subsequent thrombosis again occurred. A third report, of a patient who died of multi-organ failure at day 229 post implant confirmed layered thrombus of differing age on the rotor of the explanted HM3 (17). It is evident, from all the reports thus far, that the thrombosis event rate in the HM3 is low compared to previous VADs. However, it is possible that the pump thrombosis rate is under reported. Reports of clot ingestion, as opposed to in situ thrombosis are almost always assumed and difficult to prove unless the VAD is explanted.

The design features of the HM3 were aimed specifically at reducing hematological complications and it appears at this stage that they have been successful in that endeavor. Specifically, the larger rotor gaps aim at reducing shear stresses on blood cells which are implicated in the acquired von Willebrand syndrome seen in almost all patients with implanted continuous flow LVADs. A recent study comparing the multimeric structure of von Willebrand factor (vWF) between patients with a HM3 and HVAD found less reduction of high molecular weight multimers and a higher concentration of factor VIII in the HM3 patients indicating less shear stress to blood components in those patients (17). The authors proposed that better flow characteristics due to larger blood flow paths and extended gaps between rotating elements were responsible for the higher stability of vWF multimers and lower platelet activation seen in the HM3 patients. This is a likely proposed mechanism for the lower thrombotic events being seen with this device in studies to date as outlined above.

Further support of the lower tendency to thrombotic events in the HM3 is the significantly lower stroke event rate seen over the longer term (181 – 730 days) in the 2 year pre specified ‘as treated’ secondary analysis of the MOMENTUM 3 (18). Although no difference in stroke events was found between the HM3 and HMII arms in the first 180 days post implant, the longer term follow up revealed a 3.3 times lower event rate for the HM3 patients.

Conclusions

Although we have presented a single centre retrospective cohort of patients, it is completely uncensored, with all patients receiving a HM3 device in our institution being included for analysis. The study shows excellent survival and very low thrombosis rates in a real world setting, confirming the findings in the more restricted enrolment environment of the landmark trials.

Author contributions:

Concept/design – SM, JF, Data analysis/interpretation- SM, JF, MB, Drafting article- JF, Critical revision of article- SM, DMcG, Approval of article- SM, DMcG, Statistics - MB, Data collection- JF, Other –RS, CK.

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FIGURES

Figure 1. Biochemical results pre-operatively, post-operatively, at discharge, and 3 months, 6 months and 12 months post HM3 implantation, presented as geometric means and 95% CI: A. Lactate dehydrogenase (U/L; A), B. Creatinine (umol/L), C. Bilirubin (umol/L) and D. Alanine transaminase (U/L).

Figure 2. Competing risks curve for the HM3 LVAD patient series

Figure 3. Kaplan-Meier survival curve for the time to all-cause mortality in patients who had a HM3 implant.

Table 1. Pre-operative and demographic data

Variable	HM3 (n=33)
Male/Female	31/2 (94/6%)
Age (years)	50 (13)

Height (cm)	177 (7)
Weight (kg)	79 (15)
Body Mass Index	25.7 (4.2)
<i>Diagnosis</i>	
Dilated Idiopathic cardiomyopathy	16 (49%)
Ischaemic cardiomyopathy	9 (27%)
Other	8 (24%)
<i>Preoperative status</i>	
Preoperative invasive ventilation	4 (13%)
Preoperative ECMO support	6(18%)
Preoperative renal replacement therapy	2 (6%)
<i>Preoperative hemodynamics</i>	
LVEF (%)	17 (6)
Cardiac Index (L.min.m ²)	2.2 (0.7)
Heart rate (bpm)	85 [70-100]
LVEDD (mm)	72 (10)
Mean right atrial pressure (mmHg)	11 (6)

Mean pulmonary artery pressure (mmHg)	25 (5)
Right ventricular stroke work index	707 (352)
Pulmonary capillary wedge pressure (mmHg)	25 (5)
Pulmonary vascular resistance (Woods units)	3.8 (2.2)
Transpulmonary gradient	13.4 (7.5)
<i>Preoperative biochemistry results</i>	
Estimated glomerular filtration rate	81 (26)
International Normalised Ratio	1.3 [1.2-1.6]
Activated Partial Thromboplastin Time	34 [30-46]
Platelets	175 (66)
<i>Preoperative echocardiography results</i>	
Right ventricular systolic pressure	54 (19)
TAPSE	1.6 (0.5)
<i>Right ventricular failure severity</i>	
None	2 (6%)
Mild	8 (18%)
Moderate	16 (49%)

Severe	9 (27%)
<i>Preoperative Tricuspid regurgitation</i>	
None	5 (15%)
Mild	5 (45%)
Moderate	11 (33%)
Severe	2 (6%)
<i>Preoperative mitral regurgitation</i>	
None	0
Mild	10 (30%)
Moderate	11 (33%)
Severe	12 (36%)

Data presented as n (%); mean (SD); or median (IQR).

ECMO (extra corporeal membrane oxygenation); HM3 (HeartMate 3); TAPSE (Tricuspid Annular Plane Systolic Excursion); LVEDD (left ventricular end diastolic diameter, mm); LVEF (left ventricular ejection fraction)

Table 2. Peri-operative data

Variable	HM3 (n=33)
ECMO support at time of HM3 implant	6 (18%)

Redo sternotomy	5 (15%)
Aortic Valve replacement	6 (18%)
PFO closure	2 (6%)
Temporary RVAD insertion	14 (42%)
Permanent RVAD insertion	7 (21%)
Cardiopulmonary bypass time (mins)(n=33)	100 (40)
Aortic cross clamp time (mins) (n=6)	36 (15)
Blood loss first four hours (mls)	350 (233-1700)
Return to theatre post sternotomy bleeding	12 (36%)
Intensive care unit stay (hours)	254 (158 – 1323)
Invasive ventilatory support (hours)	71 (27-768)
Cerebrovascular accident – permanent	1 (3%)
Cerebrovascular accident – temporary	1 (3%)
Haemofiltration – new renal failure	8 (24%)

Data presented as n (%); mean (SD); or median (IQR).

ECMO (extra corporeal membrane oxygenation); HM3 (HeartMate 3); PFO (patent foramen ovale); RVAD (right ventricular assist device)

Table 3. VAD operating parameters

Data presented as mean (SD)

LVAD (left ventricular assist device); RVAD (right ventricular assist device)

LVAD	Discharge (n=28)	3 months (n=27)	6 months (n=16)	12 months (n=9)
Pump speed rpm	5639 (386)	5663 (401)	5669 (353)	5733 (283)
Pump power watts	4.3 (0.6)	4.5 (0.6)	4.4 (0.5)	4.6 (0.5)
Pulsatility index	4.7 (0.7)	4.8 (0.7)	4.7 (0.8)	4.8 (0.8)
RVAD	Discharge (n=7)	3 months (n=7)	6 months (n=4)	12 months (n=2)
Pump speed rpm	4867 (455)	5071 (482)	4900 (356)	5100 (283)
Pump power watts	3.2 (0.6)	3.5 (0.5)	3.3 (0.5)	3.7 (0.4)
Pulsatility index	3.7 (1.2)	4.4 (0.7)	4.4 (1.1)	4.9 (0.8)

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