First series of left ventricular assist device exchanges to HeartMate 3

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Abstract

OBJECTIVES: Left ventricular assist device (LVAD) exchange is becoming a standard surgical procedure. The exchange procedure is an opportunity to upgrade patients to a new generation pump that offers advanced reduction of adverse events or longer battery hours.

METHODS: We performed an analysis of 6 consecutive patients who underwent LVAD exchange to HeartMate 3 either from a HeartWare or HeartMate (HM) II device. Minimally invasive operations were performed through a lateral thoracotomy. Follow-up time was 6 months after LVAD exchange.

RESULTS: We present 4 patients with the HM II and 2 patients with the HeartWare ventricular assist device (HVAD) who underwent LVAD exchange to HM III. The average age was 57.5 years. At the time of the LVAD exchange, all patients were classified as Interagency Registry for Mechanically Assisted Circulatory Support level 3. In 5 cases, LVAD infection led to LVAD exchange (83%, 5/6). The remaining patient underwent LVAD exchange due to pump thrombosis (16%, 1/6). The 6-month survival rate after LVAD exchange was 100% (6/6). None of the patients was postoperatively supported by extracorporeal membrane oxygenation. No patient experienced postoperative relevant bleeding. One patient suffered minor cerebral bleeding (16.6%, 1/6). At the 6-month follow-up examination, 1 patient reported a single syncpe and several low-flow alarms (1/6). The remaining 5 patients showed no adverse events or technical malfunctions of the VAD (5/6).

CONCLUSIONS: LVAD exchanges from HM II as well from HVAD to HM 3 are proven to be technically feasible. Due to the advantages and technical improvements of the new-generation pumps, this procedure is an excellent opportunity to give patients access to a superior generation of assist device.

Keywords: LVAD • Left ventricular assist device • HeartMate II • HeartMate 3 • HeartMate III • LVAD exchange • Driveline infection • Pump thrombosis • Upgrade

INTRODUCTION

Infection and thrombosis are still major complications of left ventricular assist device (LVAD) therapy that need to be treated by pump exchange if conservative treatment fails. Due to the increased implantation rates and the rising numbers of patients having destination therapy, LVAD exchanges are becoming a standard surgical procedure of any mechanical circulatory support program [1, 2].

The exchange procedure is an opportunity to upgrade patients to a new-generation pump that offers advanced reduction of adverse events or longer battery hours.

The current trend of miniaturization and less invasive procedures has led to the development of smaller LVADs [3-5]. The HeartMate 3 (HM 3; St. Jude Medical Cooperation, St. Paul, MN, USA) is a novel compact LVAD with a fully magnetically levitated pump rotor without mechanical or hydrodynamic bearings [4]. Compared to its predecesor, HeartMate II (HM 2, Thoratec Corporation, Pleasanton, CA, USA), it is associated with superior short- and midterm outcomes and a reduction in adverse events. Additionally, due to reduced power consumption, the HM 3 has longer battery capacity than the HM II, which likely improves the quality of life of patients with VADs [4, 6, 7].

Our group has previously proven the technical feasibility of LVAD exchange from HM II to HM 3 [7]. Now, we present the first results of a series of LVAD exchanges with an upgrade from HM II and the HeartWare ventricular assist device (HVAD) to HM 3.

METHODS

We performed a retrospective analysis of 6 consecutive patients who underwent LVAD exchange to HM 3 between January 2016 and March 2016 at a single institution.
All patients treated at Hannover Medical School, Hannover, Germany who were previously supported by an HM II or HVAD and underwent the exchange procedure to HM 3 were included in this study.

Data were acquired using our in-house clinical database. Follow-up time was 6 months postoperatively. Preoperative baseline characteristics, adverse events and survival data were collected and analysed. A complete 2D echocardiographic examination was performed prior to LVAD exchange and 6 months after discharge. The investigation conformed to the principles outlined in the Declaration of Helsinki. All patients signed a full consent form, and the study was approved by the local institutional ethics committees.

Surgical procedure

In all exchange cases, a lateral thoracotomy was performed to gain access to the pump corpus. Partial rib resections became necessary in half (50%, 3/6) of the cases. After surgical exploration of the pump position, the venous and the arterial cannulas of the extracorporeal circulation were placed in the femoral artery and vein. The outflow cannula of the HM II or HVAD was clamped after the onset of the extracorporeal circulation and the device was turned off, the driveline cut and the pump removed from the thorax. After complete removal of the pump housing from the old ring, the left ventricular cavity was carefully inspected and the remaining endothelial tissue was carefully removed.

For former HM II patients, the old HM II sewing ring was kept, and a sterile cable tie and 2 ligatures were positioned around the silicone part of the old HM II ring (Fig. 1A). Four mosquito clamps were located on the top part of the silicone to keep the cable tie in position and to stabilize the heart for the insertion of the new pump. Because the inflow cannula of the HM 3 is shorter than the inflow cannula of the HM II, the silicone part of the former HM II ring was reduced by 0.5 cm to allow the deeper insertion of the HM 3 inflow cannula into the ring (Fig. 1B) [6].

For an implantation in a former HVAD setting, a sterile rubber seal was placed around the inflow cannula of the HM 3 to bridge the minimal leak between the HVAD fixation ring and the HM 3 (Fig. 2A-C).

The preparation and set-up of the HM 3 were executed according to the standard instructions for use of the company protocol. The inflow cannula of the new HM 3 was placed into the established fixation ring. The cable tie and in some cases 2 additional ligatures were tightened around the inflow cannula.

To de-air the left ventricle and the pump itself, the suction device of the extracorporeal circulation was placed into the outflow graft of the HM 3 and slowly started. Next, the driveline was tunnelled through the abdominal wall via the standard technique, and the residual parts of the bend relief were removed. The old outflow graft was still clamped and was kept within the thorax. Finally, an anastomosis was performed between the remaining outflow graft and the new outflow graft prosthesis of the new HM 3. The outflow graft mismatch between the HVAD (10 mm) and the HM 3 (14 mm) was carefully adapted surgically.

After control of surgical haemostasis and inspection of the outflow graft position, 1 or 2 chest drainage tubes were placed, and the wound was closed.

For improved haemostasis during LVAD exchange, the procedure was performed with red blood cells, thrombocytes, fresh frozen plasma and coagulation factors. Heparin was started intravenously 6 h postoperatively [6].

Follow-up

During the follow-up period, the following variables were collected: survival rate, LVAD settings, renal and liver parameters, technical device parameters and adverse events. A complete 2D echocardiographic examination was performed in all patients 6 months after discharge. Echocardiographic data included left ventricular end-diastolic diameter, left ventricular ejection fraction.
and valve diseases. The left ventricular ejection was determined using the biplane 2-dimensinal modified Simpson method.

**RESULTS**

We had 4 patients with the HM II (66%, 4/6) and 2 with the HVAD (33% 2/6) who underwent LVAD exchange to HM 3. All patients were men. Baseline characteristics are shown in Table 1. The average age was 57.5 years. Three patients underwent initial LVAD implantation due to dilated cardiomyopathy (50%) and 3 patients, due to ischaemic cardiomyopathy (50%). At the time of the LVAD exchange, all patients were classified as Interagency Registry for Mechanically Assisted Circulatory Support level 3. Renal and liver parameters showed no significant pre or postoperative abnormalities. The average number of days on the device was 1354.5. In 5 cases, LVAD infection led to LVAD exchange (83%). The sixth patient underwent LVAD exchange due to pump thrombosis (16%).

The 6-month survival rate after LVAD exchange was 100%. None of the patients was supported postoperatively by extracorporeal membrane oxygenation. The average stay in the intensive care unit was 4.6 days. The average clinical stay was 23 days until discharge to a rehabilitation centre (Table 2).

None of the patients experienced postoperative relevant bleeding such as re-thoracotomy or pericardial tamponade. Two patients (33%) showed postoperative renal failure with the need for temporary dialysis. One patient suffered minor cerebral bleeding (16.6%), underwent tracheotomy on postoperative day 4 and had a prolonged stay in the intensive care unit with an extended respiratory weaning process of 30 days. After rehabilitation, the patient was successfully discharged home.

At the 6-month follow-up examination, 1 patient had had a single syncope event and several low-flow alarms. The remaining 5 patients showed no adverse events or technical malfunctions of the VAD. A synopsis of all adverse events is shown in Table 3.

Mitral regurgitation grade I was present in 2 patients before and in 1 patient after LVAD exchange. Echocardiographic results before and after LVAD exchange are displayed in Table 4.

LVAD settings and parameters before and after LVAD exchange are displayed in Table 5. In 4 patients, the VAD flow parameter decreased, whereas in 2 patient flow levels increased or remained the same 6 months after surgery.

**DISCUSSION**

Exchange of ventricular assist devices has become standard treatment for the treatment of LVAD-associated complications such as pump thrombosis and driveline infection [1, 2, 7–10]. Upgrading to a newer generation pump through an exchange procedure allows the patient to profit from advanced technologies such as new software features, longer battery capacity, reduced shear stress and reduction of adverse events [6, 7].

The HM 3 device does not fit perfectly into the fixation ring of the older generation LVADs. The newly developed ‘click-in’ mechanism for pump fixation of the HM 3 does not function with the HM II or HVAD ring. Therefore, surgeons have to develop their own alternative strategies for pump fixation. In the exchange procedures described, the fixation was effected using a sterile cable tie-in combination with the standard fixation method for the HM II inflow cannula, by tying 2 ligatures around the silicone part of the fixation ring [7]. For the HVAD, we used an additional rubber seal around the inflow cannula. As in vitro testing before implantation showed, both strategies successfully sealed the cannula, and no bleeding complications were observed.

LVAD exchange can technically be performed without the use of the heart–lung machine [1, 2]. In this novel surgical procedure, we forgo this technique for safety reasons (e.g. less blood loss, better inspection of the left ventricular cavity, possibility to harvest endothelial/thromboembolic material). Generally, LVAD exchanges are associated with a risk of air embolism or stroke; therefore, we recommend using on-pump techniques in most of these cases.

Patient selection is of major importance in these high-risk procedures. All patients selected were in a good general condition despite their acquired device infection. We do not recommend performing these procedures in Interagency Registry for Mechanically Assisted Circulatory Support level 1 patients.

At the follow-up examinations, higher rotations per minute were present in the 2 former HVAD patients who were exchanged to HM 3. Due to the outflow graft size mismatch between HVAD...
(10 mm) and HM 3 (14 mm), a higher rate of revolutions per minute was necessary to establish sufficient flow rates.

LVAD pump thrombosis has been extensively discussed in previous years. For HM II, Starling et al. reported that pump exchange or death due to pump thrombosis increased during 2011 and 2012, but the level of the increase remained small [8, 11–13]. A risk factor analysis suggested that a number of patient-related factors contribute to the risk of thrombosis [8]. Although other centres reported increased thrombosis rates, we reported a steady rate of 2.2% [12]. Smedira et al. analysed 995 thrombosed pumps and reported an increase in pump thrombosis in 2010, which reached a maximum in 2012 and then plateaued at a level that was reportedly 3 times higher than that pre-2010 [13]. We did not observe any cases of pump thrombosis in our study cohort.

Table 1: Baseline characteristics of the study group

<table>
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<tr>
<th>ID</th>
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<th>VAD</th>
<th>Reason for exchange</th>
<th>NYHA</th>
<th>INTERMACS</th>
<th>Cardiac index (l/min/m²)</th>
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Table 2: Postoperative outcome data after left ventricular assist device exchange

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Table 3: Adverse events after left ventricular assist device exchange

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Y: Yes; N: No.
Compared to other LVADs, one of the distinctive features of the HM 3 is its fully magnetically levitated (Mag-Lev™) rotor, which eliminates the need for mechanical bearings or hydrodynamic blood bearings. There are large secondary flow-path gaps of 0.5 mm along the side of the rotor and 1.0 mm above and below the rotor, which are 10–20 times that of other devices being used [4]. In addition, the pump is capable of automatic speed modifications (reduction and increase of rotor speed every 2 s), creating a washout cycle as well as an ‘artificial pulse’. These features might lead to the reduction of complications such as pump thrombosis and strokes. Yet, larger studies are needed to reconfirm the favourable outcomes of patients with the HM 3.

The exchange from the HM II to the HM 3 and from HVAD to HM 3 is now proven to be feasible. The results of the HM 3 CE Mark study promise improved results compared to its predecessor HM II [4, 5]. LVAD exchange should now always be discussed if upgrading to a new generation assist device would be beneficial for the patient.

Due to the lack of experience with the exchange from one device to another, expert experience is needed to establish appropriate adaptations of the new device settings. Continuous echocardiographic and haemodynamic monitoring is therefore needed in the first days after surgery. Changes in flow are likely to be similar to those seen in our patient cohort.

A clinical trial is now underway to study the results of a larger cohort of patients undergoing LVAD exchange from HM II to HM 3.

**Limitations**

This study has some limitations. The data were retrospectively collected and analysed; therefore it is subject to the limitations associated with retrospective studies. All implants were performed at 1 institution, so generalisability may be limited and affected by institutional experience. The results of surgical studies are prone to learning curves and the specific characteristics of a single centre.

Additionally, the number of patients who underwent the procedure was small, which reduces the statistical power and ability to infer positive findings. As such, larger studies need to be done to further evaluate the outcomes of patients receiving the HM 3. Larger, randomized controlled studies need to be performed to compare the long-term outcomes after the exchange procedure.

**CONCLUSION**

It has been proven that upgrading the old generation LVADs to an HM 3 during a minimally invasive LVAD exchange is feasible and shows results comparable to those of conventional exchange procedures. Due to the advantages and technical improvements of the new generation of pumps, this procedure is an excellent opportunity to upgrade patients to a superior generation of assist device.

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**Conflict of interest:** Jan D. Schmitto is a consultant for Thoratec Corporation. Jan D. Schmitto and Sebastian V. Rojas are also
consultants for HeartWare Corporation. The other authors have no disclosures.

REFERENCES