

Left ventricular assist device exchange for the treatment of HeartMate II pump thrombosis

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Background: Pump thrombosis is the most severe and acute complication of left ventricular assist device (LVAD) therapy and treatment remains challenging. Whilst lysis therapy is often not successful, the exchange of the occluded LVAD is currently the most applied therapeutic treatment for this event. With this study we examine the effects of minimal-invasive LVAD exchange on the rate re-thrombosis and outcomes as well as adverse events in the study group.

Methods: Between February 2004 and December 2015 more than 600 LVADs were implanted at our institution. We retrospectively studied a patient cohort of 41 patients who underwent LVAD exchange because of pump thrombosis at a single institution. Outcomes, rates of re-thrombosis and adverse events were analyzed.

Results: Between February 2004 and December 2015, 87 exchanges of LVADs were performed at a single center. In 41 cases pump thrombosis was the reason for LVAD exchange. A total of 28 patient years (10,276 days) were analyzed. Average ICU stay was 15.8 ± 20.4 days and average in-hospital stay 38.1 ± 37.3 days after LVAD exchange. After thirty days the survival rate was 80.5%, 75.6% after 6 months and 70.7% one year after LVAD exchange. Out of the study cohort, three patients have successfully undergone heart transplantation. Twelve patients suffered a stroke postoperatively (29%). Twelve patients needed postoperative dialysis (29%). No technical complications of the VAD were recorded in the study group. Two patients underwent successful LVAD explantation due to myocardial recovery. One year after LVAD exchange, 14 patients underwent re-exchange due to pump thrombosis (34%). Eight patients suffered from a LVAD related infection out of which two patients were treated by pump exchange. A total of 12 patients died during the complete one year follow up of this study (29%). Four patients died in the second, two in the third and one in the fourth year after LVAD exchange. The remaining 17 patients are still ongoing on the device.

Conclusions: It is generally feasible to treat pump thrombosis via LVAD exchange. Yet, the exchange procedure is not without risk and the risk of re-thrombosis (34%), stroke (29%), postoperative dialysis (29%) and perioperative complications remains high.

Keywords: Left ventricular assist device (LVAD); LVAD infection; LVAD exchange; driveline infection; upgrade

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Introduction

Despite medical successes, left ventricular assist devices (LVADs) continue to have several deficiencies such as infection, bleeding complications, and permanent lifestyle changes for the patient, which need to be considered before implantation (1-7).

With respect to complications in LVAD therapy, pump thrombosis demonstrates the most severe and acute one. Thrombosis most likely occurs due to compliance irregularities with anticoagulation medications, infections which lead to unsteady Coumadin levels, as well as acquired hemostatic disorders (4,8-10). In addition, thrombi might also form as a result of technical difficulties such as surface unevenness of the implanted device.

Because standardized treatment guidelines are missing, pump thrombosis treatment largely varies across centers (11-13). While lysis therapy is widely considered as a first choice, it possesses a high risk of cerebral bleeding as well as embolic stroke. Likewise, a large number of centers are performing LVAD exchange which is expected to treat pump thrombosis. However, this procedure comes at a high risk of thrombus release which may be followed by stroke or bleeding complications.

Within this study, we examine the effects of LVAD exchange for the HeartMate II on the rate of re-thrombosis, complications and outcome of patients.

Methods

Patient selection

Between February 2004 and December 2015 more than 600 LVADs were implanted at our institution. Out of those, we retrospectively studied a patient cohort of 65 patients who underwent LVAD exchange (*Figure 1*). Forty-one patients underwent LVAD exchange due to pump thrombosis. Out of those 16 HeartMate II patients underwent LVAD exchange for pump thrombosis. Twenty-four patients underwent LVAD exchange due to other reasons such as LVAD infection or device malfunction and were excluded from the study. For the performance of this retrospective study the database of a single center was used. All causes of death and adverse events were determined through retrospective examination of medical records.

LVADs

The LVADs used in this study was the HeartMate II

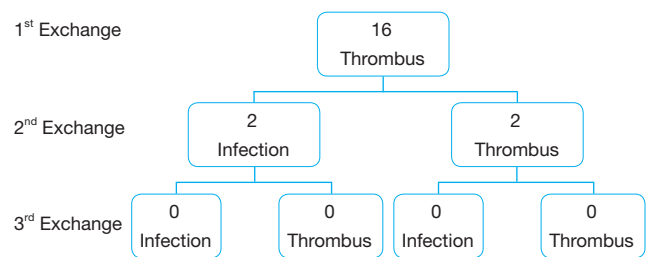


Figure 1 Flow chart depicting re-exchange rates in the study group.

(St. Jude Medical, USA). Other implanted LVADs (e.g., HeartMate 3, Thoratec; MVAD, HVAD HeartWare; HA5, ReliantHeart; other types) and biventricular assist devices and were excluded from the study.

Study design

Data was collected by retrospective electronic medical record review. Endpoints of the study were death, device explantation or heart transplantation. Baseline characteristics were obtained for all patients before LVAD implantation. After LVAD implantation survival results and adverse events were recorded. All causes of death and adverse events were determined through examination of medical records. Because this was a retrospective study, the hospital ethical review board waived the need for patient consent to the study.

Statistical methods

Data collection and analysis were performed retrospectively using IBM SPSS Statistics for Windows Version 23.0 (IBM Corp., Armonk, NY, USA). Categorical and continuous variables were summarized as frequencies, percentages and mean/median with interquartile range, respectively. Paired Student's *t*-test and non-parametric Wilcoxon signed-rank test were used for comparisons across groups of continuous variables, respectively. Survival estimates were calculated by the product-limit method of Kaplan-Meier. Differences across groups were quantified using the log-rank test. Two-tailed $P \leq 0.05$ were considered significant.

Operative technique

All patients gave informed consent to the procedure. After echocardiographic assessment of the pump position,

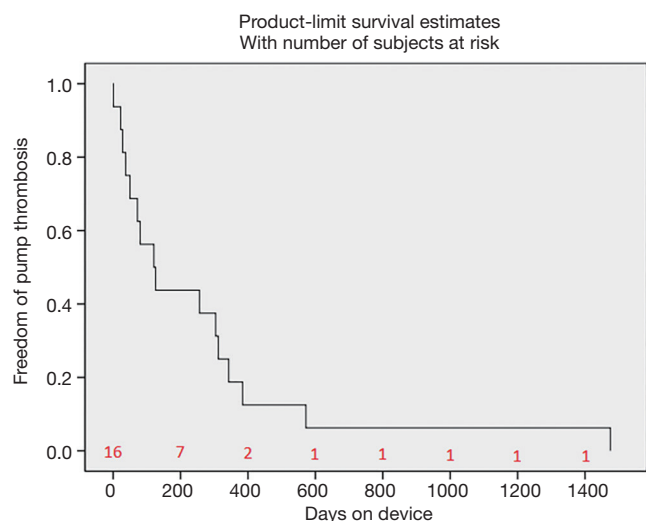


Figure 2 Kaplan-Meier curve for the freedom of device thrombosis in the study cohort.

a lateral thoracotomy was performed to gain access to the pump corpus. Partial rib resection became necessary in half of the cases. After surgical exploration of the old pump position, the venous and the arterial cannulas of the extracorporeal circulation (ECC) were placed in the femoral artery and vein. The outflow cannula of the LVAD was clamped after the onset of the ECC 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 thrombi as well as remaining endothelial tissue were carefully removed to prevent suction events.

Preparation and set up of the new pump was executed according to standard instructions for use (IFU) of the company's protocols.

For HMII, the new pump corpus was connected to the established outflow and inflow cannula. All of the parts of the pump were flushed and de-aired multiple times. Next, the driveline was tunneled through the abdominal wall via standard technique.

After control of surgical hemostasis and inspection of the outflow graft position, a chest tube was placed and the wound was closed. For improved hemostasis during LVAD exchange, all procedures were performed with the use of red blood cells, thrombocytes, fresh frozen plasma and coagulation factors. Intravenous Heparin was started 6 hours postoperatively and administered as a bridge until anticoagulation with phenprocoumon was in the therapeutic range, with a target

INR of 2.0–3.0, plus aspirin at 100 mg/day.

Results

Between February 2004 and December 2016, 87 exchanges of LVADs were performed at a single center. Out of those, 41 LVAD exchange were performed due to pump thrombosis (study group). In 24 cases other diagnoses led to LVAD exchange (LVAD infections, technical malfunctions).

In the study group 25 patients (61%) were supported by HeartWare and 16 patients (39%) were supported by HeartMate II.

A total of 9 patient years (3,272 days) were analyzed. Mean days on device until the occurrence of pump thrombosis was 261 days with a minimum of 1 and a maximum of 1,475 days on device (Figure 2).

Detailed baseline characteristics of the study group can be found in Table 1. Preoperative laboratory values are listed in Table 2.

In nine patients of the study group (56%) dilative cardiomyopathy was the primary heart disease prior to LVAD implantation. The majority of patients were INTERMACS level III. 0 patients of the study group (0%) were initially classified as NYHA IV prior to LVAD implantation.

All patients showed flow irregularities and increase of power. 26 patients presented with hematuria (63%) out of which 1 patient (6.3%) needed preoperative dialysis.

Average ICU stay was 4.2 ± 6.2 days and average in-hospital stay 35.7 ± 50.8 days after LVAD exchange.

Outcomes after LVAD exchange due to pump thrombosis

The Kaplan-Meier curve in Figure 3 illustrates the patient survival. After thirty days the survival rate was 75.0%, 75.0% after six months and 62.5% one year after LVAD exchange.

Out of the study cohort, two patients have successfully undergone heart transplantation on postoperative day (POD) 102 and 140. One patient underwent successful LVAD explantation due to myocardial recovery on POD 248.

A total of six patients died during the complete one year follow up of this study (29%). Two patients died in the second year after LVAD exchange. The remaining five patients are still ongoing on the device. The longest ongoing patient out after LVAD exchange because of pump thrombosis is on device for more than 7 years as of April 1st, 2017.

Table 1 Baseline characteristics of the study group

Characteristic	HeartMate II patients, N=16
Male	15 (93.8)
Female	1 (6.2)
Average age (years)	52.13±12.99
Average body mass index (kg/m ²)	27.52±4.45
Diagnoses	
Dilated cardiomyopathy	9 (56.3)
Ischemic cardiomyopathy	7 (43.8)
NYHA profile	
IV	6 (37.5)
III	8 (50.0)
II	2 (12.5)
INTERMACS profile	
I	1 (6.3)
II	0 (0.0)
III	15 (93.8)
IV	0 (0.0)
Atrial fibrillation pre-OP	0 (0.0)
Dialysis pre-OP	1 (6.3)
Dialysis post-OP	4 (25.0)
ECMO pre-OP	1 (6.3)
ECMO post-OP	3 (18.8)
Mean days on support	604.94±550.39
Mean days until LVAD exchange	261.44±363.03
Stay	
Average in-hospital stay after LVAD implantation (days)	35.73±50.78
Average ICU stay (days)	4.14±6.20
Average erythrocyte concentrate until discharge	7.67±5.35
Status	
Cardiac transplantation	2 (12.5)
LVAD explantation due to recovery	1 (6.3)
Death after LVAD implantation	8 (50.0)

Data are shown as number (%) or mean ± SD. ECMO, extracorporeal membrane oxygenation; LVAD, left ventricular assist device.

Table 2 Laboratory parameters before and after LVAD exchange

Parameter	Pre-operative	Post-operative/ pre-discharge	P
SAST, U/L	163.1±139.4	297.1±552.3	0.600
SALT, U/L	44.7±41.9	154.0±267.0	0.442
GLDH, U/L	6.7±5.2	78.5±241.1	0.540
Gamma-GT, U/L	61.6±43.2	138.8±149.3	0.139
SCHE, U/l	5.3±2.3	4.2±2.1	0.917
Total bilirubin, μmol/L	45.3±40.3	82.2±215.2	0.374
Creatinine, μmol/L	161.3±118.4	148.6±173.3	0.140
Urea, mmol/L	8.3±4.7	7.7±6.0	0.975
eGFR, mL/min	48.1±15.8	53.7±11.1	0.176
Sodium, mmol/L	140.0±3.2	136.4±1.8	0.236
C-reactive protein, mg/dL	66.0±69.3	126.1±119.9	0.007
INR (ratio)	2.0±1.0	1.8±0.6	0.691
PPT, sec.	52.9±18.2	45.9±9.1	0.132

LVAD, left ventricular assist device; SAST, serum aspartate aminotransferase; SALT, serum alanine aminotransferase; GLDH, glutamate dehydrogenase; SCHE, serum cholinesterase; eGFR, glomerular filtration rate; INR, international normalized ratio; PTT, partial thromboplastin time.

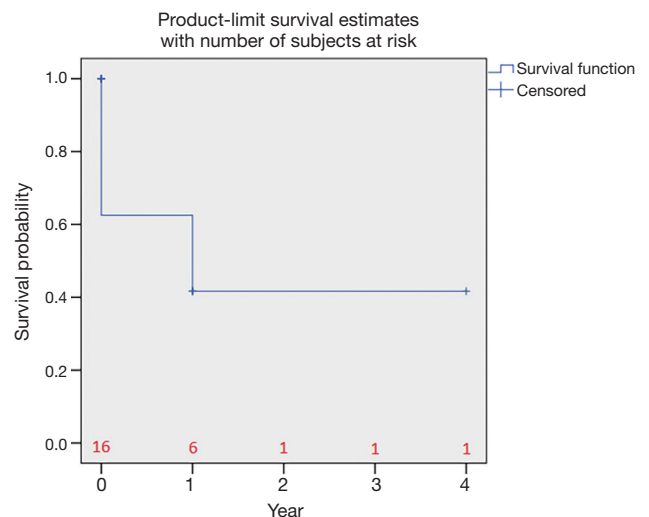
**Figure 3** Kaplan-Meier curve for the survival of the study group.

Table 3 Adverse events in the study group

Adverse event	1 month, n=16		6 months, n=11		1 year, n=9		All (1 year), n=16		Events per patient month
	Patients	Events	Patients	Events	Patients	Events	Patients	Events	
Bleeding									
Bleeding event	5 (31.3)	5	3 (27.3)	4	1 (11.1)	1	7 (43.8)	10	0.091743119
Requiring surgery	5 (31.3)	5	2 (18.2)	2	0 (0.0)	0	6 (37.5)	7	0.064220183
GI bleeding	0 (0.0)	0	1 (9.1)	1	0 (0.0)	0	1 (6.3)	1	0.009174312
Cerebral bleeding	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0
Pump thrombosis	1 (6.3)	1	2 (18.2)	2	0 (0.0)	0	3 (18.8)	3	0.027522936
Technical complication	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0
Infection									
LVAD related	0 (0.0)	0	3 (27.3)	4	2 (22.2)	2	5 (31.3)	6	0.055045872
Non LVAD related	4 (25.0)	4	2 (18.2)	4	2 (22.2)	3	5 (31.3)	11	0.100917431
Right heart failure	2 (12.5)	2	0 (0.0)	0	0 (0.0)	0	2 (12.5)	2	0.018348624
Stroke	5 (31.3)	5	0 (0.0)	0	1 (11.1)	1	6 (37.5)	6	0.055045872

Data are shown as number (%). LVAD, left ventricular assist device.

Re-operation

Out of the study group a total of 4 patients (25%) underwent a second LVAD exchange.

Two patients underwent a second LVAD exchange because of recurrent pump thrombosis on POD 0 and 133 respectively. Two patients underwent a second LVAD exchange because of device infection on POD 409 and 566.

Causes of death

One year after LVAD exchange, out of 16 patients, 6 patients had died (38%). Main cause of death was multi-organ failure with 5 deaths on POD 1, 15, 18, 204 and 321 respectively. One patient died because of sepsis on POD 4.

Complications

Complications and adverse events are listed in *Table 3*. In the first month after LVAD exchange, five strokes occurred in the study group (31.3%) and one patient presented re-pump thrombosis (6.3%). Five patients required (31.3%) re-operation because of bleeding events. Two patients presented right heart failure (12.5%) and four patients presented with infections, out of which four

were non LVAD-related. Dialysis was needed in 4 patients postoperatively (25.0%).

Six months after LVAD exchange one presented with GI bleedings (9.1%). Two patients suffered from recurrent pump thrombosis.

One year after LVAD exchange, 14 patients underwent re-exchange due to pump thrombosis (34%). Eight patients suffered from a LVAD related infection out of which two patients were treated by pump exchange. Twelve patients suffered a stroke postoperatively (29%). No technical complications of the VAD were recorded in the study group.

Lactate dehydrogenase (LDH) and free hemoglobin (fHb)

The LDH (U/L) as well as fHb (mg/L) laboratory values in the course of LVAD pump thrombosis are displayed in *Figure 4*. The fHb as well as the LDH curves show a steep decline. After the sixth month, the curve is decreasing to normal values. LDH levels showed a decrease during the whole study period. With an average LDH value of 395.4 U/L and an average fHb of 93.5 mg/L six months after LVAD exchange. After 1-year average LDH level was 400.2 U/L and average fHb level was 106.3 mg/L respectively.

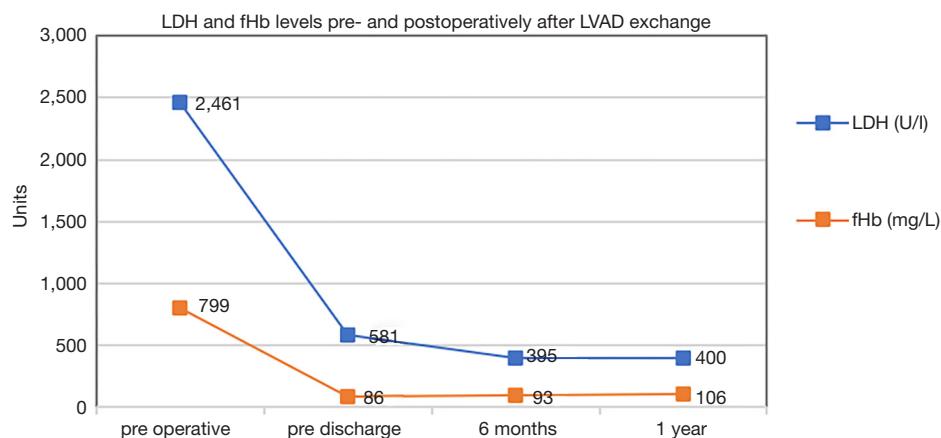


Figure 4 Free hemoglobine (fHb, mg/L) and lactate dehydrogenase (LDH, U/L) levels pre- and post-operatively after LVAD exchange due to pump thrombosis. LVAD, left ventricular assist device.

Discussion

Pump thrombosis is the most severe and acute complication of LVAD therapy with an emergent need for therapy which has been extensively discussed in the past years. For HeartMate II, Starling *et al.* reported that pump exchange or death due to pump thrombosis increased during 2011 and 2012, but the level of increase remained small (14-18). A risk factor analysis suggested that a number of patient-related factors contribute to the risk of thrombosis (15). While other centers reported increases thrombosis rates, others reported a steady rate of 2.2% (16). Smedira *et al.* analyzed a total of 995 thrombosed pumps and also 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 pre-2010 (17).

Due to the limited therapeutic options, prevention of the development of pump thrombosis is of highest importance. The angle of the inflow cannula plays an important role in thrombus formation by creating un-physiological blood flow patterns (18). High pump speeds $\geq 9,000$ RPMs for the HMII are associated with a lower risk for pump thrombosis according to Maltais *et al.* (19). Diligent patient education about the use of anticoagulation and strict monitoring (e.g., via CoaguCheck[®]) improve therapy safety. A recent study suggests a higher pump thrombosis risk for patients BMI >30 kg/m². Therefore, weight reduction for obese patients should be essential (20). Furthermore, high blood pressure is associated with an increased risk of pump thrombosis (10).

Since atrial fibrillation is a risk factor for thrombus

formation and is often associated with a high risk of stroke, a number of studies examined the effects of cardiac arrhythmias on LVAD therapy. Xuereb *et al.* report no significant effect of preoperative atrial fibrillation on postoperative rates of pump thrombosis or stroke (21). Stulak *et al.* even showed that Patients with preoperative AF have a lower freedom from thromboembolic events after LVAD implantation (22). Enriquez *et al.* examined 106 HMII patients and differentiated between paroxysmal atrial fibrillation (PAF) and persistent atrial fibrillation (PeAF). They concluded that although PAF is not associated with worse outcome, PeAF may be associated with increased mortality and re-hospitalizations (23). Concomitant cryoablation for tachycardias combined with LVAD implantation has been described before (24) and might be a solution to reduce the risk of pump thrombosis in patients with AF.

Anticoagulation is a major factor in preventing pump thrombosis. Yet, too strict regimens increase the risk of bleeding complications such as GI bleeding or stroke (25). The TRACE study questioned the need of double anti-coagulation in HMII patients to reduce the risk of pump thrombosis. The 1-year results revealed that reducing anti-thrombotic therapies in response to bleeding among HMII patients was achievable but may be associated with a higher risk for device thrombosis (8,9). The recently published 2 years results of this study showed that managing HMII patients with a vitamin K antagonist with a target international normalized ratio of 2.3 without antiplatelet therapy may help to reduce the incidence of major bleeding

without increasing the risk of thromboembolic events, including ischemic stroke and pump thrombosis (9).

Koene *et al.* showed that following HeartMate II implantation HAS-BLED and CHA₂DS₂-VASc scores of ≥ 3 conferred significantly higher risks of bleeding and thromboembolic events, respectively (25). Also, a newly developed left ventricular dimension decrement index at optimized speed setting on pre-discharge echocardiography is associated with LVAD thrombosis (26). Therefore, these scores might be useful to detect patients with a high risk of pump thrombosis.

Even though the need for LVAD exchange is a hazardous complication in VAD therapy, it can be used to upgrade a patient to a new generation assist device e.g., HeartMate 3 (27-30). The exchange procedure offers an opportunity to upgrade patients to a new generation pump which offers e.g., advanced reduction of adverse events or longer battery capacities (27). New generation pumps such as the HeartMate 3 trials reported no pump thrombosis in the CE mark study as well as in the U.S. based MOMENTUM study. Debilitating strokes were reported in 8% of the patients in the CE mark study and in 7.9% of the patients in the MOMENTUM trial (31,32). Consequently, exchange to a new generation device should be considered when exchanging an LVAD for pump thrombosis.

Generally, LVAD exchanges are associated with high risk of stroke or air embolism as seen in a perioperative stroke rate of 29% in this study. Therefore, we highly recommend using on-pump techniques in the majority of these cases (33,34). Using the on-pump techniques offers the opportunity to inspect and remove endothelial tissue as well as thrombotic material from the left ventricle (35).

To conclude, the treatment and the prevention of pump thrombosis remain challenging. In general, the question of risk factors for thrombus formation as well as treatment options need to be further assessed with controlled studies and increased patient populations.

Limitations of the study

This study has some limitations. The data is retrospectively collected and analyzed and therefore it is subject to the limitations associated with retrospective studies. All exchange procedures were performed at one institution and therefore generalizability may be limited and affected by institutional experience. The results of surgical studies are prone to learning curves and single center's specific characteristics. Moreover, the study period began

several years ago. Therapeutic strategies and increased clinical experience might have improved today's results. Additionally, the number of patients with pump thrombosis was small, which reduces the statistical power and ability to infer positive findings. As such, larger studies need to be done to further study the outcomes after LVAD exchange due to pump thrombosis.

Conclusions

It is generally feasible to treat pump thrombosis of the HeartMate II via LVAD exchange. Yet, the exchange procedure is not without risk and the risk of re-thrombosis, stroke, postoperative dialysis and perioperative complications remains high.

Acknowledgements

None.

Footnote

Conflicts of Interest: JD Schmitto receives consultation fees from Thoratec Cooperation. JD Schmitto and G Dogan are consultants for HeartWare Cooperation. The other authors have no conflicts of interest to declare.

Ethical Statement: The study was approved by the hospital ethical review board and the hospital ethical review board waived the need for patient consent to the study.

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