Editorial

Left ventricular assist devices exchange: why, when and how to do it—experience from experts

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Introduction

Left ventricular assist devices (LVAD) became a routine instrument in the treatment of severe heart failure with constantly increasing number of patients treated with LVAD (1). Continuous technical development and large empirical knowledge in this field has led to a very high reliability and excellent long-term results (MOMENTUM III). Recently published results for the first time reported even better 2-year survival in LVAD compared to heart transplantation (HTx) (2). However, there is an inevitable risk of device failure alongside which may result in the need for device exchange. Mainly three causes are associated with the need for exchange, specifically (in the order of frequency) (I) device thrombosis, (II) infection and (III) device malfunction.

LVAD thrombosis is a rare but feared complication in the course of durable LVAD treatment. Insufficient levels of vitamin-K antagonism and/or platelet inhibition therapy and (wound-)infection can result in a device thrombosis. Literature reports rates LVAD thrombosis of about 1.4% to 11% within the first 2 years increasing by the time of support (3-6). A recent meta-analysis including a total of 5,454 patients found a LVAD thrombosis rate of 11.8% (7). However, the MOMENTUM III 2-year results showed an excellent performance and low risk of pump thrombosis for the HeartMate III device with suspected pump thrombosis in only 2 out of 168 patients (1.2%). None of the patients needed a re-operation (2).

According to the INTERMACS registry, freedom from pump related infection (PRI) is about 84% at 1 year on LVAD support, coming down to 78% at 2 years and 72% at 3 years. Interestingly, no association between the INTERMACS profile at the time of implantation and the occurrence of PRI is present (1). Nevertheless, PRI may result in a deep wound infection which may become untreatable by medication and/or (deep) local wound treatment alone and may result in the need for pump exchange to overcome the persisting bacterial colonization. Additionally, PRI can cause bacteraemia and sepsis, which themselves can cause coagulopathy including embolism and device thrombosis (8).

Overall, true LVAD malfunction, requiring pump replacement are very rare. Regarding to the literature, the results of numerous studies have to be analysed carefully because pump thrombosis and/or device (including) driveline infection are regularly attributed as “device malfunction” which unjustifiably increased the rate of device malfunction. If only technical reasons are considered, the device malfunction rate reaches about 0.9 to 5.8 percent of patients on support (9-11). Malfunction can be caused

by a failure of the inner electrical component of the pump or the integrated driveline, especially if the damage/failure (e.g., cable fracture or unintentional damage by sharp objects) of the driveline is located very close to the exit site, a phenomenon called "short to shield" meaning the repair of the driveline is impossible or not safe (12,13).

LVAD thrombosis—risk stratification of LVAD exchange *vs.* systemic lysis

In case of suspected LVAD thrombosis, contrast-enhanced and ECG-gated computer tomography can ensure the diagnosis. However, in most cases clinical assessment including laboratory findings and (acute) changes in the LVAD measured values (rpm, energy consumption and estimated flow) are sufficient to determine LVAD thrombosis.

In order to prevent major surgery, the concept of direct thrombolytic therapy using tissue plasminogen activator (tPA) to resolve LVAD thrombus formation is known for over a decade (14). Beside systemic application, fluoroscopy guided direct tPA application has been described in the concept of reduction of total amount of tPA (15).

Typical complications following lysis therapy in LVAD thrombosis are severe haemorrhage, haemorrhagic stroke, intracranial bleed and unsuccessful thrombolysis leading to emergency surgical exchange implicating higher risk and death (16,17).

In support of thrombolysis, Saeed *et al.* reported results in contrast to an early surgical approach (exchange) to proof beneficial results of a conservative approach. However, this single centre experience including 13 patients and 23 events, no standard LVAD exchange procedure was given, but HTx or device explantation were performed over the course of time if thrombolysis success was not sustained (18).

A systematic review article involving 43 individual trials thematically considering medical therapy *vs.* early LVAD exchange in the circumstance of device thrombosis was recently published by Luc *et al.* (7). The Meta-analysis rendered a clear benefit for device exchange in terms of success rate compared to medical therapy resulting in a significant lower 30 days mortality and a significantly higher rate of freedom from re-thrombosis as compared to thrombolysis (7).

Notably, the LVAD exchange procedure can be performed very safely with low rates of mortality reported (10,17,19). Further risk-reduction can be achieved by leaving some form of neo-pericardium around the device during the initial implantation procedure to prevent adhesions. Especially the modern 3rd generation fully intrapericardial implantable devices can be exchanged with an acceptable risk profile (20). In the vast majority of the cases, a present sewing ring and the outflow graft can remain *in situ* with either end to end anastomosis of the new outflow graft or connection of the present outflow graft to the device. Stulak *et al.* reported their outstanding results with LVAD exchange proofing a 100% success rate without significant early complication or death after exchange in contrast to the medical treatment (17).

Technical aspects of the LVAD exchange procedure

Performing LVAD exchange with or without cardiopulmonary bypass (CPB) is an ongoing debate similar to LVAD implantation technique. To date, no clear advice can be given, to perform exchange with or without extracorporeal circulation. While CPB implicates relevant advantages such as excellent vision, the ability to remove LV-thrombus or LV-muscle impairing inflow in a controlled manner and the reduced risk of (air) embolism, certain disadvantages (full heparinization inevitable, retrograde CPB pump and risk for vessel injury if CPB is established thru the groin vessels) of CPB must be considered, too. The off-pump technique, however, may provide advantages like a quicker procedure, no need for full heparinization and no groin access needed. On the downside off-pump exchange is associated with less control of the situs, especially no certain proof of LV-thrombus removal and a (potentially) greater blood loss and (air) embolism of an ejecting undrained heart.

LVAD exchange with device upgrade procedure and the challenge of repetitive LVAD exchange

To date, common durable LVADs are mostly 3rd generation fully implantable centrifugal pumps (e.g., Medtronic/HeartWare HVAD and Abbott/St. Jude Medical HeartMate III). However, there are still numerous patients on 2nd generation axial flow support, mainly the HeartMate II device. If indication for exchange of these devices is seen, whether for malfunction or device thrombosis, upgrade strategies are described. Hanke *et al.* published their experiences and technique in successful LVAD upgrade procedure from 2nd generation axial pumps to a 3rd generation centrifugal HeartMate III LVAD (21,22). The exchange procedure, if need be, allows the patient to benefit from the newest available technology.

Repetitive LVAD exchange can elicit unlike more eminently challenges. Radwan *et al.* published their technique of LVAD exchange including inflow canula and outflow graft repositioning in a complex re-re-do procedure through minimal-invasive technique on CPB (23). While the previously not ideally placed sewing ring was left in place, the inflow canula was only inserted half of the length to prevent further suction phenomena. The new outflow graft was then anastomosed into the subclavian artery to prevent another (partial) median sternotomy to reach the ascending aorta.

Independently of the technique applied for the initial implantation (minimal-invasive, bilateral thoracotomy or full sternotomy), the LVAD exchange procedure can be performed via left-lateral thoracotomy. In the majority of device thrombosis cases, LVAD outflow graft is not involved and can easily be re-attached to the device or with an end-to-end graft anastomosis. If graft thrombosis is seen on CT imaging, thrombectomy using a Fogarty-catheter might become necessary. In these cases, the diameter and volume of the balloon-catheter should completely block the graft and avoid antegrade embolization.

Summary

The growing imbalance of available donor hearts and transplant candidates plus the destination therapy concept urges the need for a close understanding of long-term complication management in LVAD patients, including device exchange indication and procedure execution.

In cases of immediate device malfunction (not controller or battery), decision-making process is rather simple leading to the requirement of urgent device exchange since weaning is not an option in the vast majority of adult LVAD patients. In terms of infection related disease, caused by an ascending infection initially entering thru the driveline exit point, an individual strategy is mandatory whether conservative treatment including limited local debridement is sufficient or an exchange of the device and all infected foreign material becomes inevitable. One has to consider that infection related complications (e.g., thrombosis, bleeding and sepsis) may influence patients' outcome dramatically, too.

In the circumstance of LVAD thrombosis, giving a reliable recommendation how to treat these patients is clearly more difficult. Though, available literature trends towards LVAD exchange rather than thrombolysis, it has to be considered that the underlying data are based on retrospective single (or circumscribed multi-centre) experience only. The authors expert opinion, in line with the recent meta-analysis, however, is also trending towards an early exchange strategy. Empirically, thrombosis trends to be recurrent and the need for repetitive lysis puts patients at risk for life-threatening bleeding each single application while LVAD exchange sustains.

Nevertheless, current data situation does not favour one of both strategies mentioned above in terms of treatment for LVAD thrombosis. Prospective randomized trials are urgently needed to generate reliant data. Until then, each individual patient needs to be discussed independently and within a functioning and experienced interdisciplinary heart team including the specific benefit-risk-profile to achieve the best possible treatment, especially as these patients are already in a complicated situation due to the underlying cardiomyopathy.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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