

HFA of the ESC Position paper on the management of LVAD supported patients for the non LVAD specialist healthcare provider Part 1: Introduction and at the non-hospital settings in the community

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Abstract

The accepted use of left ventricular assist device (LVAD) technology as a good alternative for the treatment of patients with advanced heart failure together with the improved survival of the LVAD-supported patients on the device and the scarcity of donor hearts has significantly increased the population of LVAD-supported patients. The expected and non-expected device-related and patient–device interaction complications impose a significant burden on the medical system exceeding the capacity of the LVAD implanting centres. The ageing of the LVAD-supported patients, mainly those supported with the ‘destination therapy’ indication, increases the risk for those patients to experience comorbidities common in the older population. The probability of an LVAD-supported patient presenting with medical emergency to a local emergency department, internal, or surgical ward of a non-LVAD implanting centre is increasing. The purpose of this trilogy is to supply the immediate tools needed by the non-LVAD specialized physician: ambulance clinicians, emergency ward physicians, general

cardiologists, internists, anaesthesiologists, and surgeons, to comply with the medical needs of this fast-growing population of LVAD-supported patients. The different issues discussed will follow the patient's pathway from the ambulance to the emergency department and from the emergency department to the internal or surgical wards and eventually to the discharge home from the hospital back to the general practitioner. In this first part of the trilogy on the management of LVAD-supported patients for the non-LVAD specialist healthcare provider, after the introduction on the assist devices technology in general, definitions and structured approach to the assessment of the LVAD-supported patient in the ambulance and emergency department is presented including cardiopulmonary resuscitation for LVAD-supported patients.

Keywords LVAD; General description; Emergency medical systems; CPR

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Introduction

The prevalence of patients with advanced heart failure (HF) is increasing with the growing number of total HF patients, comprising an estimated number of 1–10% of the overall HF population.^{1,2} The gold standard for treatment of these patients is heart transplantation (HTx), but this option is limited by several factors, mainly due to the restricted supply of donor organs, but also by the presence of contraindications to HTx, such as elevated pulmonary vascular resistance or recent malignancy.³ During the past two decades, as a consequence of the donor organ's shortage, the mechanical circulatory support (MCS) and primarily, the left ventricular assist devices (LVADs) have become one of the most important tools for the treatment of advanced HF patients. This shortage of organs for donation is not expected to improve, and thus, an increase in the number of LVAD-supported patients is foreseen.

There are three major indications for MCS in end stage HF patients:

- i Bridge to transplantation (BTT) or to candidacy
- ii Destination therapy (DT)
- iii Bridge to recovery.

The BTT and DT indication includes advanced HF patients who need the LVAD support due to very poor prognosis and reduced quality of life as an immediate life sustaining measure. Included in the BTT and bridge to candidacy group are advanced HF patients on the waiting list for HTx and those with relative contra-indications to HTx, which are expected to improve on the LVAD support, such as cardiac cachexia, high pulmonary vascular resistance, or those with recently treated malignancy whereby bridging with the LVAD support the time needed to reduce the recurrence rate of the malignancy post HTx.⁴ Included in the DT group are advanced HF patients who are not expected to undergo HTx due to contraindications that are not likely to change during LVAD support, such as advanced age.

The bridge to recovery group consists of deteriorating advanced HF patients with potentially reversible aetiologies such as viral myocarditis or per-partum cardiomyopathy.

The survival of the patients with advanced HF who are supported with the new generations of LVADs is constantly improving reaching 86.6% and 82.3% 1 and 2 year survival rates with the HeartMate3 (HM 3) LVAD,^{2,4} very similar to the survival post HTx. The shortage of donor organs and improved quality of the modern LVADs practically implies that many of patients with advanced HF will be getting the devices as DT.⁵ The total number of LVAD-supported patients and in particular those implanted as DT is expected to increase significantly. The regained independence of the patient who is supported with the LVAD results in extended periods when the patient is alone, without the surveillance of his close caregiver. Consequently, it will become more common for the LVAD-supported patient to be found in an emergent medical situation where there is no close caregiver to rely on by the emergency medical suppliers.

Furthermore, the improved survival on LVAD support results in longer support times, with patients ageing on the MCS, facing an extended risk for device-related complications as well as for the occurrence of the variety of chronic diseases and comorbidities prevalent in the ageing population. These patients may be in the need for different medications and may require non-cardiac surgeries. The growing population of LVAD-supported patients will pose a challenge to all the medical community starting from their family physicians, nurses, the emergency medical services (EMS) teams through the emergency department (ED), the internal and surgical wards and to the anaesthesiologists in the operating rooms, the cardiologists in the clinics, and in the general or cardiac intensive care units, the LVAD coordinators and the LVAD specialists.

The aims of this paper are to introduce the LVAD-supported patients and the common medical issues they encounter to the multidisciplinary non-LVAD specialist physicians; to suggest when and how to approach, evaluate, manage, and treat those patients; to supply the immediate

tools needed; and to comply with the medical needs of this fast-growing population of being an LVAD-supported patient.

The different issues discussed will follow the patient's path from the ambulance to the ED, from the ED to the internal or surgical wards, and eventually to his discharge home and to the general practitioner.

Left ventricular assist device description

Until June 2021, the most used LVADs were HeartWare™ (HW™), HeartMate II™ (HM II™), and HeartMate3™ (HM 3™). The three are all continuous flow devices: the HW™ and HM 3™ produce centrifugal flow and the HM II™ axial flow. Recently, the manufacturer of HeartWare has announced stopping its production. In the schematic LVAD system shown in *Figure 1*, the *inflow cannula* connects the LV cavity to the *pump* (the body of the LVAD) and transfers the blood from the LV cavity to the pump. The pump is connected to the ascending aorta via the *outflow graft* through which it pumps the blood to the ascending aorta thus by-passing the failing left ventricle. The pump is also connected by the *driveline* (DL), a cable that exits the body at the lower abdominal wall, to the *external controller* and the energy supply. The DL contains two sets of three wires: two for the transfer of power to the device and one for transferring data to the controller and a spare set of wires. The controller is the system's computer and is connected to the DL in one side and to two power

sources on the other: *the batteries*. The controller can also be connected to a wall socket as an external power source.

Left ventricular assist device parameters

Understanding of the device function and knowledge of its basic parameters are essential to ensure the appropriate management and care of LVAD patients. The following definitions of the displayed LVAD parameters are important to the understanding of how mechanical circulatory support devices operate. The typical operating parameters of the 3 most used LVADs is presented in *Table 1*.

Pump speed

Pump speed is displayed by the revolutions per minute and determine the pump flow. This pump speed is set for each device by the LVAD team and may be modified as needed according to changes in the patient's clinical parameters. Optimization of the pump speed can be performed using a ramped speed study: increasing and decreasing the pump speed with concomitant monitoring of haemodynamic and/or echocardiographic parameters to determine the optimal speed.

Pump power

The LVAD pump power is a measure of the current and voltage applied to the motor and varies directly with pump speed and flow. Pump power is displayed in Watts.

Pump flow

The amount of blood flowing through the pump and reported on the system controller, displayed in litres per minute. Notably, the flow is an estimated value based on pump speed and the power needed to exert that speed. The device flow is directly proportional to the rotor speed and inversely related to the difference of pressure in the inflow and outflow cannulas. The flow estimation may not be accurate in the cases of physiologic derangements such as aortic insufficiency or LVAD dysfunction, including pump thrombosis.

Figure 1 Schematic illustration of an left ventricular assist device (LVAD) with its components.

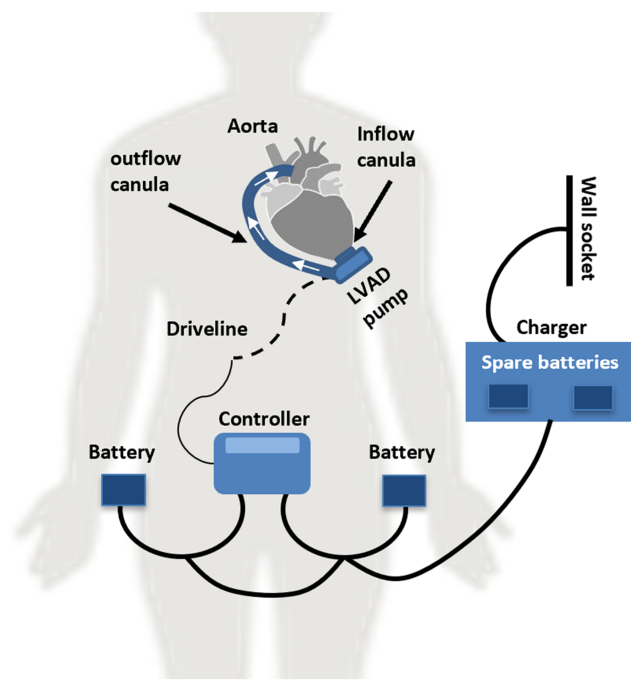


Table 1 Typical left ventricular assist device operating parameters

	HeartMate II	HeartMate 3	HeartWare
Typical speed, rpm	8000–10 000	5000–6000	2400–3200
Speed adjustment increment, Rpm/increment	200	100	20
Flow, Litre per minute	4–7	4–6	4–6
Power, Watts	5–8	4.5–6.5	3–7
Pulsatility index (PI) (peak to trough)	5–8	3.5–5.5	2–4

Pulsatility index

The pulsatility index (PI) corresponds to the magnitude of flow pulse through the pump and is determined by pump speed and the patient's native heart function. The controller measures temporal power fluctuations to give an estimate of pulsatility through the pump in numbers for the HeartMate devices and represented graphically as a waveform for the HeartWare™ device. The magnitude of the PI value is related to the amount of assistance provided by the pump: higher values indicate more ventricular filling and higher left ventricular pulsatility while lower values indicate less ventricular filling and lower pulsatility. The PI fluctuates with changes in the volume status and in the heart's contractility. It increases when LV preload and contractility increase, and it decreases when blood volume and LV afterload are reduced and when there is an obstruction to the inflow cannula or to the outflow graft that causes low flow and abnormal power. PI values should be routinely monitored and should not vary significantly during resting conditions.

It is important to remember that one single pump parameter is not a surrogate for monitoring the overall clinical status of the patient and any change in parameters should be evaluated with all clinical considerations in mind.

Management of left ventricular assist device-supported patients by the 'first to contact' in the ambulance and/or emergency department

Despite the technological advances and improved survival, device-related complications, and patient-device interaction, impose a significant burden on the medical system exceeding the capacity of the LVAD implanting centres. The probability a patient who is supported by an LVAD will present with medical emergency to either his general practitioner, the local EMS team, the emergency department (ED), or to the medical wards (internal or surgical) in a non-LVAD implanting centre close to their home is increasing.

The EMS clinician, ED physician, general cardiologist, and internist are all expected to be familiar with the emergencies and other medical needs an LVAD-supported patient may face.

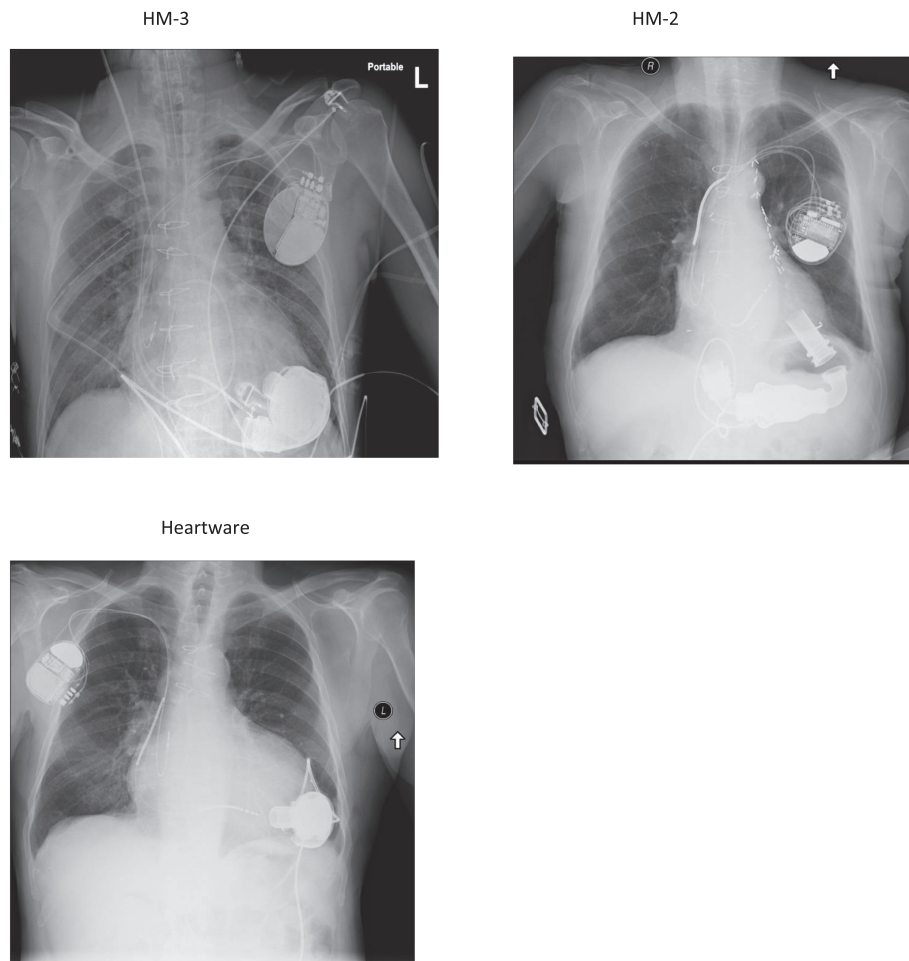
The LVAD implanting centres are encouraged to train healthcare providers, including general practitioners and members of the EMS team, who might be called upon in an emergent setting. The EMS team should learn how to manage the LVAD patient in the acute scenario and should have the appropriate equipment available. The EMS team should learn how to guide bystanders during rescue attempts.

Initial assessment of the left ventricular assist device-supported patient in the ambulance and/or emergency department

Despite the impressive improvement in survival, LVAD-supported patients yet retain significant morbidity. Up to 60% of the patients recorded in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database have significant adverse events within the first 6 months of support and 60% need re-hospitalization within this time period. The increasing number of LVAD-supported patients and their retained morbidity calls for better understanding of LVAD-related care within broader circles of healthcare providers. These include distinguishing the unique clinical characteristics, reasons for seeking unplanned medical care, and the initial evaluation scheme of the LVAD-supported patients.

The LVAD-supported patients are dependent on the appropriate function of the LVAD: acute malfunction or a simple lack of electrical energy may necessitate urgent assistance. The LVAD maintains its function by electrical supply utilizing rechargeable batteries (lasting between 6 and 19 h) or by the external electrical system. The energy supply is connected to the LVAD motor via a controlling element (controller) and a cable (driveline). (*Figure 1*). Malfunctioning of this system may trigger specific alarms and necessitate an appropriate response. A few LVAD systems are currently used, and each has its own specific characteristics. The three systems mostly used in Europe and the USA are the HeartWare™ (HW™) also named HVAD™ (Medtronic), the HeartMate II™, and the HeartMate 3™ (Abbott). These three devices maintain a constant flow from the left ventricle to the aorta leading to a non-pulsatile physiology. *Figure 2* shows three X-ray images of the three devices. Because pulse pressure under usual circumstances of LVAD support is very small, the patients usually do not have a palpable pulse. Therefore, blood pressure and oxygen saturation are unattainable in approximately 50% of patients using standard automatic cuffs and pulse oximeters. On physical examination, a distinct humming of the LVAD may be heard over the precordium. The driveline exit site may be seen (preferably dressed and secured) at the abdominal wall.

Despite the LVAD support, patients may maintain some of the clinical characteristics of HF including fatigue and weakness, volume overload, cachexia, and other comorbidities. Furthermore, these patients are usually treated with multiple medications targeting hypertension, diabetes, and dyslipidaemia as well as anticoagulation and anti-platelets. Furthermore, LVAD patients have some typical and common complications leading to medical attention. These include thromboembolic complications (stroke and LVAD thrombosis), bleeding tendency (minor, major, gastrointestinal, or surgical), infections (with the driveline exit site a constant concern), aortic incompetence, arrhythmias, and worsening HF.

Figure 2 X-ray images of the most used left ventricular assist devices (LVADs).

Any of the medical issues listed above may cause the LVAD-supported patient to seek urgent or unplanned medical attention. Most LVAD-supported patients are in direct contact with the LVAD coordinator who will respond to the majority of logistic and non-urgent issues. Therefore, many patient's visits to the ER will lead to hospitalization. The reasons for referral are diverse and include both specific and nonspecific LVAD-related issues. The reported frequency of LVAD-related complaints seems to differ between centres^{6,7} and change according to the time post implant.^{8–10} Hospitalizations of LVAD patients form a distinct array of device-related and patient-related complaints justifying specialized education and training.

During the initial evaluation, it is advised to consult with the LVAD coordinator and close caregiver. In the absence or difficulty of acquiring the blood pressure and peripheral pulse, the stability of the patient should be assessed based

on alertness and obtainable signs of shock (such as shortness of breath, cold clammy skin, perspiration, and capillary refill). An unstable patient should undergo rapid evaluation for the adequate function of the LVAD system. An electrocardiogram (ECG) and bedside echocardiography may be helpful in diagnosing arrhythmia and causes of haemodynamic instability. Cardiopulmonary resuscitation (CPR) must be started according to the protocol elaborated in this document. A stable patient should be evaluated routinely with focus on history and vital signs (using the Doppler technique to evaluate mean arterial pressure). The thorough physical examination should include auscultation to the LVAD precordial hum and the visible LVAD system: the batteries, controller, and driveline. Alteration in mental status needs to be rapidly evaluated with low threshold for brain computed tomography (CT). An ECG is useful to diagnose arrhythmias and a chest X ray should be performed to evaluate pulmonary conditions and the LVAD position.

Echocardiography is a useful tool to assess the volume status, right ventricular function aortic incompetence, and adequate LVAD function. Noteworthy, the constant cardiac output generated by the LVAD may alter expected clinical responses to acute cardiac and non-cardiac events: LVAD-supported patients may remain non-symptomatic or only mildly symptomatic despite undergoing ventricular tachycardia (VT) or ventricular fibrillation (VF), event of otherwise life-threatening outcome.

Medical history and sources of information

The anamnesis of an LVAD-supported patient should start with determining the following:

- i Manufacturer and model of the device.
- ii Date of device implantation.
- iii LVAD implanting centre.
- iv Emergency contact phone number (24/7).

Some centres provide an 'identity document' bracelet that includes all this data. In others, a quick response (QR) code might also exist on the bracelet, and scanning it would bring up more data on the patient's specific device, alarms, and troubleshooting.

The next stage should include asking the patient or his close caregiver for any recent alarms. In most of the modern devices today, an alarm is usually accompanied by a text message explaining the possible problem and advises on how to manage it. Following these LVAD-specific information, the more clinical-oriented, continuous flow-related issues, should be addressed: has there been any bleeding event that can be related to the patient's complaints and symptoms or a significant driveline infection suggesting that the patient might be having an acute infection or be in septic condition? In those patients implanted with an implantable cardioverter defibrillator (ICD) or cardiac re-synchronization therapy with a defibrillator, have there been any discharges from the defibrillator implying that the symptoms are caused by a tachyarrhythmia?

Some centres supply the LVAD-implanted patients with an emergency card: ask the caregiver, or the patient if responsive, to the presence of such a document: usually, a simple one-page card describing the different device alarms and how to troubleshoot them. Patients are instructed to keep this emergency card in a visible and easily accessed place. All the LVAD accessories, batteries as well as their recharging docking and the controllers, should also be examined for major malfunction and carried with the patient in the need for transportation. For troubleshooting the device, ask first the caregiver or the patient himself for help as in most cases, they will probably know how to respond, explain the significance of the

alarms, and may be of help by knowing the basic patient's parameters of the device.

Flow adequacy and patient stability

Most of the automated blood pressure (BP) devices and pulse oximeters will be effective in measuring BP in approximately 50% of the LVAD-supported patients¹¹; therefore, it is advised to apply this simple approach first. If the automated BP device fails, then use the Doppler to measure mean arterial BP (MAP): First, the Doppler transducer is placed on either the brachial or radial artery and the arterial flow detected in the resting condition. The manual cuff (sphygmomanometer) is then inflated and deflated slowly. The BP recorded when an arterial flow sound is heard is approximately the MAP.

A MAP value of less than 50 mmHg indicates an unstable patient, because the normal MAP range for LVAD-supported patients is 60–80 mmHg. One of the most important and simple signs in the physical examination of the LVAD-supported patient for evaluating the flow adequacy is assessing the patient's capillary refill. A capillary refill of more than 2 s indicates pathologic low BP. Cool and abnormal skin colour also indicate inadequate flow.¹² Evaluate the patient's respiratory status—is the patient breathing normally or has agonal breathing or even apnoea.

Another good option for evaluating the flow adequacy of an LVAD patient is the Capnograph. Since 2015, the American Heart Association (AHA) EMS recommends evaluating the correct placement of the advanced airway and the efficacy of the chest compressions, with the capnograph. It is therefore expected that all EMS teams are equipped with this equipment, making it the most important tool in evaluating the LVAD patient. Pulmonary end-tidal CO₂ (PETCO₂) > 20 suggests that the patient has adequate ventilation and BP¹³ with the restriction that for patients without advanced airway support the value could be inaccurate. Furthermore, similar to the pulse oximeter, the capnograph is not a reliable tool for all LVAD-supported patients, but if it does supply a reading in the normal range, that can be trusted. Auscultating to the patient's chest can help diagnose lung congestion but most importantly also allow assessing the hum produced by the functioning LVAD. The LVAD hum is loud and easily heard: It can be monotonic with the HarteMate II and pseudo-pulsatile with HeartMate 3 representing the artificial pulse that occurs every 2 s. The hum of the HeartWare is monotonic unless the Lavare ('washing') cycle is activated, in which case, every minute, a pulsatile tone is heard reflecting abrupt speed decrease followed by speed increase: decrescendo/crescendo tone. Importantly, irrespective of the device, if no hum is heard, the LVAD is not functioning.

Common acute medical scenarios in the LVAD-supported patient

Pump failure

The most common cause of pump failure is disconnection from the power supply or a driveline fault. The patient should be examined from the driveline exit site through the controller and batteries to the wall socket. In case a problem is found in the power supply, the issue of re-connecting the device to the power supply will be raised.

Low flow alarms

The flow signal in the controller is a calculated value that although presented in units of litre per minute is based on calculation of parameters derived from the speed and power consumption of the device: In the contemporary LVADs, the flow is not measured directly. Therefore, low flow alarm does not necessarily mean that the patient has low cardiac output. Common causes of a low flow alarm can be acute right-sided HF, pulmonary embolism, or dehydration. In the case of low flow alarm, it is advised to lay the patient down in the Trendelenburg position with his legs lifted. In case this simple manoeuvre silences the low flow alarm, dehydration as the cause of the alarm is probably the reason. After a brief haemodynamic assessment, if the patient is not with overt volume overload, fluid resuscitation with a bolus of 500 cc saline can be a good diagnostic and therapeutic option.

Pump thrombosis

Pump thrombosis can also present as an acute event the LVAD-supported patient. The thrombosis can be in the pump itself but also in the inflow or outflow cannulas. Pump thrombosis can be difficult to diagnose in the community setting, but if after consulting the LVAD centre this complication is raised, immediately transferring the patient to the nearest LVAD centre is vital.

Stroke

Haemorrhagic or thrombotic stroke have been reported in about 7% of the LVAD-supported patients per year.¹⁴ Stroke in an LVAD-supported patient may be hard to diagnose as unresponsiveness with no pulse can be wrongly interpreted as absence of signs of life. In such a case, evaluate the patient's haemodynamics, first by physical examination: capillary refill and the capnograph. In the case of suspected stroke, the LVAD centre needs to be consulted regarding the most beneficial next step: either immediately treat the patient in the

closest stroke unit, or if time permits, transfer the patient to the LVAD centre.

Ventricular tachyarrhythmias: ventricular fibrillation/ventricular tachycardia

The VF/VT will occur in approximately 50% of LVAD patients.¹⁵ VF reduces the effective device flow by 32%.¹⁶ Some of the common aetiologies for VF/VT in LVAD patients are myocardial scar post previous myocardial infarction, HF exacerbation, suction event (suction mostly of the interventricular septum by the LVAD inflow cannula), dehydration, and electrolyte imbalance.¹⁷ During a VT/VF episode, the LVAD patient can be clinically unstable, although, more often, will be mildly symptomatic (complaints may include shortness of breath, weakness, or lightheadedness) or even completely asymptomatic. In the event of a VT/VF caused by a suction event due to dehydration, the VF/VT can be sustained until the patient receives fluid resuscitation. Diagnosing this sequence of events might not be feasible by the EMS team. The unstable LVAD patient with VT/VF needs to be treated promptly as indicated for the non-LVAD patient with defibrillation and medications. Management of the haemodynamically stable LVAD patient with VT/VF is challenging: if the event is short, measured in minutes, immediate cardioversion may prevent thrombus formation in the RV and/or on the aortic valve. If the event is prolonged, thrombus formed in those two locations cannot be ruled out. The patient should be immediately transferred to a VAD centre for further evaluation and management.¹⁸

Bleeding

Bleeding, mainly from the gastrointestinal tract or nasopharynx, can occur in up to 22% of the LVAD patients.¹⁴ In the case of acute major blood loss in the community, LVAD-supported patients should be treated as non-LVAD patients to reach MAP of 60–80 mmHg if BP can be measured, to reach capillary refill of less than two seconds or normal PETCO₂ value.

Driveline infection

The driveline is the very source of infections at the port of entry of the driveline cable through the abdominal wall. The patient and caregiver should be enquired regarding recent driveline infections. Evaluating and taking a swab from the driveline exit site must be part of the routine physical examination of the LVAD-supported patients.

Non-ventricular assist device-related complications

The incidence of any infection in LVAD patients while on the mechanical support is as high as 37%.¹⁹ The characteristics of the continuous flow LVAD, being afterload dependent, can result in increased cardiac output as a result of systemic arterial vasodilatation caused by the septic event. Furthermore, the deleterious effects on the myocardium caused by the catabolic and inflammatory state of the septic event do not affect the function of the LVAD resulting in a potential delay in the occurrence of the common symptoms of an infection, even of the state of septic shock. The management of this acute scenario is just as for the non-LVAD patients.

In the presence of acutely altered mental status, after ruling out the above LVAD-related causes, investigate other aetiologies such as hypoglycaemia, drug overdose, and hypoxia.

In summary, LVADs are implanted more frequently in patients with advanced HF and significantly prolong their survival. However, the LVAD-supported patients retain significant morbidity necessitating unplanned medical attention. The LVAD-supported patients have some unique distinguishing features and LVAD-related complaints that necessitate specific education and training of the attending medical staff. This document is intended to fill this gap in knowledge and supply useful information for all medical care suppliers not experts in the field of MCS who might need to take care of LVAD patients.

- Educate and train the medical staff for the medical emergencies unique to the LVAD patient.
- Most of the LVAD patients do not have a palpable pulse so measuring BP and oxygen saturation may be difficult.
- Use clinical evaluation to assess the patient's stability.
- In cases of device malfunction consult the patient or caregiver and contact the LVAD centre.

Cardiopulmonary resuscitation for left ventricular assist device-supported patients

Although some of the causes for haemodynamic collapse of an LVAD-supported patient are like those of the non-LVAD-supported patients, others are device related and may pose a complex diagnostic challenge.

The first to contact the patient should look for the signs of life. Absence of signs of life is determined when the patient is apnoeic (not breathing at all) or in agonal breathing, unresponsive, and pale.

If the patient is known as an LVAD-supported patient, inspect the cables, controller, and batteries. Expose the

abdomen of the patient and look for the integrity of the driveline exiting the abdominal wall.

Concomitantly, try to contact the LVAD centre, but do not delay emergency treatment. In the absence of signs of life, the first to have contacted the patient is encouraged to immediately start CPR.

Chest compression

Chest compressions for LVAD patients although intuitive raises certain issues that need to be addressed: Might chest compressions cause pump dislodgement, tamponade, or intrathoracic bleeding? And also, is chest compression indeed useful and if so, should it be performed manually or also mechanically?

In a retrospective case study from a single centre²⁰ comparing CPR in nine LVAD and non-LVAD patients, a delay was found in starting in-hospital CPR in the LVAD patients. Although in that study all nine patients included died, there were no device dislodgement, dislocation, or bleeding issues related to the chest compression. In another study,²¹ CPR was successful in 50% of the eight LVAD patients described. The survivors had no major neurologic deficit and no device dislodgement, dislocation, or bleeding issues related to the chest compression.

In the total of 25 LVAD patients who underwent chest compression described in the literature, no dislocation, dislodgement, bleeding, or tamponade have been reported.^{20–22}

Due to the scarcity of the data and the emergent nature of those events, a controlled study with data regarding the utility of CPR in LVAD-supported patients is not expected. From the existing case reports, it can be assumed that CPR with chest compression in VAD patients is safe and might even be helpful.

There are no data regarding mechanical chest compression in LVAD patients but being much more aggressive than manual can be harmful.

Left ventricular assist device reconnection

When the LVAD is disconnected from its power supply, it will take approximately 20 min until it shuts off for the HM II and HM 3™ although the HW™ will shut off immediately if the controller is disconnected from its energy supply. Although anticoagulated, the combination of stasis and artificial material may result in thrombus formation in the system: in the pump itself, and/or in the inflow or outflow cannulas. In considering reconnecting a non-operating LVAD, three important issues should be taken into account:

- What is the patient's condition
- How long has the LVAD been disconnected?
- Is it in or out of hospital resuscitation?

The first thing that can help in the decision-making process on whether to reconnect or not the disconnected LVAD is the patient's haemodynamic condition: Is the patient haemodynamically stable or not? The reasoning for reconnecting an unstable patient, for the sake of general organ perfusion, particularly the brain, does not apply for the stable LVAD-supported patient. As long as the patient with a disconnected LVAD remains stable, it is advised to transfer the patient with the disconnected device to the nearest LVAD centre where, based on a quick evaluation including determining how long has the device been disconnected, assessment of the anticoagulation state of the patient, the device model, echocardiography as well as CT scan or CT angiography, the safety, and need for re-connection of the LVAD can be made.

A simple protocol based on the combination of the time the LVAD has been disconnected, and the patient's haemodynamic condition has been suggested²³ and revised here. This protocol can be easily followed by the EMS:

- i *Short pump stop* (minutes; LVAD still alarming)
 - Restart the device immediately.
- ii *Long pump stop* (hours; no alarm sounds) and *stable patient*
 - Do not restart the pump.
 - Transport to the nearest LVAD centre.
- iii *Short or long pump stop and unstable patient* (shock or non-responsive)
 - Restart the pump immediately.
 - As in any shock, start vasopressors.
 - If there is no overt bleeding, start intravenous (IV) heparin.

Advice for the left ventricular assist device implanting centres

- Make an 'identification document' (ID) bracelet and/or add a QR code with the relevant medical information. The bracelet or QR code can include the device manufacturer, identification of the implanting centre, phone number of an LVAD coordinator 24/7, and a short summary of the patient clinical characteristics.
- Regularly train and re-train the patient, his close caregiver, and family members.
- Supply a backup controller.
- Have an on call LVAD coordinator 24/7.
- Train the EMS teams, the general practitioner, and other healthcare professionals working within non-LVAD implanting hospitals.
- Make a pocket-size emergency card for the patient and local medical centres.

Advices for the emergency medical service instructing a non-trained personnel

When bystanders encounter a collapsed LVAD patient, they will probably contact the EMS team. The EMS team are advised to follow the algorithm presented below guiding the bystander on how to manage the collapsed LVAD patient until the EMS team arrives.

The bystander will be asked to verify that this is a case of a collapsed LVAD patient, and if so, inspect the cables, controller, and batteries. Expose the abdomen and the cable coming out from the patient's abdomen confirming this it is indeed an LVAD patient!

Immediately thereafter, the bystander is instructed to look for signs of life. Absence of signs of life is determined when the patient is not breathing at all or in agonal breathing, unresponsive, and pale.

In the absence of signs of life, the bystander is encouraged to immediately start CPR as the likelihood of a favourable outcome improves with the prompt initiation of CPR after cardiac arrest from any cause.

In summary:

- First verify that there is an LVAD...
- If no sign of life, immediately start CPR and connect an AED (automated external defibrillator).²⁴
- Look for a bracelet.
- Keep CPR until EMS arrives.

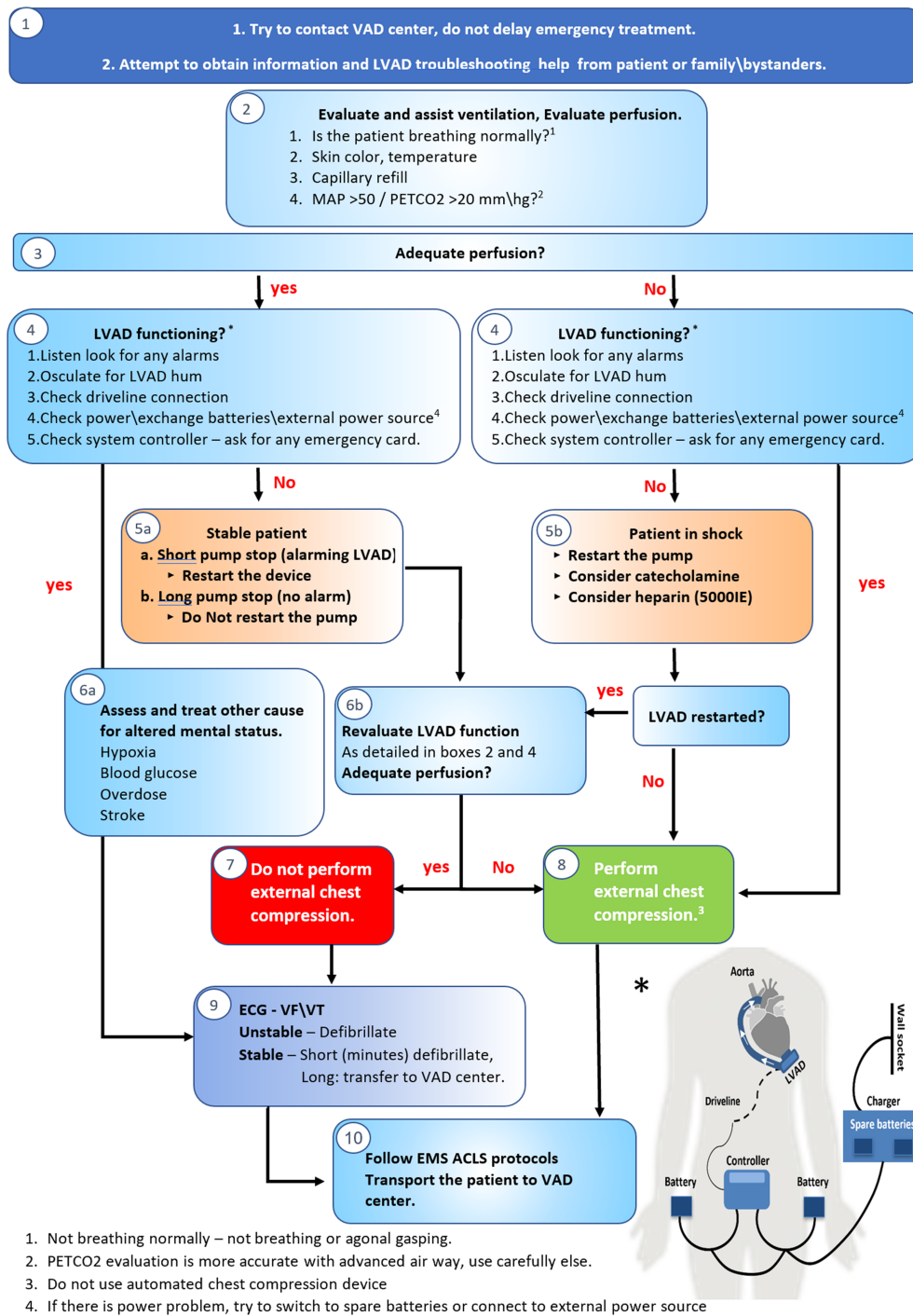
Emergency medical service teams

There have been some recent publications addressing the unmet need for a structured protocol on the approach and management of the non-responsive LVAD patient by the EMS teams. The American scientific statement paper by Peberdy *et al.* on *CPR in adults and children with MCS*²⁴ is simple and concise, but has not enough data on troubleshooting the device, and the issues of reconnecting a disconnected LVAD and ventricular arrhythmias in the LVAD-supported patient have not been thoroughly addressed. On the other hand, the very detailed manuscript by Bowels *et al.* from the UK¹⁸ provides comprehensive detail at the expense of been less user friendly.

Accordingly, with the intention to be a reference protocol for the EMS at the emergency site, the following protocol is presented in *Figure 3*:

- **Box 1: Anamnesis.** Try to obtain a brief history and information on device type and troubleshooting from patient, caregiver, and/or bystanders. Call the LVAD centre or LVAD coordinator. Ask for the emergency card.
- **Box 2–3 Evaluate patient's ventilation and perfusion** using breathing pattern, skin colour, temperature, and capillary

Figure 3 ACLS algorithm for the left ventricular assist device (LVAD)-supported patient.



refill technique. If the equipment is available, check mean arterial pressure by cuff or Doppler and PETCO2. Values above 50 and 20 mmHg, respectively, indicate normal perfusion.

- Box 4: Assess the LVAD function using alarms and auscultation of the patient’s chest. An LVAD hum indicates that the

LVAD is functioning. Check for integrity and/or disconnection of the LVAD components: driveline, system controller, power cables, and batteries. Ask the patient and caregiver for help with troubleshooting the device alarms.

- If the patient is unstable with nonfunctioning LVAD, follow Box 8, and perform immediate chest compression.

- Box 5 a: Nonfunctioning LVAD in the *stable* patient. In case of a short pump stop (*if the alarm is still on*), try to restart the device. In case of a long pump stop (*no alarms*), do not try to restart the device.
- Box 5 b: Nonfunctioning LVAD in the *unstable* patient Try to restart the device, consider administering catecholamines and heparin.
- Box 6 a: In the case of a stable patient with functioning LVAD, consider other causes of altered mental status such as hypoxaemia, hypoglycaemia, substance abuse, or stroke and follow to Box 9.
- Box 6 b: After restarting the LVAD, re-evaluate the LVAD function and perfusion as detailed in Box 4 and Box 2.
- Box 7: Do not perform external chest compression in the stable patient.
- Box 8: Perform external chest compression in the persistently unstable patient.
- Box 9: ECG. If the patient is in VF\VT and unstable, defibrillate. If the patient is stable, do not defibrillate. Organize immediate transfer to the nearest LVAD centre.
- Box 10: Follow EMS and ACLS protocols. Before transferring the patient to the nearest LVAD centre, ask the family for all the LVAD equipment.
- When evaluating LVAD patients in the acute scenario, look for any identification, ask the patient and/or family for help, and try to contact the LVAD centre.
- When indicated, start CPR as soon as possible.
- Chest compression is safe in LVAD patients. Avoid using automated devices.
- Defibrillation is safe in LVAD patients. Avoid defibrillation of the stable patient.

Arrhythmias in the left ventricular assist device-supported patient

Arrhythmias are common in LVAD patients, leading to hospitalization in 30–40% of the patients within the first 2 years after the LVAD implantation.⁷ Some arrhythmias are related to the underlying heart disease, but others can be induced by the cardiac surgery (scar around the LVAD inflow cannula) or by mechanical irritation of the left ventricular wall by the pump.

Atrial fibrillation (AF) is present prior to LVAD implantation in 40–60% of patients.^{25,26} In some patients, even long-standing AF may convert to sinus rhythm after the LVAD implant presumably due to improvement in left atrial pressure, but in others AF may develop *de novo* after the LVAD implant. In some LVAD-supported patients, AF will become acutely symptomatic if the RV function is marginal, and in others, it may lead to poor exercise capacity. Anticoagulation is rarely an issue for most of the patients receive vitamin K

antagonists as part of their regular LVAD management. Treatment of AF follows the principles applied in non-LVAD-supported patients,²⁶ but ablation is only rarely considered. The main determinant of the aggressiveness of the therapeutic strategy is the patient symptoms. In most patients, however, an attempt to obtain sinus rhythm should be made. Many patients have been treated with amiodarone prior to LVAD implant or in the postoperative phase, so ruling out thyrotoxicosis is important in LVAD patients presenting with *de novo* AF.

Ventricular tachycardia or fibrillation (VT/VF) are also very commonly reported in up to 20–50% of LVAD recipients.¹⁵ The main predisposing factor for VT/VF post-LVAD implantation is ventricular arrhythmias prior to the implant.²⁷ VT/VF may arise because of the underlying heart disease, from scar tissue related to the LVAD operation or due to mechanical irritation of LV inflow cannula, especially if excessive LV unloading is present ('suction' events).

Sustained VT or even VF does not necessarily lead to acute haemodynamic compromise in LVAD patients. In fact, patients living for weeks with resistant VF have been reported²⁸ during which, the patient may present with only mild symptoms such as shortness of breath, weakness, and lightheadedness or even be completely asymptomatic. During sustained VT or VF, although the right ventricular function is hampered, the systemic blood flow can persist if the LV preload is maintained with the LVAD functioning independently of the arrhythmia. The patient in VT/VF is in a Fontan-like circulatory situation; thus, maintaining adequate systemic circulation depends on the balance between the resistance in pulmonary circulation (PVR) and the central venous pressure. Hence, in patients with low PVR and adequate venous filling, normal cardiac output at rest may be maintained, resulting in LVAD patients presenting with VT/VF but with only mildly, or occasionally not at all, symptomatic. In case the LVAD patient has also been implanted with an ICD, the patient might experience multiple shocks while being completely awake. Eventually, VT/VF will lead to right HF and circulatory compromise and thus needs immediate therapeutic intervention.

The management of LVAD patients with VT/VF depends on the clinical presentation of the patient, which, in turn, depends on the PVR and central venous pressure. Patients should be immediately admitted to a cardiology department specialized in taking care of cardiac arrhythmias. Telemonitoring and IV access should be ensured. If the patient has an ICD, and is conscious, a magnet should be placed over the ICD immediately to prevent painful discharges. If the patient is haemodynamically unstable but awake, immediate sedation and cardioversion is indicated as for the non-LVAD patient. In the haemodynamically stable LVAD patient with VT/VF, if the event is short, measured in minutes, immediate cardioversion may prevent thrombus formation in the RV and/or on the aortic valve. If the event is prolonged,

thrombus formed in those two locations should be suspected and the patient immediately transferred to a VAD centre for further evaluation and management.¹⁸ In the VAD centre, after ruling out thrombus formed in the LV or by the aortic valve, IV amiodarone (300 mg) and reduction in pump speed (if possible, echo guided) should be attempted. If the patient is dehydrated and echocardiography suggests an unfilled LV, IV fluid should be administered. In patients not responding to these measures, sedation and cardioversion must be performed. Further treatment includes optimization of beta-blocker doses, prolonged antiarrhythmic therapy (often amiodarone), and ablation in refractory cases.²⁹

It is unclear whether LVAD patients in general benefit from prophylactic ICD implantation. A meta-analysis of data from the USA did not suggest this, whereas a recent European multicentre study found a benefit both from having an ICD prior to MCS and also from receiving an ICD after LVAD implantation.^{30,31} All studies are retrospective and should be interpreted with caution. It is clear, however, that LVAD patients with activated ICD are at high risk of experiencing shocks while awake, and even ultra conservative programming of the device does not prevent this unpleasant adverse event.³²

Currently, the shock therapy mode is kept activated in patients with ICDs implanted *prior* to LVAD surgery. Implanting an ICD while on LVAD support is reserved for those with haemodynamically significant ventricular arrhythmias occurring post-LVAD implantation or in individual patients considered to be at high arrhythmic risk. In LVAD patients experiencing awake shocks, a discussion with the patient and family members regarding the benefits and risks of deactivating the ICD is indicated.

A significant proportion of LVAD patients have been treated with a CRT device prior to LVAD implant. It is unclear whether the LV lead function is to be left on or turned off. Most likely there is only a minor gain in terms of prognosis from LV pacing as the patient has already declared him or herself as a non-responder by requiring an LVAD implant. Furthermore, one study has suggested that exercise capacity might improve in CRT treated LVAD patients if the CRT function is turned off.³³ The mechanism behind this finding is unclear. Finally, turning off the LV lead increases battery life of the device, which might be of importance in deferring the need for battery exchange with its inherent increased infection risk, especially in the DT population. Therefore, attempt turning off the LV lead after LVAD, and if no symptoms occur, keep it off.

- Atrial fibrillation may present as right ventricular failure. In such cases, perform cardioversion.
- Stable LVAD patients presenting with VF\VT must be immediately transferred to a hospital with a cardiology centre where appropriate method to cardiovert the patient can be applied.
- In patients with cardiac re-synchronization therapy with a defibrillator and LVAD, attempt turning the LV lead off

for longer battery life and possible improvement of RV function.

Considerations for referral (urgent/non-urgent) to advanced heart failure centre

Optimal management of patients with LVAD requires a multi-disciplinary and specialized approach, involving a team that includes medical technicians, nurses, cardiologists, and surgeons. However, because a full range of such expertise cannot be developed in all cardiology units, a shared care model based on communication, cooperation, and clear shared responsibilities in patients care between peripheral cardiology units and the advanced HF referral centre is advisable, within a hub and spoke network model.^{34–36} The key of such an approach is to design education and shared responsibility models based on the level of care that each centre of the network can provide. In this context, peripheral centres with outpatient and/or inpatient LVAD specific care programmes may guarantee patient outcomes comparable to tertiary LVAD hubs.³⁶ Thus, the need and level of referral depends on whether a shared care network between the tertiary and peripheral centres is in place.

Within this framework, the complications that may occur in an LVAD patient are to be classified based on the level of urgency and the corresponding level of expertise in LVAD management required, although in most cases communication with the tertiary advanced LVAD hub is advisable. Level of expertise may be framed on the basis of the recent paper from Yin *et al.*³⁶ Centres with no LVAD experience and no dedicated teams should communicate for any kind of complication with the LVAD centre, while centres with trained personnel for at least outpatient management may manage non-urgent interventions, and centres with dedicated and trained team for inpatient management could deal also with electively urgent clinical scenarios.

In *Table 2*, we outline several scenarios: regardless of the underlying cause, the urgency of the intervention is related to clinical presentation in the context of LVAD patient. For example, low flow alarms may be benign when related to hypovolaemia and thus may be self-resolving or managed with fluid intake (a condition that can be remotely managed by a VAD coordinator), or, if recurrent and associated with significant symptoms such as dizziness or even loss of consciousness, may also be related to life threatening complications such as outflow obstruction or twisting needing urgent surgical referral to a highly experienced LVAD centre.

Management of extracardiac conditions require knowledge as well of basic LVAD functioning principles and interpretation of clinical scenarios. For example, gastrointestinal bleeding is a

Table 2 Different clinical scenarios, urgency and level of expertise required

Level of urgency requiring intervention	Cardiac/LVAD-related conditions	Extracardiac/non-LVAD-related conditions	Level of expertise
Immediately life threatening	<ul style="list-style-type: none"> • Pump failure • Pump thrombosis (of high watt alarm) • Recurrent or prolonged low-flow alarms with syncope or hypotension 	<ul style="list-style-type: none"> • Haemorrhagic shock • Haemorrhagic/ischemic stroke^a • Septic shock • Emergent non cardiac surgery (i.e. bowel perforation) 	High level LVAD expertise
Electively urgent	<ul style="list-style-type: none"> • VT/VF • Low-flow alarms • Self-resolving syncope • Symptoms of heart failure • Driveline infection 	<ul style="list-style-type: none"> • GE bleeding • Haemorrhagic/Ischemic stroke^a • Peripheral embolism/limb ischemia • Non-LAD related infections (i.e. pneumonia) • Urgent non cardiac surgery (i.e. cholecystitis, bowel obstruction) • Elective non cardiac surgery 	Dedicate inpatient LVAD care
Delayed/planned	<ul style="list-style-type: none"> • Driveline infection: superficial • Clinical signs of right heart failure with no or minor symptoms • Severe aortic regurgitation with no or minor symptoms • Isolated hypotension or hypertension 	<ul style="list-style-type: none"> • Elective minor non cardiac surgery (i.e. cataract etc.) • Worsening of any medical non cardiac chronic condition (i.e. COPD) • Malignancy 	Dedicated outpatient LVAD care

COPD, chronic obstructive pulmonary disease; LVAD, left ventricular assist device; VAD, ventricular assist device; VF, ventricular fibrillation; VT, ventricular tachycardia.

^aThis facility must have a stroke unit.

frequent complication in LVAD patients, which requires withholding of anticoagulation, but also careful monitoring of pump parameters, in particular energy consumption, to detect promptly indirect signs of possible LVAD thrombosis.³⁷ Similarly, management of extra cardiac surgery requires appropriate cooperation with trained personnel to monitor and manage volume, BP, and coagulation, to avoid LVAD complications and malfunction in the operative and post-operative phase. It is important to underline that LVAD does not represent a contraindication for even major non-cardiac surgery, which can be appropriately managed by multidisciplinary approach and training.³⁸ The level of training in the peripheral facility dictates the need for referral to the LVAD centre.

Immediately life threatening includes condition for which immediate interventions are needed and high level of expertise is needed. Early transfer of the patient to advanced HF centre with LVAD expertise and cardiac surgery is advisable. Electively urgent indicates conditions needing urgent intervention but which may be initially managed, and in some cases even resolved in the peripheral centre with personnel trained for LVAD management and in-hospital facilities including intensive care units with staff familiar with LVAD, able to perform LVAD-specific echocardiography, and able to understand LVAD parameters and waveforms. These patients

do not necessarily need to be transferred to the advanced HF hub centre. Delayed/planned indicate conditions that require attention but that may be managed in the context of outpatient department or in the context of planned in-patient interventions. Basic training for LVAD management is needed as well, although in-patient facilities may not be required, and the patient can be managed in the peripheral hospital, with advanced HF centre remote supervision. When any of these conditions is detected by a centre with no expertise or training in LVAD management, guidance of the local LVAD hub should be sought.

Components of the LVAD system:

- Inflow cannula—stationed inside the left ventricle connects the LV cavity to the pump directs blood into the pump
- Pump—the body of the LVAD, located at the apex of the left ventricle and houses the impeller (magnetically levitated frictionless rotor), connected to the ascending aorta via the outflow graft
- Outflow graft—flexible conduit that directs blood from the pump to the ascending aorta
- Driveline—the pump is connected by the DL, a cable subcutaneously tunnelled from the pump exiting the body at

the lower abdominal wall, to the external controller and the energy supply. The cable contains double set of wires that provide power and operating details to the pump from the controller

- External controller—the controller is the system's computer. It monitors pump function (flow, speed, and power), controls pump speed and power supply, records pump data and alarms; displays battery life and function. The controller is connected to the driveline and to the power sources (the batteries or external power supply like the wall socket)
- Batteries—two lithium batteries.

Statement of previous publication

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