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Mechanical circulatory support for destination therapy

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Summary

Patients with chronic heart failure who are not eligible for heart transplant and whose life expectancy depends mainly on the heart disease may benefit from mechanical circulatory support. Mechanical circulatory support restores adequate cardiac output and organ perfusion and eventually improves patients' clinical condition, quality of life and life expectancy. This treatment is called destination therapy (DT) and we estimate that in Switzerland more than 120 patients per year could benefit from it. In the last 10 years, design of the devices, implantation techniques and prognoses have changed dramatically. The key to successful therapy with a left ventricular assist device is appropriate patient selection, although we are still working on the definition of reliable inclusion and exclusion criteria and optimal timing for surgical implantation.

Devices providing best long-term results are continuous flow, rotary or axial blood pumps implanted using minimally invasive techniques on a beating heart. These new devices (Thoratec HeartMate II and HeartWare HVAD) have only a single moving part, and have improved durability with virtually 10 years freedom from mechanical failure. In selected patients, the overall actuarial survival of DT patients is 75% at 1 year and 62% at 2 years, with a clear improvement in quality of life compared with medical management only. Complications include bleeding and infections; their overall incidence is significantly lower than with previous devices and their management is well defined. DT is evolving into an effective and reasonably cost-effective treatment option for a growing population of patients not eligible for heart transplant, showing encouraging survival rates at 2 years and providing clear improvement in quality of life. The future is bright for people suffering from chronic heart failure.

Key words: mechanical circulatory support; heart failure; destination therapy; heart transplant; ventricular assist device

The need

"Mechanical problems need mechanical solutions" summarises well our 10 years of experience in the management of heart failure patients. When even the most advanced pharmacological therapy fails to achieve adequate organ perfusion in patients with chronic heart failure (CHF) with reduced ejection fraction, the only effective solution is mechanical circulatory support (MCS) [1].

MCS clearly provides better haemodynamic support compared with pharmacological treatment, restoring adequate organ perfusion and preventing organ dysfunction [1–3]. In patients with CHF who are not candidate for heart transplant (HTx), or are candidates but have a low chance of getting an organ and whose life expectancy depends mainly on the heart disease, MCS treatment could become lifelong, hence the name "destination therapy" (DT). The efficacy of DT compared with other combined medical treatments in patients with end-stage heart failure ineligible for transplantation was demonstrated for the first time in the REMATCH trial, back in 2001 [1]. In 2003, MCS therapy was expanded to include the intent of long-term therapy in patients not eligible for HTx, introducing the concept of DT [2]. Since then, several trials involving different types of left ventricular assist devices (LVADs) have supported the clinical benefits of MCS for the treatment of patients deemed unsuitable for HTx [3].

The majority of heart transplant centres consider as contraindications to HTx age above 70 years, fixed pulmonary hypertension with a transpulmonary gradient of above 15 mm Hg and vascular resistance above 6 Wood units, history of recent cancer disease or any other comorbidity reducing life expectancy despite HTx [4]. Moreover, there are candidates for HTx who have a small chance of being transplanted because of their morphology or blood group, and a shortage of donors.

The number of HTx worldwide has reached a plateau at 4 500 per year [5], while potential candidates for DT therapy are increasing. The number of patients who could potentially benefit from DT per year in Switzerland is estimated at 120. In a nationwide survey in 2005, the incidence of heart failure in our country was 64.9 per 100 000 adult inhabitants [6], with a clear predominance in the group aged 55–85 years. It is estimated that the number of people >65 years of age will double in the next 20 to 30 years [5, 7] and CHF may affect nearly 10% of people >65 years of age [5].

In 2005 in Switzerland, there were 63 patients on the waiting list for HTx and 33 were transplanted. In 2014, the number of patients on the waiting list for HTx had in-

creased by 100% (124 patients), but the number of patients transplanted had not increased accordingly since only 36 received an organ. This growth in the number of CHF patients is probably a result of the reduction in death from myocardial infarction thanks to improvements in coronary revascularisation treatments and implantation of cardiac defibrillators and resynchronisation therapy.

Because of the organ shortage and the rapid progression of heart failure despite optimal medical treatment, a considerable number of patients pass away while waiting for an organ. In the Swisstransplant 2015 annual report, the mortality rate of patients listed for HTx during the period 2010–2014 was 6.5%.

Based on these epidemiological data, we could speculate that in our country, about 120 patients per year could benefit from a LVAD as DT. From January 2015, this therapy has a specific reimbursement code (SwissDRG version 5.0), even if consumables such as battery packages and technical controls are not reimbursed yet. However, in our country, DT will probably be generally accepted as one of the treatment options only if a national cost-effective analysis related to the Swiss healthcare system were to clearly prove its benefit.

The right candidate

The key of successful therapy with a LVAD is appropriate patient selection, but most of the patient selection criteria are broad, and are based on clinical experience of single centres and data collected by multi-institutional registries. Moreover, almost all the parameters considered as selection criteria change over time owing to fluctuation of organ function, making the selection criteria dynamic. The risk/benefit evaluation is an iterative process that is affected by even small changes in the patient's physical condition. The first step in patient selection is the assessment of disease severity based on clinical status, inotrope dependence and invasive haemodynamic parameters, followed by operative risk estimation. Ultimately, confirmation of adequate psychosocial support and capacity for self-care is also crucial for successful surgery in the long run [8] (table 1). With worsening clinical status, the need for LVAD increases, but so does the perioperative risk and optimal operative timing becomes difficult.

Comorbidity limiting the patient's survival to less than 2 years, such as an advanced malignancy, severe liver disease (particularly if cirrhotic), severe lung disease or a severe neurological or neuromuscular disorder, should be viewed as a major contraindication to DT.

Another key point for success is to choose the best time to implant the LVAD and this is still an open issue. Based on the first poor results, many clinicians implanted left ventricular support only when patients were severely ill. But longer durability and fewer complications with modern devices, as well as recognition of the unpredictability of heart failure deterioration, has led to a shift toward less catastrophically ill patients. In our experience, up to 30% of stable patients listed for HTx deteriorate far enough to require high-urgency HTx or emergency LVAD and we now propose earlier implantation, before right-ventricular and multiorgan failure. It is well documented that patients with

INTERMACS categories above 3 have the best outcome [2]. INTERMACS is a US registry acquiring data on patients supported with MCS devices approved by the US Food and Drug Administration (FDA). INTERMACS clinical profiles are illustrated in table 2. Patients receiving a durable MCS at INTERMACS patient profile 1 or 2 have a postoperative mortality that is 44% greater than that of those receiving a long-term MCS at INTERMACS patient profile 3 or 4 [9]. However, we should remember that these levels and their corresponding prognosis have not been tested or validated in actual patient sets but are helpful for overall clinical assessment.

As recently outlined by Kirklin et al., DT candidates are older than candidates to bridge to transplant (mean age 61.7 vs 52.7 years) and have significantly worse multimorbidity [10]. Although age by itself should not be considered as an absolute contraindication to DT, older patients often have more coexisting morbidities and thus are more vulnerable to complications.

Seventeen percent of DT recipients achieve improvement or resolution of contraindications to transplantation during MCS and ultimately receive a HTx and one third of bridge to transplant patients became noncandidates for transplantation [11].

The clinical experience of the surgeon still plays a major role in choosing the right moment to implant the pump because it helps to consider the patient's frailty. Frailty is impairment in multiple, interrelated organ systems causing a decreased homeostatic reserve and increased vulnerability to stress [12].

LVAD implantation is still associated with high perioperative mortality: in our experience over the last 5 years the 30-day mortality was 18% (7 patients out of 38, all as bridge to transplant) and morbidity and costs were considerable as well. However, 80% of our patients had repeated hospitalisations and were inotrope dependent at the time of ventricular assist device implantation.

There are several clinical scores created to predict long-term survival after LVAD implantation, the most used being the Lietz-Miller score analysing 45 baseline parameters (laboratory, haemodynamic and clinical) to stratify patients into low, medium and high risk. However, all the existing risk models have several important limitations. They are based on data from patients who underwent implantation of pulsatile LVADs and the risk models have not yet been validated with continuous-flow devices. Comorbidities such as diabetes, severe cachexia or obesity were under-represented but could affect long-term results. There is a clear and immediate need for more prospective models to define the timing of and risk associated with LVAD implantation.

Physicians also have to take into account psychosocial and behavioural issues before including the patient in a DT programme and adherence to a complicated heart-failure medical regimen predicts success. The candidate should be able to self-care the driveline exit site, to handle the maintaining/alternating power source, and to know the emergency procedures in the case of device alarms.

Clinical challenges

Right ventricular failure

In our experience, all patients with in end-stage heart failure have moderate pulmonary artery hypertension and some degree of right ventricular dysfunction. Predicting the residual function of the right ventricle after LVAD implant is a real challenge. As a result of its different anatomy and embryological origin, the right ventricle has a completely different functional reserve compared with the left ventricle and works in on-off mode: it works, providing good left ventricular filling, or it fails completely. There is nothing in between. Left ventricle unloading, and reduction in left ventricular filling pressure and pulmonary vascular resistance often induce an improvement in right ventricular function after LVAD, but in the early postoperative period complex mechanisms may contribute to right ventricular failure. These include a sudden increase in cardiac output, leading to increased venous return and thus right ventricular preload, septal shift causing increased right ventricular wall stress and increased pulmonary vasoreactivity in the setting of cardiopulmonary bypass, blood transfusions and inflammation leading to increased right ventricular afterload. Right ventricular failure after LVAD implantation is a serious complication, leading to an estimated 19 to 43% increase in operative mortality and decreased survival [13]. There is no general consensus on the parameters predicting right ventricular failure and all existing scores have low reliability. However, in our experience, right atrial pressure above 20 mm Hg, mean pulmonary artery pressure below 25 mm Hg, and a large and hypokinetic right ventricle (>200 ml) are all poor prognostics for isolated left ventricular support. The risk of developing right ventricular failure is clearly associated with the underlying disease: it is more likely to occur in dilated idiopathic than ischaemic cardiomyopathy. Also, the rapid unloading of the left ventricle due to the LVAD can cause left displacement of the interventricular septum, eventually worsening right ventricular function. Therefore, pump speed has to be adapted to left ventricular unloading in the early days after LVAD implant. Peroperative management that includes possible tricuspid annuloplasty for moderate to severe tricuspid regurgitation [14] and the use of selective pulmonary vasodilators (nitric oxide, prostanoids or type 5 phosphodiesterase inhibitors) may attenuate the development of early right ventricular failure [15]. However, interpretation of scientific data is difficult because most publications identified only univariate predictors and describe mostly first-generation devices. In critical situations, the use of temporary circulatory support for the right ventricle, such as extracorporeal membrane oxygenation with a centrifugal pump and cannulas inserted into the femoral vein and pulmonary artery, may act as bridge to recovery for the right ventricle, but there are limited prospective data on evidence of its efficacy.

Pulmonary arterial hypertension with an elevated pulmonary vascular resistance (above 5 Wood units) was once thought to predict right ventricular failure after LVAD because these factors are associated with poor outcome after heart transplantation. More recent studies suggest that depressed right ventricular myocardial function is more accurately characterised by a low right ventricle stroke work index, low pulmonary arterial pressure and elevated right atrial pressure. Thus, pulmonary hypertension should not be considered an absolute contraindication to DT [16, 17]. In our limited experience, the capacity of the right ventricle to generate high pressure and flow is a favourable prognostic factor, whereas high central venous pressure and severe tricuspid regurgitation are detrimental. The impact of long-term LVAD support on right ventricular function and on the intrinsic progression of right ventricular dysfunction needs to be investigated and could be a barrier to the wide acceptance of the DT.

Aortic valve disorders

Because of the possible development of a closed loop of LVAD flow (blood recirculates from aorta to the left ventricle with poor organ perfusion), patients with more than mild aortic valve regurgitation need correction of the re-

Table 1: Adapted from American Heart Association recommendation for long-term mechanical circulatory support [8].		
DT is beneficial for patients with advanced HF, high 1-year mortality resulting from HF, and the absence of other life-limiting organ dysfunction; who are failing medical, surgical, and/or device therapies; and who are ineligible for heart transplant.	Class I	Level of Evidence B
Elective rather than urgent implantation of DT can be beneficial when performed after optimisation of medical therapy in advanced HF patients who are failing medical, surgical, and/or device therapies.	Class IIa	Level of Evidence C
Patients who are ineligible for heart transplantation because of pulmonary hypertension related to HF alone should be considered for bridge to potential transplant eligibility with durable, long-term MCS	Class IIa	Level of Evidence B
DT is not recommended in patients with advanced kidney disease in whom renal function is unlikely to recover despite improved haemodynamics and who are therefore at high risk for progression to renal replacement therapy.	Class III	Level of Evidence C
Assessment of nutritional status is recommended as part of the evaluation for patient selection for DT.	Class I	Level of Evidence B
Assessment of psychosocial, behavioural, and environmental factors is beneficial as part of the evaluation for patient selection for durable, long-term MCS.	Class I	Level of Evidence C
DT = destination therapy; HF = heart failure; MCS = mechanical circulatory support		

Table 2: INTERMACS classes and optimal timing for mechanical circulatory support. Data from: Kirklin JK, et al. Sixth INTERMACS annual report: A 10 000-patient database. J Heart Lung Transplant. 2014;33:555–64 (table 7) [25].							
HF severity NYHA class	III		IIIB		IV		
INTERMACS profiles	7		6	5	4	3	2	1
VAD implants %	1		1.4	3	14.6	29.9	36.4	14.3
Acceptance	None		Limited adoption		Growing		
NYHA = New York Heart Association; VAD = ventricular assist device							

gurgitation concomitant to LVAD implantation. Among the different surgical options, the primary closure of the aortic valve using pericardial pledgets (modified Park's stitch) or complete closure of the ventricular aortic junction with a circular patch, seem to be the most effective techniques, which avoid late thromboembolic complications and recurrence of aortic regurgitation in DT patients [18]. However, the primary closure of the aortic valve precludes any recovery of the left ventricle and rarely induces coronary embolism due to blood stagnation in the aortic root. Mechanical or biological prosthesis have shown poor long-term results due to leaflet blockage (mechanical) or stiffening (biological), and consequent cerebral embolism due to thrombus formation [18]. The risk of cerebral embolism will probably decrease with the introduction of a pump activation algorithm allowing the left ventricle to eject two to six times per minute and making biological aortic valve replacement the best treatment for aortic regurgitation. Even if the aortic valve works properly at the time of LVAD implant, 25 to 52% of patients with a continuous-flow pump develop aortic regurgitation at 1 year owing to the progressive stiffness and fusion of the aortic valve leaflets [19]. Handling of this situation is difficult and could require surgical correction. In order to prevent aortic regurgitation developing, it is reasonable to consider a device-management strategy that promotes the opening of the aortic valve, as recently shown by Inamura et al. [20]. However, randomised data that clearly support the benefits of such a practice are lacking.

Device technology and surgical aspects

The largest international registry on ventricular assist device therapy started in 2006 during the era in which only pulsatile pumps were implanted. These devices had several limitations such as large volume requirements and important surgical trauma, and were prone to device malfunction with the need for reoperation within the first 12 months. Therefore, long-term results were unpromising.

The concept of continuous flow pumps was developed in 1988 with the support of NASA engineers and the first human implant of the Micro Med DeBakey Noon ventricular device was in Germany 10 years later [21]. During the last decade, improvements in pump design resulted in a new generation of LVADs consisting of small, continuous flow, rotary and axial blood pumps that are more reliable and durable. Many devices have been designed and implanted, but only the two illustrated in figures 1 and 2 have shown excellent clinical results and currently cover 80% of worldwide implants.

The continuous flow is generated by a rotor spinning on an axis parallel to blood flow, a so-called axial pump (HeartMate II; Thoratec Corp, Pleasanton, CA), or by a rotor revolving in a bell-like chamber conveying blood by means of centrifugal force (HeartWare HVAD; Heartware Corp, Framingham, MA). Because the flow is continuous there is no need for valves or compensating chambers. Axial and centrifugal pumps both need an inflow cannula placed into the apex of the left ventricle, an outflow cannula sutured to the ascending aorta and a cable piercing the skin for the energy supply. The axial pump produces the same flow as the centrifugal pump at a similar mean pressure of 100 mm Hg, but left ventricular unloading is lower. They both need anticoagulation and antiplatelet treatment in order to reduce thrombus formation. The HVAD is significantly smaller than the HeartMate II and its design better fits the minimal invasive approach. However, the rationale behind device selection depends on the surgeon's experience in implanting either of them since each system has its pitfalls to avoid and, at least in Switzerland, implanting institutions still have too low a case load to implant all devices successfully.

The safest surgical technique requires the establishment of cardiopulmonary bypass, usually through femoral vessels when the minimal invasive approach is chosen. However, some authors propose LVAD implantation without cardiopulmonary bypass even if the procedure is more challenging for the surgeon and more dangerous for the patient [22]. Schmitto first described the minimal invasive approach that gives excellent exposure of the cardiac apex through a left
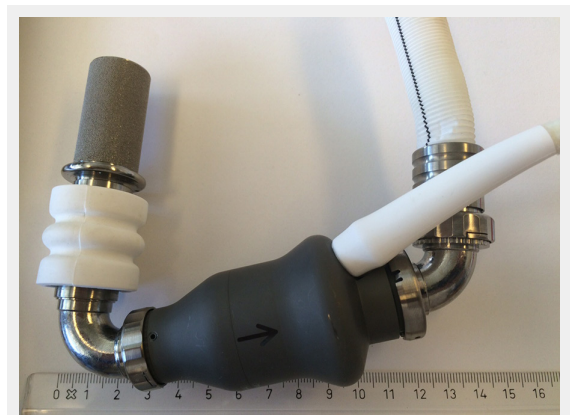

Figure 1

The HeartWare (HeartWare Corporation, Framingham, Massachussetts, USA) device (HVAD) is a centrifugal, continuous flow pump with a wide-blade impeller that is magnetically and hydrodynamically suspended. HVAD pump flow is preload dependent and afterload sensitive with a speed range of 1800–4000 RPM and a maximum outflow of 10 l/min. HVAD weight is 160 g and it fits in a hand.

Figure 2

The HeartMate II (Thoratec Corporation, Pleasanton, California, USA) is a continuous flow axial pump with a magnetically activated impeller. It weighs 400 g and provides up to 10 l/min flow. It is the only ventricular assist device for destination therapy approved by the US Food and Drugs Administration.

anterolateral thoracotomy, associated with mini-upper sternotomy or anterior right thoracotomy for the placement of the outflow cannula (fig. 3) [23]. The new generation devices (HeartMate III and MVAD) are significantly smaller than the former generations and will perfectly match the minimal invasive approach (fig. 4) [24].

Worldwide, here are over 6 000 implants of continuous flow LVADs annually, and over 40% are implanted for DT [25]. The support time has progressively increased to an average length of 3 years, with individual cases exceeding 8 years [25, 26].

Outcomes after left ventricular assist device placement

Outcomes after LVAD placement depend on the era of implant, surgical experience and patient characteristics. The perioperative phase is crucial, with the vast majority of deaths occurring prior to hospital discharge and associated with multiorgan failure, bleeding and acute right ventricular failure [25, 26]. With more patients on long-term continuous flow LVAD support, the research focus has shifted

Figure 3

Surgical technique: the minimal invasive approach. Patient's head is on the right hand side. Left anterior thoracothomy to expose cardiac apex and insert the inflow cannula (A), the mini right anterior thoracotomy to expose the ascending aorta to suture the outflow graft (B) and the point where the driveline pierces the skin (C).

Figure 4

The MVAD (HeartWare Corporation; Framingham, Massachussetts, USA). New generation devices are significantly smaller and lighter than previous generations. They have the possibility to adapt the orientation of the inflow cannula after the insertion to reduce the risk of inflow cannula mis-positioning. From: Cheung A, Chorpenning K, Tamez D, Shambaugh C Jr, Dierlam AEet al. Design concepts and preclinical results of a miniaturized HeartWare platform: The MVAD system. Innovations (Phila). 2015;10(3):151-6.

from survival to morbidity, quality of life and a better comprehension of the altered physiology induced by continuous flow.

Improvements in DT outcomes have come primarily from advances in device technology and not from changes in patient selection. The evolution from pulsatile to continuous-flow pumps has dramatically improved survival [2]. The sixth INTERMACS report showed that, from a total of 10 542 MCS implantations, nearly half of the patients from 2011–2013 (41%) received an LVAD as DT [25]. During the year 2011, 96% of devices implanted were continuous-flow pumps and DT, which accounted for 38% of implants, involved only continuous-flow devices [2]. These new pumps represent a milestone for LVAD therapy, providing much better patient outcomes. The overall actuarial survival among all DT patients was 75% at 1 year and 62% at 2 years, with a freedom from device exchange of 94% at 24 months compared with 51% for pulsatile pumps [2].

In another multicentre study involving 200 transplantation-ineligible patients who received the HeartMate II, the survival rate was 68% at 1 year and 58% at 2 years [13]. Compared with the medical management arm of the REMATCH trial, in which survival was 25% (1 year) and 8% (2 years), the survival benefit of DT appears evident [26].

More recently, the ADVANCE trial has reported 90% survival at 12 months as a bridge to transplantation [27].

A single-centre study demonstrated an almost 3-fold improvement in survival after durable MCS for profile 3 and 4 patients compared with profile 1 and 2 patients (p = 0.05) [28] Profile 6 or 7 patients, who by definition have advanced New York Heart Association (NYHA) class III symptoms, are, in general, considered too well for MCS on the basis of current data. However, a clinical trial is now underway to investigate MCS in this group [29].
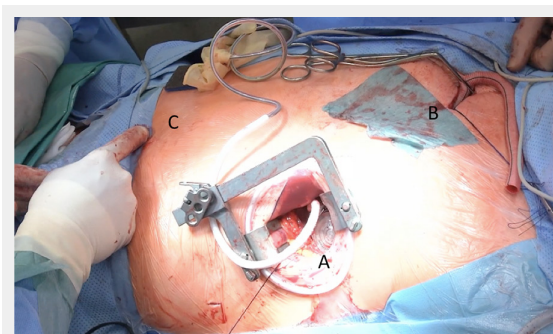
Managing the complications

Continuous flow pumps are not immune to complications, and are associated with specific clinical problems including gastrointestinal bleeding, acquired von Willebrand disease, arteriovenous malformations, haemolysis, pump thrombosis and aortic regurgitation.

Bleeding

Bleeding problems have become more prominent than strokes with the latest devices and occur in 20 to 40% of patients in the first 12 months after implant [30–32]. The propensity for bleeding in patients supported by continuous-flow devices may be driven by acquisition of a von Willebrand syndrome because of the effect of shear forces on the von Willebrand multimer [30]. The molecule is composed of four polymers and continuous flow induces the malformation of multimer 4 rendering the patient coagulopathic. All patients develop this acquired deficiency within a month or two of pump implantation [31]. The bleeding is typically manifest as mucosal bleeding observed primarily from arteriovenous malformations in the gastrointestinal tract.

There is speculation that the decrease in arterial pulsatility contributes to these complications, even though the pathophysiology is still unclear [33]. The latest generation of

continuous-flow pumps takes into account the pulsatility issue, although it is still unknown how much pulsatility is sufficient to normalise vascular response avoiding specific complications. The Heartware HVAD has developed a specific algorithm of pump activation called "Lavare cycle" that allows intermittent aortic valve opening for washing the aortic root [34], even if the systemic pressure has not the physiological pulsatile profile. The new HeartMate III, which is still under investigation, can produce near-physiological pulsatile pressure of about 25 mm Hg, which is a considerable step forward towards physiological pulsatile flow [33]. Almost half of our patients (15 out of 38) experienced some bleeding complications during LAVD support, but only one required surgical resection of bleeding bowel.

Bleeding management includes cessation of anticoagulation and endoscopy with control of bleeding sources. Rarely, resection of the bleeding area is required. Despite its high incidence, the bleeding was responsible for death only in 3% of patients in a long-term study involving the HeartMate II [25, 33].

Pump thrombosis

Anticoagulation and antiplatelet therapy are necessary to prevent thrombus formation within the flow path of any or all of the components that constitute the pump, including the titanium inflow cannula, the outflow graft and the pump housing that contains the rotor. The initial recommendations (FDA study) for the HeartMate II were a prothrombin time international normalised ratio (INR) of 2 to 3 and a full dose of acetylsalicylic acid (ASA), later reduced to an INR of 1.5 and ASA dose 100 mg/day. However this regimen has been associated with a higher incidence of pump thrombosis.

In a recent meta-analysis including 12 studies, Xie et al. reported an overall weighted incidence of device failure of 3.9% (range 1–11.3%) at 1 year and 6.5% at 2 years. Pump thrombosis was the most common cause of device failure (50.5%), followed by lead or cable damage (21.7%), mechanical pump failure (11.6%), device-related infection (11.1%) and surgical complications from implantation (2.5%) [34]. Thrombus formation within the pump should be suspected in cases of increased power consumption without increase in pump flow and isolated lactate dehydrogenase rise above three times the normal value. Echocardiography and computed tomography are the most effective tools to investigate pump thrombosis. If the thrombus is confirmed, heparin is administered to bring the partial thromboplastin time to above 50 sec. Persistent haemolysis, power spikes and/or heart failure symptoms may be addressed with more aggressive antithrombotic therapy with direct thrombin inhibitors, although the only evidence of the effectiveness of these interventions at this time is anecdotal. If haemolysis persists despite aggressive antithrombotic therapy, pump exchange should be considered if the patient is deemed a surgical candidate. We have had three patients suffering from this dreadful complication, two successful received a new pump and one did not survive thrombolytic agent (tissue plasminogen activator) administration.

Driveline infection

The "Achilles heel" of current VADs is the driveline piercing the skin at the level of the abdominal wall (fig. 5). Patients are given instructions on how to handle the wound with sterile technique; however, infection of the driveline is frequent and the longer the implant, the higher is the infection rate. The prevalence rate of driveline infections is 23% at 1 year and 35% at 2 years when the velour coating is used. The use of silicon coating for the cable piercing the skin seems effective in reducing the incidence of driveline infection by 50% [35].

When infection sets in, aggressive antibiotic treatment is necessary in combination with surgical debridement and use of vacuum assisted closure dressing in order to avoid pump infection. The risk that the driveline infection could spread to the pump is very low. If this dreadful complication should occur, the pump needs to be changed. This occurs in less than 3% of patients [36]. The surgical procedure is technically demanding and is associated with high mortality and morbidity rates.

The technology for solving the driveline infection problem exists and is called transcutaneous energy transfer (TET). It was first used with the LyonHeart system (Arrows Inc.) almost 20 years ago. Over time this technology has become more efficient and reliable and we believe in the near future all devices will be equipped with TET systems, improving also patients' comfort.

The physician in charge of MCS therapy should have a dedicated profile and we definitely need to create a dedicated subspecialty in cardiology and cardiac surgery to clearly define the profile of the heart failure specialist.

Conclusions

DT is evolving into an effective and reasonably cost-effective treatment option for the growing population of patients not eligible for heart transplantation, showing encouraging survival rates at 2 years and providing clear improvement in quality of life. The most important predictor of positive outcome is proper patient selection, which requires comprehensive assessment of the indication and contraindications, risk factors and of right ventricular failure, as well as optimal surgical timing. As suggested by Miller et al. [37], we should abandon the approach based on preimplant de-
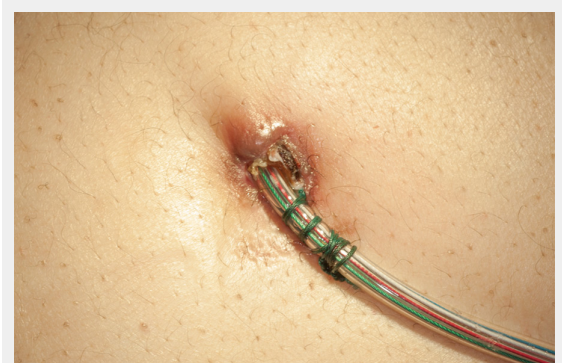

Figure 5

Driveline pierces the skin. This area is at high infection risk even if appropriate care is given.

termination of whether a ventricular assist device for a given patient is a bridge to transplant or recovery or destination therapy. In the future, we will establish that a patient is in need of mechanical circulatory support, based on the presence of indications and absence of contraindications, and leave the question of duration of the support open depending on clinical evolution and organ availability. The clinical results at 5 and 10 years associated with DT could be so exceptionally good as to prove the noninferiority of ventricular assist device therapy compared with heart transplantation. The future is bright for people suffering from chronic heart failure.

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Figures (large format)

Figure 1

The HeartWare (HeartWare Corporation, Framingham, Massachussetts, USA) device (HVAD) is a centrifugal, continuous flow pump with a wide-blade impeller that is magnetically and hydrodynamically suspended. HVAD pump flow is preload dependent and afterload sensitive with a speed range of 1800–4000 RPM and a maximum outflow of 10 l/min. HVAD weight is 160 g and it fits in a hand.
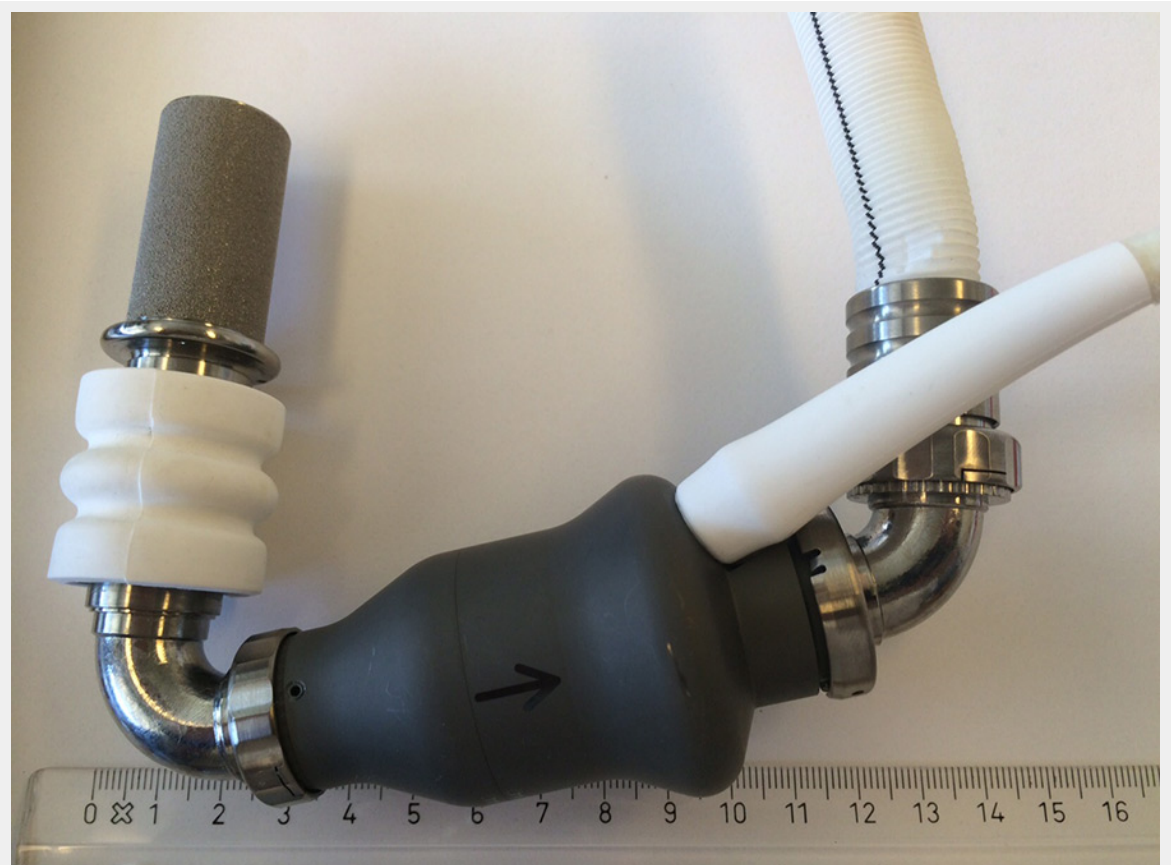
Figure 2

The HeartMate II (Thoratec Corporation, Pleasanton, California, USA) is a continuous flow axial pump with a magnetically activated impeller. It weighs 400 g and provides up to 10 l/min flow. It is the only ventricular assist device for destination therapy approved by the US Food and Drugs Administration.
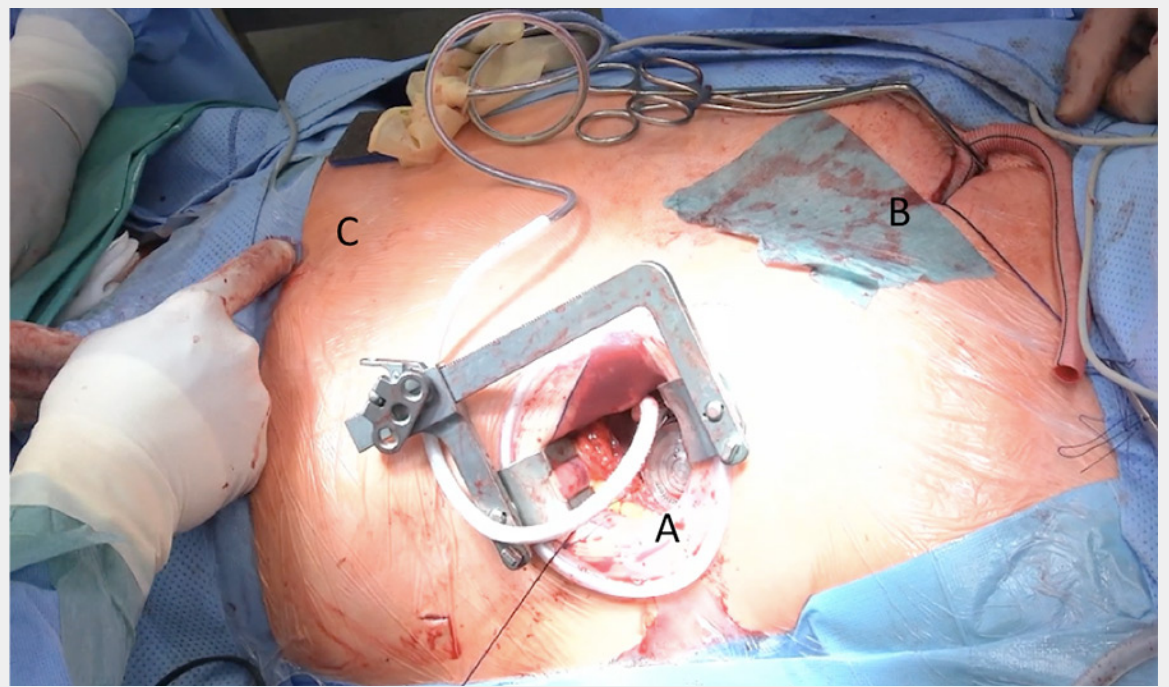
Figure 3

Surgical technique: the minimal invasive approach. Patient's head is on the right hand side. Left anterior thoracothomy to expose cardiac apex and insert the inflow cannula (A), the mini right anterior thoracotomy to expose the ascending aorta to suture the outflow graft (B) and the point where the driveline pierces the skin (C).

Figure 4

The MVAD (HeartWare Corporation; Framingham, Massachussetts, USA). New generation devices are significantly smaller and lighter than previous generations. They have the possibility to adapt the orientation of the inflow cannula after the insertion to reduce the risk of inflow cannula mis-positioning.
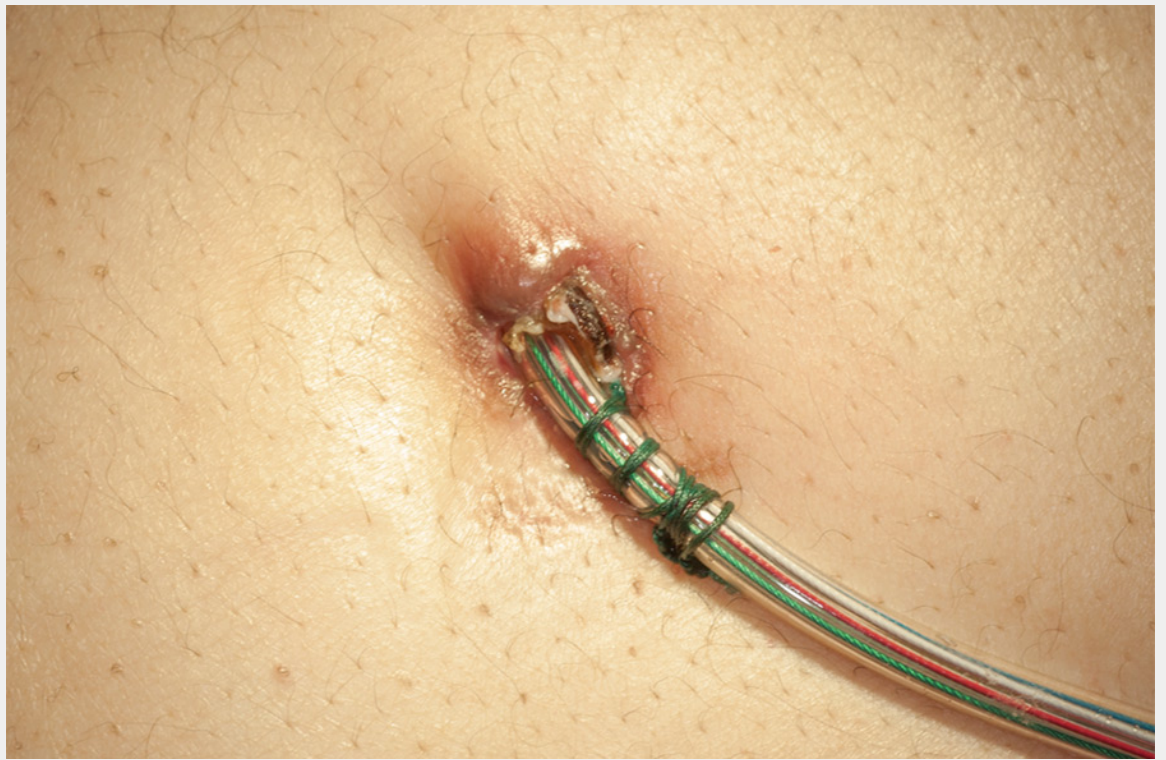
Figure 5

Driveline pierces the skin. This area is at high infection risk even if appropriate care is given.