

TAKE THE BEST – HOW TO CHOOSE THE RIGHT DEVICE?

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Summary

An increasing number of patients suffering from end-stage heart failure require VAD implantation as either a bridge-to-transplantation or destination therapy. The choice of the right device depends upon the medical urgency; the need of uni- or biventricular support; the duration of support expected; and the institutional availability. Patients with multi-organ failure and unclear neurological situation can be supported with rotary pumps/ECMO first, and in case of recovery, a paracorporeal system can be connected to the previously implanted cannulas. In stable patients qualifying for left ventricular support, an intracorporeal system of the second generation can be implanted, allowing freedom of movement for 6-8 hours before recharging becomes necessary, and support intervals exceeding 1 year. Restrictions are given by the need of high-dose anticoagulation and a certain complication rate, especially in the first 3 months (bleeding, thromboembolism, infection, mechanical failure). The survival rate after the primary LVAD implantation is 74 % after 12 months and 55 % after 24 months; this is significantly better than the survival rate after RVAD, BVAD or TAH.

Keywords: cardiac failure; mechanical assist device; heart transplantation

Considering cardiac support, the selection of the best device for individual patients in their particular situations is a major challenge, besides technical issues and postoperative management. This is especially the case if long-term support is required. The patients' outcome after the implantation of a ventricular assist device (VAD) is affected by their health status, including medical urgency, the need for inotropes, the extending of end-organ failure, the right ventricle function, coagulation disorders, the suspicion of infection, severe myocardial necrosis, and previous cardiac surgery. Elective patients suffering from chronic heart failure without myocar-

dial necrosis, with no or low-dose inotropic support and intact end-organ function, are at low risk. Patients in acute low cardiac output following myocardial infarction, resuscitation or cardiac surgery, requiring high doses of inotropes and with imminent multi-organ failure (MOF) are exposed to high risk after a VAD implantation. One of the most critical factors for implant success, however, is the age. According to Deng et al. (J Heart Lung Transplantation 2005), 41 % of patients \leq 65 years were still alive 12 months after a VAD implantation, while 20 % had undergone heart transplantation. In contrast, the one-year survival rate of VAD patients $>$ 65 years was only 26 %, and none of these patients had a transplant option.

Nowadays, a variety of VADs are commercially available. They are categorized into extra-/ paracorporeal devices (ECMO, Excor, ThoratecPVAD, Medos, Abiomed), intracorporeal systems and fully implantable total artificial hearts (Cardiowest TAH). The intracorporeal systems of the first generation were large displacement pumps (Novacor, Heartmate I), followed by the second-generation impeller pumps (Incor, Heartmate II, DeBakey LVAD, Jarvik Heart). The centrifugal technique (Heartware, Terumo, Coraid) is yet to be established on the market.

For device selection, several issues have to be considered. In many institutions, the costs determine the availability and the spectrum of mechanical support systems. A special expertise with one or the other device improves the results, but also influences the support strategies. Eventually, the device selection is based on the clinical setting to optimise the resources. Most patients are provided with a left-ventricular assist device (LVAD). Due to the inability of the current allocation system to provide donor hearts in time, and the consequently longer waiting periods, there is a clear trend towards the use of implantable systems. In the US, the Heartmate II device has the most widespread use, whereas in Europe and Asia, the BerlinHeart Incor is equally favoured. It may well be that all miniaturized LVADs serve the same purpose alike, provided that the implant team has the necessary expertise. The impeller devices have a low weight, allowing 5,000-10,000 rotations per minute, and generate the pump flow up to 6 l/minute. The INCOR system operates without any mechanical contact and ensures a wear-free long-term support for patients with terminal heart failure. A driveline is connected to a double-battery power pack, allowing the system to operate for 6-8 hours before recharging becomes necessary. During the past years, the number of implantations has dramatically increased, and the support intervals exceeding one year are no longer an exception.

Paracorporeal devices were primarily designed for biventricular use, i.e. for combined left and right heart failure. In fact, there is still no implantable biventricular rotary pump available today. Another suitable indication for paracorporeal systems are patients with multi-organ failure, as they demand higher pump flows than

urgent cases. A third indication is a borderline patient with a high risk of failure, who compromises the clinical budgets. Especially for the latter cases, new strategies have been developed to optimise the financial resources. Patients presenting with unclear neurology in an emergency situation are placed on ECMO first, for a short-term support as a bridge-to-decision. If recovery from MOF is doubtful but the patient is awake, two rotary pumps may be used as well. After the stabilisation of end-organ function, the rotary pumps/ECMO are converted to a biventricular assist device (BVAD). To simplify the conversion, we recommend the use of four implantable cannulas (right atrium / pulmonary artery; left ventricular apex / aorta) during the initial procedure. Later, the BVAD can easily – under mild sedation – be connected on ICU. The main problem associated with a paracorporeal device is its suitability for short- and medium-term support only, as well as the risk of ascending conduit infection.

Apart from multi-organ failure (MOF), the main early complications include bleeding and right heart failure (in case of an LVAD placement), thromboembolism occurs mid-term, and infection usually later. Therefore, meticulous surgical hemostasis during surgery is mandatory. After the cessation of cardiopulmonary bypass, heparin is completely antagonised and restarted only after 6-24 hours, if there is no evidence of bleeding (PTT ~ 60-80 seconds). Aspirin is added after the normalisation of platelet function, and the daily dosage is adjusted (100-200 mg max.) to the results of aggregometry. For hospital discharge, the patient is placed on warfarin (INR 2.0-4.0). In cases of aspirin resistance or embolic events under aspirin medication, clopidogrel or dipyridamol is added to achieve the adequate inhibition of the platelet function.

If severe right heart failure is present, the use of two paracorporeal pumps is recommended. After the LVAD implantation, right ventricular failure is responsible for approximately 30 % of early deaths. In cases with only mild to moderate right heart insufficiency, pharmacological intervention is sufficient. After the implantation, the LVAD flow should be increased gradually to avoid the right ventricular overload. Additionally, the right ventricle can be stimulated by inotropes, and pulmonary vascular resistance can be lowered specifically by the systemic application of PDE-5-inhibitors, prostaglandins and nitrates and/or by the inhalative application of prostaglandins and nitric oxide. A temporary support with a centrifugal pump is possible, too; however, it hinders patient mobilization.

The occurrence of neurological events depends on a patient's condition, the anticoagulation regime, and the VAD system. The average risk varies between 5 and 30 %, and it is highest during the first three months. However, asymptomatic thromboembolism is not infrequent, predominantly in the liver, spleen and kidney.

VAD-related infection is a major limitation of the long-term support, and it is responsible for approximately 20 % of the deaths after the first month after the LVAD implantation. Besides the highly aseptic surgery, daily careful wound dressing of the cannulas and driveline ports is mandatory. A proper fixation of the driveline closely to the skin outlet facilitates the healing and prevents the driveline infection as well. In case of an infection, the early onset of antibiotic therapy, as well surgical wound care, are imperative. In rare cases, an exchange of the VAD system or urgent heart transplantation remains the only option.

Results with VADs strongly depend on patient selection. Accordingly, a careful and individualized patient and VAD selection improve the results and lower the costs. The overall outcome data are best documented in the US INTERMACS Registry. From June 2006 to March 2009, a total of 1,092 patients on LVAD were reported there. The survival rate after the primary LVAD implantation was 74 % after 12 months and 55 % after 24 months (event death, censored at transplant or recovery). These are significantly better results than with the survival after the RVAD, BVAD or TAH (six-month survival rate of approximately 50 % in all instances). The following problems/complications after the VAD implantation were reported: major bleeding events; thromboembolism; infection; right ventricular failure on LVAD; persistent ventricular fibrillation on LVAD; and inadequate mobilisation possibility of the patient.

In conclusion: with the current VAD systems, good results may be obtained with a low complication rate and a high quality of life during support. The implantable and miniaturised VAD systems allow for increasing the support intervals and paving the way for destination therapy.

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Sažetak

Najbolji izbor – kako izabrati odgovarajući uređaj?

Sve veći broj pacijenata u terminalnoj fazi zatajivanja srca zahtijevaju ugradnju mehaničke potpore srcu i cirkulaciji, kao premoštenje do transplantacije srca ili kao destinacijska terapija. Odabir odgovarajućeg uređaja ovisi o kliničkom stanju pacijenta, potrebi za jednostrukom ili dvostrukom ventrikularnom potporom, očekivanom trajanju ugrađene potpore i mogućnostima institucije. Pacijentima s multi organskim zatajenjem i nejasnim neurološkim smetnjama može se prvo ugraditi rotacijska pumpa/ECMO, te u slučaju oporavka, parakorporalni uređaj može biti povezan s ranije implantiranim kanilama. Kod stabilnih pacijenata, predodređenih za ugradnju potpore lijevom ventriklu, moguće je ugraditi intrakorporalni uređaj druge generacije, koji dozvoljava slobodno kretanje 6-8 sati do punjenja baterija i podupire intervale preko jedne godine. Ograničenja nastaju zbog potrebe za visokim dozama antikoagulacijske terapije i pojave određenih komplikacija, posebno u prva tri mjeseca nakon implantacije (krvarenje, tromboembolija, infekcija, mehaničke nepravilnosti). Stopa preživljenja 12 mjeseci nakon ugradnje LVAD-a je 74% i 55% nakon 24 mjeseca što je značajno bolje nego preživljenje nakon ugradnje RVAD, BVAD or TAH.

Ključne riječi: zatajivanje srca; mehanička potpora srcu; transplantacija srca