Review Article

Permanent Implantable Cardiac Support Systems

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Summary

Background: Nearly 1000 permanent ventricular assist devices (VADs) are implanted in patients with severe congestive heart failure in Germany each year. VADs are miniaturized centrifugal pumps that generate continuous blood flow; they are powered and controlled through a cable that passes through the skin. Paracorporeal systems are only rarely implanted, usually in children.

Methods: In this selective review of the literature, including guidelines and registry data, we discuss the indications, therapeutic effects, and complications of permanently implantable cardiac support systems.

Results: The optimal time for VAD implantation cannot be precisely defined. A comparative assessment of the various available systems is not possible, as no randomized trials have been performed on this topic. Registry data indicate that 69% to 81% of patients survive one year after VAD implantation, which is significantly better than the natural course of (conservatively treated) severe congestive heart failure. The distance patients are able to walk is 129 to 220 m longer at six months, depending on the system implanted. Scores on the EQ-5D health status questionnaire are 28 to 37 points better at six months. The potential severe complications include infection, right-heart failure, hemorrhage, pump thrombosis, stroke, and death.

Conclusion: A VAD system can be implanted as an alternative to cardiac transplantation or as a bridging treatment until the patient can be listed for transplantation and receive the transplant. Because of the organ shortage in Germany, only a minority of VAD patients ever receive a transplant.

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The prevalence of advanced heart failure will continue to increase due to demographic trends and better survival rates for persons with cardiac disease. In Germany, the number of hospital admissions for advanced heart failure continues to steadily increase, especially among people over 65 years of age. Nonetheless, there is a marked reduction in the rate of death due to advanced heart failure, from 63.7 per 100 000 inhabitants in 2006, to 42.8 in 2016. This is especially due to the improved treatment options (1, 2), for which permanent mechanical circulatory support also plays a role.

Taking into account current guidelines, registries, and clinical studies, the following provides an overview of the current reality of care of permanent-use implantable mechanical circulatory support systems.

Permanent implantable systems of mechanical circulatory support

The development of mechanical circulatory support (MCS), from the first fully implantable artificial heart system up to advanced ventricular assist devices (VAD), addresses aspects such as pump size, biocompatibility, durability, effectiveness, and susceptibility to infection (3). Modern VADs generate continuous flow (CF) of blood, and patients who received an implant benefit from improved functional status and higher quality of life. One-year survival after left-ventricle assist device (LVAD) implantation improved to over 80% (68% to 81%), which is better compared to the early pulsatile systems (4, 5). Mortality with the current system is primarily due to treatment-related adverse events.

Currently, centrifugal CF pumps for left ventricular support are the primary ones implanted. The first system of this type was the HeartWare ventricular assist device (HVAD). The more recent HeartMate 3 has a fully magnetically levitated vane rotor (6, 7).

Biventricular MCS

The paracorporeal EXCOR from Berlin Heart GmbH is the clinically most widely used and approved system for biventricular support. This extracorporeal displacement pump is approved for both left-, right-, and biventricular support. It is the only system available for pediatric use (8, 9).

Clinically, two CF-LVAD systems have been implanted for biventricular support (10); however, these

TABLE 1

INTERMACS profiles for classification of end-stage heart failure patients (1)

1.	**Cardiogenic shock ("crash and burn")** NYHA class: IV System: ECLS, ECMO, percutaneous MCS One-year survival: 52.6 ± 5.6%
2.	**Progressive decline despite inotrope ("sliding on inotropes")** NYHA class: IV System: ECLS, ECMO, LVAD One-year survival: 63.1 ± 3.1%
3.	**Stable but inotrope dependent ("dependent stability")** NYHA class: IV System: LVAD One-year survival: 78.4 ± 2.5%
4.	**Resting symptoms ("frequent flyer")** NYHA class: IV ambulatory System: LVAD One-year survival: 78.7 ± 3.0%
5.	**Exertion intolerant ("housebound")** NYHA class: IV ambulatory System: LVAD One-year survival: 93.0 ± 3.9% *
6.	**Exertion limited ("walking wounded")** NYHA class: III System: LVAD/LVAD can be discussed as therapy option
7.	**Placeholder** NYHA class: IV System: LVAD/LVAD can be discussed as therapy option

ECLS, extracorporeal life support; ECMO, extracorporeal membrane oxygenation; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; LVAD, left ventricular assist device; MCS, mechanical circulatory support; NYHA, New York Heart Association

* Kaplan–Meier rate of overall survival ± standard error for one-year survival with LVAD therapy. Patients were censored at the time of the last contact, recovery, or heart transplant. Due to the small numbers of patients, the results for patients with INTERMACS profiles 5, 6, or 7 were combined (1).

devices are not approved for either sole or additional right ventricular support.

The Syncardia Total Artificial Heart (TAH) can be used as a full-heart replacement in selected patients. The pulsatile pneumatic displacement pumps replace both chambers of the heart. Due to the relatively low number of cases, the experience of the center plays a decisive role in patient survival (11).

Although not yet approved or tested in clinical trials, the Carmat TAH could represent a major evolution in TAH technology through an imitation of autoregulation by variable filling pressure (12). The goal of developing a fully implantable, biocompatible TAH with physiological modulation of cardiac output and transcutaneous energy transfer, has not yet been reached.

Indications for VAD/TAH implantation

The optimal time to implant a VAD/TAH for permanent MCS is not clearly defined by clinical parameters. In a multicenter trial, the German Center for Cardiovascular Research (DZHK, *Deutsches Zentrum für Herz- und Kreislaufforschung*) is currently comparing the results of early, more elective implantation versus emergency VAD implantation for patients on the heart transplantation waiting list (13). VAD/TAH therapy is efficacious in patients with end-stage heart failure with impaired pumping function (heart failure with reduced ejection fraction, [HFrEF], EF ≤ 25%) and inotropic dependence or permanent New York Heart Association (NYNHA) stage IIIb–IV with optimized drug therapy (14). A reduced maximum oxygen uptake of less than 12 mL/kg/min is a possible indicator. The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) and the European Registry for Patients with Mechanical Circulatory Support (EUROMACS) stratify heart failure patients in seven stages that help evaluate VAD/TAH therapy (*Table 1*).

- According to the European Society of Cardiology (ESC) guidelines for the diagnosis and treatment of heart failure, VAD / TAH therapy can be considered as a bridge to transplantation (BTT) indication in HFrEF patients under optimal drug therapy in order to improve symptoms, avoid hospitalization, and reduce risk of sudden cardiac death (Class IIa recommendation, evidence level C) (1).
- A VAD/TAH therapy can be evaluated to reduce mortality risk in HFrEF patients who are not eligible for heart transplantation (alternative to transplantation [ATT] / destination therapy [DT]; IIa, evidence level B).
- In individual cases, for example for patients with myocarditis, the indication strategy can be retrospectively formulated as "bridge to recovery" (BTR) if the support system can be explanted again after recovery of the ventricular function.
- Some severe heart failure patients with mitral valve regurgitation do not seem to benefit from valve intervention, such that mechanical circulatory support should also be evaluated for prognostic reasons (15).

Importance of heart transplantation

Due to the dramatic lack of organs in Germany, a planned heart transplantation after VAD/TAH implantation in the BTC/BTT indication (BTC, "bridge to candidacy") is an almost theoretical treatment goal, and many patients with VAD support never leave the waiting list. The almost 1000 VAD/TAH implantations in Germany each year are now performed based on an ATT/DT indication. The European Association for Cardio-Thoracic Surgery (EACTS) has agreed not to differentiate between the different strategies, but speaks in general of permanent support (14).

Patient evaluation

In general, VAD/TAH therapy requires a multidisciplinary approach, preferably at experienced transplant centers. Early presentation allows a possible

TABLE 2

Currently used systems for permanent mechanical circulatory support

System	One-/two-year survival*1	Functional status/life quality*2	Relevant complications (%) after six months/two years
HeartWare HVAD (HeartWare ventricular assist device) (6, 23)	86%/60%	+129/+28	Gastrointestinal bleeding 11.4/35.1 Ischemic or hemorrhagic stroke 9.6/29.7 Driveline infection 12.1/19.6 Right heart failure 32.4/38.5 Pump thrombosis with system exchange 2.1/6.4
HeartMate 3 (7, 25)	84% / 75%	+220 m/+37	Gastrointestinal bleeding 6.1/24.5 Ischemic or hemorrhagic stroke 7.6/10.9 Driveline infection 11.7/23.8 Right heart failure 14.7/31.7 Pump thrombosis with system exchange 0/1.4
Berlin Heart GmbH EXCOR (9)	92%/–	–/–	Gastrointestinal bleeding 0/– Ischemic or hemorrhagic stroke 25/– Driveline infection 25/–
Syncardia TAH (total artificial heart) (11)	53%/34%	–/–	Gastrointestinal bleeding 20.0/– Ischemic or hemorrhagic stroke 22.7/–

*1 Study data and/or registry data with different inclusion criteria and data evaluations

*2 Functional status/quality of life are reported as the mean improvement in the six-minute walk test/EQ-5D visual analogue scale six months after implantation compared to baseline.

–, no reliable study or registry evaluation available. System-specific register data is only available for the SynCardia TAH and the HeartMate 3. Evidence of the studies: (6) randomized multicenter study, 297 patients; (23) non-randomized multicenter study, 140 patients; (7) randomized multicenter study, 190 patients; (25) registry investigation, 544 patients; (9) post market study, 12 patients; (11) Registry investigation, 450 patients

listing for primary heart transplantation, VAD/TAH therapy, or an initially outpatient visit together to be planned with the patient and ideally with the supervising physicians. The continuous involvement of the various disciplines goes far beyond the perioperative time frame into the close-knit and usually lifelong outpatient care. Optimum care requires round the clock availability of specialized cardiologists, surgeons, psychologists, technicians, and physiotherapists. Last but not least, long-term psychological care must be available for the entire social environment of patients (16, 17).

Results of VAD/TAH therapy

General aspects

The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) study in 2001 showed for the first time that implantation of a pulsatile LVAD in end-stage heart failure patients had a significant survival benefit (52% versus 25% one-year survival) and improved quality of life versus optimized drug therapy (18). In a non-controlled, prospective multicenter trial, patients on the heart transplant waiting list were treated with the then more advanced Heartmate II, a CF axial pump. These LVAD patients showed improved resilience (walking distance 250 ± 232 m after three months) and quality of life (5) during the six-minute walk test. Another milestone was the ROADMAP study, a prospective, non-randomized observational study with 200 ambulatory heart failure patients in NYHA stage IIIb/IV. The results of LVAD versus optimized drug therapy (ODT) were compared (19). One- and two-year survival rates with improved functional status in patients undergoing original therapy were better after LVAD implantation. The intention-to-treat analysis showed comparable survival, as 22% of ODT patients received LVAD during the study. Depending on the right heart function, LVAD therapy achieves a measurable improvement in clinical resilience and quality of life that is superior to ODT as early as three months after implantation.

The clinical status of a patient has a significant influence on the results after VAD/TAH implantation (*Table 1*), regardless of implantation strategy (1, 4). The current INTERMACS registry data generally show a one-year survival after LVAD implantation of 81% (20). The EUROMACS register has documented a one-year survival rate of 69% (21). To date, different calculation models can only attempt to predict the individual risk, such as the Heartmate II Risk Score, the Destination Therapy Risk Score, and the non-LVAD-specific Seattle Heart Failure Model (22).

System-specific treatment results

Left or right ventricular support

A comparative assessment of the systems is hardly possible as there are no reliable randomized studies in the field of VAD/TAH therapy. Some specific characteristics of VAD/TAH therapy systems currently used in Germany are summarized in *Table 2*.

The non-randomized multicenter study ADVANCE investigated the results of LVAD therapy for BTT indication and demonstrated non-inferiority of the intrapericardial implantable HV centrifugal pump HVAD as compared to current systems (23). ADVANCE showed a one-year survival rate of 86%

after HVAD implantation and marked improvements in functional capacity and quality of life. The HVAD received FDA approval for the 2012 BTT indication and was evaluated in the manufacturer-sponsored randomized, multicenter ENDURANCE study that compared it to the standard LVAD, the Heartmate II CF axial pump, for DT indication (6). This revealed that the smaller HVAD was not inferior after two years with regard to survival free from strokes or pump changes (55% versus 57%). Less frequently, device malfunctions led to surgical intervention (8.8% versus 16.2%). However, the HVAD study showed higher rates of stroke (29.7% versus 12.1%), right heart failure (38.5% versus 36.8%), and sepsis (23.6% versus 15.4%). The one-arm, multicenter LATERAL study confirms that HVAD implantation shows good results as compared to a less invasive anterolateral thoracotomy (24).

For the HeartMate 3, the randomized multicenter study MOMENTUM 3 showed a good one- and two-year survival rate free of severe adverse effects of 84% and almost 78%, respectively. In comparison, this was approximately 74% and 56% in the control group of patients with the older HeartMate II (7). After 2 years, none of the HeartMate 3 patients had had to change the system due to pump thrombosis, probably due to the modern pump design; in contrast, 12.2% of control patients had changed. The care reality of the European registry data likewise attests to the HeartMate 3's high reliability, almost thrombosis-free, low stroke rates, and improved functional capacity and quality of life (25) (*Table 2*). There is currently no direct randomized comparison between HeartMate 3 and HVAD.

Biventricular support

In general, the indication for implantation of permanent, biventricular support (BVAD or TAH) is rarely provided. Reliable study results for the individual systems approved and used in Germany (Berlin Heart EXCOR, SynCardia TAH) are not available (*Table 2*). Survival with a BVAD is, according to registry data, clearly limited at just 50% after one year (20). The results contradict the basic idea of biventricular support, of giving complete relief of the heart and efficient end-organ perfusion. When considering the sobering survival data after BVAD/TAH implantation, however, the particular severity of advanced biventricular heart failure of these especially ill patients must be considered. Perhaps the previous biventricular support systems are being used too reluctantly.

Adverse events

Severe adverse events of permanent MCS include infections, bleeding (gastrointestinal), pump thrombosis, stroke, or death following LVAD implantation (3, 20, 22). In general, the adverse events rates are highest in the early phase after VAD/TAH implantation and decrease after about 30 days (*Table 2*).

Right heart failure

Right heart failure in particular can complicate the early postoperative course following LVAD implantation. In addition, the INTERMACS data for LVAD patients with preoperative, secondary organ dysfunction also show a significantly higher morbidity and mortality in the long-term after implantation (20). The need to implant an additional right ventricular assist device (RVAD) at the same time or in the course of severe right heart failure depends on the INTERMACS status at the time of LVAD implantation. So far, there is no prospective predictive indicator of perioperative right heart failure. Thus, it remains unclear which patient benefits from direct care with a permanent BVAD system. Also in the centers of the authors, isolated LVAD implantation is the first and foremost aim of clinical practice (22). If peri-procedural right heart failure occurs, an extracorporeal centrifugal pump with or without an oxygenator is usually used as a temporary RVAD. With this bridging until a possible recovery of right heart function, patients have the opportunity to be discharged to outpatient care with pure LVAD support. Whether this concept provides the same long-term results as the sole and straightforward LVAD implantation offers remains unclear. However, if weaning from a temporary RVAD is not possible, either a two-state implantation of a permanent RVAD system, the implantation of the so-called total artificial heart (TAH), or an urgent heart transplantation can be sought.

Pump thrombosis

Thrombosis of a VAD system is a serious adverse effect requiring either systemic thrombolysis or system replacement. The latter is technically possible, but survival after VAD exchange is significantly reduced as compared to after the primary implantation (20). Pump thrombosis has been extensively studied in HeartMate-II patients, and comparable rates of 4% within the first six months after implantation have also been documented in the ADVANCE study for the HVAD (6, 23). The risk of developing a thrombosis is increased with high body mass index, non-compliance, right heart failure, and infection. Changing the pump to the HeartMate 3 can be done in case of pump thrombosis or recurrence. Systemic changes due to pump thrombosis did not occur with the HeartMate 3 in the available studies (7).

Bleeding

Bleeding adverse events, which are primarily gastrointestinal, are a particular risk factor for mortality after LVAD implantation (3, 20, 22). Severe bleeding can occur in up to 23% (20% to 26%) of patients and can recur in up to 9.3% (7.1% to 12%). It is not yet known why VAD systems with continuous blood flow favor the occurrence of arterio-venous malformations and hemorrhages. An artificial pulse mode, such as in HeartMate 3, does not seem to favorably affect the rate of bleeding adverse events (7). The use of CF systems

is also associated with the development of acquired von Willebrand syndrome (26).

In Germany, anticoagulation therapy of patients with a VAD/TAH usually uses the vitamin K antagonist phenprocoumon. New oral anticoagulants (NOAC) are not approved. The therapeutic target range is an international normalized ratio (INR) of 2.0–3.0. Self-determination of INR in the home environment achieves an effective therapeutic setting in 70% (45% to 90%) of the patients (27).

Infections

Systemic infections are a common adverse event in VAD patients. These are often caused by ascending and (at the beginning) mostly staphylococcus-dominated driveline infections. Reported incidence rates vary between 13% and 80%, depending on the definition (6, 7, 20). In addition to an ascending infection that is transcutaneous, germs can also colonize a VAD system via the bloodstream as a systemic endocarditis. It is difficult to diagnose a systemic infection as positive blood culture cannot be proven, echocardiography due to artifacts is not reliable, and positron emission tomography combined with computed tomography (PET-CT) can often be false-positive. If antibiotic therapy is not effective, a system change may be necessary or an urgent heart transplant may be sought. Indication for heart transplantation must, however, regularly be critically examined with respect to the comparative usefulness of the to-be-transplanted organ.

Cerebrovascular adverse events

The risk of cerebral adverse events—that is, stroke or bleeding—is up to 20% in the first two years after implantation of an LVAD system, depending on the underlying definition used (7, 20). Clinical manifestations range from a transient ischemic attack to a life-threatening stroke or hemorrhage. Onset is favored by a previous neurological adverse event, hyponatraemia, low albumin, increased right atrial pressure, atrial fibrillation, infection, and variations in anticoagulation (28). The INTERMACS status at the time of implantation of a VAD/TAH has no causal relation to the occurrence of neurological adverse events (20).

Malfunction of the system

About 50% of patients with a permanent circulatory support system experience equipment malfunction within the first year that is not due to thrombosis of the system (22). However, considering that the reported one-year survival after VAD/TAH implantation is approximately 70% to 80%, such device malfunctions only marginally affect morbidity and mortality. Malfunctioning of the extracorporeal system components can often be easily controlled and rarely requires an operative system change.

Conflict of interest statement
Prof. Jan Gummert has received consulting honoraria and travel expense reimbursement from Medtronic, as well as speaker honoraria and travel expense reimbursement from Abbott.

Key messages

- Permanent implantable ventricular assist devices (VADs) are now an important and established treatment as an alternative to heart transplantation for end-stage advanced heart failure.
- Permanent therapy with mechanical circulatory support requires a multidisciplinary approach, preferably at an experienced center with an active heart transplantation program.
- The implantation strategy may be used in some cases as a bridge for listing and heart transplantation, but it is more frequently used as an alternative to transplantation.
- Advanced heart failure patients experience a significant improvement in functional status and quality of life after implantation of a VAD system.
- Decision-making about VAD implantation should take into consideration the natural course of advanced heart failure, the expected improvement in quality of life and functional status, the rate of overall survival, and the incidence of system-associated adverse events.

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Prof. Axel Haverich declares that no conflict of interests exists.

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