

The role of ventricular assist device in the management of advanced heart failure: a literature review

El papel del dispositivo de asistencia ventricular en el tratamiento de la insuficiencia cardíaca avanzada: una revisión de la literatura

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ABSTRACT

The ventricular assist device has become a reliable and enduring therapy for patients with end-stage heart failure, with over 22,000 implantations to date. Initially designed as a bridge-to-transplant option but now it has become permanent cure for patients with acute heart failure. VAD has significant advancements in medical management and technology, particularly with the introduction of newer-generation devices, have greatly enhanced patient outcomes. This progress has led to an increasing use of ventricular assist devices as a destination therapy. Nonetheless, the substantial burden of adverse events remains a critical challenge in the current state of ventricular assist device therapy, despite this, its viable alternative of heart transplantation as it has solved the complications of donor heart and proved significant success among patient with acute heart failure.

Key words: Ventricular Assist Device. Advanced Heart Failure. End-Stage Heart Failure. Permanent Cure. Destination Therapy. Surgery. Patient Outcomes.

RESUMEN

El dispositivo de asistencia ventricular se ha convertido en una terapia fiable y duradera para pacientes con insuficiencia cardíaca terminal, con más de 22.000 implantes hasta la fecha. Inicialmente diseñado como una opción puente hacia el trasplante, ahora se ha convertido en una cura permanente para los pacientes con insuficiencia cardíaca aguda. Los avances significativos en la gestión médica y la tecnología de VAD, particularmente con la introducción de dispositivos de nueva generación, han mejorado enormemente los resultados de los pacientes. Este progreso ha llevado a un uso cada vez mayor de dispositivos de asistencia ventricular como terapia de destino. No obstante, la carga sustancial de eventos adversos sigue siendo un desafío crítico en el estado actual de la terapia con dispositivos de asistencia ventricular, a pesar de esto, su alternativa viable al trasplante de corazón, ya que ha resuelto las complicaciones del corazón de un donante y ha proporcionado un éxito significativo entre los pacientes con insuficiencia cardíaca aguda.

Palabras clave: Dispositivo de asistencia ventricular. Insuficiencia cardíaca avanzada. Insuficiencia cardíaca terminal. Cura Permanente. Terapia de destino. Cirugía. Resultados del paciente.

INTRODUCTION

Advanced heart failure means chronic heart disease progression. Heart failure is a leading cause of death among American citizens and it affects over 6 million people in the United States; of which 10% has advanced heart failure that cannot be treated with standard therapies and symptom management. The use of mechanical circulatory support system _the ventricular assist devices (VADs) are shown through research to be a safe and effective treatment option for end-stage heart failure (HF) patients who do not respond other medical therapies. However, there are several issues that continue to affect the patients such as infection risk, thromboembolism, bleeding, device malfunctioning, driveline complications, limited mobility, high costs infection, still VADs have shown significant success in cardiology.

A VAD is a type of mechanical pump used to treat heart failure often at stage 4 in individuals who have badly weakened hearts or heart failure. Generally, survival rate for those who underdo VAD implantation vary and depends on patients characteristics such as age, physical health, or severity of disease, and other factors but trials proved 1-year survival

rate of 81% and a 2-year survival rate of 70% (Advanced Heart Failure, 2023; Han et al., 2018).

In 1966, Dr. Michael DeBakey was a pioneering cardiovascular surgeon who initially started the implantation of a VAD at Baylor College of Medicine in Houston, Texas. At that time, it became a groundbreaking discovery, and VAD devices use begin to start for pumping blood from its lower chambers towards the body by providing enough support for patients with heart failure. Primarily, VADs were used as a temporary solution while awaiting a heart transplant and donor or as a long-term therapy for those who cannot undergo transplantation. The left ventricular assist device (LVAD), placed in the heart's left ventricle, is the most common type, delivering continuous blood flow. According to various evidence, its use is supported because even if risks associated with open-heart surgery and potential complications persist, LVAD can significantly improve survival and quality of life in severe heart failure cases (MacIver & Ross, 2012; Poredos, 2017; Arnold et al., 2016).

METHODOLOGY

We conducted our research on PubMed, Medline, and Google Scholar. Primary Keywords: Permanent cure, Ventricular assist device, Advanced heart failure, Systematic review, End-stage heart failure.

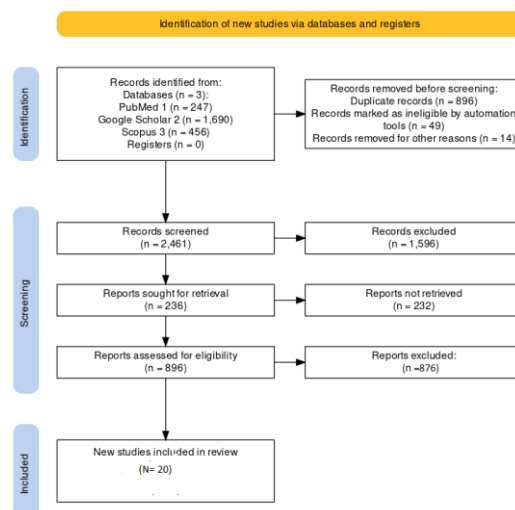
Secondary Keywords: Bridge-to-transplant, Destination therapy, Adverse events, Patient outcomes, VAD, Heart transplantation, Acute heart failure, Medical management, Technology advancements, Newer-generation devices, Complications of donor heart

Search Strategy:

1. "Ventricular Assist Device"[MeSH] OR VAD) AND ("Advanced Heart Failure"[MeSH] OR "End-Stage Heart Failure"[MeSH]) AND ("Permanent Cure"[tiab] OR "Destination Therapy")
2. ("Ventricular Assist Device"[MeSH] OR VAD[tiab]) AND ("Patient Outcome Assessment"[MeSH] OR "Treatment Outcome"[MeSH] OR "Adverse Events")
3. ("Ventricular Assist Device"[MeSH] OR VAD[tiab]) AND ("Heart Transplantation"[MeSH]) AND ("Comparative Study"[MeSH.Subheading] OR "Comparative Effectiveness Research"[MeSH])
4. ("Ventricular Assist Device"[MeSH] OR VAD) AND ("Technology"[Subheading] OR "Equipment Design"[Subheading]) AND ("Newer Generation Devices")

We filtered papers published in English from January 2012 to May 2024. The inclusion criteria were a study of patients with advanced heart failure who received VADs and only those papers were selected which addressed outcomes like survival rates, quality of life, and adverse events. Paper on historically VADs use and discussing new interventions till 2024 were selected. This paper includes RCTs, cohort studies, literature studies, and systematic reviews. It is important to note that this review is based on previous studies and only authentic and peer reviewed papers are selected. Exclusion criteria filtered out studies on non-human subjects, non-English publications published in 2013, and studies focused on pediatric or non-cardiac VAD applications. We reviewed selected papers and extracted qualitative data of interest emphasizing VADs' efficacy in improving survival rates and quality of life and managing adverse events.

Table 1. Identification of new studies via databases and registers



Source: the authors.

RESULTS AND DISCUSSION

Ventricular Assist Devices Types and Indications

Three main types of Ventricular Assist Devices (VADs) are Left Ventricular Assist Device (LVAD), Right Ventricular Assist Devices (RVAD), and Biventricular Assist Device (BiVAD) (Farag et al., 2021). LVAD is implanted in the heart is designed to pump blood from the left ventricle to the ascending aorta through a specially formed graft which directs the blood flow into the aorta. The second type is known as Right Ventricular Assist Devices (RVAD) and it is used to offer structural support at the right ventricle. RVAD helps to maintain the arterial blood flow in the correct direction from the right atrium or right ventricle to the pulmonary artery to control the pulmonary circulation. RVAD can be used with LVAD in patients with biventricular failure meaning that both sides of the heart are failed. RVAD can be external or internal depending on the placement and transplantation process involves a meticulous setup where cannulas are placed inside the right atrium or right ventricle to supply blood and subsequently route it to the pulmonary artery.

BiVAD which is the third type of VAD can be placed outside or inside the body just like RVAD. BiVAD device can assist both the left and right ventricles which are responsible for systemic and pulmonary circulation. They are mostly applied for patients with severe biventricular failure on either side of aorta and other conditions such as those in post-acute myocardial infarction or post-cardiotomy shock. BiVAD can be inserted either during surgery or through percutaneous procedures. These devices have specific orifices to each ventricle and separate outlets to augment both the systemic and the pulmonary blood flow. Similar to RVAD, BiVAD is designed to meet certain heart failure conditions and different levels of heart failure. By lending mechanical assistance to the failing heart, they work wonders in improving blood flow dynamics, easing symptoms, and ultimately enhancing the overall prognosis for patients.

VADs Evolution and Advances

Stewart and Givertz (2012) have highlighted the transformative evolution of mechanical circulatory support (MCS) devices, and they focused on ventricular assist devices (VADs) and researched alongside heart transplantation (HT) practices. He stated that it was initially intended as a temporary measure to bridge patients to transplants. There was always a shortage of donor organs, and this device promoted a shift towards utilizing VADs as perpetual destination therapy (DT) for those patients who lose hope at end-stage heart failure (HF), now VADs devices are not solely as a bridge-to-transplant (BTT) intervention. Castrodeza et al. (2022) declared that the advent of continuous-flow (CF) devices marked a groundbreaking leap forward in MCS technology, surpassing the earlier-generation pulsatile-flow mechanisms. The axial and centrifugal flow designs emerged as distinct subclasses, each carrying its physiological implications. Leading the charge were devices like the HeartMate II and HeartWare HVAD, showcasing a shift towards smaller, intrapericardial configurations aimed at sustaining cardiac support over the long haul. Recent breakthroughs, epitomized by the HeartMate III, signify a paradigm shift in MCS. By integrating fully magnetically levitated rotors and artificial pulsatility to mimic native heart function, these innovations promise to revolutionize patient outcomes through a blend of scientific prowess and engineering brilliance (Castrodeza et al., 2022).

Optimal Candidates, Risks, and Assessment Guidelines

According to guidelines from the American College of Cardiology and the American Heart Association, VAD implantation is advocated for patients experiencing Stage D heart failure and reduced ejection fraction, impacting an estimated 100,000 to 250,000 patients, Benjamin et al. (2018). VAD implantation is a minimally invasive procedure but necessitates a comprehensive, interdisciplinary evaluation of patient suitability. Asleh et al. (2019) have pointed out the patient populations at risk for adverse events and bad outcomes that led to the identification of the contraindications for therapy which include conditions that preclude the patient from living a long life, such as ongoing malignancy or irreversible end-organ failure, conditions that are more likely to lead to adverse events after implantation, such as significant pulmonary hypertension or right ventricular dysfunction, and factors that interfere with the patient's ability to adhere to follow-up, such as psychosocial factors. Nonetheless, with the technological innovations that continue to improve and protect patients from AEs, the boundaries of the concept are continually shifting. (Asleh et al., 2019).

Survival Rate, Complications and Adverse Events

According to Han et al. (2018), the survival rates for patients with CF-VADs are quite promising, 81% surviving the first year and 70% making it to the second year post-implantation. In his cohort research, there were two groups, patients in

the BTT group fare better than those in the DT group; 30% of BTT patients receive a heart transplant within a year, and 77% survive for at least two years. Even with more severe health issues, the DT group shows a solid 68% survival rate at two years. These positive outcomes are echoed in studies of the Heartware HVAD and HMII devices, where 46% to 59% of patients reached the goal of surviving two years without a major stroke or needing another surgery. The Heartmate III device has shown even better results, with a 79.5% success rate for this same composite outcome, largely due to fewer strokes and PT complications. These results mark a significant improvement over the 2009 study by Slaughter et al., where only 11% of patients with pulsatile-flow VADs met the survival criteria without major complications. While the long-term survival rate for VAD patients, at 30% after five years, still lags behind heart transplant outcomes, the continuous advancements suggest that VAD therapy is becoming a more viable long-term treatment option (Han et al., 2018).

Han et al. (2018) research highlighted possible challenges that patients faced in his research, due to right Heart Failure (RHF) following VAD implantation, affecting 15-25% of patients, with 4% requiring RVAD within a mere two weeks. Risks factors rise because of pre-existing RV dysfunction or pulmonary hypertension or other condition such as hemodynamics shifts, culminating in a reshaping of the RV and unveiling latent dysfunction. Precise mechanisms remain indefinable but signs like echocardiographic and hemodynamic markers can be alarming sign of complications, for example when a person's INTERMACS profile is showing heightened sensitivity, it can signal that they might be at risk of developing right heart failure soon. If chances of failure are high, taking quick action is key which involve using inotropic support and VADs (Han et al., 2018). Additionally, Pump Thrombosis (PT) appears as a significant threat, driven by flow dynamics and anticoagulation strategies. Mitigation relies on surgical precision, anticoagulation, and speed control. Bleeding, particularly gastrointestinal (GIB), affects older patients, challenging management despite engineering efforts. Stroke incidence remains significant, requiring nuanced approaches. Aortic Insufficiency (AI) impedes long-term support, necessitating innovative solutions. Driveline Infection, primarily *Staphylococcus* species, underscores hygiene's critical role. BiVAD face technical challenges, from pump malfunctions to controller failures, demanding meticulous maintenance and monitoring. Cannula issues and systemic technical challenges further complicate management, emphasizing the need for comprehensive strategies to optimize patient outcomes (Han et al., 2018).

Boruah et al., conducted his research in 2019 where he recommended VAD implantations for patients with Heart failure Class IV who have had their conventional surgery with EF below 25% and those who have severely reduced functional capacity with exercise peak $\text{VO}_2 < 14 \text{ mL/kg} \cdot \text{min}^{-1}$. Atluri et al. (2013) asserted that patients with a limited life span, those more than 75 years of age, patients with concurrent comorbidities and are at risk of death or other complications that render the implantation procedure futile are not recommended for VADs. Han et al. suggested several additional contraindications for patients who should be considered for VAD transplantation. These include those with end-stage renal disease, a glomerular filtration rate below 30, creatinine clearance under 30, or severe liver disease (bilirubin above 2.5 or an international normalized ratio over 2.0 in the presence of cirrhosis or portal hypertension). Patients with severe lung disease or a recent pulmonary infarction also need careful evaluation. Those with severe vascular disease, severe arthritis, unresolved neurological issues, or severe neuromuscular disorders may not be suitable candidates. Hematologic contraindications, as noted by Han et al. (2018), include active severe bleeding, chronic thrombocytopenia, active infection, refusal of blood transfusions, confirmed heparin-induced thrombocytopenia, and intolerance to anticoagulation. Anatomically, patients with congenital heart disease, hypertrophic cardiomyopathy, a large ventricular septal defect, or a body mass index that prevents implantation or rehabilitation are not candidates. Feldman et al. identified hemodynamic contraindications such as severe independent right ventricle failure and high pulmonary vascular resistance (greater than 6) or a transpulmonary gradient above 15, even after testing with inhaled nitric oxide, flolan, or intravenous nitroprusside. Finally, psychosocial factors like ongoing substance abuse, inability to provide informed consent, non-adherence to medical regimens, inability to maintain the VAD, and active mental illness or psychosocial instability also disqualify patients from VAD implantation (Feldman et al., 2013).

Akkawi et al., 2024 suggested that patients aged 18-59 had lower in-hospital mortality rates (6-7%) compared to those aged 60-69 (12%) and over 70 (17%). Older patients faced higher risks due to more comorbidities, as indicated by the Charlson Comorbidity Index. Despite higher mortality, LVAD remain viable for selected older patients, especially for Destination Therapy. Thus, younger patients (18-59) are optimal for both BTT and DT, while careful selection and management are crucial for older patients to improve outcomes. Age should be a key factor in LVAD patient selection and care. (Akkawi et al., 2024). Hemodynamic assessments are right heart catheterization, precise gauge cardiac pressures and output, and identifying individuals with severe hemodynamics is crucial. Other procedures include imaging techniques, echocardiography, and cardiac MRI, where we can assess precise heart structure and function, which helps in making decisions about the need for mechanical help in cardiac care. Diagnostic techniques like laboratory markers gives profiles of severity of heart failure and the overall health of essential organs. In critical cases, Experienced professionals' teams evaluate these markers to create a detailed plan for selecting patients who are most likely to benefit from VAD (Ventricular Assist Device) therapy and ensure that the patient is most likely to get more benefits with reduced adverse effects. The INTERMACS profiles approach really stands out as a top-notch tool for risk assessment as it offers a systematic way to categorize patients,

taking into account how serious their condition is and whether they need prompt intervention or not. INTERMACS profiles truly provides reliable roadmap for understanding where each patient stands in terms of their health journey (Masarone et al., 2023).

Efficacy of VADs in Advanced Heart Failure

VAD therapy has consistently demonstrated remarkable improvements in exercise capacity for patients with advanced heart failure. Post-implantation studies show a noticeable increase in peak oxygen consumption (VO₂ max) and prolonged exercise duration, reflecting enhanced cardiac output and better tissue perfusion. Previous evidence suggests that most of the patients with HF experience a significant shift from (Class III/IV) to milder ones (Class I/II). This shift shows the improvement in the function of the heart and, more importantly, the well-being of the patient. In addition, the VADs eliminate symptoms of heart failure, such as dyspnea and fatigue, as well as exertional intolerance. Several patients also claim a decrease in the level of diuretic consumption, which reinforces the advantages of therapy. Symptom burden components are closely linked to quality-of-life metrics and are improved through therapy, increasing patient satisfaction and well-being. The benefits from VAD usage are, therefore, clear, and this technology supports the advancement of heart failure management. (Merkaš et al., 2021). This has led to a decline in HF-related hospital admissions globally today due to the massive success of VAD therapy. Most of the previous clinical trial studies indicate the advantages of the survival benefits, the reduced mortality caused by pump failure and the enhanced long-term prognosis among end-stage heart failure patients. Heart VADs are extraordinary lifelines that jumpstart patients on the pathway to transplant. VAD therapy shows set improvements in functional capacity, symptoms, and quality of life that persist in the long run. Most research studies posited that patients are more independent, less anxious, and experience better general and psychosocial well-being. These benefits are supported by the results of PROMs that evidence the substantial positive long-term effects of VADs and provide promise for patients with heart failure (Mayo Clinic Research, 2019).

Future advancements and Durability of Ventricular assist device

Historically, the first VAD implantation in 1963 marked a pivotal moment, leading to VAD-BTT surgeries with Novacor in 1984. First-generation dVADs struggled with size, noise, and malfunction issues, limiting their utility. Second-generation dVADs, like HeartMate II, introduced continuous flow technology, improving patient outcomes significantly. However, they faced challenges with heat production and thromboembolism risks. Third-generation dVADs, exemplified by EvaHeart and HeartMate III, integrate magnetic levitation and enhanced pumping efficiencies, minimizing blood component destruction. HeartMate III, with FullMagLev technology, stands out for its durability and reduced complications. MOMENTUM 3 study confirms its superiority in patient outcomes, underscoring the continual evolution of VAD technology (Tu et al., 2024).

Research by Tu et al. (2024) described evolution of durable ventricular assist device (dVAD) engineering, particularly third-generation models, epitomizes a fusion of advanced engineering and clinical ingenuity. Durable ventricular assist device (dVAD) have shown more positive outcomes for advanced heart failure (HF) patients compared to previously used devices. dVAD has been effective in mitigating hemolysis and thrombosis risks since the advent of magnetic or hydrodynamic-levitated rotors, which is the latest technological leap.

Latest advancements in dVAD technology focuses on we can control blood regulation at optimal level and what strategies and tools ca reduce damage to blood cells so that we can prevent complications of thrombosis and bleeding that exist in conventionally used VADs. Science in this decade has innovated magnetic and hydrodynamic rotor levitation technology. These specifications are coming in advanced devices such as HeartWare Ventricular Assist Device (HVAD) and HeartMate III which has gained popularity in cardiology. These are completable enough to reduce chances of thrombosis and bleeding. Latest technology has worked on reducing friction and wear on the device components which increase patient's comfort and these novel advancements greatly improve the durability of the device, Tu et al. (2024) stated. Formation of microthrombi should be prevented which is possible in advanced VAD devices like the HeartMate III, because it ensures that blood is moving smoothly through the device and clot formation risk is minimal. Despite advancements in these innovative technologies certain challenges persists. Tu et al. in 2024 declared that there remains the risk of infection at driveline site and skin breakdown is also a concern. Future work might focus on reducing blood clot risk and improving impeller designs where blood can flow effectively without further consequences. Latest technology is still working on adjusting pump flow and using AI for real-time optimization (Tu et al., 2024). This research noted viable evolution in durable ventricular assist device (dVAD) use with a surge in implantations coinciding with severe HF patient profiles, favoring destination therapy over bridge to transplant which has become possible with invent of dVAD technology (Tu et al., 2024).

CONCLUSION

It is concluded that VADs has resulted in a significant increase in the survival of patients with severe heart failure. The 1-year and 2-year survival rates of continuous-flow VAD patients are approximately 81% and 70%, respectively, after the implantation. In addition, the results are especially positive for patients receiving BTT therapy: 30% of patients received a heart transplant within 1 year and 77% survived to 2 years. The two-year survival rate for the DT population is still high at 68% despite the higher comorbidities. These results highlight the benefits of VAD therapy in improving the quality and longevity of life for patients with end-stage heart failure.

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