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Bivad bi-ventricular assist device complications of BIVAD Therapy

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ABSTRACT

Background: Heart failure remains a leading global cause of morbidity and mortality, with advanced cases often requiring mechanical circulatory support (MCS). While left ventricular assist devices (LVADs) have become standard in advanced left-sided failure, patients with biventricular dysfunction require more comprehensive support through biventricular assist devices (BiVADs). BiVAD therapy has evolved as a life-saving intervention, primarily serving as a bridge to transplant, destination therapy, or bridge to recovery.

Methodology: This narrative review synthesizes evidence from clinical registries, cohort studies, and recent device innovations to evaluate complications associated with BiVAD therapy. Key focus areas include hemodynamic imbalances, thromboembolic and hemorrhagic events, device-related dysfunction, infectious risks, neurological complications, and multiorgan dysfunction. Preventive strategies, monitoring protocols, and advances in device design are also discussed.

Results: BiVAD therapy significantly improves survival and quality of life in patients with refractory biventricular failure, but is associated with substantial risks. Hemodynamic imbalance, suction events, device thrombosis, hemolysis, thromboembolism, gastrointestinal and intracranial bleeding, driveline and pocket infections, renal and respiratory dysfunction, and neurological complications remain major concerns. Registry data highlight survival rates approaching those of LVAD recipients with ongoing improvements in outcomes due to advances in device technology, perioperative care, and individualized anticoagulation management. Emerging strategies—such as magnetically levitated pumps, improved cannulation techniques, biofilm-resistant coatings, telemonitoring, and AI-based predictive systems—offer promise in reducing complication rates.

Conclusion: BiVAD therapy is a vital option for patients with advanced biventricular heart failure, but its clinical utility is limited by complex complications that require vigilant multidisciplinary care. Standardized anticoagulation, infection prevention, patient education, and structured follow-up programs are central to improving outcomes. Future directions emphasize fully implantable systems, AI-enabled monitoring, and hybrid artificial heart technologies to enhance safety, reduce infection risks, and extend therapeutic possibilities. Continued collaboration between clinicians, engineers, and researchers will be key to overcoming challenges and advancing the role of BiVADs in modern cardiac care.

Keywords: *Biventricular assist device, Mechanical circulatory support, Heart failure, Complications, Anticoagulation, Infection, Artificial intelligence, Transplantation.*

1. INTRODUCTION

Heart failure, which has reached epidemic proportions globally, remains one of the leading causes of morbidity, mortality, and hospitalization among adults and children alike. Contemporary estimates indicate that acute heart failure syndromes, particularly those complicated by cardiogenic shock, exhibit in-hospital survival rates below 50% despite standard medical therapy, highlighting the need for adjunctive mechanical circulatory support (MCS) to improve clinical outcomes. Mechanical circulatory support encompasses a variety of devices designed to augment cardiac output and systemic perfusion in patients experiencing refractory circulatory collapse. These devices range from temporary options such as intra-aortic balloon pumps (IABP), Impella, TandemHeart, and veno-arterial extracorporeal membrane oxygenation (VA-ECMO), to more durable implantable systems including LVADs and BiVADs[1]. The evolution of these modalities has very clearly

2. EVOLUTION FROM LVADS TO BIVADS IN BIVENTRICULAR DYSFUNCTION

Historically, LVADs emerged as the primary MCS strategy for advanced left-sided heart failure, initially introduced to bridge patients to transplantation or recovery and subsequently adopted as destination therapy for those ineligible for transplant. LVADs demonstrated survival rates exceeding 80% at one year, with substantial improvements in hemodynamics and functional status. However, despite these considerable advances, a subset of patients with pronounced right ventricular dysfunction and global biventricular failure do not derive adequate benefit from isolated LV support and remain at significant risk of multi-organ failure and mortality. This clinical need catalyzed the development of biventricular assist devices (BiVADs), capable of supporting both ventricles simultaneously by mechanically unloading both the left and right chambers of the heart[2]. The evolution from LVAD-only strategies to BiVAD therapy marks a critical paradigm shift. Early BiVAD systems were largely experimental or employed as total artificial hearts (TAHs) in selected populations. Current BiVAD configurations utilize synchronous support, with specialized devices or combinations of LVAD and right ventricular assist device (RVAD), either sequentially or simultaneously, depending on patient-specific anatomical and hemodynamic requirements. Not only have survival rates for BiVAD recipients begun to approximate those seen with LVADs in certain registries (with 12-month survival near 62% for chronic BiVAD patients), but device-specific innovations, such as advances in surgical technique and the growing use of less invasive approaches, continue to optimize outcomes and reduce complications[3].

3. INDICATIONS FOR BIVAD IMPLANTATION: BRIDGE TO TRANSPLANT, DESTINATION THERAPY, BRIDGE TO RECOVERY

Although precise indications for BiVAD therapy depend on local practices, device availability, and individual patient profiles, contemporary consensus recognizes three cardinal roles—bridge to transplant (BTT), destination therapy (DT), and bridge to recovery (BTR).

Bridge to transplant remains the most well-established indication, with BiVADs serving as a temporizing measure to preserve end-organ function and improve overall clinical condition in patients with refractory biventricular failure awaiting cardiac transplantation. Notably, current regulatory approvals for adult biventricular devices predominantly restrict use to BTT situations. Destination therapy, although less common due to the complexity and risk associated with long-term biventricular support, is increasingly considered for select patients ineligible for transplantation, particularly those who would not survive without durable MCS. The bridge to recovery indication, while rarely achieved, refers to cases in which biventricular support is implemented to allow sufficient myocardial rest and reverse remodeling, with the goal of device explantation following meaningful cardiac functional improvement—a scenario observed in particular pediatric cases and select adult patients with myocarditis or chronic heart failure responsive to aggressive unloading and medical therapy[4]. Latest registry data reveal promising trends in temporary RV assist device (RVAD) use following LVAD implantation, demonstrating successful weaning rates exceeding 86% and survival to discharge in select cohorts. In pediatric populations, bridge to recovery may be more readily attainable, as underlying etiologies such as myocarditis portend more favorable potential for myocardial reverse remodeling and device removal. Meanwhile, for chronic end-stage biventricular failure, the prevalence of bridge to transplant as the primary indication for BiVAD remains high, with clinicians emphasizing stringent selection criteria to minimize procedural risk and maximize survival[5].

Contemporary Clinical Considerations:

Modern BiVAD therapy is associated with several unique challenges and complications, which will be discussed extensively in subsequent sections. The main risks include bleeding, infection, cardioembolic events, device malfunction, and end-organ impairment (renal or hepatic), all of which must be carefully considered in the context of patient selection, device choice, and long-term management strategies. Surgeons and multidisciplinary teams increasingly recognize the importance of optimizing peri-implant care, monitoring for device-specific complications such as driveline infection, and systemically managing anticoagulation and immunosuppression to reduce the incidence of adverse outcomes[6].

Registry-based and prospective cohort studies, particularly those using multicenter databases such as INTERMACS, form the cornerstone for evidence-based guidance in this domain, regularly shaping international and national guidelines affecting patient management decisions. Emerging device technologies, innovative surgical techniques, and the growing application of molecular profiling and targeted pharmacological adjuncts promise to further refine the approach to BiVAD support, making it both more effective and safer for an expanding population of heart failure patients[7].

4. HEMODYNAMIC AND DEVICE-RELATED COMPLICATIONS

Hemodynamic and device-related complications in BiVAD therapy present a complex and multifaceted clinical challenge, affecting both patient outcomes and device longevity. The various types of complications in BIVAD therapy are shown below in **Figure-1.**

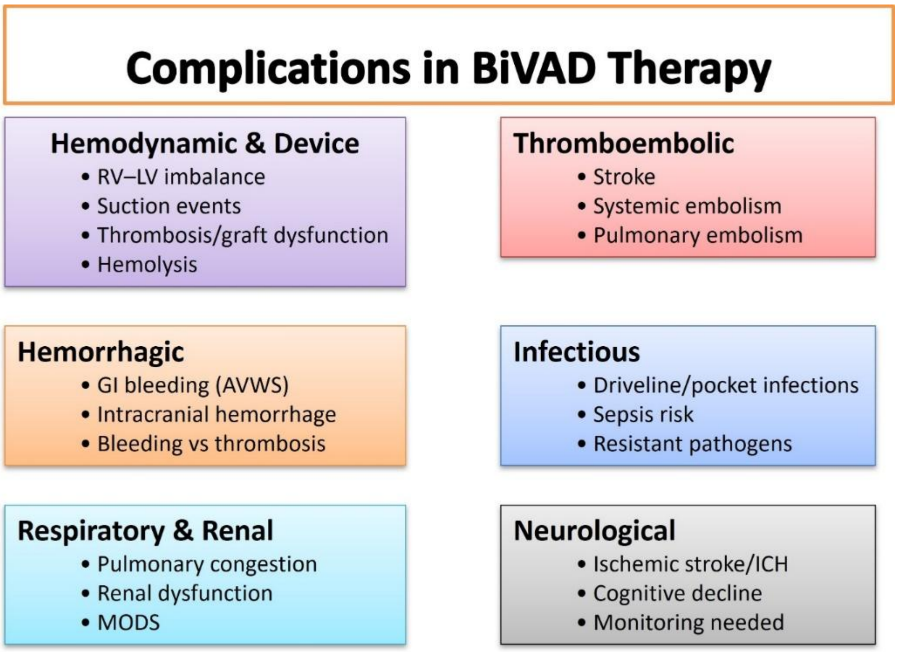

Figure 1: Complications in BIVAD Therapy

Right-Sided vs. Left-Sided Device Imbalances

A hallmark complication in biventricular mechanical support is the physiological and flow imbalance between right and left-sided assist devices. Right ventricular failure (RVF) remains especially challenging after LVAD implantation, complicating 10–40% of cases and contributing to multiorgan dysfunction, longer hospitalizations, and increased mortality. Hemodynamic imbalance often results when the LVAD provides high left ventricular output while the right ventricle is unable to match this flow, leading to elevated central venous pressure (CVP), hepatic congestion, renal dysfunction, and impaired perfusion of end organs. Risk of RVF is most effectively predicted using preoperative biochemical and hemodynamic parameters such as CVP > 15 mmHg, CVP/PCWP > 0.6, reduced RV stroke work index (<300 mmHg·mL/m²), and pulmonary artery pulsatility index (PAPi < 2 but especially below 1.01). Echocardiographically, a tricuspid annular plane systolic excursion (TAPSE) <7.5 mm, RV/LV end-diastolic dimension ratio >0.75, and impaired RV free wall strain are associated with greater RVF risk after LVAD placement[8]. In BiVAD therapy, careful synchronization and adjustment of pump speed are crucial to avoid over-unloading one ventricle and under-unloading the other; mismanagement can result in pulmonary over-circulation or systemic congestion, leading to pulmonary edema, hypoxia, or systemic shock. Continuous monitoring and early intervention strategies, such as temporary support or adjustment in device settings, are necessary to mitigate these complications and optimize multisystem organ perfusion.

Suction Events and Inflow Cannula Malposition

Suction events represent another significant device-related complication and are often directly linked to inappropriate inflow cannula positioning or dynamic changes in cardiac geometry. These events are frequently observed in patients with small ventricular cavities, hypertrophied apices, or altered wall motion, which can lead to sudden drops in pump flow as the cannula tip becomes occluded by myocardial tissue. Suction can precipitate negative pressure effects in the device circuit, cause endocardial trauma, and result in arrhythmias, such as ventricular tachycardia or asystole, especially when LV flows are severely compromised. Adaptive surgical strategies, such as repositioning the cannula from apical to atrial locations or using smaller cannulas or grafts, can resolve persistent suction events and restore adequate flow. In modern systems, real-time device monitoring algorithms with automated adjustments attempt to preemptively detect and alleviate suction by modulating pump speeds[9]. Prolonged suction can lead to thrombogenesis, hemolysis, and even device stoppage or failure; therefore, rapid diagnosis using echocardiography, dynamic imaging, and careful post-operative surveillance are imperative for early correction.

Device Thrombosis and Outflow Graft Dysfunction

Pump thrombosis and outflow graft dysfunction remain serious and potentially life-threatening complications after BiVAD or LVAD implantation. Device thrombosis often results from stagnation, improper anticoagulation, repetitive suction events, or device malposition, leading to abrupt drops in flow, power surges, and systemic embolization. Outflow graft dysfunction includes kinking, stenosis, extraluminal compression, and intraluminal clot formation. The most common clinical presentation is low flow alarms, often without overt symptoms, making timely imaging, especially computed tomography angiography (CTA), essential for accurate diagnosis. Management options include endovascular stenting for extrinsic graft compression, surgical revision for kinks or thrombi, heart transplantation in intractable cases, and supportive care for patients with multiple comorbidities[10]. The true prevalence of outflow graft obstruction is likely underestimated, as standard echocardiography is often insufficient for diagnosis. Device thrombosis can manifest as hemolysis, jaundice, pump malfunction, or embolic stroke. Prevention hinges on meticulous anticoagulation protocols, device speed optimization, and, increasingly, the use of magnetically levitated centrifugal-flow pumps which demonstrate substantially reduced thrombosis rates compared to earlier generation devices.

5. HEMOLYSIS AND BLOOD TRAUMA DUE TO MECHANICAL FLOW

Hemolysis is a direct consequence of non-physiological flow patterns, high shear stress, and repetitive mechanical interaction between blood and device surfaces. Modern CF-LVAD and BiVAD designs strive to minimize hemolysis by increasing the size of blood passages and employing magnetic levitation technologies, but blood trauma remains a concern, especially during episodes of low flow alarms, suction, or pump thrombosis. Hemolytic complications may present as mild subclinical LDH elevation or escalate to severe anemia, hemoglobinuria, and renal impairment. Prolonged hemolysis increases the risk of platelet consumption, acquired von Willebrand factor deficiency, and gastrointestinal bleeding, particularly in continuous-flow settings[11]. In some cases, hemolysis can contribute to the formation of microthrombi and embolic events in vital organs, necessitating close laboratory and clinical monitoring, routine LDH measurement, and prompt device interventions. Failure to address underlying device or hemodynamic problems may ultimately precipitate device failure or multisystem complications, reducing both transplant eligibility and long-term survival.

Thromboembolic Events

Thromboembolic events remain a formidable complication in mechanical circulatory support, with BiVAD recipients exhibiting unique risk profiles compared to those on isolated LVAD therapy. Critical elements in thrombosis include device design, anticoagulation management, diagnostic strategies, and preventive protocols, all of which have rapidly evolved as per latest PubMed-indexed research.

Risk of Device-Related Thrombosis in BiVAD Compared to LVAD

Recent data indicate that BiVAD therapy is inherently associated with a higher risk for device-related thrombosis compared to single LVAD systems, primarily due to increased flow complexity, the multiplicity of circuits, and greater blood-contacting surface area. In chronic BiVAD configurations, the rate of RVAD pump thrombosis has approached 36–37%, though risk in LVAD systems remains relatively lower and has further declined with the adoption of fully magnetically levitated, centrifugal-flow devices such as HeartMate 3 (HM3). This enhanced risk in BiVAD systems is compounded by challenges in adequate anticoagulation, differences in pump geometries, and inherent hemodynamic fluctuations[12]. Notably, recent multicenter INTERMACS registry analyses demonstrate that thrombosis is a leading cause of adverse events, frequently resulting in systemic embolism, device dysfunction, and diminished transplant eligibility in BiVAD-supported patients.

Influence of Anticoagulation Management

Anticoagulation management remains central to minimizing thromboembolic risk in both LVAD and BiVAD populations, but recent research highlights unique considerations for dual-ventricular support. Traditionally, combined warfarin and aspirin have been used, but the ARIES-HM3 trial showed that aspirin withdrawal could reduce bleeding risk without significantly increasing thromboembolic events in LVAD recipients. More recent investigations—including the DOT-HM3 and DOAC LVAD trials—suggest the feasibility of using direct oral anticoagulants (DOACs), particularly apixaban, in place of warfarin in some patients, with equivalent thrombosis prevention and reduced hemorrhagic complications. Notably, therapeutic INR targets for warfarin in LVAD/BiVAD recipients generally range from 2.0–3.0, but wide inter-individual variability and frequent need for monitoring place an additional burden on BiVAD populations, especially those with more complex device interactions[13]. Any periods of subtherapeutic anticoagulation sharply increase both thrombosis and neurologic event rates, demanding a careful balance between bleeding and clotting risk. Special caution is advised in "bridging" therapy with low-molecular-weight heparin, which has been shown to heighten bleeding risks without proportionately reducing thromboembolic events.

Clinical Presentation: Stroke, Systemic Embolism, Pulmonary Embolism

Thromboembolism in BiVAD patients manifests primarily as ischemic stroke, systemic arterial embolism, and occasionally pulmonary embolism, depending on the device configuration and clot origin. Stroke rates following device implantation remain substantial, with recent studies noting events in up to 13–19% of LVAD cohorts and higher rates in complex BiVAD scenarios. Hemorrhagic and ischemic strokes both contribute to elevated mortality rates, ICU stays, and prolonged hospitalizations; additionally, systemic thromboemboli can affect peripheral arteries, kidneys, spleen, and other organs[14]. Pulmonary embolism, while less frequent, can occur following right-sided device-associated thrombosis, leading to severe hypoxia or right ventricular failure. The clinical picture is typically acute: sudden neurologic deficit, chest pain, limb ischemia, or hypoxemia, often necessitating emergent intervention.

Diagnostic Strategies (Echocardiography, CT)

Early and accurate diagnosis is essential to minimize morbidity in device-related thromboembolic events. Echocardiography serves as a first-line imaging modality, enabling visualization of inflow/outflow cannula thrombi, valvular changes, and evidence of device dysfunction. However, sensitivity for detecting embolic phenomena and non-device-based thrombi is limited. CT angiography is increasingly used for definitive evaluation, especially of suspected outflow graft obstructions or systemic/pulmonary embolism, providing high-resolution images of both the device architecture and the vascular system[15]. Neurological complications particularly stroke are evaluated through a combination of non-contrast CT, MRI, and vascular imaging to determine ischemic burden and identify intervention targets. Routine laboratory monitoring, including LDH (for hemolysis), INR, and platelet counts, complements imaging to clarify the etiology of symptoms and guide therapy.

Preventive Anticoagulation Protocols

Preventive protocols have evolved substantially, with best-practice guidelines advocating for continuous anticoagulation using vitamin K antagonists or DOACs, alongside carefully managed adjunctive antiplatelet therapy. Current recommendations for LVAD—and extrapolated to BiVAD—therapy advise maintaining INR between 2.0–3.0, regular monitoring, and judicious use of low-dose aspirin (81–325 mg), with rapid dose adjustment in cases of bleeding or elevated risk. The DOT-HM3 and DOAC LVAD studies support apixaban as a promising alternative to warfarin for select device recipients, offering comparable antithrombotic protection with a reduced bleeding profile[16]. Individualization of protocols is emphasized, accounting for patient comorbidities, genetic factors, history of bleeding, and device-specific considerations. Special vigilance is required in periods of device manipulation, perioperative care, or bridging therapy, where risk profiles are dynamically altered.

Hemorrhagic Complications

Hemorrhagic complications are among the most challenging issues encountered in BiVAD therapy, due to multifactorial mechanisms encompassing acquired coagulopathies, mechanical trauma, and anticoagulation management demands.

Gastrointestinal Bleeding & Angiodysplasia: Acquired von Willebrand Syndrome

Gastrointestinal (GI) bleeding is a frequent and significant complication in patients with continuous-flow mechanical assist devices, including BiVADs, largely due to acquired von Willebrand syndrome (AVWS). AVWS develops through degradation of high-molecular weight von Willebrand factor (vWF) multimers induced by sustained shear stress in device circuits. This defect leads to impaired platelet aggregation and defective primary hemostasis, predisposing to bleeding from mucosal surfaces and angiodysplasia—vascular malformations primarily arising in the GI tract. GI bleeding in BiVAD or LVAD patients is often recurrent and severe, with angiodysplasia being both a cause and consequence of chronic vWF abnormalities; nuclear scans, angiography, and endoscopic investigations confirm these lesions and help localize bleeding sources[17,18]. Importantly, studies show higher rates of bleeding in BiVAD patients than LVAD recipients, suggesting that biventricular support may independently exacerbate AVWS and subsequently GI hemorrhage.

Intracranial Hemorrhage and Stroke Risk due to Anticoagulation

In addition to GI bleeding, BiVAD recipients are exposed to increased risk of intracranial hemorrhage (ICH) and hemorrhagic stroke, primarily related to mandatory anticoagulation. Anticoagulant therapy—whether vitamin K antagonists (warfarin) or direct oral anticoagulants—significantly raises the risk of spontaneous ICH, especially among those with pre-existing cerebral microbleeds or white matter hyperintensities on baseline imaging. Large-scale analyses demonstrate that ICH risk rises markedly in patients with multiple microbleeds, with VKA users exhibiting 4.2-fold higher risk than patients treated with NOACs. Discontinuing anticoagulation is generally discouraged due to the ongoing risk of thrombosis; however, dose reductions and transitions to safer agents (favoring NOACs over VKAs) have been proposed for those at highest bleed risk[19]. Intracranial hemorrhage represents one of the most devastating complications, leading to abrupt neurological deterioration, increased mortality, and loss of transplant eligibility in advanced heart failure populations.

Management Challenges: Balancing Bleeding and Thrombosis

Clinical management in BiVAD patients is inherently complicated by the persistent need to balance thrombosis prevention (requiring anticoagulation and often antiplatelet therapy) with minimization of hemorrhagic complications. GI hemorrhage related to angiodysplasia and AVWS often proves refractory to standard treatments, requiring advanced GI interventions, replacement therapy with vWF concentrates, and, in some cases, adjunctive medications such as octreotide or angiotensin II antagonists to reduce vascular fragility. Patients experiencing ICH must undergo rapid reversal of anticoagulation, careful hemodynamic monitoring, and multidisciplinary neurological care; anticoagulant therapy may be cautiously resumed following stabilization, but requires individualized risk stratification. Bridging anticoagulation (for surgical or peri-procedural situations) heightens bleeding risk further, and protocols call for tailored approaches based on both device type and patient comorbidities[20]. Modern management strategies emphasize close laboratory monitoring deployment of adjunctive pharmacotherapies, and multidisciplinary input to optimize the delicate balance between bleeding and thrombosis in BiVAD care

Infectious Complications

Infectious complications associated with BiVAD (biventricular assist device) therapy are among the leading causes of morbidity and mortality in advanced heart failure management. As device complexity and support duration increase, so do infection risks, spanning both superficial and deep-seated anatomical sites.

Drive-line Infections and Pump Pocket Infections

Driveline infections (DLIs) and pump pocket infections remain the most common and challenging infectious complications in BiVAD therapy. DLIs typically originate at the skin exit site and can spread along the subcutaneous tunnel and into deeper tissues, ultimately encroaching on the pump or pocket, which is particularly problematic for BiVAD patients due to dual-device leads and longer support durations. Risk factors for severe or recurrent DLIs include younger age, hypoalbuminemia, underlying diabetes, poor local skin integrity, and suboptimal dressing care. Advanced management strategies such as driveline relocation through muscle tissue and vacuum-assisted wound closure have demonstrated efficacy in controlling infection and preserving device function in otherwise refractory cases[21]. However, deep tissue infections and pump pocket involvement may necessitate prolonged antimicrobial therapy, non-invasive wound care, or, rarely, device explant or complete exchange.

Sepsis Risk and Immune Compromise in BiVAD Therapy

BiVAD recipients face an elevated risk for systemic infections, including sepsis, due to both device-related factors and therapy-induced immune modulation. Persistent foreign body exposure, frequent breaches of skin and subcutaneous barriers, and chronic antibacterial therapy all contribute to heightened vulnerability to both local and bloodstream infections. Evidence suggests that LVAD/ BiVAD therapy may contribute to subtle cellular and humoral immune suppression, particularly through reduced T cell proliferation, altered cytokine production, and chronic inflammation at device-tissue interfaces. Recent cohort studies show that while total infection rates decline with experience and improved protocols, bloodstream infection (BSI) after device implantation significantly increases the risk of poor survival and complicates transplant candidacy[22]. Prolonged device support can also facilitate opportunistic infections from resistant organisms and potentially non-traditional pathogens, complicating the clinical course and increasing the incidence of sepsis-related morbidity and mortality.

Microbiology of Common Pathogens

The microbiology of BiVAD-related infectious complications is dominated by classic skin and soft tissue pathogens, most notably *Staphylococcus aureus*, including[23]. methicillin-resistant forms (MRSA), as well as *Staphylococcus epidermidis*, and Gram-negative bacilli such as *Pseudomonas aeruginosa* and *Escherichia coli*. *Staphylococcus aureus* poses a particular threat, given its propensity to form biofilms on device surfaces, evade immune clearance, resist standard antibiotics, and persist as small colony variants, leading to repeated recurrences. Biofilms and altered metabolic activity confer increased resistance, requiring prolonged and sometimes multi-agent antibiotic therapy. Gram-negative pathogens, including *Pseudomonas* and *Enterobacterales*, account for a substantial minority of device-related infections, especially in hospital settings with prior broad-spectrum antibiotic exposure. Antimicrobial resistance continues to evolve rapidly among both Gram-positive and Gram-negative organisms in the BiVAD population, requiring dynamic and evidence-based therapeutic strategies[24]. Fungal organisms, notably *Candida* species, may rarely be isolated in immunocompromised or long-term device recipients, demanding aggressive management[25].

Strategies for Prevention and Long-Term Management

Prevention and management of infectious complications require an aggressive, multimodal approach. Meticulous aseptic technique for driveline exit site care—including routine cleansing, use of sterile dressings, and regular inspection for signs of infection—is fundamental. Preoperative and ongoing antibiotic prophylaxis, tailored to local microbiological flora and patient risk profiles, is recommended to reduce perioperative infection rates and to sterilize device components before and during implantation. Advanced preventive strategies, such as vitamin D optimization, have recently been shown to lower infection rates, highlighting individualized nutritional adjuncts. For established infections, aggressive wound care with vacuum-assisted closure, muscle flap relocation, and chronic suppressive antibiotics can help salvage device function in non-candidacy for transplantation. Device biofilm remains a persistent challenge; research now emphasizes therapies targeting both planktonic and biofilm states of bacterial pathogens[26]. Multidisciplinary review involving infectious disease specialists, surgeons, nursing, and wound care experts optimizes outcomes, prevents transmission, and guides decisions regarding device retention or removal.

Respiratory and Renal Complications

Respiratory and renal complications are significant concerns in patients undergoing BiVAD therapy, impacting morbidity and long-term outcomes. These complications arise largely due to hemodynamic imbalances, altered systemic and pulmonary flow, and prolonged device support.

Pulmonary Congestion and Right-Left Device Mismatch

One critical respiratory complication in BiVAD patients is pulmonary congestion resulting from mismatch between right- and left-sided device outputs. When the right ventricular assist device (RVAD) provides higher flow relative to the left ventricular assist device (LVAD), blood can accumulate in the pulmonary circulation, leading to elevated pulmonary capillary wedge pressure, pulmonary edema, and compromised gas exchange. This phenomenon occurs even in absence of intrinsic left heart failure, triggered primarily by flow imbalances between ventricles. Clinical manifestations include dyspnea, hypoxemia, and radiographic evidence of interstitial or alveolar edema. Furthermore, temporary RVAD use beyond seven days or flows exceeding 4 L/min have been linked with pulmonary hemorrhage and bleeding complications. Careful titration of pump speeds and real-time hemodynamic monitoring is paramount to prevent such pulmonary complications during BiVAD support[27].

Renal Dysfunction Due to Altered Systemic Flow

Renal impairment is a frequent and complex sequela in BiVAD patients, shaped by altered systemic flow, neurohormonal changes, and prior renal status. Continuous-flow devices disrupt physiologic pulsatile circulation, adversely affecting baroreceptor sensitivity and triggering enhanced sympathetic activity and renin-angiotensin-aldosterone system (RAAS) activation. These neurohormonal alterations lead to arterial thickening, renal periarteritis, and progressive damage to renal parenchyma. Hemolysis related to device interaction further contributes to pigment nephropathy, exacerbating renal injury. Studies highlight that baseline kidney function prior to device implantation significantly predicts outcomes, with worse preoperative glomerular filtration rates (GFR) correlating to higher risk of right heart failure post-implant and stagnation or decline of renal function during follow-up[28]. These findings underscore the critical need for preoperative renal assessment and ongoing renal function monitoring in BiVAD recipients.

6. MULTIORGAN DYSFUNCTION IN PROLONGED BIVAD SUPPORT

Prolonged BiVAD therapy subjects patients to increased risk of multiorgan dysfunction syndrome (MODS), encompassing more than two organ systems with reversible physiological impairments. Hemodynamic instability, persistent low cardiac output, systemic inflammation, and recurrent infections contribute to cumulative organ injury. Pulmonary, renal, hepatic, and neurological complications often co-exist, limiting recovery potential and transplant candidacy. Data indicate that careful timing and patient selection for BiVAD implantation, with strategies optimizing right ventricular support duration (typically median 13-17 days), improve rates of organ recovery and successful device weaning[29]. Continuous surveillance and multidisciplinary management geared toward early recognition and mitigation of MODS components are essential to improve survival and functional outcomes during extended BiVAD support.

Neurological Complications

Neurological complications are a significant concern in BiVAD therapy, contributing substantially to patients' morbidity and mortality.

Ischemic Stroke, Embolic Events, and Hemorrhagic Complications

Ischemic stroke remains one of the most common and severe neurological complications in BiVAD and LVAD recipients, with incidences reported around 10-19% in the chronic support population. These strokes typically result from embolic events, where thrombi form either within the device pumps or circulation and subsequently occlude cerebral arteries. Emboli can arise due to device thrombosis, suboptimal anticoagulation, or hemolysis-induced platelet activation. Hemorrhagic stroke, including intracranial hemorrhage (ICH), is a major concern especially given the mandatory anticoagulation regimens. Risk factors include anticoagulant overdose, blood pressure variability, and existing cerebral microbleeds[30]. Hemorrhagic and ischemic strokes contribute to high stroke-related mortality rates and long-term neurodisability, worsening functional outcomes and transplant eligibility.

Cognitive and Neuropsychological Impact of Long-Term Device Therapy

Beyond acute events, long-term BiVAD therapy impacts cognition and neuropsychological health. While published data directly focused on BiVAD are limited, extrapolation from LVAD cohorts and related studies suggest mild to moderate cognitive impairments predominantly affecting executive function, attention, processing speed, and memory domains. These changes may result from cumulative microemboli, recurrent subclinical ischemic events, chronic inflammation, and device-related factors such as altered cerebral perfusion. Psychosocial stress and altered quality of life further impair cognitive outcomes[31]. Neuropsychological rehabilitation has demonstrated potential for improving executive function and quality of life in such patients, underscoring the need for integrated multidisciplinary care.

Monitoring Strategies: Imaging and Biomarkers

Effective neurological monitoring in BiVAD patients incorporates multimodal approaches. Neuroimaging remains central, with MRI and non-contrast CT routinely employed for acute stroke diagnosis, and advanced techniques such as diffusionweighted imaging (DWI), perfusion imaging, and MR angiography providing detailed vascular and tissue injury assessment. Emerging PET-based imaging techniques and functional MRI are being explored to detect subtle metabolic and functional brain changes longitudinally. Biomarkers including serum neurofilament light chain, glial fibrillary acidic protein, and inflammatory cytokines show promise for early detection of neuronal injury and stroke risk stratification but require further validation in device-supported patients[32]. Digital biomarker technology, integrating wearable sensors and AI-based gait and typing analysis, presents an innovative frontier for objective cognitive and motor monitoring with potential application in this population.

Management and Prevention Strategies

Management and prevention strategies for complications in BiVAD (biventricular assist device) therapy require a comprehensive, multidisciplinary approach tailored to the complex physiological and clinical challenges associated with biventricular mechanical support. Advances in patient monitoring, anticoagulation and anti-infective protocols, alongside continuous innovations in device technology, have collectively contributed to improved outcomes and reduced complication burdens. This review synthesizes the latest evidence from PubMed-indexed studies published since 2023, with an emphasis on multidisciplinary care models, evidence-based medical management, and future directions in device innovation.

Multidisciplinary Monitoring and Follow-Up Care

The cornerstone of successful BiVAD management is an integrated multidisciplinary care paradigm involving cardiologists, cardiothoracic surgeons, specialized nurses, infectious disease experts, hematologists, rehabilitation specialists, and psychosocial support teams. Structured outpatient clinics with regular, often tri-monthly follow-up visits have emerged as best practice, facilitating surveillance for early detection of complications such as device thrombosis, infection, and right ventricular failure. These clinics employ standardized protocols encompassing clinical evaluation, hemodynamic assessment, laboratory tests, and device parameter monitoring to promptly identify and manage adverse events. Immediate access to specialized care teams for urgent interventions ensures timely responses to emergent issues, thereby minimizing hospital readmissions and preserving device function[33].

Moreover, patient education and engagement remain vital components. Empowering patients and caregivers with knowledge about device care, symptom recognition, anticoagulation adherence, and lifestyle adjustments enhances self-management and adherence to prophylactic measures. Rehabilitation programs focusing on physical conditioning, psychological support, and cognitive rehabilitation contribute to improved quality of life and functional capacity. Telemonitoring, leveraging remote digital platforms and data analytics, is an evolving adjunct that can augment traditional follow-up by enabling continuous physiological and device data transmission, facilitating early complication recognition and personalized intervention plans.

Anticoagulation and Anti-Infective Protocols

Optimal anticoagulation management in BiVAD therapy seeks to prevent thromboembolic complications while minimizing bleeding risks, requiring individualized, closely monitored regimens. The standard of care typically involves a perioperative course of intravenous unfractionated heparin, transitioning to long-term oral vitamin K antagonists such as warfarin, with adjunctive low-dose aspirin for antiplatelet effect. Target international normalized ratio (INR) levels are generally maintained between 2.0 and 3.0, adjusted based on bleeding or thrombosis risk profiles, device type, and patient-specific factors. Emerging evidence supports the use of direct oral anticoagulants (DOACs) such as apixaban, which provide advantages of predictable pharmacokinetics, fewer drug-food interactions, and reduced monitoring burdens. However, robust prospective trials are still needed before universal adoption in BiVAD cohorts[34].

Anti-infective strategies emphasize preoperative prophylaxis against both Gram-positive and Gram-negative pathogens, typically with cephalosporins or vancomycin-based regimens depending on local antibiograms. Maintenance of sterile technique and rigorous driveline infection prevention protocols, including meticulous exit-site care, antimicrobial dressings, and prompt management of incipient infections, are critical in reducing device-related infections. In cases of established infection, prolonged culture-guided antibiotic therapy targeting biofilm-producing organisms such as Staphylococcus aureus including methicillin-resistant strains is essential. Multidisciplinary infectious disease collaboration promotes appropriate antimicrobial stewardship and mitigates antimicrobial resistance development[35].

Device Innovation for Reducing Complication Burden

The evolution of BiVAD technology has been pivotal in addressing many of the challenges historically associated with mechanical circulatory support. The latest devices incorporate magnetic levitation and centrifugal flow mechanisms, which significantly reduce shear stress, hemolysis, and thrombotic tendencies compared to axial-flow predecessors. For example, the HeartMate 3, originally an LVAD now being utilized in BiVAD configurations, utilizes fully magnetically levitated impellers that reduce blood trauma and improve hemocompatibility, translating into lowered rates of pump thrombosis and stroke. Innovations also focus on optimizing inflow/outflow cannulation techniques to reduce suction events, repositioning pumps to better mimic physiological flows, and integrating advanced sensor technology for real-time flow adjustment. Computational fluid dynamics is increasingly employed to refine device geometry and flow pathways, minimizing areas of stasis or turbulence that predispose to thrombosis. Research into biocompatible and antimicrobial device coatings aims to mitigate biofilm formation and reduce infection risks[36]. Additionally, hybrid surgical techniques, such as atrial cannulation or total artificial heart (TAH) hybrid configurations, offer tailored approaches to reduce complications associated with incorrect pump orientation and device mismatch. Future directions include the development of universal, adaptable VAD systems capable of supporting either ventricle or both, streamlining inventory and surgical complexity. Integration with remote monitoring, AI-driven predictive algorithms, and smart alert systems also represent frontiers poised to advance complication surveillance and personalized care.

Future Directions

Management and prevention strategies for complications in BiVAD (biventricular assist device) therapy require a comprehensive, multidisciplinary approach tailored to the complex physiological and clinical challenges associated with biventricular mechanical support. Advances in patient monitoring, anticoagulation and anti-infective protocols, alongside continuous innovations in device technology, have collectively contributed to improved outcomes and reduced complication burdens.

Multidisciplinary Monitoring and Follow-Up Care

The cornerstone of successful BiVAD management is an integrated multidisciplinary care paradigm involving cardiologists, cardiothoracic surgeons, specialized nurses, infectious disease experts, hematologists, rehabilitation specialists, and psychosocial support teams. Structured outpatient clinics with regular, often tri-monthly follow-up visits have emerged as best practice, facilitating surveillance for early detection of complications such as device thrombosis, infection, and right ventricular failure. These clinics employ standardized protocols encompassing clinical evaluation, hemodynamic assessment, laboratory tests, and device parameter monitoring to promptly identify and manage adverse events. Immediate access to specialized care teams for urgent interventions ensures timely responses to emergent issues, thereby minimizing hospital readmissions and preserving device function[37]. Moreover, patient education and engagement remain vital components. Empowering patients and caregivers with knowledge about device care, symptom recognition, anticoagulation adherence, and lifestyle adjustments enhances self-management and adherence to prophylactic measures. Rehabilitation programs focusing on physical conditioning, psychological support, and cognitive rehabilitation contribute to improved quality of life and functional capacity. Telemonitoring, leveraging remote digital platforms and data analytics, is an evolving adjunct that can augment traditional follow-up by enabling continuous physiological and device data transmission, facilitating early complication recognition and personalized intervention plans.

7. ANTICOAGULATION AND ANTI-INFECTIVE PROTOCOLS

Optimal anticoagulation management in BiVAD therapy seeks to prevent thromboembolic complications while minimizing bleeding risks, requiring individualized, closely monitored regimens. The standard of care typically involves a perioperative course of intravenous unfractionated heparin, transitioning to long-term oral vitamin K antagonists such as warfarin, with adjunctive low-dose aspirin for antiplatelet effect. Target international normalized ratio (INR) levels are generally maintained between 2.0 and 3.0, adjusted based on bleeding or thrombosis risk profiles, device type, and patient-specific factors. Emerging evidence supports the use of direct oral anticoagulants (DOACs) such as apixaban, which provide advantages of predictable pharmacokinetics, fewer drug-food interactions, and reduced monitoring burdens. However, robust prospective trials are still needed before universal adoption in BiVAD cohorts[38]. Anti-infective strategies emphasize preoperative prophylaxis against both Gram-positive and Gram-negative pathogens, typically with cephalosporins or vancomycin-based regimens depending on local antibiograms. Maintenance of sterile technique and rigorous driveline infection prevention protocols, including meticulous exit-site care, antimicrobial dressings, and prompt management of incipient infections, are critical in reducing device-related infections. In cases of established infection, prolonged culture-guided antibiotic therapy targeting biofilm-producing organisms such as Staphylococcus aureus—including methicillin-resistant strains—is essential. Multidisciplinary infectious disease collaboration promotes appropriate antimicrobial stewardship and mitigates antimicrobial resistance development[38].

8. DEVICE INNOVATION FOR REDUCING COMPLICATION BURDEN

The evolution of BiVAD technology has been pivotal in addressing many of the challenges historically associated with mechanical circulatory support. The latest devices incorporate magnetic levitation and centrifugal flow mechanisms, which significantly reduce shear stress, hemolysis, and thrombotic tendencies compared to axial-flow predecessors. For example, the HeartMate 3, originally an LVAD now being utilized in BiVAD configurations, utilizes fully magnetically levitated impellers that reduce blood trauma and improve hemocompatibility, translating into lowered rates of pump thrombosis and stroke[39]. Innovations also focus on optimizing inflow/outflow cannulation techniques to reduce suction events, repositioning pumps to better mimic physiological flows, and integrating advanced sensor technology for real-time flow adjustment[40]. Computational fluid dynamics is increasingly employed to refine device geometry and flow pathways, minimizing areas of stasis or turbulence that predispose to thrombosis. Research into biocompatible and antimicrobial device coatings aims to mitigate biofilm formation and reduce infection risks. Additionally, hybrid surgical techniques, such as atrial cannulation or total artificial heart (TAH) hybrid configurations, offer tailored approaches to reduce complications associated with incorrect pump orientation and device mismatch. Future directions include the development of universal, adaptable VAD systems capable of supporting either ventricle or both, streamlining inventory and surgical complexity. Integration with remote monitoring, AI-driven predictive algorithms, and smart alert systems also represent frontiers poised to advance complication surveillance and personalized care[41].

9. CONCLUSION

biventricular assist device (BiVAD) therapy represents a critical and evolving treatment modality for patients with end-stage biventricular heart failure who are not candidates for immediate heart transplantation. Despite significant advances, BiVAD support remains associated with considerable challenges, including hemodynamic imbalances, thromboembolic and hemorrhagic complications, infectious risks, and multisystem organ dysfunction. These complications contribute to the complexity of patient management and limitations in long-term survival and quality of life. Multidisciplinary monitoring and follow-up care have emerged as essential components for optimizing outcomes, with structured clinical programs integrating cardiology, surgery, infectious disease, hematology, rehabilitation, and psychosocial support. Anticoagulation and anti-infective protocols remain foundational to reducing thrombotic and infectious complications, with evolving strategies favoring individualized therapy and emerging agents like direct oral anticoagulants. Technological innovations in BiVAD device design, including magnetic levitation pumps, improved hemodynamics, biocompatible coatings, and computational optimization, are progressively reducing the burden of blood trauma, thrombosis, and infection.

Looking to the future, fully implantable BiVAD systems promise enhanced patient mobility and reduced infection risk, while artificial intelligence and machine learning integration are poised to revolutionize real-time device function monitoring and early complication prediction. Hybrid systems and total artificial hearts represent exciting avenues to provide complete cardiac replacement or more adaptable circulatory support, addressing limitations of current devices and extending therapeutic options. The BiVAD therapy has advanced substantially, ongoing research, technological innovation, and comprehensive multidisciplinary care are imperative to overcoming remaining challenges and improving survival and quality of life for patients with refractory biventricular heart failure. The convergence of device engineering, AI-enabled precision medicine, and optimized clinical protocols holds great promise for the future of mechanical circulatory support in advanced cardiac care.

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