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OVERVIEW OF MAJOR COMPLICATIONS FOLLOWING HEARTMATE 3 (HM3) LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION

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ABSTRACT

The HeartMate 3 (HM3) left ventricular assist device (LVAD) has become the current standard for mechanical circulatory support in patients with advanced heart failure. Its innovative design, including a fully magnetically levitated rotor and artificial pulse generation, has improved hemocompatibility and reduced mechanical failures. However, device-related complications remain a significant concern affecting patient outcomes. The main side effects of HM3 implantation, such as bleeding, infections, neurological events, and pump thrombosis, are examined in this review along with how they affect survival. Data from major clinical trials and observational studies were examined to identify complication rates, risk factors, and trends over time. Bleeding is the most frequent adverse event, occurring in approximately one-third of patients, with gastrointestinal bleeding observed in nearly 10%. 23–30% of recipients experience infections, especially driveline infections, and 3–5% experience neurological problems like ischaemic and hemorrhagic stroke, usually in the first six months following implantation. Pump thrombosis rates with HM3 remain among the lowest reported, ranging from 1.4% at two years to 2.8% at five years. Long-term results are positive in spite of these difficulties, with survival rates surpassing 80% at two years and 58% at five. Continued refinement of device technology and patient management is essential to further reduce complications and improve overall survival and quality of life.

KEYWORDS

Heartmate 3, Left Ventricular Assist Device, LVAD Complications, Neurological Complications, Stroke, Bleeding, Pump Thrombosis, Driveline Infection, Survival Outcomes, Destination Therapy, Bridge to Transplant

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Introduction

A Left Ventricular Assist Device (LVAD) is a mechanical pump that supports the function of the heart's left ventricle. LVADs are often implanted in patients with end-stage heart failure who are waiting for a heart transplant (bridge to transplant and bridge to recovery) or for whom transplantation is not an option (destination therapy). Two magnetically levitating Continuous-flow-LVADs are in use today and represent the current gold standard in LVAD therapy HeartMate3 (HM3) and HeartWare HVAD (HW) [1]. Initially, we intended to compare HM3 to HVAD, however, HVAD has been withdrawn from production. Given that HVAD is no longer implanted, HM3 has become the primary choice for many centers, making an in-depth discussion of its benefits and complications essential for clinicians and researchers.

HeartMate 3 is an FDA-approved device for short and long-term mechanical support in New York Heart Association (NYHA) Class III or IV heart failure patients [2]. The design of the HeartMate 3 includes a magnetically levitated rotor, wide blood flow gaps, and an artificial pulse, which are intended to optimize hemocompatibility during support [3].

HeartMate 3 has revolutionized LVAD therapy with its cutting-edge design, significantly reducing the risk of complications and improving patient survival and quality of life.

Ongoing technological advances applied in newer-generation LVADs have reduced the rates of reoperation due to a malfunctioning device, yet, broader use is often limited by inherent complications of the system, such as infections, thrombosis and stroke, which ultimately affect a patient's quality of life and survival [4]. This review focuses on discussing the possible complications following the use of HM3 as an LVAD in destination therapy or as a bridge therapy to heart transplantation.

Neurological Complications

Neurological complications, particularly strokes, are a significant cause of morbidity and mortality in patients with LVADs. Strokes are a leading neurological event associated with LVAD therapy, influenced by several risk factors, including hypertension, LVAD-specific infections, left ventricular thrombus, atrial fibrillation, and complications from antithrombotic therapy [5]. In the ELEVATE study, stroke accounted for 15% of deaths within two years, emphasizing its critical impact on long-term survival [2].

In patients treated with the HeartMate 3 (HM3), the risk of neurological complications is highest during the first six months post-implantation, after which it stabilizes at a slightly lower level over the following five years. According to the MOMENTUM 3 study, the probability of stroke was 3.7% at 30 days post-implant, 3.8% at 180 days, and 3.0% at five years [6,7]. This trend may be attributed to the evolving dynamics of patient health and the complexities of anticoagulation management, which could explain the increasing proportion of hemorrhagic strokes over time [8]. Additionally, in a cohort of older and sicker patients compared to those in the ELEVATE and MOMENTUM 3 studies, the risk of stroke was found to be higher in the first six months post-implant compared to the subsequent six months [3]. In a more recent single-center study, stroke incidence gradually increased over a five-year follow-up, underscoring the importance of postoperative care for survival [9].

Regarding stroke types, the ELEVATE and MOMENTUM 3 trials demonstrated similar outcomes. The probability of hemorrhagic stroke was 4.9%, while ischemic stroke was 5.6% over a two-year follow-up. Additionally, 5.0% of patients experienced a disabling stroke, defined as a modified Rankin Score (mRS) greater than 3 [10,11]. Notably, ischemic stroke was significantly more common in patients whose LVAD outflow graft was sutured to the descending aorta (75%) compared to those with grafts sutured to the ascending aorta (6%) [12].

Following HM3 implantation, patients who experienced either ischemic or hemorrhagic strokes had markedly worse survival rates compared to those without strokes. The two-year survival was 57% for ischemic stroke patients and 43% for hemorrhagic stroke patients, compared to 85% for those without a stroke. There was no significant difference in two-year survival between patients with disabling and non-disabling strokes (both at 51%), with most deaths following disabling strokes occurring within the first six months post-implantation [7].

When comparing therapeutic strategies, no significant differences in neurological complication rates were found between patients receiving bridge-to-transplant (BTT) therapy (89.2% free from neurological symptoms) and those undergoing destination therapy (DT) (88.1% free from neurological symptoms) [13]. However, patients with a history of stroke before implantation exhibited a slightly higher risk of subsequent strokes, indicating that baseline patient health is a crucial factor in post-implant outcomes.

In patients supported by HM3 and later undergoing orthotopic heart transplantation (OHT), the incidence of post-OHT stroke was higher compared to those not receiving LVAD support (4.4% vs. 2.0%).

BTT-HM3 patients had lower 30-day survival rates, although 90-day and 1-year survival rates were comparable. This suggests that optimizing patient selection and perioperative management is critical to improving outcomes in HM3-supported patients [12].

The transition from the HeartWare HVAD to the HM3 has led to a significant reduction in neurological complications. The MOMENTUM 3 trial showed that stroke rates in the HM3 group were 3.3 times lower than in patients who received the HVAD, likely due to improvements in device design and hemocompatibility [15,16,4,7]. Over a five-year follow-up, HM3 patients demonstrated greater freedom from hemorrhagic stroke (90.5% vs. 70.1%) compared to HVAD patients [17,18].

Comparisons of outcomes between patients who underwent HVAD-to-HM3 exchange and those who continued on HVAD support revealed that while survival rates were higher following HM3 exchange, the procedure was still associated with increased mortality risk compared to continuing HVAD support. Replacement of HVAD or HM2 with HM3 is recommended only in the presence of complications [19,20].

Figure 1. Freedom from disabling and nondisabling stroke at initial presentation (modified Rankin Scale score adjudicated at 60 days). A and B, Freedom from disabling and nondisabling strokes (isolated and recurrent strokes) at 60 days after stroke (the time for adjudication of the primary end point outcome of the strokes within the MOMENTUM 3 trial. [7]

Figure 2. Post–left ventricular assist device implantation survival analysis through 2 years. A, Survival by stroke subtype at initial presentation. Survival of patients who had either an ischemic stroke (IS) or hemorrhagic stroke (HS) was compared with that of patients who did not experience a stroke. Significantly more nonstroke patients were alive at 2 years after implantation compared with IS and HS patients. No significant difference in survival between the IS and HS patients was found. [7]

Table 1. Summary of the studies mentioned, focusing on stroke incidence, types, survival rates, and differences in therapeutic strategies.

Study/Author	Main Findings on Neurological Complications
ELEVATE Study [2]	Stroke accounted for 15% of deaths within two years.
MOMENTUM 3 Study [6,7]	Probability of stroke: 3.7% at 30 days, 3.8% at 180 days, 3.0% at 5 years. Increasing proportion of hemorrhagic strokes over time.
Garbade et al. 2019	Higher risk of stroke in the first 6 months compared to the next 6 months, especially in older/sicker patients.
Mondellini et al. 2023	Stroke incidence gradually increased over 5 years.
ELEVATE & MOMENTUM 3 (Mehra et al. 2021, Mueller et al. 2020)	Hemorrhagic stroke: 4.9%, ischemic stroke: 5.6%, disabling stroke (mRS > 3): 5.0%. Ischemic stroke more common with descending aorta grafts (75%) compared to ascending aorta grafts (6%).
Colombo et al. 2019	2-year survival: ischemic stroke patients (57%), hemorrhagic stroke patients (43%), no stroke patients (85%). No significant survival difference between disabling and non-disabling stroke patients (51%).
Goldstein et al. 2020	No significant differences in neurological complication rates between BTT (89.2% free from symptoms) and DT (88.1%). Slightly higher stroke risk in patients with prior stroke.
Kilcoyne et al. 2022	Higher incidence of post-OHT stroke in HM3 patients (4.4% vs. 2.0%). Lower 30-day survival in BTT-HM3 patients, but comparable 90-day and 1-year survival rates.
MOMENTUM 3 (Coyle et al. 2020, Schramm et al. 2020, Itzhaki Ben Zadok et al. 2019)	Stroke rates 3.3x lower in HM3 group compared to HVAD group. Freedom from hemorrhagic stroke in HM3 patients (90.5% vs. 70.1% in HVAD patients).
Cogswell et al. 2022, Hanafy et al. 2024	HM3 replacement associated with higher survival rates but increased mortality risk compared to continuing HVAD support.

Bleeding

The bleeding is one of adverse effects linked to Heart Mate 3 implementation. It is amongst the hemocompatibility-associated events apart from stroke and pump thrombosis. We can differentiate two notable types of bleedings related to LVAD installation - bleeding requiring surgery (meaning they required surgical re-exploration, excluded the cause being which the inflow or outflow sutures nor to the pump connections [14] and non-surgical bleeding.

In many cases, the bleeding is one of the most common adverse effects after Heart Mate 3 implementation.

The retrospective single-center study noted that amongst their 42 patients implanted with HeartMate 3, the bleeding was the second most often occuring issue after RV failure (16 patients) [14]. It comprised of 31% (13) patients requiring surgical re-exploration, 14% (14) patients with gastrointestinal bleeding, and rest of bleedings related to other systems such as nasopharyngeal (5 patients), bronchopulmonary (2 patients) and muscular (2 patients). Most of these instances of blood loss happened primarly at the time of hospital stay associated with LVAD implantation. In 31 cases devices were implanted as a bridge to transplantation, as destination therapy in 7 cases,, and as a bridge to candidacy in 5 cases.

In multicenter cohort study, the number and the character of Emergency Department encounters of patients implanted with LVAD was observed (7 of those 290 visits were patients with HM3) [21]. The second most frequently occurring cause of the ED encounter was bleeding - 18,6% of total visits, in which the melena (25 visits) and epistaxis (25) were occurring the most. Other specified types of bleeding were hematochezia (13 visits) and there was noted one incident of hematemesis. Between the patients in whom devices were implanted as a bridge to transplantation (BTT) and as a destination therapy (DT), there was no significant difference in 30-day mortality rate after an remarked ED encounter, but DT patients were 37.4% less likely to return to the ED within 30 days. The ED encounters of patients implanted with LVAD were more likely caused by obligatory anticoagulation therapy rather than the concern directly connected to function of the device.

The results from the ELEVATE registry, which reported the two year outcome after Heart Mate 3 implantation in 463 patients showed that 7% (5 of 75 total deaths) of deaths during the observation were caused by bleeding [15]. Major bleeding was the second (after major infection) most commonly noted adverse effect - it was observed in 156 (33,3%) cases, which included gastrointestinal bleeding (45 - 9,7%) and bleeding requiring surgery (57 - 12,3%). It was reported that gastrointestinal bleeding events have been associated with the degradation of multimers of Von Willebrand factor and continuous blood flow. Nonetheless, this phenomenon is lower compared with other devices therefore it is linked to an overall decrease GI bleeding rate.

In analysis of the outcome of 430 patients implanted with LVAD between the 2016 and 2020 in Netherlands, 288 of them were implanted with Heart Mate 3 [22]. 50% of the patients had been implanted with LVAD as a bridge to transplantation (BTT), 29% as a destination therapy (DT) and 21% as a bridge to candidacy (BTC), and the results showed that BTT patients had better survival outcome than DT patients (1 year survival outcome 86% vs 72%, 2 years survival outcome 83% vs 59% and 5 years survival outcome 58% vs 33%). Major bleeding was the second most frequently occuring major adverse event after major infection - a total of 253 cases, with similar frequency across BTT/BTD/DT patients. 40% of patients had a first major bleeding event after 24 months of device implantation, yet even 62% of patients had it after 5 years. The first postoperative days was a significant factor contributing in these adverse effect (15% cases of bleeding happened during that time). There was no significant difference between BTT patients and BTD/DT patients when it comes to bleeding risk.

Table 2. The following details are provided: the author and publication year, the total number of patients and cases with HeartMate III, the number of patients sustaining bleeding incident, the percentage of types of occuring bleeding events, the division of patients into categories (bridge to transplant, destination therapy, bridge to candidacy, bridge to decision, and bridge to myocardial recovery) and the type of study.

Author	Number of overall patients (n)	Number of HM3 patients (n)	Number of patients with incidences of any bleeding event (n)	Number of patients with incidences of any bleeding event (%)	Number of patients with incidences of gastrointestinal bleeding (%)	Number of patients with incidences of bleeding requiring surgery (%)	Bridge to transplant patients (%)	Destination therapy patients (%)	Bridge to candidacy patients (%)	Type of study
(Nowacka et al. 2020)	42	42	16	38,0	14,0	31,0	71,0	17,0	12,0	single-center retrospective study
(Finch et al. 2023)	290 (number of visits)	7	54	18,6	not applicable (n/a)	n/a	51,7	48,3	0,0	retrospective cohort study
(Zimpfer et al. 2020)	463	463	156	33,3	9,7	12,3	66,0	26,0	8,0	multicentre cohort study
(Damman et al. 2023)	430	288	253	58,9	n/a	n/a	50,0	29,0	21,0	single-center retrospective study

Pump thrombosis

Pump thrombosis is a serious complication of left ventricular assist devices (LVADs), involving thrombus formation in the pump or its conduits, which can potentially lead to circulatory failure. Suspected device thrombus is identified when clinical signs or parameters indicate clot formation, such as elevated hemolytic biomarkers like lactate dehydrogenase or sudden spikes in pump power [23,24,25].

The enhanced hemocompatibility of the HM3 device is largely due to its design features, comprising a large-diameter outflow graft, increased retrograde flow during pump cessation, and textured blood-contacting surfaces As a result, the HM3 device exhibits the lowest incidence of pump thrombosis compared to other LVADs [24,25].

Overall pump thrombosis was reported only in four out of the eleven studies included in this section of the review.

Pump thrombosis was suspected in a two-year review of the MOMENTUM 3 trial, with a reported rate of 1.4%. At the five-year follow-up this rate had increased to 2.8%. Additionally, three single-center studies reported suspected pump thrombosis rates of 2.2% in the Bansal et al. study, 2.8% in the Mihalj et al. study, and 3.6% in the Merlo et al. study [26,6,1,27].

It is important to note that in a prospective, observational study of the ELEVATE registry of HM3 by Garbade et al. with a follow-up at 30 days, as well as in a prospective, multi-center study by Schmitto et al with a follow-up at 2 years, prospective, multi-centre study by Suarez-Pierre et al. with a follow- up at 6 months, and other single-center studies, no cases of pump thrombosis were observed [3,28,29].

Table 3. The following details are provided: the author and publication year, the total number of subjects and those with HeartMate III, the division of subjects into categories (bridge to transplant, destination therapy), the number of patients with suspected pump thrombosis, and the type of study.

Author	Patients Overall/HM3	Thrombosis Events (%)	Bridge to transplant	Destination therapy	Type of study
(Nowacka et al. 2020)	42/43	0	31	7	SC
(Schramm et al. 2020)	364/106	0	72	34	SC
(Itzhaki Ben Zadok et al. 2019)	105/26	0	10	8	SC
(Suarez-Pierre et al. 2019)	1978/177	0	177	0	MC
(Marasco et al. 2019)	33/33	0	-	-	SC
(Schmitto et al. 2019)	50/50	0	27	23	P-NR
. (Garbade et al. 2019)	463/463	0	304	122	P-O
(Mehra et al. 2019)	1028/515	7	113	317	P-R
(Mehra et al. 2022) *	295/178	5	43	176	P-R
(Bansal et al.2022)	189/92	2	23	69	SC
(Mihalj et al. 2022)	106/36	1	23	13	SC

*Suspected or confirmed device thrombosis between 2-5 years of trial

Infections

Infections associated with left ventricular assist device (LVAD) implantation are significant complications that can lead to life-threatening conditions.These infections can be categorized into LVAD-specific infections, such as driveline infections, which are the most prevalent, as well as pump housing infections or inflow/outflow/pump pocket infection, and LVAD-related infections[14,8]**.**

In the studies reviewed, infections were a frequent complication following HeartMate 3 (HM3) implantation. Driveline infections were diagnosed based on clinical signs such as erythema, purulent discharge with a positive microbiological culture, tachycardia, tachypnea, pyrexia, elevated C-reactive protein (CRP) levels, and increased white blood cell count. These infections were generally managed successfully with antibiotic therapy, though surgical intervention was occasionally required.[16,12,1].

A pivotal trial, MOMENTUM 3, along with the continued access protocol (CAP) post-trial, reported a single pump replacement due to infection among 515 patients in the MOMENTUM 3 cohort, and seven pump replacements due to infection in the 1685-patient CAP cohort. Driveline infection rates were 23.3% in the MOMENTUM 3 cohort and 23.1% in the CAP cohort[10].

Driveline infections following HeartMate 3 implantation typically occur more than 30 days post-surgery, with a significant increase in incidence observed over time. The 30-day follow-up of the ELEVATE registry indicated a low rate of driveline infections (2%), but by the 2-year follow-up of this registry, the incidence had risen to 29.6%[3,8].

A single-center study reported that LVAD-specific infections occurred in 7% of patients during their hospitalization (with a mean post-implant hospital stay of 53.4 ± 54.4 days), whereas 41% of patients developed LVAD-specific infections after hospital discharge, with 36% of these being driveline infections [14].

Another single-center study demonstrated that 88.2% of driveline infections occurred after 30 days from implantation, while all other device-related infections also appeared after this period [1].

The 5-year follow-up data revealed that 28% of patients experienced a driveline infection within the first two years of implantation, while 32% encountered such infections between the second and fifth year post-implantation [17].

In general, infections related to the HeartMate 3 device are less frequent compared to those associated with HeartMate 2 (HM2) or HeartWare HVAD devices [29,16,22].

In the Suarez-Pierre study, the rate of HM3-related infection was slightly lower compared to HVAD and HM2 [29].

Freedom from driveline infection at one year was significantly higher in HM3 recipients compared to HVAD recipients (50.3% vs. 25.3%), with this trend persisting at two years (38.9% vs. 25.3%) [16].

Notably, only one article in this review indicated a higher incidence of driveline infections in HM3 patients compared to HVAD, though this difference was not significant for recurrent infections [1].

Infections remain a significant concern for patients implanted with the HeartMate 3. While technological improvements have led to better outcomes in areas such as pump thrombosis, the need for fully implantable LVAD systems to mitigate the risk of HM3-related infections has been emphasized.

Acute limb ischemia was reported only in the Bansal et al. study, with two cases of this event (2.2%) [6].

Table 4. The following details are provided: the author and publication year, the number of subjects with HeartMate III, the division of subjects into categories (bridge to transplant, destination therapy, bridge to candidacy, bridge to decision, and bridge to myocardial recovery), and the number of patients with LVAD-specific infections.

Author	Number of HM3 patients (final analysis)	Number of patients with infections event (n)	Number of patients with infections (%)	Bridge to transplant HM3	Destination therapy HM3	Bridge to candidacy+ bridge to decision+bridge to myocardial recovery HM3
(Mehra et al. 2021)	515	120	23.3%	112	317	86
(Garbade et al. 2019)	463	11	2	304	122	26
(Netuka et al. 2021) *	25	8	32	-	-	-
(Netuka et al. 2021)**	50	14	28	27	23	-
(Nowacka et al. 2020)	42	19	45	31	7	5
(Mihalj et al. 2022)	36	17	47.2	23	13	-
(Schramm et al. 2020)	106	42	39,6	72	34	-
(Suarez-Pierre et al. 2019)	177	21	11,9	177	-	-

*-between 2 and 5 years after implantation

**-At 2 years after implantation

Survival

The survival rates following HM3 implantation have been the subject of extensive research and clinical analysis. Recent studies indicate promising outcomes for patients receiving this device.

The MOMENTUM 3 trial included 1,020 patients, with 515 receiving HM3. After two years, 88.4% of these patients were alive, and 76.9% were free from disabling stroke or device-related reoperation. Mehra et al. reported on long-term outcomes from the pivotal trial and the continued access protocol (CAP) phase, which together included 2,200 patients with 515 participating in the pivotal trial and 1,685 in the CAP. At two years, survival without disabling stroke or reoperation was 76.7% in CAP and 74.8% in the pivotal trial, with overall survival rates of 81.2% and 79%, respectively. A recent 5-year follow-up showed 58.4% survival in the centrifugal-flow group [23,26,30].

In CE Mark Study- a multicentre, prospective, non-randomized, single-arm study conducted by Schmitto et al. involving 50 HM3 subjects, the 6-month, 1-year, and 2-year survival rates were reported as 92 ± 4%, 81 ± 6%, and 74 ± 6%, respectively [28].

The ELEVATE registry followed 540 patients implanted with HM3, including 463 primary implants (Primary Implant Cohort). The 24-month survival rate for this cohort was 83.4%, with 78.3% stroke-free. The overall two-year survival for the Full Cohort, which also included pump upgrades and patients with outcomes prior to signing informed consent, was 74.5% [8].

The MIRAMACS Italian Registry included 447 patients, with 214 (47.9%) implanted with HM3 and 233 (52.1%) with HVAD. A 1:1 propensity-score matching analysis of 130 recipients each revealed a significantly better 5-year survival rate for HM3 at 64.1%, compared to 41.7% for HVAD [18].

A retrospective analysis of survival data from the EUROMACS registry examined patients supported with either HW or HM3 devices. After 1:1 propensity score matching, each group included 361 patients. The 2-year survival rates were comparable between the two groups, with HW at 61% and HM3 at 68% [13].

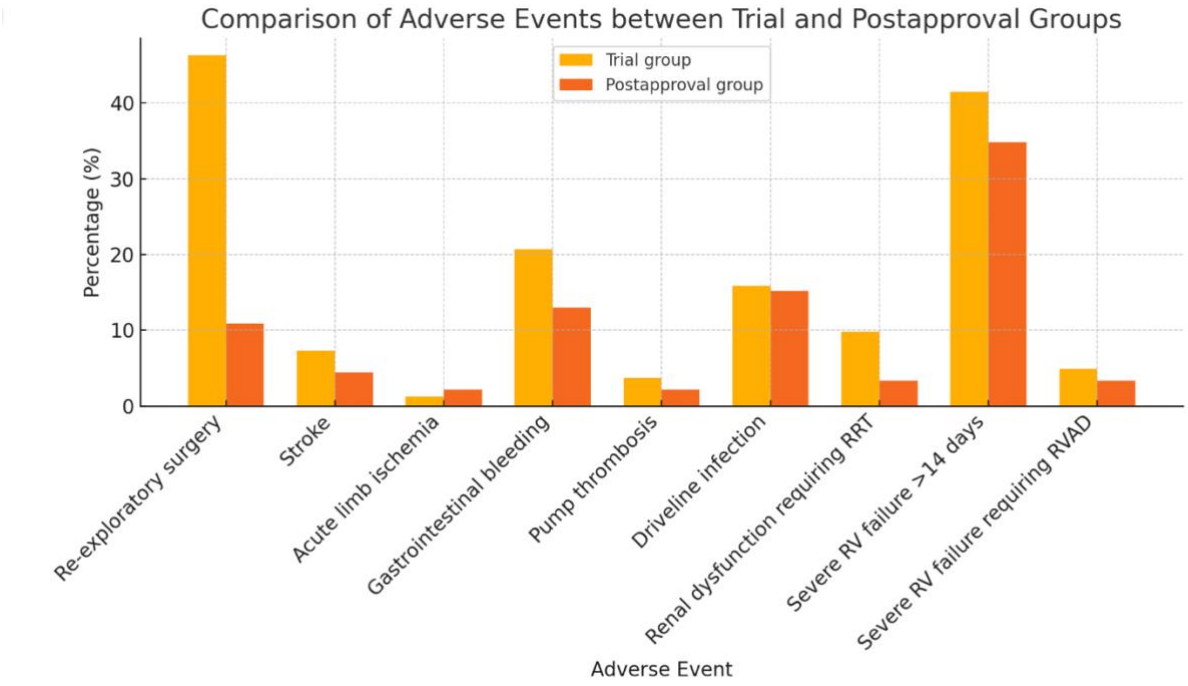

Figure 3. The table presents a comparison of adverse events between the trial group and postapproval group in a single-center study evaluating the real-world experience with the HeartMate 3 (HM3) device following FDA approval. This study was a retrospective, observational analysis of patients who received the HM3 as a primary implant between October 2017 and March 2020 [18].

Conclusions

In conclusion, the HeartMate 3 (HM3) left ventricular assist device (LVAD) has demonstrated significant improvements in patient outcomes compared to earlier LVAD models, especially in reducing pump thrombosis, with rates as low as 1.4% at two years and 2.8% at five years, and in some studies, showing no pump thrombosis events at all. However, complications such as bleeding, infections, and neurological events continue to pose clinical challenges. Bleeding remains the most frequent complication, affecting 33.3% of patients in the ELEVATE registry, with gastrointestinal bleeding in 9.7% of cases. Infections, particularly driveline infections, occur in 23.3% to 29.6% of patients, contributing significantly to morbidity. Neurological complications, including strokes, are also prevalent, with stroke rates reaching 3.7% at 30 days and remaining at 3.0% after five years. The data emphasize the importance of patient management post-implantation, particularly in the first six months, and the need for ongoing improvements in device design to further reduce complications.

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