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Omentoplasty for ventricular assist device infections: Encouraging outcomes

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BACKGROUND: LVAD infections are associated with substantial morbidity and mortality. We explored the impact of surgical Omentoplasty (OMP) added to Incision and Debridement (I&D) plus Antibiotic therapy (AB) on survival and infection-related readmissions in patients with LVAD infections.

METHODS: Thirty-three patients with deep LVAD-specific infections were studied over a period of 12 years. Survival and readmissions for recurrent infection in subjects receiving I&D and ABs alone (Group A, n = 15) were compared to those in whom OMP was added to I&D and ABs (Group B, n = 18).

RESULTS: Baseline characteristics were similar between groups, as well as infectious organisms. Two-year survival was significantly improved in Group B (OMP + I&D + ABs) as compared to Group A (I &D + ABs without OMP) [77% vs. 7%; $p < 0.001$]. Recurrent infection-related readmissions were notably lower in Group B compared to Group A (0.18 vs. 0.24 admissions/patient-year), with a significant reduction within Group B following the application of OMP (0.13 to 0.06 admissions/patient-year). Following OMP, intravenous (IV) antibiotics were successfully replaced with oral long-term ABs in the 78% of patients. No long-term antibiotic-related complications were noted.

CONCLUSION: This report, comprising the most extensive such experience to date, indicates that combining surgical Omentoplasty (OMP) with incision and debridement (I&D) plus antibiotic (AB) treatment is remarkably effective for suppressing deep LVAD infections, improving survival and decreasing infection-related readmissions. Filling the open space around an implanted LVAD with

Abbreviations: OMP, Omentoplasty; I&D, Incision and Debridement; AB, Antibiotic; IV, Intravenous; DLES, Driveline Exit Site; NPWT, Negative Pressure Wound Therapy; VAC, Vacuum-assisted Closure

Preliminary findings were presented at the 42nd annual meeting of the International Society for Heart and Lung Transplant, Boston, Massachusetts.

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highly vascularized omentum, as a living tissue with anti-infective properties, appears to be effective for improving outcomes with LVAD infections.
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Introduction

Mechanical circulatory support (MCS) has become a well-established and effective treatment for advanced heart failure (HF) patients, as a bridge to transplant (BTT) or long-term destination therapy (DT), providing improved survival and quality of life.[1,2] Marked advancements with Left Ventricular Assist Device (LVAD) therapy have been made although device-associated infection remains challenging.[3]

In the REMATCH trial (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure), overall infection rates of 42% at one year and 52% at two years were reported.[4] More recently, in the MOMENTUM 3 trial (Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with HeartMate 3), device-associated infection rates of 58% for HeartMate 3 (HM3) and 56% for HeartMate II (HMII) at two years were identified.[5] An ISHLT (International Society for Heart and Lung Transplantation) MCS Registry analysis revealed that 37% of LVAD patients experienced multiple infections, most frequently within three months after implantation.[6] These infections have a profound impact on patients' quality of life, morbidity and mortality as well as healthcare costs.[7–10]

Major infections are among the leading causes of death in LVAD patients.[11] Survival rates are significantly lower in LVAD patients with major infections as compared to those without infection (73.6% vs. 84.8% at 2 years).[5]

Infections associated with LVAD therapy are categorized within the ISHLT consensus statement into two main groups: (a) MCS-specific infections and (b) non-MCS-specific infections.[12] Among these categories, pump and pocket infections pose serious, life-threatening challenges. In addition to surgical implant-related etiologies. these deep LVAD infections may occur as an extension of driveline exit site (DLES) infections or through hematogenous spread.[8]

The ISHLT consensus guidelines for the management of MCS-specific/related infections recommend (a) prompt institution of empiric, systemic antimicrobial therapy, tailored to microbiologic assessments, (b) consideration for surgical drainage, with or without NPWT (negative pressure wound therapy) using VAC (vacuum-assisted closure) dressings, then (c) antibiotic therapy, pathogen specific, for 6–8 weeks followed by long-term antibiotic suppression.[13,14] For definitive cure, or for addressing recalcitrant infections, it has been recommended that transplant listing or device exchange should be considered.

Additional intervention involving the mobilization and transfer of viable, vascularized tissues around the involved pump components, following surgical debulking of gross contamination, has been suggested in published guidelines arising out of a combined analysis by the AATS (American Association for Thoracic Surgery) and ISHLT.[15] In support of this, there have been limited reports of encouraging outcomes with viable tissue transpositions, involving omental tissue transfer, or Omentoplasty (OMP), and/or muscle transposition into proximity with the infected VAD components for managing extensive DLES infections or deep LVAD pocket infections.[16–19]

Omentum is a specialized adipose tissue in the peritoneal cavity with excellent vascularization, plasticity, and immunologic properties, making it uniquely suited to defend against microorganisms and injuries in the peritoneal cavity.[20,21] Omentoplasty has been used with success in cardiothoracic surgery for severe wound infections, infected vascular grafts, immunosuppressed patients after heart transplant, complex chest wall and mediastinal reconstruction among other procedures.[22–24]

The objective of this retrospective review was to assess the impact of adding surgical Omentoplasty (OMP) to the conventional treatment of surgical incision and debridement (I&D) plus antibiotics (ABs) on survival and infection-related readmissions in patients with deep LVAD-specific infections.

Methods

The setting of this study is an advanced HF program in a moderately large healthcare system serving a multi-state region. The program offers a wide range of HF services, from general cardiovascular care to advanced therapies, including LVAD and total artificial heart (TAH) implantation, percutaneous short-term MCS, heart transplantation and a region-wide, emergent-care ECMO (extracorporeal membrane oxygenation) cardiopulmonary support network. The research protocol was approved by the Institutional Review Board and complies with ISHLT ethical guidance. All data were extracted from electronic medical records and de-identified.

Study population

A retrospective review of the medical records of 515 patients implanted with LVADs between 2011 and 2023 identified 37 patients who had developed deep LVAD-specific infections (0.006 events/patient-year). Two study groups were identified. Group A patients (n = 15) received generally established, conventional therapy, including surgical washout with incision and debridement (I&D), antibiotic-containing beads, NPWT & VAC wound management, and IV Antibiotics (ABs). Group B

patients (n = 18) underwent Omentoplasty (OMP) surgery in addition to the conventional therapy that Group A patients received. Patients with LVAD infections in which infection management did not follow the protocols employed in groups A and B (n = 4) were not included in this study.

Among the two groups, Group A (without OMP) and Group B (with OMP), patient demographics and clinical characteristics were analyzed, as were infectious organisms. Two-year survival was compared between Group A and Group B, as well as the number of recurrent infection-related readmissions in each group.

Infection management

Infections were confirmed with cultures, clinical findings, lab results, and/or radiographic evidence. All patients, in both Groups A and B, initially received intravenous antibiotics (IV ABs) based on culture results, and subsequently, both groups of patients underwent conventional treatment, including surgical debridement, washout, NPWT & VAC wound management and antibiotics. Additionally, patients in Group B underwent omentoplasty (OMP), once gross contamination was controlled and infectious burden minimized. The administration of IV ABs continued indefinitely for those in Group A (without OMP). On the other hand, IV ABs with Group B (with OMP) were continued only for an average of 6 weeks after the OMP, following which patients transitioned, as tolerated, to oral antibiotics for long-term chronic suppression.

Surgical technique

The surgical approach followed general principles as outlined in the AATS-ISHLT guidelines.[15] Surgical exploration of the deep LVAD components was generally approached through a left subcostal incision, exposing the infected segments of the pump, driveline and outflow graft. Exploration was extended as needed to drain all abscess fluid and debride grossly infected and non-viable tissue. Samples were obtained for culture and for microbial DNA analysis. Extensive irrigation with an antimicrobial solution using pulsing lavage was undertaken. The wound was closed with a VAC dressing employing Negative Pressure Wound Therapy (NPWT). Prior to closure, antibiotic containing and eluting beads were left in place around the pump components unless continuous infusion of an antimicrobial solution via a VAC-instillation setup was employed instead. This process was repeated every few days until gross contamination was cleared and microbial assays indicated little to no detectable residual infection.

The antibiotic beads were created using the OSTEOSET™ Resorbable Bead Kit – Fast Cure (Wright Medical Technology, Memphis, TN). Each kit comprises 25 gm of powder and 7.8 mL of mixing solution. Additionally, 1.2 gm of Tobramycin Sulfate and 0.5 gm of Vancomycin Sulfate were added to the mixture.

In Group B patients, Omentoplasty (OMP) was included as the final step. The peritoneal cavity was entered and the greater omentum was mobilized through the incision which was extended as needed for adequate exposure and mobilization of the omentum. Caution was exercised to avoid injuring abdominal organs or leaving them mal-positioned. Bleeding from the highly vascularized omentum was carefully controlled. The omental pedicle was placed around the pump and exposed internal percutaneous lead. The pedicle was advanced further into the thorax substernally along the outflow graft. The omentum was secured into position with absorbable sutures. The communication between the peritoneum and thorax, having been created by transecting the diaphragm anteriorly, was left open enough to allow free passage of peritoneal fluid through the pathway but sufficiently approximated around the omentum to prevent herniation of abdominal organs (Supplemental Figure 1).

Adsorbable antibiotic beads were placed as were drains. The incision was closed assuring a secure, tension free closure of the abdominal wall.

Statistical analysis

Statistical analysis was performed using the SPSS statistical package (IBM, version 26, New York). Results were presented as mean ± standard deviations (median) or number (%). Differences between groups were analyzed using the independent *t*-test for continuous variables and Fisher's exact test for categorical variables. Two-year survival curves were generated using the Kaplan-Meier method and compared by the log-rank test. All statistical tests were two-sided, and differences were considered significant when $p \leq 0.05$.

Results

Baseline characteristics

Demographics and clinical characteristics of Group A (without OMP) and Group B (with OMP), at the time infection was diagnosed, are compiled in Table 1. Baseline demographic and clinical characteristics were similar between groups with the two exceptions, more HM3s in Group B and longer Time from implant to infection in Group B. These differences reflect the evolution of practice over the 12 years of the study. As experience with OMP and evidence of its benefit accrued, a greater proportion of patients received OMP (Group B) in the latter half of the study. With improving infection prevention, the time from implant to infection was longer in more patients receiving OMP. In the later years of study, more HM3s were being implanted than HMIIs as the older technology phased out of use. We did not identify any significant differences between the use of OMP with HM3 in comparison to its use with HMII.

Infectious agents

Infectious agents were similar between Groups, with the most common organism being *Staphylococcus aureus,* followed by *Pseudomonas* (Table 2). The presence of virulent organisms, particularly *Pseudomonas* and methicillin-resistant *Staphylococcus aureus* (MRSA), was associated with higher mortality rates in both groups.

Table 1 Baseline Demographics and Clinical Characteristics of Patients in Group A and Group B.

	Group A (without OMP, n = 15)	Group B (with OMP, n = 18)	*p* value
Mean age – yrs	57 ± 14 (median = 62)	61 ± 11 (61)	0.42[a]
Sex – n (%)	M = 9 (60%), F = 6 (40%)	M = 14 (78%), F = 4 (22%)	
Cardiomyopathy – n (%)	ICM = 7 (47%), NICM = 8 (53%)	ICM = 9 (50%), NICM = 9 (50%)	1.00[b]
LVAD type – n (%)	HMII = 14 (93%) HM3 = 1 (7%)	HMII = 11 (61%) HM3 = 7 (39%)	0.05[b]
Time from implant to infection – yrs	1.2 ± 1.1 (median = 0.8)	2.3 ± 1.7 (1.8)	0.04[a]
BMI – kg/m²	29.4 ± 5.2 (29)	29.6 ± 4.8 (28.3)	0.81[a]
DM – n (%)	5 (33%)	7 (39%)	1.00[b]
CKD – n (%)	8 (53%)	11 (61%)	0.73[b]
DLES involvement – n (%)	7 (47%)	5 (28%)	0.30[b]
WBC – x10³/uL	12 ± 5.7 (median = 10.5)	9.4 ± 3.5 (8.4)	0.13[a]
Platelet count – x10³/uL	218 ± 115 (209)	211 ± 102 (199)	0.85[a]
Creatinine – mg/dL	1.4 ± 0.8 (1.3)	1.4 ± 0.5 (1.4)	0.81[a]
BUN – mg/dL	22 ± 14 (18)	26 ± 16 (20)	0.47[a]
Total Bilirubin – mg/dL	1 ± 0.7 (0.7)	1.1 ± 0.7 (0.8)	0.53[a]
AST – unit/L	35 ± 19 (28)	32 ± 19 (29)	0.67[a]
ALT – unit/L	36 ± 39 (20)	30 ± 21 (24)	0.60[a]
Albumin – g/dL	2.8 ± 0.6 (2.9)	3.1 ± 0.5 (3.2)	0.12[a]
LDH – unit/L	354 ± 144 (352)	294 ± 78 (279)	0.17[a]

Data presented as mean ± standard deviations (median) or number (%). *P* values derived from [a]independent *t*-test or [b]Fisher's exact test.

OMP, Omentoplasty; M, Male; F, Female; ICM, Ischemic Cardiomyopathy; NICM, Nonischemic Cardiomyopathy; HM, HeartMate; BMI, Body Mass Index; DM, Diabetes Mellitus; CKD, Chronic Kidney Disease; DLES, Driveline Exit Site; WBC, White Blood Cells; BUN, Blood Urea Nitrogen; AST, Aspartate aminotransferase; ALT, Alanine aminotransferase; LDH, Lactate Dehydrogenase.

Table 2 Microbial Culture Results by Patients in Group A and Group B

Group A (without OMP, n = 15)		Group B (with OMP, n = 18)	
Staphylococcus aureus, Methicillin-susceptible (MSSA)	n = 2	*Staphylococcus aureus*, Methicillin-susceptible (MSSA)	n = 3
Staphylococcus aureus, Methicillin-resistant (MRSA)	2	*Staphylococcus aureus*, Methicillin-resistant (MRSA)	3
MRSA + *Enterobacter aerogenes*	1	MRSA + *Proteus mirabilis*	1
Pseudomonas aeruginosa	3	*Pseudomonas aeruginosa*	1
Enterococcus faecalis	1	*Pseudomonas aeruginosa* + *Candida albicans* + *Streptococcus agalactiae*	1
Mycobacterium abscessus	1	*Staphylococcus lugdunensis*	1
Mycobacterium chelonae	1	*Klebsiella pneumoniae*	1
Serratia marcescens	1	*Legionella*	1
Staphylococcus epidermidis, Methicillin-resistant	1	*Staphylococcus epidermidis*, Methicillin-resistant	1
Corynebacterium	1	*Propionibacterium acnes*	1
Escherichia coli + Extended-spectrum β-lactamase (ESBL) + *Candida glabrata*	1	*Gemella haemolysans*	1
		Negative culture (with clinical diagnosis of infection)	3

OMP, Omentoplasty

Outcomes

The two-year survival in Group B, with OMP, was 77%, significantly better than 7% in Group A, without OMP, ($p < 0.001$, Figure 1). Over the course of this study, there were 13 deaths in Group A and 4 deaths in Group B. Causes of death are in Table 3.

One patient in Group A and one patient in Group B underwent heart transplantation. The procedures were uneventful with no unexpected findings associated with prior surgical intervention, with or without OMP.

Recurrent infection-related readmissions were notably lower in Group B when compared to Group A (0.18 vs. 0.24 admissions/patient-year). Additionally, within Group B, infection-related readmission decreased significantly following the application of OMP, from 0.13 to 0.06 admissions/patient-year. After OMP treatment, 14 patients in Group B (78%) were transitioned to oral ABs, with only 3 patients (17%) remaining on IV ABs, in contrast to Group A, where all patients (100%) continued on IV ABs. Of note, no long-term antibiotic-related complications were noted in either group.

Our approach to LVAD-related infections underwent a valuable evolution over the course of 12 years contributing to improved outcomes. Preventative measures and follow-up were intensified. Surgical intervention, when needed, was initiated earlier, especially with percutaneous lead exit

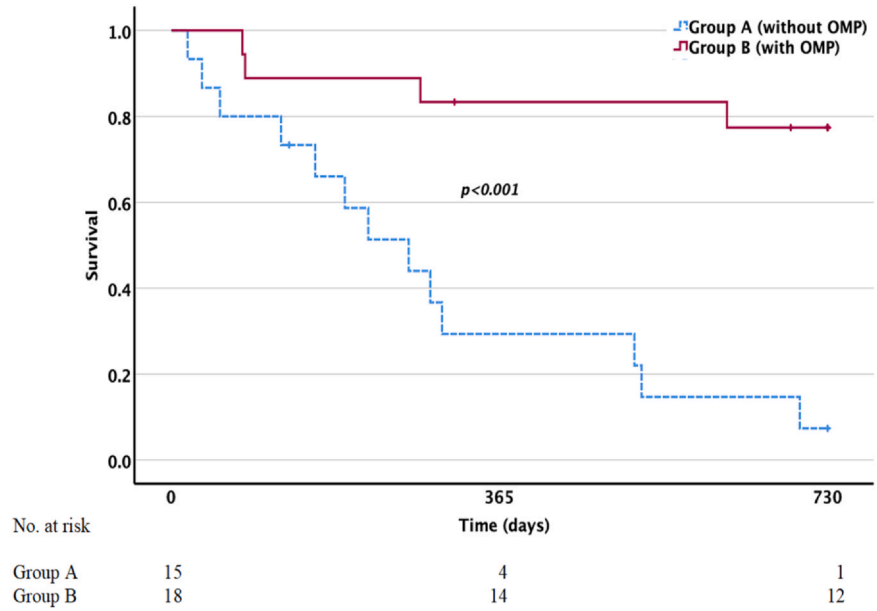

Figure 1 Two-year Kaplan-Meier (KM) survival curves for Group A (without OMP) versus Group B (with OMP). *P* value generated by log-rank test. OMP, Omentoplasty.

site infections refractory to conservative, antibiotic therapy. Percutaneous lead exit site infections were the most common precursor to deeper, LVAD pocket infections.

In our early experience with OMP, the selection of patients and the timing of its application varied considerably as we first began to explore and, subsequently, better understand the utility and best use of OMP. Our approach evolved into more unified practice emphasizing earlier use of OMP. We noted a significant reduction in infection-related readmissions with earlier OMP use within 60 days of first identifying infection versus after 60 days (0.30 vs. 0.10 admissions/patient-year).

Discussion

The cumulative findings of this retrospective study demonstrate a remarkable impact of omentoplasty (OMP) for improving outcomes with deep LVAD-specific infections when deployed as a complementary supplement to otherwise conventional approaches. Survivorship at two years was markedly improved with OMP (Group A, without OMP = 7% vs. Group B, with OMP = 77%, $p < 0.001$) as seen in Figure 1. Rehospitalization for infection was notably lower in Group B (0.18 vs. 0.24 admissions/patient-year), with a pronounced reduction observed following the application of OMP (0.13 to 0.06 admissions/patient-year). The prolonged use of IV antibiotics was reduced by 78% without an increase in recurrent infection, lessening the challenges of long-term, outpatient IV delivery.

While the emphasis of this study is on the value of OMP, the utility of integrating and standardizing fundamental strategies for managing infections of implanted devices cannot be overlooked. This begins with the basics of intravenous antibiotics and surgical I&D. Wound management with NPWT and VAC dressings is believed to be beneficial.[25–28] The use of antibiotic beads, releasing high levels of antibiotics locally around infected implanted devices has an established track record with infected orthopedic hardware and vascular grafts [29,30] and has been effectively adopted for LVAD infections.[31,32] It should be noted that standardizing all these elements of care into our guidelines and harmonizing our practices among our caretakers were central to our learning over time. Further, it set the stage for providing a controlled platform which allowed for a careful evaluation of the effect of OMP as a single change in practice.

This study, demonstrating the value of omentoplasty (OMP) extends prior findings, which have been encouraging but have been limited to smaller experiences with variable outcomes. Among the earliest reports was a single case study reporting OMP for salvaging a Novacor LVAD pump pocket infection.[18] An early series of 5 cases managed with OMP

Table 3 Causes of Death by Patients in Group A and Group B

Causes of death	Group A (without OMP, n = 15)	Group B (with OMP, n = 18)
Refractory infections complicated by neurologic adverse events	n = 10	n = 2
Refractory infections with sepsis	3	1
Perioperative complications	0	1

OMP, Omentoplasty

reported suppressing infection long enough for most to undergo transplantation.[33] In a series of 12 patients, OMP and muscle flaps allowed salvage but with a 50% mortality.[34] A more encouraging report was a 15-patient series undergoing OMP or muscle flaps without failure to salvage and avoiding pump replacement but noting a high rate of periprocedural complications including flap loss.[35] A meta-analysis of surgical approaches to LVAD pocket and driveline infections reported a salvage rate of 59% using flap-reconstruction, half of which were with omentum.[36] Another study focused on 17 LVAD patients with refractory mediastinitis, treated with omental flaps in addition to surgical debridement and IV antibiotics, reported a 47% survival rate at discharge from index hospitalization and a one-year survival rate of 23%.[37] Other, smaller, case reports have noted successful salvage of LVADs with deep LVAD infections employing omentoplasy in combination with the conventional treatments.[19,38,39] The largest experiences have reported OMP for managing percutaneous lead infections.[40] A study involving 13 LVAD patients with chronic driveline exit site (DLES) infection, who received omentoplasty, reported that 69% of the patients were infection-free upon hospital discharge but, within one year, 23% of the patients experienced a recurrent infection.[40]

We believe the outcomes reported in this study set a new standard for what is achievable in managing LVAD-specific infection. This is encouraging, given the limited prior availability of high-quality evidence and well-established guidelines for managing such complex infections and achieving acceptable outcomes.

Going forward, the use of OMP as a supplement to conventional surgical maneuvers should now be considered before resorting to more extensive measures, including LVAD replacement or bailout transplantation. Further studies to explore this are warranted.

Omentoplasty should be considered as a viable alternative to LVAD replacement for infection, given the complexity, challenges, risk and expense of removing all hardware, providing temporary MCS, performing repeated operations over days to weeks to clear infection and then reimplanting another LVAD, all of which adds substantially to the burden of care. The reported experience and level of evidence supporting LVAD replacement for infections [15] is not yet compelling.

The experience with bailout transplantation for resolving LVAD infections exceeds that with LVAD replacement and is reasonably encouraging.[15] However, it seems appropriate, given this study, to consider OMP as providing sufficient likelihood of controlling infection, for at least an extended period of time, that OMP should be considered before resorting to transplantation as a bailout. The impact of prior OMP on the heart transplantation procedure is not deemed to be prohibitive, as has been the case in our experience.

Overall, this study demonstrates the effectiveness of using omentoplasty (OMP) as a supplement to surgical I&D and ABs in managing deep LVAD infections and preventing recurrence of infection. Early consideration of OMP upon recognizing deep LVAD infections may result in decreased infection-related hospitalizations and fewer adverse events associated with severe LVAD infections.

Limitations

This study is limited to a single-center, retrospective review and, thus, replication is warranted. A proactive, controlled study design with randomization into two groups was not practical, given our overall low occurrence rate of deep LVAD-specific infections – as well as uncertainties of the early and novel use of OMP. Nevertheless, it represents the largest such experience to date with encouraging results.

The follow-up period in this study is limited to two years. Whether these encouraging outcomes can be viewed as a long-term solution, with indefinite suppression, is subject to further analysis. We did not attempt to discontinue antibiotics as an effort to demonstrate eradication of infection, believing that chronic antibiotic administration was a more acceptable risk.

Procedural challenges not as well addressed in this study include managing LVAD infections extending well beyond the pump pocket into the superior mediastinum. Positioning the omental pedicle along the outflow graft substernally has thus far been successful in preventing the progression of infection into the superior mediastinum. However, more extensive intervention involving sternotomy and muscle flaps may be required as a supplement to omentoplasty with these extended infections.

An obvious point of caution includes prior abdominal surgery or pathologies that would preclude mobilization of an omental pedicle. Fortunately, the omentum was usable in all cases in this study.

For both of these procedural limitations, the inability to use omentum and/or upper mediastinal infections, the use of alternative tissue flaps would be required.

The addition of reconstructive, plastic surgeons to the team managing these complex infections would extend the surgical expertise, especially with the use of muscle transposition as an alternative, or supplement, to omentoplasty. The same could be expected should skin flaps be needed for wound coverage.

Ultimately, this experience highlights ongoing opportunities to reduce LVAD infections. We look forward to continued advancements in prevention and management as well as technological innovations, such as the elimination of percutaneous leads.

Conclusion

Deep LVAD-specific infections are associated with significant mortality and morbidity. This report, comprising the most extensive such experience to date, indicates that combining surgical Omentoplasty (OMP) with incision and debridement (I&D) plus antibiotic (AB) treatment is remarkably effective for suppressing deep LVAD infections, improving survival and decreasing infection-related readmissions. Filling the open space around an implanted LVAD with highly vascularized omentum, as a living tissue with anti-infective properties, appears to be effective for improving outcomes with LVAD infections.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Douglas A. Horstmanshof reports a relationship with Abbott Medical that includes: consulting or advisory and speaking and lecture fees. Aly El Banayosy reports a relationship with Abbott Medical that includes: consulting or advisory. James W. Long reports a relationship with BrioHealth Solutions that includes: consulting or advisory. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Author contributions

AMB, SG, and JWL conceptualized the study. DWV, DRF, MTB, CCE, and JWL provided patient resources. AMB, SG, DAH, AB, and JWL acquired, analyzed, and interpreted the data. AMB, SG, DWV, HS, MRM, and JWL drafted the manuscript, with contributions from all authors.

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Appendix A. Supporting information

Supplemental data associated with this article can be found in the online version at doi:10.1016/j.jhlto.2025.100264.

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