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ORIGINAL CLINICAL SCIENCE

Heterogeneity in HeartMate 3 implanting center infection management reveals opportunities for quality improvement and best practice initiatives during left ventricular assist device support

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BACKGROUND: There is marked variability in device-related (DR) infection frequencies across HeartMate 3 (HM3) centers. The goal is to correlate center driveline (DL) management and infection mitigation practices with DR-infection development, laying foundation for development of best practice recommendations for one facet of HM3 patient care.

METHODS: Coordinators at 30 HM3 centers were surveyed about center practices for infection prophylaxis, intraoperative DL placement and postoperative care, and infection mitigation. Early (≤90 days) and late (>90 day) center DR-infection frequencies were calculated from Society of Thoracic

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Surgeons Intermacs data linkage. Correlations between center practice patterns and incident DR-infection were examined with multivariable Cox modeling (clustering adjusted hazard ratio [aHR]).

RESULTS: Within Intermacs (3,725 patients), 1-year freedom from DR-infection was 87% (80.6–87.3%). Initially, DL dressing changes were performed daily, weekly, and variably at 48%, 21% and 31% of centers. After 4 weeks, 57% deescalated dressing changes to weekly. Chlorhexidine cleanser with a silver-impregnated dressing (Chl-Sil) was standard at 52.7% of programs; 47.3% used chlorhexidine alone or other supplies. Use of Chl-Sil was associated with reduced early (aHR 0.48, $p = 0.004$) and late (aHR 0.64, $p = 0.02$) DR-infection while frequent dressing changes conferred higher late DR-infection (aHR 1.4, $p = 0.05$). Antibiotic prophylaxis, DL tunneling, and diabetes practices did not correlate with DR-infection.

CONCLUSIONS: Given the burden of DR-infections, best practice recommendations are needed to standardize care. Application of Chl-Sil DL dressings could be a first step in achieving care standardization, while frequent dressing changes following DL incorporation should be avoided.

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Mechanical circulatory support (MCS) with contemporary durable left ventricular assist devices (LVADs) continue to improve survival and quality of life for appropriate candidates with advanced heart failure (HF). In a post hoc analysis of data from the Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy With HeartMate 3 (MOMENTUM 3) clinical trial, the dispersions from clinical trial medians in HeartMate 3 (HM3, Abbott, Abbott Parkway, IL) patient outcomes according to LVAD implanting center were examined.[1] While median HM3 patient mortality in the trial was 6.6% at 90 days, the unadjusted implanting center 90 day mortality ranged from ≤3.5% (25th percentile) to as high as ≥10.4% (75th percentile) and mortality at 2 years ranged from < 10% to ≥18.7% (median 13.2%).[1] While some adverse events (AE) such as stroke displayed minimal overall variability in frequency across the implanting centers, overall infection frequencies were highly variable at both the 90 day (ranging from ≤0.1% to ≥8.4% [median 4.9%]) and 2 year time frames (ranging from ≤0.13 to ≥0.26 events per patient year [eppy] [median 0.19 eppy]).[1] The Society of Thoracic Surgeons (STS) Intermacs registry has demonstrated similar center-level outcome variability around published national averages.[2]

While outcomes following LVAD implant have continued to improve, the ''time at risk'' for developing infection complications on support has also increased secondary to gains in long-term survival. Infection adversely impacts long term success on LVAD support.[1–3] Thus, there is a critical need to understand key sources driving variability in infection during LVAD support, allowing the field to narrow gaps in care quality. Various patient characteristics (e.g. age and body mass index)[4–7] and behaviors (e.g. driveline water exposure),[8] have been correlated with the development of driveline infections. However, the roles of center-specific and/or surgical practices on the incidence of infections and relationship to clinical outcomes are not well understood.[5,9]

To this end, the primary goal of the Assessing Site-sPecifIc PatteRns of LVAD patient management leading to Exemplary outcomes with HM3 (ASPIRE) project is to characterize LVAD center practice patterns in the preoperative, intraoperative, and postoperative care phases of HM3 support. Using center-level data from The STS National Intermacs Database, we also aimed to correlate frequency of infections with clinical practice pattern variability nationally and at the level of the individual implanting center. For this ASPIRE report, we focused on the variability in device-related infection rates at HM3 implant centers across the United States (U.S.) with the aim to identify practices in infection prevention and management that favorably or negatively impact infection development during HM3 support. Ultimately, our goal is to lay foundation for learning and to prompt discussion of best care practices for infection mitigation for the field, reducing variability and elevating long-term outcomes.

Methods

The ASPIRE project is a quality initiative supported by Abbott, Inc (Abbott Parkway, IL) and assisted by the International Consortium of Circulatory Assist Clinicians (ICCAC) and other field thought leaders. The project's aim is to improve HM3 patient outcomes through scrutiny of AEs in the context of individual implanting center practice patterns. From the 69 centers participating in the MOMENTUM 3 pivotal trial (NCT02224755) and/or continue access protocol (NCT02892955),[10] 30 sites were randomly selected to participate in a multidimensional survey about patient and device management. The survey ($n = 419$ questions, 79 applicable to the study herein) was electronically distributed in 2022 by an ASPIRE LVAD coordinator and completed by one programmatic LVAD coordinator/representative from each of the 30 selected MOMENTUM 3 implanting centers. The LVAD coordinator could choose to solicit input from their physician teammates as they deemed fit. Surveys were voluntary, uncompensated, and took on average 2–3 hours to complete in total. Study authors were fully blinded to individual center Intermacs results. The study was exempt from Institutional Review Board approval.

The aims of the ASPIRE infection project were as follows:

1) Examine variability in infection control practices in the perioperative (preoperative, intraoperative, and early postoperative) and chronic phases of HM3 support across ASPIRE centers. The specific focus herein was on driveline care.
2) Characterize center variability in management of device-related infections within the ASPIRE cohort.
3) Using patient level data from STS Intermacs, correlate infection AE frequency in the context of implant center clinical practice patterns.
4) Using results from aims 1-3, propose best care practices for infection mitigation and management to reduce unnecessary variability in LVAD care.

ASPIRE Survey

The electronic survey contained questions pertaining to the perioperative and long-term care of the HM3 patient. Questions specifically related to the topic of infection (n = 79) are presented in abbreviated form in Table S1. Briefly, center care of the driveline in the perioperative and long-term care periods, as well as antibiotic utilization and diabetes care were evaluated as follows (Table 1).

1) *Diabetes management*: Includes a HgA1C target of ≤6.5%.
2) *Antibiotic utilization*: Includes duration of pre- and postoperative antibiotic prophylaxis and threshold to initiate antibiotics for management of a suspected or confirmed device-related infection.
3) *Driveline care*: Includes questions related to early (< 4 weeks) and late (≥4 weeks) postoperative driveline dressing and skin cleanser type and frequency of dressing change for uncomplicated sites. Dressing types included chlorhexidine cleanser with a silver-impregnated dressing; chlorhexidine cleanser with a chlorhexidine-impregnated patch; chlorhexidine cleanser without any impregnated patch or silver dressing; and other (including Medihoney or iodine). Frequency of change was also assessed and included daily, every 2-3 days, or once weekly dressing changes.

When assessing frequency of utilization of an applicable care practice in the survey, the coordinators were asked to select from the following descriptors based on their best opinion of general center practice: rarely (< 20% of the time), sometimes (20–40% of the time), often (approximately 50–60% of the time) and nearly always/always (approximately 80% or more of the time).

Permission was then obtained from the implanting centers to examine center-level infection outcomes and survival for patients on HM3 support reported to STS Intermacs (implanted between September 2018 through March 2023), focusing on incident device-related infection

Table 1 Questions Posed to ASPIRE Center Left Ventricular Assist Device (LVAD) Coordinators and Categorization of Care Intensity

Domain question	Standard intensity	High intensity
Driveline Care:		
How often are dressing changes performed in early period (< 4 weeks postop)?	Every other day to weekly	Every day
Once trained, does the patient/caregiver do driveline changes when hospitalized after training?	No	Yes
Who makes decisions on management of a driveline infection?	Individual	Team
Are images scored or characterized for longitudinal monitoring?	No	Yes
Do you use a wound vac to facilitate driveline healing?	No	Yes
Do you offer driveline debridement for infection?	No	Yes
Patients use driveline immobilization devices?	Not at all, rarely, often	Always/nearly always (80% of the time or more)
Patients are trained during hospitalization on how to safely shower	No	Yes
Antibiotic Care:		
How long are antibiotics given preoperatively?	≤24 hours	> 24 hours
How long are antibiotics continued postoperatively if no infection concerns are noted?	≤48 hours	> 48 hours
Do you irrigate the pump pocket with antibiotics?	No	Yes
Do you have a programmatic protocol you follow for infection management?	No	Yes
What is the threshold for starting an antibiotic?	Fever and/or symptoms along with driveline drainage	Driveline drainage alone
Diabetes Management:		
We optimize patients' diabetic management before LVAD implant?	No	Yes
Who manages diabetes while hospitalized?	We do not consult endocrinology	Endocrinology consultation with or without others
What percent of diabetic patients have a HgA1C ≤6.5 mg/dl during LVAD support?	Less than 80%	80% or more

frequency within 90 days of implant (early infection) and incident infection from 90 days to 2 years (late infection). Device-related infection definitions were applied using STS Intermacs adverse event definitions (version 6.1 user guide).[11]

Statistical analysis

Abbott, Inc. performed data analyses related to the ASPIRE survey. Drs. Cowger and Kanwar and Ms. Schettle has full access to ASPIRE data. STS Intermacs analyses were performed by the STS Intermacs data and clinical coordinating center (Kirso, Inc, Birmingham, AL) to maintain center de-identification. Data linkage of institutional STS Intermacs data and ASPIRE survey results were performed by the STS Intermacs Data Coordinating Center (KIRSO, Birmingham, AL) through an STS Research Center contract with Abbott. SAS (Cary, NC) and R software were used for data analyses. Categorial data are presented as counts and percentages (n, %) and were compared with Fisher's exact test. Continuous data were evaluated for normality and are presented as mean ± standard deviation or median [25th, 75th] as appropriate for distribution. Continuous data were compared between groups with Student's t-testing (normal data) or Mann Whitney U test (non-normal data).

Cox proportional hazards modeling was undertaken to examine the impact of practice patterns with time to first LVAD-related infection over 2 years of follow-up using a stepwise approach. The impact of various practice patterns examining driveline care, antibiotic use, and diabetes management were individually examined. For consideration in multivariable modeling, all care domain questions (e.g. driveline management, antibiotic use, diabetes management) were forced into binary responses of either "high intensity" or "standard intensity" answers (Table 1) using clinical expert rationale (Kormos and Kirklin) to guide classification. Classification was undertaken prior to data analysis and with implant center blinding.

Cox hazard models for comparison of incident early and late device infection within the cohort of INTERMACS patients at ASPIRE centers were adjusted for clinically relevant variables (age and BMI),[4,5,7] ASPIRE care domains, and variables with a $p \leq 0.05$ on univariable modeling (see footnote Table 3). An exit criterion of $p \leq 0.05$ as used. To account for the potential influence of unmeasured center-specific variability in the infection endpoint, we implemented separate modeling methods and assessed the differences in overall changes in model outcomes. Four models were constructed based on initial stepwise variable selection, utilizing different methodologies: the first model used basic Cox proportional hazard methodology without considering unmeasured hospital level variation, the second included the implanting hospital as a fixed effect, the third utilized a hospital level clustering methodology in the Cox model, and finally a shared frailty term of implanting hospital in the Cox model.

For the multivariable modeling and time to event (KM) analyses, continuous variables were imputed to the mean and categorical variables to the mode. Variables with > 20% missing were not included. For all analyses, a $p \leq 0.05$ was considered statistically significant. Hazard ratios (HR, [95% confidence interval]) are presented.

The data for part of this research were provided by The Society of Thoracic Surgeons. The views or opinions presented in this document are solely those of the authors, and do not represent those of The Society of Thoracic Surgeons.

Results

Of the 69 centers participating in the MOMENTUM 3 trial, 30 (randomly selected) sites participated in the ASPIRE survey. Figure S1 depicts the participating centers and Table S2 briefly outlines the characteristics of the respondents and implanting center. Center volume of active patients on LVAD support (any make/model) were as follows: 34% had < 100 active patients, 48% had between 100 and 200 active patients, and 18% had over 200 active LVAD patients. Of 11,539 patients undergoing HM3 LVAD implant with registration to STS Intermacs between 2018 and 2023, nearly one-third (n = 3,725, 32%) had a device placed at one of the 30 ASPIRE centers. Characteristics of the STS Intermacs HM3 patient sample are in Table S3 and are largely representative of those previously analyzed in larger STS Intermacs samples.[12] Within this STS Intermacs HM3 patient cohort, freedom from first device-related infection was 87% (80.6–87.3%) at 1 year and 78% (71.1–78.8%) at 2 years. Of the incident device-related infections, 90% were characterized as driveline infections while 10% involved the external surface or blood-contacting surface of an implantable component.

Preoperative antimicrobial drug use

Significant variability was noted in the count and duration of antimicrobial prophylaxis administered pre-LVAD implantation. Of 30 centers, 13% (n = 2) used one preoperative antimicrobial, 57% (n = 17) used two, 23% (n = 7) used three, and 5% (n = 4) used four preoperative antimicrobial drugs. The vast majority (70%, n = 21) of centers gave preoperative antimicrobials for ≤12 hours prior to LVAD implantation, while 20% (n = 6) and 10% (n = 3) administered them for 24 hours and > 48 hours preoperatively, respectively. Postoperatively, antimicrobials were continued for 24 hours in 25% (n = 7) of centers, 48 hours in 54% (n = 15), 72 hours in 14% (n = 4) and 5 days in 7% (n = 2) of centers. Within the cohort of ASPIRE patients enrolled into STS Intermacs, the occurrence of early (≤90 days postoperative) or late (> 90 days) device-related infection was not associated with a center's duration of pre- or post-operative antimicrobial use on univariable analysis (p > 0.05, Table 2).

Diabetes management

High intensity diabetes management (defined as having a protocol for diabetes optimization prior to LVAD implant,

Table 2 Association of Center Care Practice with Early (First 90 Days Postoperative) and Late (After 90 Days) Device-Related Incident Infection After HeartMate 3 Left Ventricular Assist Device Implant in Intermacs Patients Implanted at ASPIRE Centers*

	Intermacs early infection (%) Median [IQR]	Unadjusted hazard ratio [95% CI]	Intermacs late infection (EPPY) Median [IQR]	Unadjusted hazard ratio [95% CI]
Perioperative driveline and antibiotic management				
Timing of antibiotic prophylaxis preoperative:				
24 hours or less (*n* = 23 centers)	4.5% [1.5–6.8%]	1.7 [0.93–3.3]	0.25 [0.14–0.44]	1.1 [0.85–1.3]
> 24 hours (*n* = 6 centers)	2.2% [0.0–3.0%]	Reference	0.26 [0.17–0.34]	Reference
Antibiotic prophylaxis duration postoperative:				
48 hours or less (*n* = 21 centers)	3.3% [1.2–6.3%]	0.81 [0.52–1.3]	0.25 [0.15–0.38]	1.2 [1.0–1.5]
> 48 hours (*n* = 7 centers)	3.0% [1.9–7.7%]	Reference	0.35 [0.17–0.61]	Reference
Double tunnel driveline routinely:				
No (*n* = 15 centers)	3.2% [0.0–5.2%]	1.3 [0.78–2.0]	0.22 [0.14–0.38]	0.98 [0.82–1.2]
Yes (*n* = 10 centers)	2.8% [1.5–6.5%]	Reference	0.34 [0.19–0.44]	Reference
Driveline management postoperative				
Driveline kit contains:				
Chlorhexidine cleanser and silver dressing (*n* = 15 centers)	2.2% [1.0–4.7%]	0.48 [0.32–0.73]	61.5% [59.5–63.3%]	0.62 [0.52–0.73]
Other (*n* = 14 centers)	5.7% [3.3–7.7%]	Reference	74.2% [74.2–75.9%]	Reference
Dressing kit contains Medihoney:				
Yes (*n* = 4 centers)	8.8% [4.8–13.3%]	Reference	0.22 [0.14–0.38]	Reference
No (*n* = 25 centers)	2.6% [1.2–5.2%]	0.38 [0.24–0.59]	0.39 [0.30–0.52]	0.85 [0.67–1.1]
Driveline dressing change frequency in first 4 weeks postop:				
Less than daily (*n* = 11 centers)	5.0% [0.97–6.8]	Reference	0.37 [0.08–0.61]	Reference
At least daily (*n* = 14 centers)	3.2% [1.9–6.4]	0.93 [0.62–1.4]	0.25 [0.152–0.35]	1.3 [1.1–1.5]
Driveline dressing change frequency beyond 4 weeks postop:				
Once weekly (*n* = 17 centers)	3.3% [1.9–5.2%]	Reference	0.25 [0.15–0.38]	Reference
More than weekly (*n* = 12 centers)	3.7% [0.75–7.2%]	0.93 [0.62–1.4]	0.30 [0.15–0.50]	1.5 [1.3–1.8]
Use wound vac to assist with driveline healing during infection:				
Rarely (*n* = 22 centers)	3.3% [1.9–6.3%]	Reference	0.34 [0.18–0.44]	Reference
Yes (*n* = 7 centers)	2.3% [0.0–6.8%]	0.50 [0.30–0.96]	0.17 [0.14–0.3]	0.71 [0.60–0.90]
Diabetes Care				
We have a protocol to optimize blood sugars prior to LVAD implant:				
Yes (*n* = 14 centers)	2.6% [0.0–6.5]	Reference	0.17 [0.14–0.35]	Reference
No (*n* = 13 centers)	3.3% [2.3–5.2]	1.0 [0.68–1.5]	0.4 [0.2–0.6]	1.2 [1.0–1.5]
Endocrinology consults on all/most[a] inpatients:				
Yes (*n* = 23 centers)	3.0% [1.0–5.2]	Reference	0.3 [0.2–0.4]	Reference
No (*n* = 6 centers)	6.6% [2.3–7.7]	1.1 [0.63–1.8]	0.2 [0.1–0.3]	0.75 [0.59–0.95]

(*continued on next page*)

Table 2 (*Continued*)

	Intermacs early infection (%) Median [IQR]	Unadjusted hazard ratio [95% CI]	Intermacs late infection (EPPY) Median [IQR]	Unadjusted hazard ratio [95% CI]
The HgA1C is ≤6.5% in most[a] LVAD patients:				
Yes (n = 15 centers)	3.0% [1.0–6.5]	0.88 [0.59–1.3]	0.3 [0.1–0.6]	0.89 [0.76–1.1]
No (n =13 centers)	4.7% [2.3–6.4]	Reference	0.3 [0.2–0.4]	Reference

EPPY, events per patient year; IQR, interquartile range; LVAD, left ventricular assist device.
See text and Table 1 for definition of high intensity care.
*The unadjusted hazard ratio for infection associated with the care practice is show at each time point. There were 30 centers queried in the survey and the count of responding centers to each question is show in the first column.
[a]Most = 80% or more of patients.

routine endocrinology consultation for management during index stay, and achievement of HgA1C ≤6.5 mg/dl in approximately >80% of patients) was present in only 24% (n = 7 of 29 responding centers) of ASPIRE centers. Within the ASPIRE – STS Intermacs patient cohort, 25% (n = 899) of patients were managed at centers reporting high intensity diabetes management. While the occurrence of early device infection was not associated with protocolized blood sugar optimization or routine consultation with endocrinology in the perioperative period, incidence of late infection was lower on univariable analysis in patients with higher intensity diabetes management during the index admission (Table 2). While a cardiac surgery benchmark in STS, intraoperative blood sugar was not assessed herein.

Driveline placement and management

Intraoperative driveline placement

Of the 30 responding centers, the driveline was *nearly always/always* mapped prior to surgery at 40% (n = 12) of centers while 46% (n = 14) *rarely* marked the driveline course. Within the operative period, 100% of centers *always* ensured that driveline velour was buried for infection mitigation. Of 25 responding centers, double tunneling of the driveline was undertaken routinely in 40% of centers (n = 10); 16% of centers (n = 4 of 25) *always* double tunneled the driveline. Most commonly, the driveline was tunneled through the rectus sheath (56%) or adipose (39%) tissue. Externally, a driveline securement method (i.e. foley anchor or other securement system) was *always/nearly always* applied to abdominal skin at 93% centers. In the early postoperative phase, few centers (14%) *always/nearly always* used an abdominal binder, while 77% of centers *always/nearly always* (n = 23 of 30) used a suture ("stay stitch") for early reinforcement of driveline securement. Within the STS Intermacs HM3 patient sample from participating ASPIRE centers, driveline tunneling and pump pocket irrigation were not associated with the development of early or late infection (Table 2).

Dressing change frequency

In stable, asymptomatic early postoperative (≤4 weeks) patients, 48% (n = 14 of 29 centers answering survey) of centers performed driveline dressing changes daily as part of protocol, 21% (n = 6) changed the driveline once weekly as part of protocol, and 31% (n = 9) had variable practices (Figure 1a). All centers used a sterile technique early after implant. After 4 weeks, dressing changes were deescalated to weekly at 57% (n = 17 of 30 centers) of centers and every 2–3 days in 33% (n = 10) of centers; daily dressing changes occurred at only 10% (n = 3) of ASPIRE centers after 4 weeks (Figure 1b).

In Intermacs patients implanted at ASPIRE centers, dressing change frequency in the early postoperative period did not correlate with the development of early device-related infection (Figure 2a, Table 2). In contrast, the occurrence of incident late driveline infection was 30–50%

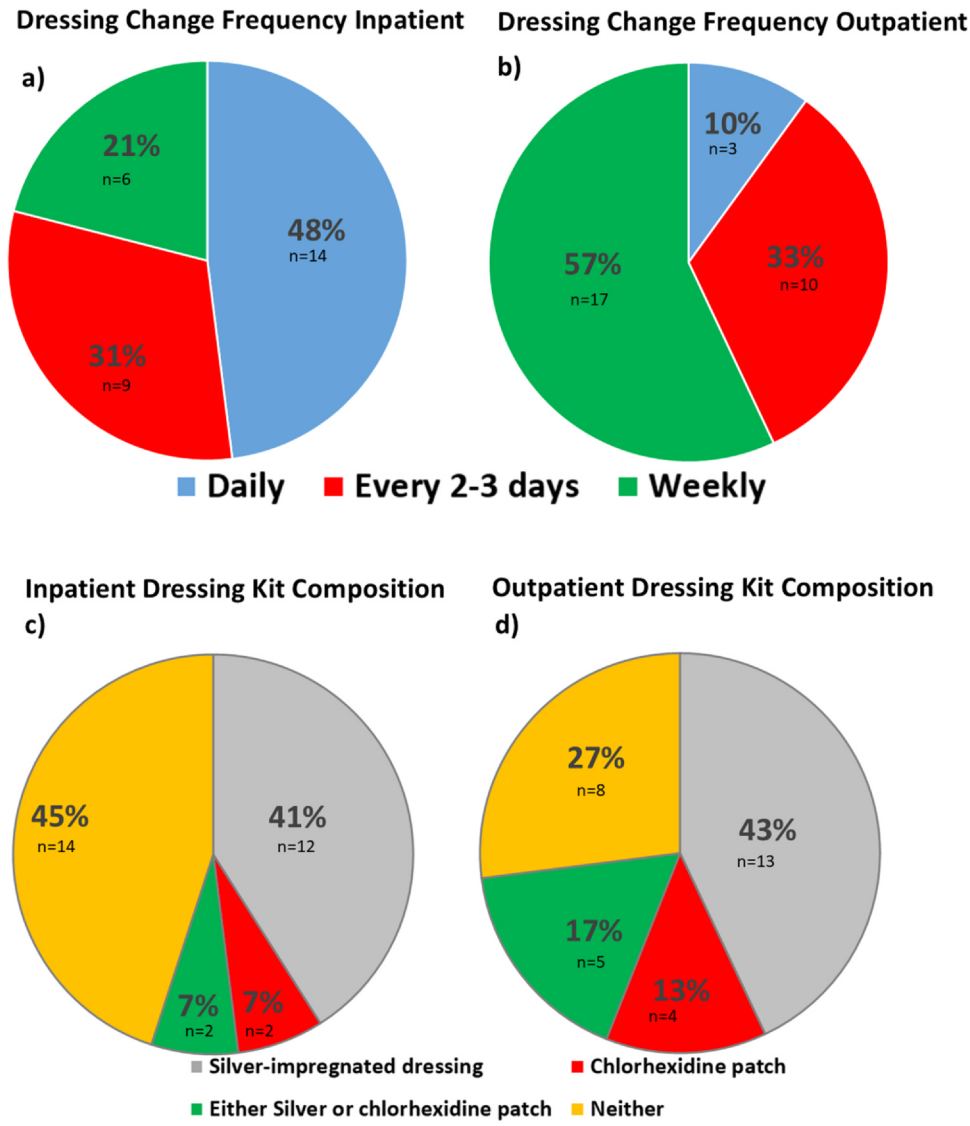


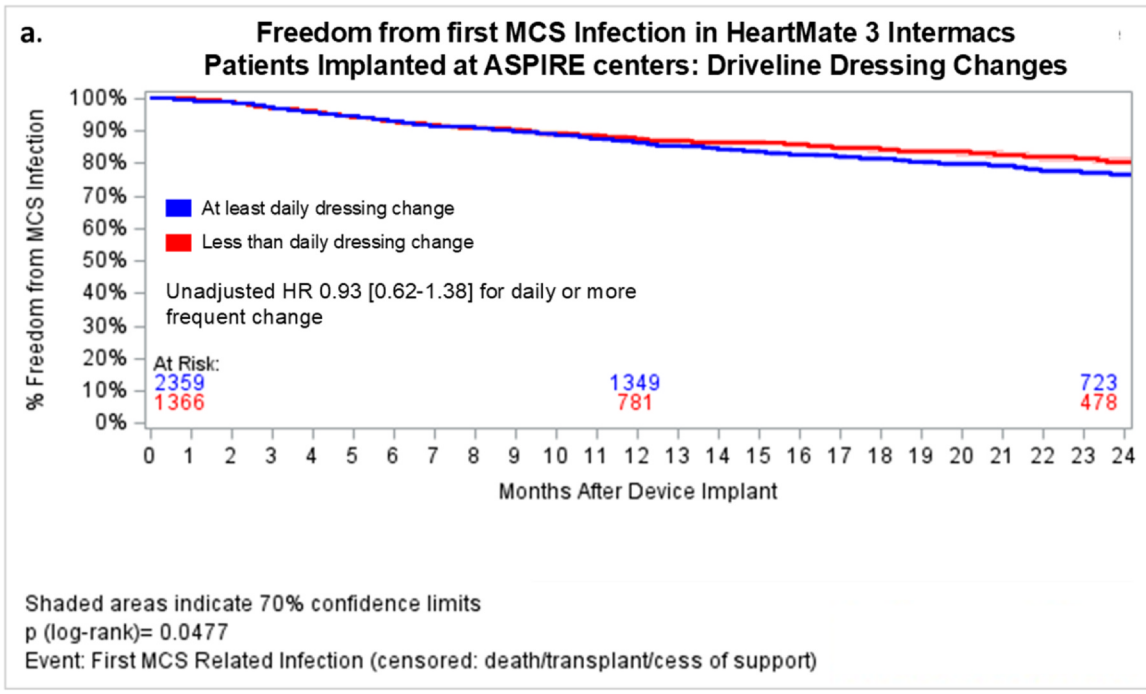
Figure 1 Driveline care in the early (≤4 weeks) and later (>4 weeks) postoperative HeartMate 3 time frames at ASPIRE centers. Dressing change frequency selected by ASPIRE centers during routine management of HeartMate 3 patients during the index admission (n = 29 centers responded) (a) and after hospital discharge (n = 30 centers responded) (b) are shown. Distribution of driveline dressing contents selected by ASPIRE centers for the routine care of HeartMate 3 inpatients during the index admission (c) and the outpatient support periods (d) are also shown (n = 30 centers). Many centers de-escalated dressing changes within the first 4 weeks of implant (daily reduced to every 2–3 days or even weekly).

higher in Intermacs patients at ASPIRE centers that employed frequent dressing changes in either the early postoperative (p = 0.013) or late postoperative (p < 0.001) periods (Table 2).

Figure 1c-d shows the dressing kit contents selected by ASPIRE centers for routine inpatient and outpatient driveline care. There were 1,962 (52.7%) Intermacs patients at ASPIRE centers who predominantly used chlorhexidine cleansers with silver impregnated dressings and 1,763 (47.3%) patients who used other dressing kit contents (e.g. chlorhexidine-impregnated patch or no silver/chlorhexidine patch). Intermacs patients at ASPIRE centers who predominantly used a driveline kit containing a chlorhexidine cleanser with a silver-impregnant gauze/dressing had 52% fewer early incident driveline infections and 38% fewer incident infections at 2 years (unadjusted p < 0.001, Figure 2b and Table 2).

Management of device-related infections

In patients with concern for device-related infections, only 10% (n = 3 of 30 centers) of ASPIRE programs primarily rely on the surgeon for derivation of an infection management plan. The threshold for antibiotic initiation was not uniform and most commonly guided by presence of multiple variables, of which a positive culture and/or drainage were frequent (Figure 3). A combination of at least 3 or more of these factors tended to prompt the majority (60%, n = 18) of ASPIRE centers to initiate antibiotics. Blood cultures were obtained at 38% (n = 11 of 29 responding centers) of centers when an LVAD patient presented with any infection concern, 31% (n = 9) of centers required presence of a fever alone to obtain blood cultures, and 31% (n = 9) required a combination of fever, infection history, drainage, or other infection concern to



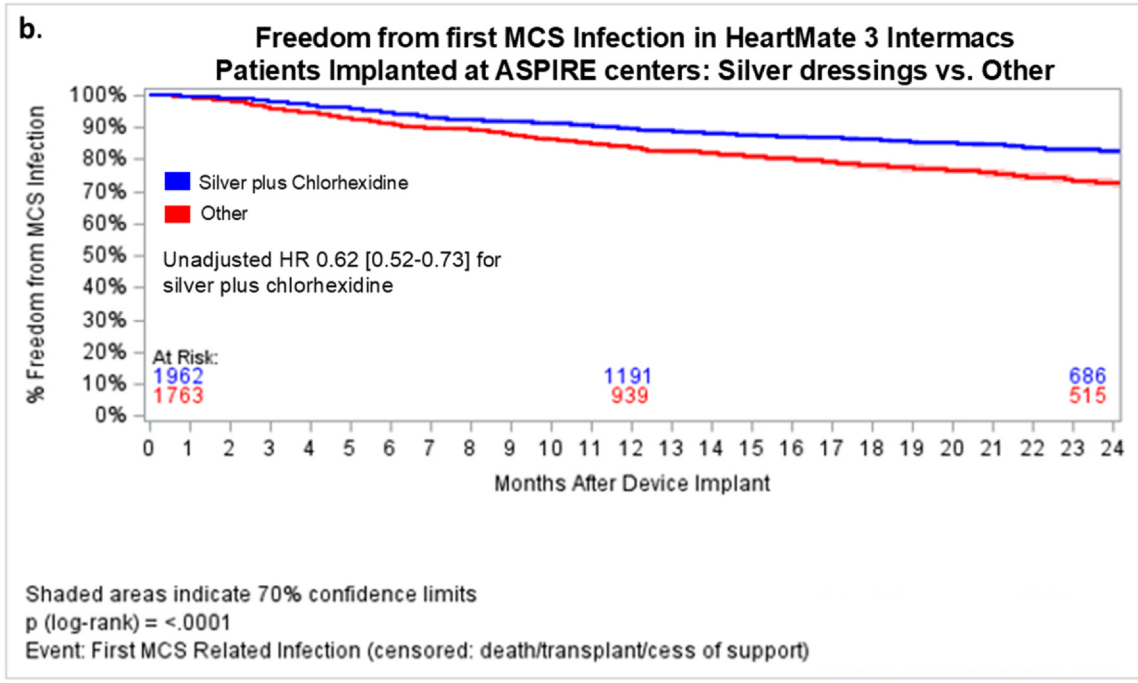


Figure 2 Freedom from incident device-related infection in HeartMate 3 Intermacs patients from ASPIRE centers. (a) Freedom from incident device-related infection in Intermacs patients at ASPIRE centers that advise daily dressing changes (blue line) vs less than daily changes (red line). (b) Freedom from incident device-related infection in patients using chlorhexidine cleanser with silver-impregnated (blue line) dressing vs others (red line).

prompt blood cultures. In the inpatient setting, use of antibiotics and blood cultures was more common (Figure S2). When an infection was suspected (complicated or uncomplicated), 84% (n = 21 of 25 centers) of centers routinely consulted an infectious disease specialist. At the remaining sites, infectious disease is consulted only if intravenous antibiotics are possibly needed, or the device-related infection is recurrent/persistent.

Multivariable analysis of infection and center care practices

Table 3 shows the results of multivariable modeling assessing care practices and the occurrence of device-related infection after LVAD in Intermacs patients at ASPIRE centers. After initial variable selection, the model adjusting for clustering of unmeasured hospital level variability is

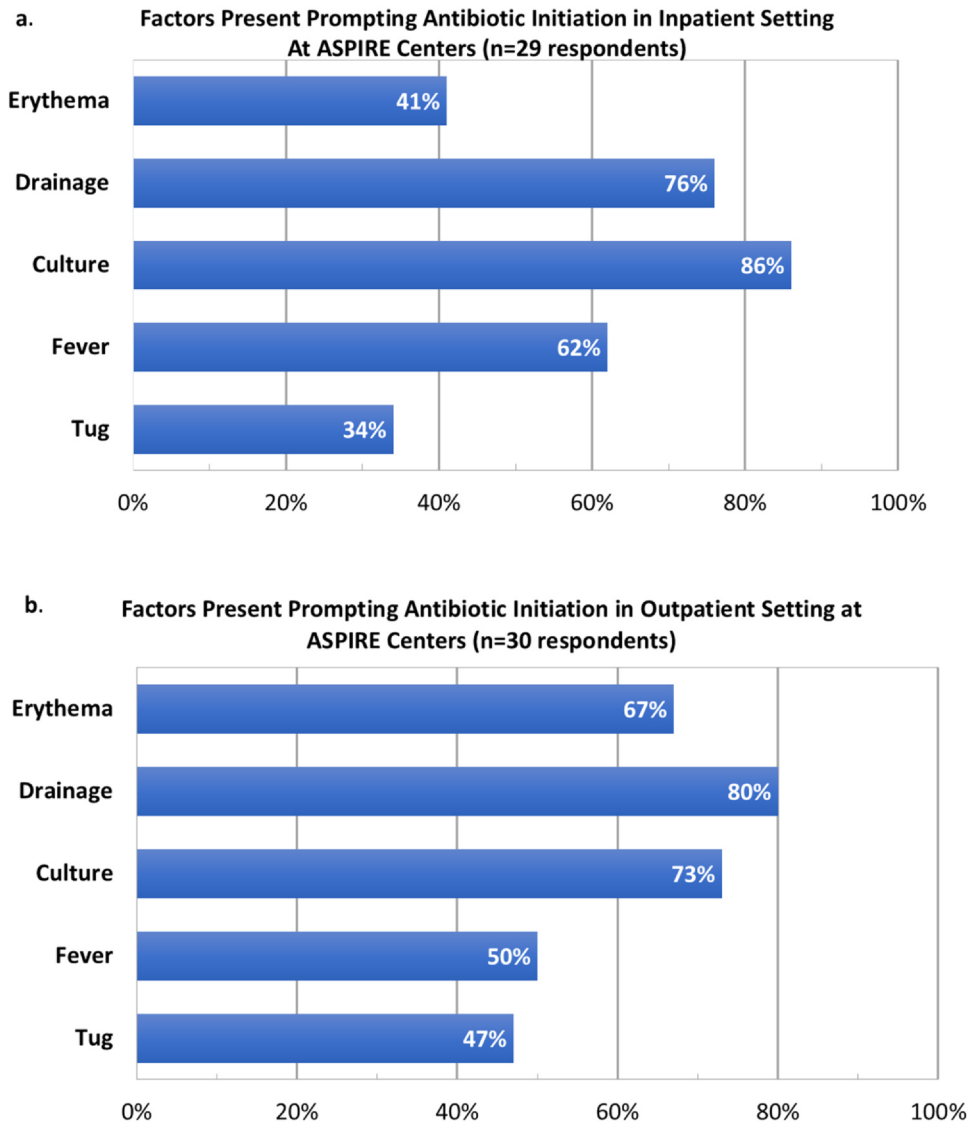


Figure 3 Factors prompting ASPIRE centers to initiate antibiotics during HeartMate 3 support. Frequency of signs or symptoms of infection that may trigger initiation of antibiotics in inpatients (a) and outpatients (b) on device support.

presented as the final model. The other models with previously described methods are presented in Table S4 (online). Among the methodologies, there were no differences in outcomes among the early infection models. Adjusting for age, BMI, use of silver impregnated dressing with chlorhexidine cleanser was associated with a 52% reduction in the hazard for developing an early incident device-related infection (HR 0.48) and a 36% reduction in the hazard for developing a late infection (HR 0.64). Additionally, the routine requirement for frequent dressing changes after 4 weeks postoperative was suggestive of an *increased* hazard for device-related infection (HR = 1.44) (Central Figure). Duration of prophylactic antibiotic use, double tunneling, and intensity of diabetic management were not significantly correlated with infection ($p > 0.05$). Despite the ASPIRE care practices examined in the modeling above, unmeasured heterogeneity (20%) in implant center-level care remains present after 90 days of implant. This unmeasured center-level heterogeneity was presented across the four variations in modeling methods.

Discussion

In this cross-sectional survey of management practices at experienced LVAD programs aiming to prevent device-related infection during HM3 support, we found the following[1]: there is marked variability across centers in the preoperative, intraoperative, postoperative, and long-term patient care phases.[2] The use of a silver impregnated dressing with chlorhexidine cleanser was associated with a 52% reduction in the hazard of developing an early incident device-related infection (most of which were driveline infections) and a 36% reduction in the development of late infection.[3] Duration of prophylactic antibiotic use, double tunneling, and intensity of diabetic management were not significantly correlated with early infection.[4] Unmeasured implant center variability remains substantial, accounting for 20% of variability in the hazard of device infection after 90 days. These results reveal how deficiencies in robust data to support development of guideline directed care recommendations impact the field's ability to achieve

Table 3 Multivariable Correlates Associated with Early (≤90 Days Postoperative, n = 3,725 Patients) and Late (>90 Days Postoperative, n = 3,175 Patients) Incident Device-Related Infection in Intermacs Patients on HeartMate 3 Support from ASPIRE Centers*

Variable	Early infection[a] HR [95% CI]	Frailty adjusted p-value	Late infection[b] HR [95% CI]	Frailty adjusted p-value
Age at implant, per 5 years	0.99 [0.97–1.00]	0.06	0.99 [0.98–0.99]	<0.0001
Body mass index, per kg/m^2	1.01 [0.99–1.04]	0.40	1.02 [1.01–1.04]	<0.0001
Use of silver dressing and chlorhexidine cleansers	0.48 [0.29–0.79]	0.004	0.64 [0.44–0.91]	0.02
High intensity dressing change frequency[c]	-	-	1.44 [1.00–2.09]	0.05

CI, confidence interval; HR, hazard ratio.

The stepwise model also included the following variables (based on p value from univariable modeling), all excluded from the final model above due to a $p > 0.05$ for early and late infection: Patient characteristics of gender, history of coronary artery bypass grafting, New York Heart Association class, time since first diagnosis, Intermacs patient profile, dialysis prior to implant, extracorporeal membrane oxygenation prior to implant, Visual Analogue Scale Score at Implant, device strategy; preoperative labs including albumin, blood urea nitrogen, glomerular filtration rate, aspartate aminotransferase, alanine aminotransferase, sodium, white blood cell count, hemoglobin, platelets, international normalized ratio; preoperative echocardiographic measures of left ventricular internal diastolic dimension, severe aortic regurgitation, severe mitral insufficiency, severe tricuspid insufficiency, severe right heart failure; preoperative hemodynamics of systolic and diastolic blood pressure, heart rate, pulmonary artery systolic and diastolic pressures, cardiac index; and concomitant surgery; Management variables of blood sugars are optimized preop using a protocol; endocrinology consultants manage diabetes preop; HgA1C < 6.5% is achieved in most patients; Medihoney is used routinely on driveline; driveline is routinely double tunneled; prophylactic antibiotics are given for ≤24 hours preop.; prophylactic antibiotics are continued ≤48 hours postop if there are no infection concerns.

*The model above accounts for the impact of unmeasured implant center care heterogeneity (i.e., unmeasured factors within a hospital that can impact the infection endpoint). The statistical significance of each variable above is represented by the shared frailty-adjusted *p-value*.

[a]Shared frailty term for hospital REML = 0.14, p = 0.09.

[b]Shared frailty term for hospital REML = 0.20, $p <$ 0.0001.

[c]High frequency driveline intensity is defined as at least daily in the first 4 weeks postop and multiple times weekly after 4 weeks postop.

consistent patient management protocols for LVAD infection prevention and management. Given the increased duration of LVAD support, both time ''at risk'' for device infection and the overall prevalence of device-related infection are increasing. This has made infection one of the most important complications to address in the present durable mechanical circulatory support era.[3] Thus, we feel best practices need urgently to be developed by a consensus of field experts to enable a baseline level of care consistency across LVAD implanting centers in the U.S., akin to the methodology employed by the pediatric Advanced Cardiac Therapies Improving Outcomes Network (ACTION). Devising best practices may not only lead to reduced variability in patient care but may also afford improved outcomes and facilitate interpretation of future clinical trial results by reducing unmeasured confounding from center-level practice variations. Finally, this consistency will be mandatory for future studies designed specifically to examine infection rates during long-term HM3 LVAD support.

Quality assessment and performance improvement interventions aim to provide an introspective look at outcomes (at either a field- or center-level) with development of interventions designed to enact favorable change. In an analysis by Kanwar et al,[1] significant variability in device-related infection frequency from MOMENTUM 3 study cohort medians was noted, during both the early postoperative period (incident infection frequency median 4.8%, ranging from 0.0% to 17.9% at 90 days) and out to two years (median 0.189 eppy, ranging from 0.00 to 0.64) after HM3 implant. The responses in the ASPIRE survey herein revealed areas of field consistency as well as marked variability in LVAD infection prevention and related patient management. For example, there was excellent consistency in surgeon practice for velour placement under the subcutaneous tissue, probably related to field level data from the driveline Silicon Skin Interface (SSI) registry[13] that supported practice recommendations in MCS guidelines,[14] as well as field level education initiatives at academies and scientific sessions. Additionally, 93% of ASPIRE centers routinely anchored drivelines and 77% of centers routinely applied an additional suture at the driveline exit site to enhance early postoperative stability. This level of care consistency supports field agreement that these driveline practices are important for reducing device-related infection.

However, other driveline management practices in the early and later postoperative periods were highly variable, especially in relation to driveline dressing kit contents, frequency of driveline dressing changes before and after driveline incorporation, and threshold for antibiotic utilization. Despite the ASPIRE questions and robust modeling, unmeasured center level variability still accounted for 20% of the hazard for device related infection after 90 days. Similar variability was noted by Wilcox *et al* when evaluating driveline care practices across 15 United States LVAD centers[15] and by the German and Austrian DESTINE (Driveline Expert STagINg and care) study group,[16] amongst others dating back to 2012.[17] Thus, in absence of robust data to guide patient management, we feel the field must agree on a "best practice recommendation."

While care practices are best defined using guideline level recommendations, others have shown that implementation of surgical protocols can lead to a reduction in surgical complications. Most notably, the Enhanced Recovery after Surgery Society (ERAS) care recommendations have been adopted by many societies and programs with improved outcomes.[18] For LVAD patients in

particular, utilization of a formal driveline protocol has been shown to reduce institutional LVAD infection rates, presumably from reduced care variability.[4,5,19] ACTION has perhaps done the most to demonstrate the benefit of establishing best practices in areas of LVAD patient management lacking robust data. The pediatric VAD space, compared to that of adults, is small and patients are highly heterogenous (e.g. single ventricles, infants to teens). To make scientific gains in the field at a rapid pace, ACTION chose to reduce variability through implementation of best practices, which were derived and agreed upon by field experts at many centers. Despite lack of initial data to support the care protocols, several ACTION initiatives have led to reductions in adverse events, especially stroke[20] and mortality. In a similar manner, best practices devised for infection mitigation and management in adults on HM3 support can evolve and hopefully yield robust data that can eventually be converted to guideline-level recommendations. At a minimum, reduction in care variability will better enable interpretation of infection-related data through a decrease in confounding that is inevitable when examining non patient care across and within institutions.

Using data from the ASPIRE study herein, current guideline and consensus recommendations,[14,21] recent data examining uncomplicated[4,5,19,22–25] and complicated[26,27] driveline management, as well as findings from the DESTINE (Driveline Expert STagINg and care) group,[16] we propose a first set of best practice recommendations for the field to consider (Central Figure):

1) In those without sensitivities and without active infection, the data herein and from others[5,19,25] support application of chlorhexidine cleanser followed by placement of a silver impregnated dressing gauze/patch for uncomplicated driveline care. In general, studies show that surgical sites prepped with chlorhexidine gluconate plus alcohol solutions have lower infection rates than when prepped with iodine plus alcohol solution.[28] Exposure to chronic and/or high concentrations of chlorhexidine can be caustic to the skin and studies suggest that the chlorhexidine can impair wound healing.[29,30] While data for operative skin preparation with chlorhexidine is robust, the field should develop consensus on the chlorhexidine concentration and formulation (aqueous vs alcohol) applied to the chronic care of both uncomplicated and infected wounds as well care recommendations for those with skin sensitivity to a cleansing agent or dressing.
2) There are no data to support long-term daily driveline dressing changes following driveline incorporation. Rather, the centers who employed frequent dressing changes herein tended to have more late infections, perhaps due to more frequent driveline manipulation by patients/caregivers. Thus, in the early postoperative period, it is reasonable to change the driveline dressing every 1-3 days. After 4 weeks in patients without a complicated driveline history, it is reasonable to change the driveline dressing every 3-7 days. Drivelines dressings that appear soiled or lack sufficient skin adherence should be immediately changed.
3) While the ASPIRE data were unable to contribute further insight into antibiotic utilization, we feel there are other data to support judicious use of antibiotics. In a systemic review and guideline comparison of ERAS recommendations, consensus was found for 21 of the current ERAS guideline core times related to pharmacotherapy, but timing of antibiotic administration and dosing remained variable.[31] In studies of different antibiotic prophylaxis strategies in adult patients undergoing cardiac surgery, a shorter duration of antibiotic prophylaxis (24 hours) yielded similar outcomes while "ensuring appropriate antibiotic stewardship."[32] The International Society of Heart and Lung Transplantation (ISHLT) 2023 MCS guidelines recommend application of an antibiotic prophylaxis against *Staph aureus* (in line with institutional resistance pattern) and other local flora, redosing intraoperatively if the procedure extends beyond the drug's half-life. If vancomycin is used, dosing should occur within 2 hours of incision; other agents should be administered within 1 hour of incision. The ISHLT and STS do not recommend extending antibiotics beyond 48 hours for routine prophylaxis, nor do they recommend routine use of antifungals.[14]
4) To assist with follow-up, photographic driveline imaging should be uploaded into the chart at each clinic visit and during hospitalization. In addition, staff should be trained to use a singular, established staging system to characterize the driveline to enable consistency.[16,17,33]
5) Given the increased hazard for driveline infection during chronic LVAD support, repeat patient and care giver education on driveline management and infection recognition is advised (at least annually) with hands on demonstration of driveline care.[16] Younger patients and obese patients, who are at increased risk of device-related infection, should receive more frequent education.

While the adult field lacks robust data to support these recommendations, inertia in developing best practices will not enable improved infection-related outcomes. The above best practices should be vetted, and additional recommendations devised through utilization of an expert work group. The field would benefit from recommendations for defining new vs. acute on chronic recurrent infection; which staging systems (Sharp[33] vs DESTINE[16] vs Utah,[17] etc.) to apply to driveline infections for characterization; management of infection with debridement and/or wound vac placement and/or phage therapy; and driveline tunneling and other interventions aimed to reduce driveline trauma and/or infection development; and recommendations regarding showering given the risk of gram-negative driveline infections.[8,21,34] An understanding of the prevalence of contact dermatitis related to dressing changes and its implications in terms of futures DLES infections is also warranted.

Limitations

Surveys do not provide robust data found in clinical trials but provide insight into "real world" behavior. There are

likely to be other patient and environmental factors (in addition to age and BMI) that may play a significant role in development of driveline infection such as nutrition, personal hygiene, etc. that could not be captured here. Some potentially important surgical details (e.g. use of antibiotic beads) and variability in provider management within a given center were not examined. There is inherent risk of response bias to the survey herein and there is no way to confirm that the responses provided by an individual coordinator reflect the generalized care practices of the associated LVAD center. However, given the heavily integrated nature of LVAD coordinators in patient care at most ASPIRE centers in both the inpatient and outpatient settings, we felt coordinators would be most informed on patient management. Additionally, we recognize care practices may vary due to differences in medical provider (cardiology or surgery) preferences, such that there is no single answer to some questions. The overall goal of the field, however, should be to remove the tendency for such variability in care by providing clear care recommendations. We included separate methodologies to account for unobserved heterogeneity by hospital and a fixed effect for ASPIRE center-level practices to assess any systematic differences. Each of these models allowed us to examine the overall effects of the final model covariates. Ultimately, across the different methods it was found that both the overall effects showed a consensus in both direction and overall magnitude of effect size, with only small variations in confidence intervals. The final model presented in Table 3 shows these effects while also considering the clustering of patients within hospitals. While this method allows one to assess both known and unknown variation, it assumes that residual hospital-level effects are independent of practice type and follow a specific distribution. This may not fully reflect real-world complexity.

In summary, variability in care practices exists in the prevention and/or management of infection- related events following HM3 implant. While data to support guideline-level care recommendations are broadly lacking, care consistency may be achieved through development and subsequent widespread application of best practices at all HM3 implanting centers. The utilization of consistent patient management practices within key facets of LVAD patient care will provide a stable foundation across the world for LVAD patient management. This foundation may elevate care at struggling centers and reduce the occurrence of key adverse events across the field in general; it may reduce confounding and improve interpretation of results from clinical trial and registry data; and it may identify key areas within LVAD patient management that warrant focused clinical study.

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Appendix A. Supporting material

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.healun.2025.07.024.

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