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MAIN TEXT

Driveline infections in left ventricular assist devices—Incidence, epidemiology, and staging proposal

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Abstract

Background: Driveline infections (DLI) are a serious complication in patients with left ventricular assist devices (LVAD). Apart from the differentiation between superficial and deep DLI, there is no consensus on the classification of the severity of DLI. Little is known about risk factors and typical bacteria causing DLI in centrifugal-flow LVADs.

Methods: In this single-center study with 245 patients, DLI were classified by their local appearance using a modification of a score suggested by the Sharp Memorial group. The driveline exit site was inspected routinely every 6 months.

Results: Severe DLI were detected in 34 patients (15%) after 6 months and in 24 patients (22%) after 24 months. The proportion of patients with DLI increased significantly during the follow-up ($p = 0.0096$). The most common bacteria in local smears were *Corynebacterium*, *coagulase-negative Staphylococcus*, and *Staphylococcus aureus*. Fifty-nine patients were hospitalized more than once for DLI. In these patients, *S. aureus* was the most common bacterium. It was also the most common bacterium in blood cultures. Higher BMI, no partnership, and a HeartMate 3 device were identified as risk factors for DLI in a multivariable cause-specific Cox regression.

Conclusion: This study is a standardized analysis of DLI in a large cohort with centrifugal-flow LVADs.

KEYWORDS

device-related, driveline infection, infections, LVAD, ventricular assist device

Elisabeth Dettbarn and Marjeta Prenga contributed equally to this work.

Johanna Mulzer and Jan Knierim share senior authorship.

1 | INTRODUCTION

Infection is one of the most frequent major adverse events after implantation of a left ventricular assist device (LVAD).[1,2] In 2011, a working group of the International Society for Heart and Lung Transplantation (ISHLT) published a standardized definition of infections in ventricular assist device (VAD) patients differentiating between non-VAD infections, VAD-related infections, and VAD-specific infections.[3] VAD-specific infections include pump and/or cannula infections, pocket infections, and percutaneous driveline infections (DLI). The latter were further divided into superficial and deep infections. The ISHLT working group suggested using surgical/histological findings, microbiological results, wound appearance, and clinical signs to differentiate between possible, probable, or proven DLI.[3] However, surgical debridement is not always performed nowadays and the differentiation between possible, probable, and proven DLI is often not mentioned in current studies.[4–7] Other, more complex classifications for DLI have been proposed.[8,9] The DESTINE classification includes the appearance of the exit site, microbiological results, blood cultures, and signs of systemic infections.[8] Another classification, suggested by the Sharp Memorial group, includes the appearance of the exit site, symptoms of systemic infection, positive blood cultures, and involvement of the pump pocket.[9] However, these classifications have not yet become widely established in centers and publications.

DLI is the most frequent VAD-specific infection.[10] The prevalence and microbiological spectrum varies significantly between different studies.[4,10,11] This is due to the inclusion of devices from different eras and of patients at different points in time post-implantation, and inconsistent definitions of DLI in the studies.

We modified the classification proposed by the Sharp Memorial group and developed a system for staging the severity of DLI that includes only the local appearance of the exit site. As part of our institutional standard operating procedure, this "modified Sharp Memorial Score" (mSC) was assessed at every outpatient visit. Microbiological smears were performed if local signs of infection were present (mSC ≥ 3). The aim of this retrospective study was to evaluate the frequency and development of local DLI through a standardized assessment of an outpatient cohort with modern centrifugal continuous-flow left ventricular assist devices.

2 | METHODS

2.1 | Patient population

Between March 2018 and January 2021 a total of 324 patients underwent implantation of an LVAD at a single center. All patients visited the outpatient department every 6 months for a standardized assessment including an interview, physical examination, echocardiography, laboratory test, and inspection of the driveline exit site. For this retrospective study, data from the patient files were collected in a REDCap database and further analyzed. The study was reviewed and approved by the ethics committee at Charité University (EA2/229/19). The ethics committee waived the need for informed written consent for publication of the study data.

2.2 | Surgical technique of LVAD implantation

Since recognizing the value of left ventricular inspection during LVAD implantation, cardiopulmonary bypass (CPB) is used by default at our institution.[12] Median sternotomy is our standard approach. In case of previous cardiac surgery without the need for additional intracardiac procedures other than thrombectomy from the left ventricle, we use a left lateral approach with anastomosis to the descending aorta.[13] If additional intracardiac procedures are necessary, redo median sternotomy is preferred. In patients on temporary mechanical circulatory support requiring no concomitant intracardiac procedures and who develop heparin-induced thrombocytopenia, the LVAD is usually implanted on temporary mechanical circulatory support to avoid complex anticoagulation for CPB. The driveline is tunneled in the left upper abdominal quadrant (in heart transplant candidates) or the right upper abdominal quadrant (in permanent support patients). The velour is placed below the skin level.

2.3 | Inspection of the driveline exit site

The dressing of the driveline (DL) exit site was changed routinely during an outpatient visit. The exit site was inspected by experienced nurses and physicians. The local finding was classified using a modification of the staging from the Sharp Memorial group (Figure 1).

If the mSC was equal to or higher than 3, a smear of the exit site was performed and sent for microbiological culture. Depending on the clinical presentation of the patient, the physician decided for outpatient treatment with oral antibiotics or hospital admission and in-hospital treatment.

2.4 | Hospitalizations

All patient files were checked for hospitalization. Admission to the hospital was at the discretion of the treating physician. Patients with higher mSC and systemic signs of

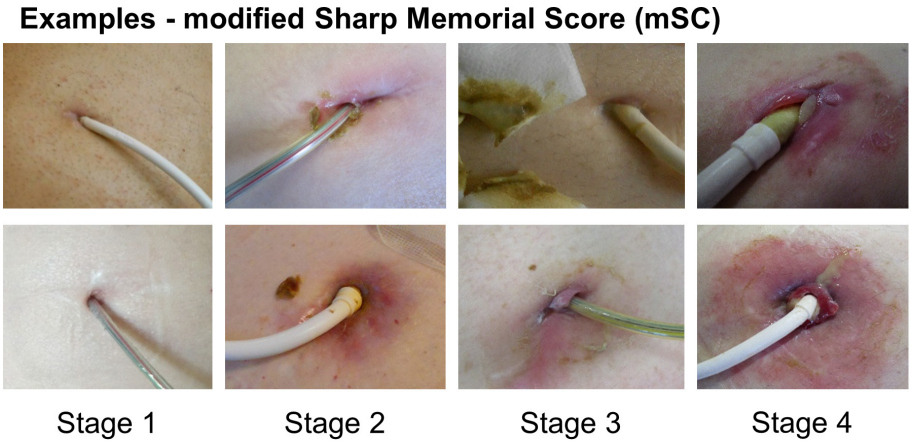

FIGURE 1 Examples of the modified Sharp Memorial score (mSC). *Stage 1*: Little or no erythema, no tenderness, no drainage, healthy tissue incorporating into the driveline. *Stage 2*: Some erythema, mild tenderness, small amount of drainage, possible local cellulitis. *Stage 3*: Erythema, tenderness, moderate to copious amounts of drainage, persistent skin disruption, gap present. *Stage 4*: Severe tenderness, severe erythema, massive amounts of drainage, severe skin disruption, bleeding, fistula. [Color figure can be viewed at wileyonlinelibrary.com]

infection were admitted more frequently. The treatment of DLI was conducted in accordance with the recommendations of the ISHLT consensus group.[10] The cause of hospitalization and the microbiological results of smears and blood cultures were assessed.

2.5 | Statistical analysis

Categorical data are summarized as frequencies and percentages and continuous variables as mean and standard deviation (SD) or median and interquartile range [IQR] in the case of non-normal data. A trend test was performed to detect changes in the proportion between patients with a Sharp score of ≤2 vs. ≥3 over 2 years. Cause-specific hazard ratios (CSH) with death and transplant as competing events were calculated for risk factors of the combined endpoint of hospitalization or a Sharp score of ≥3. Multivariable models with all combinations of risk factors were run and the best model according to the Akaike information criterion (AIC) was chosen as the final model. R software, version 4.03, was used for all statistical analyses.

3 | RESULTS

3.1 | Patient population

Between 03/2018 and 01/2021 a total of 324 patients underwent LVAD implantation at our center (220 HeartWare HVAD, 104 HeartMate 3). Of these, 245 patients visited our outpatient department 6 months (median 6.1 months [5.8, 7.1]) after implantation (154 HeartWare, 91 HeartMate 3). Their mean age was 56.2 ± 12.0 years; 206 (84.1%) were male. For details, see Table 1.

Sixty-two percent of the patients were married or lived in a relationship. Only 7% worked full- or part-time. Dressing changes were performed by a nurse in 58%, by a family member in 39%, and by the patient in 3% of cases.

3.2 | Follow-up and development of DLI

The patients visited the outpatient department every 6 months. Visit 1 took place at a median of 6.1 months [IQR 5.8, 7.1 months], visit 2 at a median of 12.1 months [IQR 11.7, 13.0 months], visit 3 at a median of 18.3 months [IQR 17.9, 18.9 months], and visit 4 at a median of 24.2 months [IQR 23.4, 25.3 months]. The results of the driveline inspection (mSC) of all patients are presented in Table 2. The proportion of patients with significant DLI (mod. Sharp stage ≥ 3) increased significantly during the follow-up period ($p = 0.0096$).

3.3 | Results of driveline exit site smear

A smear was performed in all patients with DLI and an mSC of ≥3. The microbiological result was negative in about 10% to 30% of cases. In the other cases, *Corynebacterium spec*., *coagulase-negative Staphylococcus*, and *Staphylococcus aureus* were the most common pathogens. For microbiological results, see Table 3.

3.4 | Hospitalizations due to DLI

During the follow-up period, 59 patients were hospitalized due to a single DLI (24.1%). Their median CRP level at admission was 13.9 mg/dL [3.1, 29.9]. Twenty-two of

these patients developed a second DLI and eight patients, a third DLI. Four patients underwent surgical treatment of the DLI.[14] All other patients were treated with antibiotics. Pathogens identified in the first hospitalization are listed in Table 4. In 22 patients, both the swabs from the driveline exit site as well as the blood culture results were positive. In five patients, the results from the blood culture differed from the results of the DL smear. *S. aureus* and *coagulase-negative Staphylococcus* were clearly the most common pathogens in blood cultures.

TABLE 1 Characteristics of all patients ($n = 245$).

	Overall	Missing (%)
Baseline characteristics		
Age	56.2 ± 12.0	0.0
Male, n (%)	206 (84)	0.4
BMI (kg/m^2)	27.1 ± 4.6	7.8
Hypertension, n (%)	146 (61)	2.4
Diabetes mellitus, n (%)	75 (31)	0.0
COPD, n (%)	35 (15)	5.7
Current smoker, n (%)	73 (34)	12.7
Left ventricular assist device		
HeartWare HVAD, n (%)	154 (63)	0
HeartMate 3, n (%)	91 (37)	0
Laboratory results (at 6-month follow-up)		
GFR mL/min BSA, median [IQR]	62.0 [46.4, 76.0]	9.0
Bilirubin mg/dL, median [IQR]	0.6 [0.4, 0.6]	13.9
NT-proBNP pg/mL, median [IQR]	1.206 [614, 2400]	17.1
Urea mg/dL, median [IQR]	44.4 [32.5, 58.3]	10.6
WBC K/µL, median [IQR]	7.64 [6.3, 9.2]	9.4
CRP mg/dL, median [IQR]	0.6 [0.3, 1.4]	9.0

Note: Values are expressed as mean ± standard deviation or *n* (%) unless otherwise indicated.

Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease; CRP, C-reactive protein; GFR, glomerular filtration rate; IQR, interquartile range; NT-proBNP, N-terminal pro B-type natriuretic peptide; WBC, white blood cells.

3.5 | Risk factors for DLI

In a univariable competing risk regression for first hospitalization or first mSC ≥ 3, BMI and the type of device were identified as significant risk factors. In a multivariable cause-specific Cox regression, BMI, no partnership, and a HeartMate 3 device were identified as risk factors for DLI (Table 5).

4 | DISCUSSION

Our study is a detailed analysis of the development of DLI in a single center. In contrast to all former studies, the driveline exit site was inspected routinely every 6 months and the appearance of the site was described using a modification of the known Sharp score.[9] The Sharp score is very helpful to assess and monitor disease severity. It describes not only the local appearance of the exit site but also the results of microbiological cultures and systemic signs of infection. However, we were looking for a score that is easy to assess and that only describes the local appearance. The advantage of such a score is that it can be determined by the nurse with every change of the dressing. Furthermore, such a score is immediately available and does not require waiting for laboratory tests or results of local culture or blood culture.

In our opinion, information about systemic symptoms and culture results should be added to but not be mixed with local findings. For example: culture results can only be positive if a culture is performed. The same applies for signs of infection in the laboratory analysis. In the International Mechanically Assisted Circulatory Support (IMACS) registry, a percutaneous site infection is defined as "a positive culture from the skin or tissue surrounding the drive line, coupled

TABLE 2 Results of driveline exit site inspection and modified Sharp score (mSC) at patients' visits.

	Visit 1, 6 months	Visit 2, 12 months	Visit 3, 18 months	Visit 4, 24 months
Total number of patients with (mSC)	225	186	104	100
Stage 1, n (%)	100 (45)	69 (37)	44 (40)	41 (38)
Stage 2, n (%)	91 (40)	80 (43)	35 (32)	43 (40)
Stage 3, n (%)	25 (11)	27 (15)	18 (17)	10 (9)
Stage 4, n (%)	9 (4)	10 (5)	12 (11)	14 (13)

Note: Values are expressed as *n* (%).

Abbreviation: mSC, modified Sharp Memorial group score (see Figure 1).

TABLE 3 Microbiological results of driveline smear in patients with mod. Sharp score 3 and 4.

	6 months	12 months	18 months	24 months
Negative	9/34 (26.5%)	3/37 (8.1%)	3/30 (10.0%)	–
No smear performed	–	3/37 (8.1%)	2/30 (6.7%)	1/24 (4.2%)
Corynebacterium spec.	9/34 (26.5%)	7/37 (18.9%)	4/30 (13.3%)	3/24 (12.5%)
Coagulase-neg. Staphylococcus	6/34 (17.6%)	5/37 (13.5%)	7/30 (23.3%)	4/24 (16.7%)
Staphylococcus aureus	4/34 (11.8%)	6/37 (16.2%)	3/30 (10%)	8/24 (33.3%)
Pseudomonas spec.	–	1/37 (2.7%)	2/30 (1x3MRGN) (6.7%)	1/24 (4.2%)
Proteus mirabilis		1/37 (2.7%)	2/30 (6.7%)	1/24 (4.2%)
Enterobacter cloacae	2/34 (5.9%)	1/37 (2.7%)		
Acinetobacter baumanii		1/37 (2.7%)		
Eikenella corrodens			1/30 (3.3%)	
Citrobacter koseri	1/34 (2.9%)			
E. coli				2/24 (8.3%)
Candida glabrata				1/24 (4.2%)
Corynebacterium spec. + Coagulase neg. Staphylococcus	2/34 (5.9%)	5/37 (13.5%)	2/30 (6.7%)	1/24 (4.2%)
Other mixed infection	1/34 (2.9%)	4/37 (10.8%)	4/30 (13.3%)	2/24 (8.3%)

Note: Values are expressed as *n* (%).

TABLE 4 Microbiological results in first hospitalization.

	DL smear results ($n=59$)	Blood culture positive ($n=23$)
Negative	8/59	
Corynebacterium spec.	7/59	
Coagulase neg. Staphylococcus	7/59	6/23
Staphylococcus aureus	14/59	11/23
Pseudomonas spec.	3/59	1/23
Streptococcus spec.	2/59	2/23
Mixed infection	17/59	
Aerococcus urinae	1/59	
Enterococcus faecalis		1/23
Micrococcus luteus		1/23
Candida parapsylosis		1/23

Note: Values are expressed as *n* (%).

TABLE 5 Risk factors for DLI.

Parameter	CSH [95% CI]	*p*-value
Univariable analysis		
Diabetes mellitus	1.14 [0.75, 1.74]	0.546
Smoker	1.32 [0.87, 2.01]	0.191
Married/partnership	0.69 [0.46, 1.03]	0.071
HeartWare HVAD	0.60 [0.40, 0.90]	0.013
Male	1.08 [0.60, 1.93]	0.807
BMI (kg/m^2)	1.06 [1.02, 1.11]	0.006
Age (years)	0.99 [0.97, 1.01]	0.313
GFR (mL/min)	1.00 [0.99, 1.01]	0.565
Multivariable analysis		
HeartWare HVAD	0.72 [0.47, 1.08]	0.115
Married/partnership	0.70 [0.47, 1.06]	0.093
BMI (kg/m^2)	1.06 [1.01, 1.11]	0.014

Abbreviations: BMI, body mass index; CI, confidence interval; CSH, cause-specific hazard; DLI, driveline infection; GFR, glomerular filtration rate.

with the need to treat with antimicrobial therapy when there is clinical evidence of infection such as pain, fever, drainage or leukocytosis" (IMACS Appendix D—Adverse Events Definitions 12/21/2012 Version 1.0). This definition is clinically relevant but heavily influenced by the different standards of the institutions. For example, if a physician regards the finding as not relevant, he/she will not perform a culture, will not collect blood for laboratory tests, and will not treat the disease. Another physician may view the finding completely differently and may decide to perform a swab and treat with antibiotics.

Following our standardized protocol, the appearance of the driveline exit site was routinely evaluated and the performance of microbiological smears was predefined. We found a high percentage of irritation-free exit sites at 6 months with only 15% of patients having an mSC of ≥3. However, the proportion of patients with severe DLI (mSC ≥3) increased significantly during the follow-up

period. This is consistent with the results of the IMACS registry which show that VAD-specific infections increase significantly with the duration of device implant.[2] It may be important to mention that the study by Hannan et al. included nearly 70% axial pumps, while our study focused only on modern centrifugal devices.

Only little is known about the culture results of DLI as they are not part of the assessment in the registry data. A prospective multicenter study published in 2013 including pulsatile and axial continuous-flow devices mainly identified *coagulase-negative Staphylococcus* and *S. aureus* in device-specific infections. In most cases, the pocket or the device itself were affected by the infection.[15] Another study with 22 patients with DLI and continuous-flow devices also showed a high percentage of *Staphylococcus* in microbiological results.[7] The patients in this study were obviously severely ill, with >40% being septic and >68% requiring in-hospital care. A large single-center study by Schlöglhofer et al. included 186 patients with continuous-flow LVADs. Of these, >25% developed a DLI.[4] Again *S. aureus* was the predominant bacterium, followed by *Pseudomonas spec. Coagulase-negative Staphylococcus* was found in only 4% of admitted patients and in 16% of patients treated on an outpatient basis. We standardized our microbiological assessment including a smear in every patient with mSC ≥3 and a smear plus a blood culture in every patient admitted to hospital. Using this approach *Staphylococcus* and *Corynebacterium* were the most common bacteria detected in outpatient smears from the exit site. Gram-negative bacteria were rare. In hospitalized patients, *S. aureus* followed by mixed infections was the most common finding in local smears. A positive blood culture confirming the findings of the local smear is a clear indication of the bacteria being linked to the infection. In blood cultures of hospitalized patients, *Staphylococcus* was by far the most common bacterium. Therefore, an antibiotic with strong activity against staphylococci should be part of every empiric therapy for DLI. *Corynebacterium spec*., on the other hand, were never detected in blood cultures. This suggests that they are more likely part of the skin microbiome than the cause of DLI.

The development of DLI is always multifactorial. There is a lot of research on this. However, most of the studies evaluating risk factors for VAD infections have focused on pulsatile or axial continuous-flow devices.[5,15,16] In one study with centrifugal continuous-flow LVADs, patients with DLI had a higher BMI and were more frequently diabetic when compared with patients without DLI.[6] However, this was only a retrospective comparison of the two groups and not a multivariable analysis. In the prospective study by Gordon et al., a history of depression and elevated serum creatinine at baseline were independent indicators for VAD-infections (not only DLI) in a cohort of axial continuous-flow and pulsatile devices.[15] In our study, with exclusively centrifugal continuous-flow devices, univariable and multivariable analysis was performed. We defined significant DLI as any local finding of mSC ≥3 and/or hospitalization (and treatment). While this definition is admittedly new, it is more easily reproducible than the criteria used in most other studies. In a multivariable statistical model, we identified a higher BMI, no partnership, and a HeartMate 3 device as risk factors for the combined event. Obesity has been identified as a risk factor in many studies.[6,17,18] This risk factor may be explained by the presence of skin folds providing a favorable environment for bacteria.

Another study also showed higher rates of DLI in patients with HeartMate 3 devices when compared with the HeartWare HVAD.[4] There are some characteristics of the driveline that may influence the risk of DLI. The most important factor proposed by Imamura et al is the stiffness of the driveline.[5] They found the lowest rate of DLI in patients with Heartmate II devices with a soft silicone driveline when compared with EVAHEART and DuraHeart devices.[5] The driveline of the HeartMate 3 device has a larger diameter than the driveline of the HeartWare HVAD. This affects the stiffness. The rigidity of the driveline may lead to more force and micro trauma to the exit cite during usual activities of daily life. Microtrauma may then serve as the entry point for bacteria. Further studies on suitable driveline material and driveline fixation techniques should be conducted.

Interestingly, our study was the first to identify the association between living in a partnership and the risk for DLI. This result is not surprising as local wound care is usually provided by external help and may be better performed or supervised by a partner than by an external nursing service with changing staff.

In conclusion, we present a highly standardized approach to assessing DLI using a new score and predefined time points for driveline inspections. Applying this method, we found an increase in DLI over time, identified typical pathogens for DLI, and found BMI to be an independent risk factor for DLI in patients with modern centrifugal-flow left ventricular assist devices. This is a single-center study and further research is needed. We recommend that our approach of using the mSC and predefined follow-up visits be applied in larger studies and registries.

5 | LIMITATIONS

Our work is a single-center retrospective study. Therefore, it is difficult to generalize the results. Furthermore, more than 60% of the patients in our study underwent implantation of a HeartWare HVAD that is no longer available on the market. However, our standardized assessment of DLI in a large cohort offers important insights into a clinically very common complication of modern LVAD therapy.

AUTHOR CONTRIBUTIONS

Elisabeth Dettbarn, Marjeta Prenga, and Julia Stein were involved in concept/design, data collection, and data analysis. Markus Müller, Felix Schoenrath, and Volkmar Falk contributed to critical revision and approval of article. Christoph Hoermandinger carried out data collection, critical revision, and approval of article. Evgenij Potapov handled concept/design, critical revision, and approval of article. Johanna Mulzer handled concept/design, data collection, data analysis, critical revision, and approval of article. Jan Knierim handled concept/design, data analysis/interpretation, drafting, and approval of article.

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CONFLICT OF INTEREST STATEMENT

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