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Risk of left ventricular assist device driveline infection: A systematic literature review

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ABSTRACT

Background: Left ventricular assist devices (LVADs) improve quality of life in end-stage heart failure but can cause serious complications such as infections with driveline infection causing significant morbidity and mortality.
Objectives: The purpose of this systematic literature review is to synthesize the literature to determine variables associated with driveline infection and seek opportunities to improve nursing management of LVAD drivelines.
Methods: A systematic literature review was performed. The evidence was synthesized using the Johns Hopkins Nursing Evidence-Based Practice tools and the Chain of Infection epidemiological framework.
Results: Thirty-four studies focused on vulnerable host, portal of entry, and causative organism aspects of the Chain of Infection. Increased BMI, younger age, exposed driveline velour showed increased risk of infection and driveline dressing protocol change showed lower risk of infection.
Conclusions: Although some risk factors for infection were identified, evidence is still limited. Nurses are uniquely positioned to improve driveline management, disrupting the chain of infection.
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Background

For patients with end-stage heart failure, left ventricular assist devices (LVADs) are recognized as an effective treatment to reduce symptom burden, increase functional status and improve quality of life.[1] LVADs are often used a Bridge to Transplant (BTT), but in a growing group of patients who are ineligible for transplant, many receive the device as Destination Therapy (DT), maintaining the device until death. Regardless of implant strategy, serious complications such as pump thrombosis, bleeding, cerebrovascular accidents (CVA), and infection are common among LVAD patients.[2,3] Infections are a leading cause of morbidity and mortality, particularly as a risk factor for more serious complications such as stroke and pump thrombosis. The most recent Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) report showed infection to be the most common adverse event, with driveline infection as the most common type.[4] Nurses play a key role in patient care to prevent infection, inpatient management of drivelines, education for patients and caregivers and ongoing teaching/monitoring, yet there is little evidence to drive best practices.

Recognizing the prevalence of LVAD infections, the International Society for Heart and Lung Transplantation (ISHLT) first established the consensus definition for LVAD infection and highlighted its importance in 2011[5]. In 2017, they published a consensus document for the prevention and management of LVAD infections including recommendations for surgical technique, antibiotic prophylaxis, and post-operative care.[2] Previous literature reviews have investigated risk factors for LVAD infection and their impact on patient outcomes,[6] antibiotic prophylaxis,[7,8] and diagnosis and management of driveline infection.[7] However, there are currently no literature reviews examining nursing care of LVAD patient drivelines or nurse-driven interventions to prevent infection. Additionally, none have used a theoretical framework to organize their findings.

The purpose of this systematic literature review is to synthesize the evidence related to clinical characteristics associated with LVAD driveline infection and examine opportunities to improve nursing management of LVAD drivelines with the goal of reducing infection rates. We will contribute further to current knowledge by synthesizing the existing evidence within the Chain of Infection framework.[9] The Chain of Infection is the traditional epidemiologic model describing the transmission of infectious diseases.[9] Transmission of infection occurs when a pathogenic organism leaves its host reservoir (where it normally lives and replicates) through a portal of exit (such as the

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respiratory, gastrointestinal, or genitourinary tract), travels via its mode of transmission (either direct contact, respiratory droplets, airborne, or vector), and enters a vulnerable host through its specific portal of entry (respiratory tract, fecal-oral entry, interruption in skin integrity, etc.).[9]

Methods

We performed as systematic literature review using the PubMed, CINAHL, and Embase databases using the following search strategies, respectively: ((“Heart-Assist Devices”[Mesh] OR “left ventricular assist” OR “LVAD”)) AND (“Infection”[Mesh] OR infect* [tiab]), ((MH “Heart Assist Devices”) OR “left ventricular” N3 assist* OR LVAD) AND ((MH “Infection+”) OR infect*), and (‘left ventricular assist device’/exp OR (‘left ventricular’ NEAR/3 assist*):ti,ab) AND (‘infection’ /exp OR infect*:ti,ab).

To document the systematic review process, we utilized the PRISMA guidelines (Fig. 1).[10] We included full-text clinical research articles if ventricular assist device driveline infection was a primary outcome being measured, they were written in English, and were published within the last 7 years. We selected this timeframe due to the transition from implantation of pulsatile flow to continuous flow LVADs and the changes in surgical technique that occurred as a result. We excluded articles if they only discussed intra-operative surgical interventions to treat driveline infection, examined pulsatile flow devices exclusively, were case studies, systematic literature reviews, expert opinion articles, or non-research evidence. Four expert clinicians (NP, TR, TM and MA) independently reviewed the studies for inclusion at the title, abstract and full text level of systematic review. Discrepancies regarding inclusion were resolved by consensus.

We appraised each article for evidence level and quality using the Johns Hopkins Nursing Evidence-Based Practice Appraisal tools.[11] Reviewers assigned an evidence level between I and V, and an evidence quality grade of either A, B, or C. We only included studies that were an evidence level of I (experimental study, randomized control trial), II (quasi-experimental study), or III (non-experimental study, qualitative study). Reviewers then assigned an evidence level grade of either A (high quality), B (good quality), or C (low quality) based on the consistency of findings, generalizability of results, adequacy of sample size, presence of a control group (if applicable), and whether definitive conclusions could be drawn from the data presented.[12]

Results

Our literature search yielded 3450 results. We narrowed these results to 34 papers for final review and synthesis based on our inclusion criteria. Table 1 summarizes the final studies, their key findings, and level/quality of evidence. Twenty-four studies were retrospective analyses, 9 were prospective studies, and 1 was a self-controlled study (retrospective data was compared to prospective data in the same sample of patients).

There was variability in the type of infection reported and the criteria used to define driveline infection amongst studies. Though the majority of studies reported data on LVAD driveline infection specifically, some studies reported an aggregate statistic that included driveline infection in addition to other LVAD-related infections. Those

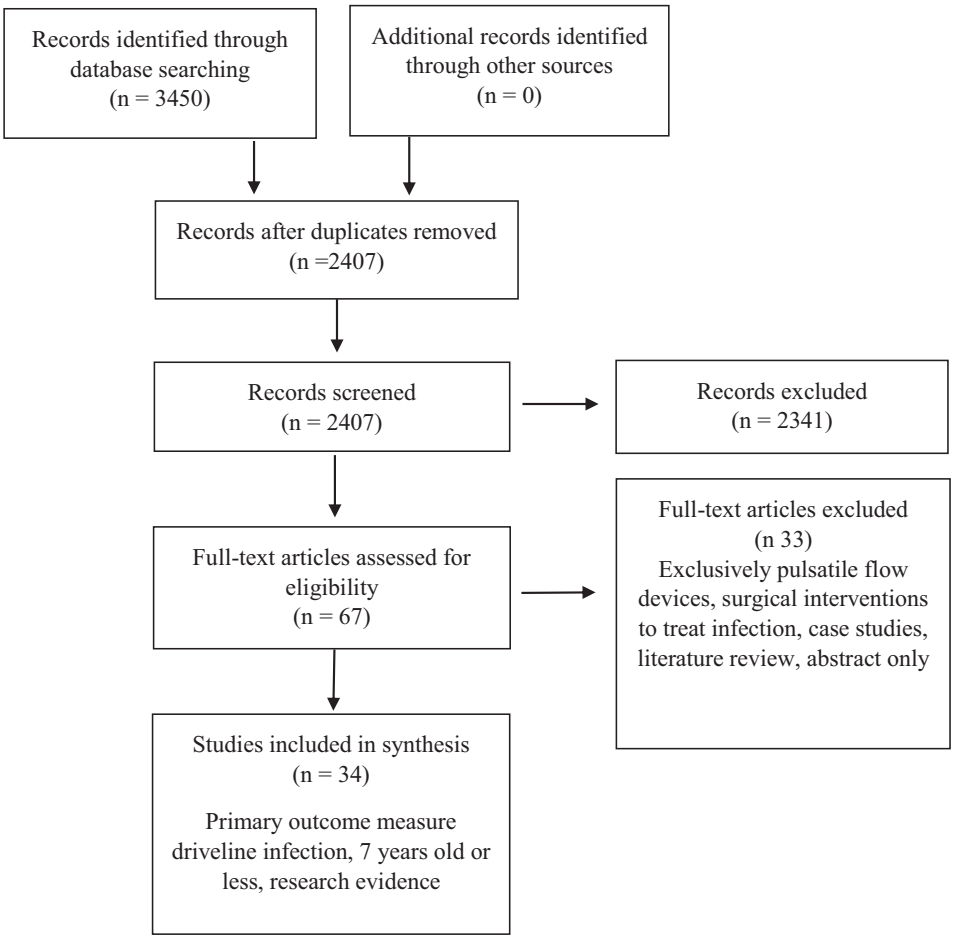

Fig. 1. PRISMA diagram summarizing the systematic literature review process.[10] Databases used included: PubMed, CINAHL, and Embase.

Table 1
Summary of all 31 articles synthesized from our systematic literature review, their article details, key findings, and evidence level and quality.

	Author	Study Design	Sample, Demographics, HF and LVAD Characteristics	Key Findings	Evidence Quality
1	John et al (2014)[28]	Retrospective Comparison of Advanced Trial Data	*N* = 332 with HW Driveline Infection (*n* = 103): Mean age = 51.9 ± 12 Gender (M) = 79 (76.7%) BMI = 29.4 ± 6.1 Device: HW DT: no, all BTT No Driveline Infection (*n* = 229): Mean age = 53.2 ± 12 Gender (M) = 157 (68.6%) BMI = 27.6 ± 6 Device: HW DT: no, all BTT	Rate of DLI: < 30 days after implant = 2.1% >30 day after implant = 15.7% 180 days = 11% 1 year = 17% Increased: Increased BMI (*p* = 0.02) History of Diabetes (*p* = 0.03)	III/A
2	Koval et al (2014)[36]	Retrospective analysis	*N* = 181 total Age = 54 ± 13.8 Gender (M)- 145 (80.1%) BMI = 28 ± 5.9 Device: HMII DT = 53 (29%)	Rate of DLI: 44/181 = 24.3% Increased risk of DLI: INTERMACS Level 5 (*p* = 0.04) Re-op for bleed (*p* = 0.01)	III/B
3	Bomholt et al (2011)[57]	Retrospective analysis	*N* = 31 Median Age = 43 Male = 74% BMI- 24.2 (21.1 – 27.3) device = HeartMate II BTT = 81% DT = 19%	Rate of DLI: 39% No variables found to be associated with increased risk of infection.	III/C
4	Gordon et al (2013)[54]	Prospective cohort study	*N* = 150 Mean Age = 57.4 ± 13.2 Male = 84% BMI- 28 (5.3%) Device: Heartmate II = 85 Heartmate I = 50 Thoratec IVAD = 5 VentrAssist = 3 Novacor = 2 Paracorporeal BiVAD = 3 Heartmate I/Abiomed RVAD = 1 HeartMate II/Abiomed RVAD = 1 DT: both DT and BTT but no report of percentages	Rate of Infection: 33/150 VAD-related infections 28/33 = 84.8% driveline infection Increased risk of LVAD-related infection: Univariate Risk - History of Depression HR = 2.62 (1.25-5.51), *p* = 0.01 Elevated Serum Cr: HR = 1.57(1.00-2.45), *p* = 0.05 Multivariate Model - HR Depression = 2.8 (1.3-6.0), *p* = 0.007 Serum Creatinine HR = 1.7 (1.1-2.7), *p*=0.03	III/B
5	Imamura et al (2017)[18]	Prospective cohort study	*N* = 72 Mean age = 40 ± 12 Male = 61 (84.7%) DT- none, all BTT Evaheart (*n* = 22) Mean age = 41 ± 11 Male = 21 (95.5%) BMI = 21.3 ± 2.9 DT- none, all BTT DuraHeart (*n* = 18) Mean age = 42 ± 9 Male = 14 (77.8%) BMI = 20.9 ± 2.7 DT- none, all BTT HeartMate II (*n* = 32) Mean age = 38 ± 13 Male = 26 (81.3%) BMI = 20.4 ± 3.5 DT- none, all BTT	Rate of DLI: 1 year = 29% Decreased risk of DLI: HeartMate II = (*p* = 0.01, OR = 0.253, 95% CI = 0.089-0.719).	III/C
6	Schaffer et al (2011)[51]	Retrospective Analysis	*N*=133 Mean Age = 49.4 ± 13.0 Male = 100 (75.2%) BMI = 27.9 ± 6.8 Device: pulsatile & continuous flow DT = 40 (30.1&) BTT = 93 (69.9%)	Rate of DLI: 45/133 = 33.8% 36/45 were >90 days after implant Decreased risk of DLI: Continuous flow devices were associated with less DLI (*p* = 0.02) Later year of implant showed greater	III/B

(*continued*)

Table 1 (*Continued*)

	Author	Study Design	Sample, Demographics, HF and LVAD Characteristics	Key Findings	Evidence Quality
				freedom from driveline infection: HR = 0.78 (CI 0.70-0.86), $p < 0.01$ Continuous flow devices showed greater freedom from driveline infection: HR = 0.31 (CI 0.19-0.52), $p < 0.01$	
7	Nienaber et al (2013)[58]	Retrospective, descriptive	*N* = 247 Mean Age = 56.8 ± 14.9 Male = 62 (79%) BMI: none reported HeartMate II = 73 (94%) Jarvik 2000 = 4 (5%) VentrAssist = 1 (1%) DT = 48 (62%)	Rate of DLI: 78/247 = 32% Did not examine risk of driveline infection.	III/B
8	Hieda et al (2014)[13]	Retrospective Descriptive	*N* = 27 Pulsatile flow LVAD (*n* = 11): Mean Age = 34.6 ± 9.6 Male = 7 (63.6%) BMI- not reported Device- not reported DT- none, all BTT Continuous Flow LVAD (*n*=16): Mean Age = 37.5 ± 11.9 Male = 16 (100%) BMI- not reported Device- not reported DT- none, all BTT	Rate of DLI: 25/27 = 92.5% There was no significant difference in exit-site infection between pulsatile and continuous flow LVADs.	III/C
9	John et al (2016)[29]	Retrospective descriptive	*N* = 267 Mean Age = 57.2 ± 14.2 Male = 214 (81.4%) BMI = 29.2 ± 7.6 HMII = 100% Bridge to transplant = 209 (78.9%)	Rate of DLI: 60/267 = 22.5% Increased risk of DLI: Younger age (HR = 0.98, 95% CI 0.97-1.00) Increased BMI (HR = 1.02, 95% CI 1.00-1.05).	III/B
10	Tuncer et al (2016)[19]	Prospective Cohort Study 2011-2014	*N* = 55 Mean Age = 49.8 ± 10.8 Male = 48 (87.3%) BMI = 25.83 ± 4.34 DT = 20 (36.4%) HW = 35 (63.6%) HMII = 20 (36.4%)	Rate of DLI: 18/55 = 32.7% Increased risk of DLI: Heartmate II > Heartware LVADs ($p = 0.039$)	III/C
11	Vest et al (2016)[59]	Retrospective Analysis	*N*=300 Mean Age = 57 (48-65) Male- Female = 54 (18%) BMI = 27.2 (23.8-31.4) Heartmate II = 281 (94%) BTT = 186 (62%)	Rate of Device-Related Infection: 68/300 = 22.6% There was not a statistically significant difference in Hazard Ratio for device-related infection between diabetes and non-diabetes LVAD patients.	III/C
12	Raymond et al (2010)[30]	Retrospective Analysis	*N* = 118 Novacor = 9 VentrAssist = 3 HM VE or XVE = 88 DT = 62 (52%) Infection group: Mean Age = 59.4 ± 15.4 Male = not reported BMI = 29.7 HMII = 22 Non-infection group: Mean Age = 58.7 ± 15.5 Male = not reported BMI = 26.1	Rate of DLI: 36/118 = 30.5% Decreased Risk of DLI: Lower BMI (p=0.011).	III/C
13	Donahey et al (2015)[14]	Retrospective chart analysis	*N* = 57 Mean age = 49.5 ± 13.5	Rate of LVAD-related infection: 27/57 = 47.4%	III/C

(*continued*)

Table 1 (*Continued*)

	Author	Study Design	Sample, Demographics, HF and LVAD Characteristics	Key Findings	Evidence Quality
			Male = 43 (70.5%) BMI = 28.4 ± 6.8 HeartWare = 9 (14.8%) Heartmate = 52 (85.2%) DT = 26 (42.6%)	Increased Risk of LVAD-related infection: Destination Therapy ($p = 0.001$) Higher BMI ($p = 0.04$) Velour exposed ($p = 0.004$)	
14	Goldstein et al (2012)[32]	Retrospective analysis	*N* = 2,006 Age = not reported Male = not reported BMI = not reported All Continuous Flow pumps DT = 291 (14.5%)	Rate of DLI: 197/2006 = 9.8% of Increased Risk of DLI: Younger age (< 50) (p < 0.0001) Risk of infection increases w/ time 1-month freedom = 99% 1-year freedom = 81% 2-year freedom = 74%	III/A
15	Gomez et al (2016)[60]	Retrospective Analysis	*N* = 128 Age 18-40 = 10.2% Age 40-60 = 52.3% Age 60+ = 37.5% Male= 82.8% BMI = not reported HM II = 100% DT = not reported	Rate of DLI: 49/128 = 38.3% Did not examine risk of driveline infection.	III/C
16	Imamura et al (2015)[31]	Retrospective Analysis	*N* = 57 Mean Age = 40 ±12 Male = 45 BMI = 20.5 ±2.9 EVAHEART = 21 Duraheart = 14 HMII = 16 Jarvik 2000 = 5 HeartWare = 1 DT = not reported	Rate of DLI: 21/57 = 36.8% Increased Risk of DLI: Lower BMI: HR = 0.843 CI (0.711 - 0.998), $p = 0.048$ Decreased Serum albumin (g/dL): HR = 0.114 CI (0.026-0.804), $p = 0.027$	III/B
17	Martin et al (2010)[20]	Retrospective analysis	*N* = 145 Median Age = 52 Male = 107 Median BMI = 28.41 HM XVE = 64 HM II = 52 Thoratec IVAD = 13 VentrAssist = 10 Abiomed = 4 MicroMed = 2 DT = not reported	Rate of LVAD-related infection: 51/145 = 35.2% Increased risk of LVAD-related Infection: HM XVE showed increased risk of infection (p=*0.0001)* w/ 4.3 OR Decreased risk of LVAD-related infection: HM II showed decreased risk of infection. *(*p=*0.0001) w/ 0.21 OR*	III/B
18	Van Meeteren et al (2016)[53]	Retrospective analysis	*N* = 734 Mean Age = 60 Male *n*=577 (78.6%) BMI- not reported Device- all continuous flow DT- 42% Mean Age = 57 Female *n* = 157 (21.4%): BMI- not reported Device- all continuous flow DT- 35%	Rate of DLI: 32% At 1 year, freedom from driveline infection was 93%, 72% at 3 years, and 68% at 5 years. Increased Risk of DLI: Bridge to transplant therapy was the only significant predictor of percutaneous driveline infection (HR 0.52 [0.31 to 0.89], $p = 0.02$).	III/B
19	Sharma et al (2012)[52]	Retrospective analysis	*N* =143 Mean Age = 61.3 ± 12.2 Male = 123 (86%) BMI = 30.8 ± 10.2 HMII = 100% DT = 87 (60.8%)	Rate of DLI: 18/143 = 12.6% Increased risk of DLI: Increased duration of support ($p<0.03$) Decreased risk of DLI: NYHA Class IV was associated with a reduced risk of driveline infection, OR = 0.18 (0.06–0.55), $p<0.01$	III/C
20	Topkara et al (2010)[61]	Prospective Cohort	*N* = 81 Infection *n* = 42 (51.9%): Mean Age = 52 ± 14.2 Male = 33 (78.6%) BMI = 29 ± 5.8 Device- HMII 64 (79%)	Rate of DLI: Before discharge: 2/81 = 2.5% After discharge: 12/81 = 14.8% There were no variables that were statistically significant predictors of LVAD-related infection.	III/B

(*continued*)

Table 1 (*Continued*)

	Author	Study Design	Sample, Demographics, HF and LVAD Characteristics	Key Findings	Evidence Quality
			VentrAssist- 17 (21%) DT = 16 (38.1%) No Infection *n*=39 (48.1%): Mean Age = 51.5 ± 13.3 Male = 30 (76.9%) BMI = 26.9 ± 5.2 Device- HMII 64 (79%) VentrAssist- 17 (21%) DT = 8 (20.5%)		
21	Singh et al (2014)[15]	Retrospective review	*N* = 125 Velour Externalized group, *n*=45 Silicone-only externalized group, *n*=80 No other demographic or clinical characteristics were reported.	Rate of DLI: Velour group (*n* = 45): 20/45 = 44.4% Freedom from driveline infection was 80% at 1 year and 63% at 2 years after implantation. Decreased Risk of DLI: Silicone group (*n* = 80): 7/80 = 8.7% Freedom from driveline infection was 91% at both 1 year and 2 years. Silicone group: greater time of freedom of infection at both 1 year and 2 years ($p < 0.001$)	II/C
22	Schibilsky et al (2012)[62]	Retrospective analysis	*N* = 43 HMII = 37 (86%) Ventrassist = 6 (14%) DT = 11 (25.6%) Conventional driveline tunneling group: *n*=11 Mean Age = 57.2 ± 11.2 Male = not reported BMI = not reported Double Tunnel group: *n* = 32 Mean Age = 55.2 ±14.1 Male = not reported BMI = not reported	Rate of DLI: 5/43 = 11.6% There was no significant difference in driveline infection rates between the conventional and double-tunnel groups.	II/C
23	Stulak et al (2013)[63]	Prospective cohort and retrospective review	*N* = 285 Mean Age = 54 Male = 232 (81%) BMI = not reported HMII = 100% DT = 117 (41%)	Rate of DLI: 27% There was no significant difference in freedom from driveline infection between antibiotic and no antibiotics groups	III/B
24	Fudim et al (2016)[55]	Retrospective analysis	*N* = 161 External Anchoring Suture (*n*=85) Median age = 54 Male- not reported Median BMI = 29 HVAD = 42% DT- not reported No External Anchoring Suture (*n*=76) Median Age = 56 Male = not reported Median BMI = 30 HVAD = 57% DT = not reported	Rate of DLI: 18/161 = 11.1% Decreased Risk of DLI: No external anchoring suture (*p*=0.056)	II/B
25	Camboni et al (2016)[33]	Prospective trial	*N* = 40 Velour group (*n*=24): Mean Age = 52.6 ± 12.9 Male = 23 (96%) BMI = 25.4 ± 3.3 Berlin Heart INCOR = 24 (100%) BTT = 24 (100%) Silicone group (*n*=16): Mean Age = 57.1 ± 8 Male = 15 (94%) BMI = 28 ± 3.9	Rate of DLI: 7/40 = 17.5% There was not a significant difference in freedom from exit site infection between the silicone and velour groups.	II/C

(*continued*)

Table 1 (*Continued*)

	Author	Study Design	Sample, Demographics, HF and LVAD Characteristics	Key Findings	Evidence Quality
			Berlin Heart INCOR = 16 (100%) BTT = 14 (88%)		
26	Dean et al (2015)[16]	Retrospective and prospective analysis	*N* = 401 SSI group (*n*=200): Median Age = 60.4 Male = 159 (79.5%) Median BMI = 28.3 HM II = 200 (100%) DT = 103 (51%) Control group (*n*=201): Median Age = 66 Male = 162 (80.6%) Median BMI = 25.9 HM II = 201 (100%) DT = 201 (100%)	Rate of DLI: Silicone-Skin Interface Group: 18/200 = 9% Control Group (exposed velour): 46/201 = 23% Decreased Risk of DLI: Silicone-Skin Interface Group at 1 year ($p = 0.002$) and most recent follow up ($p = 0.007$). Age >60: (RR = 0.23, $p < 0.001$) Left side driveline exit site: (RR = 0.40, 0.016)	II/A
27	Fleissner et al (2013)[56]	Retrospective analysis	*N* = 81 Group 1 (*n*=40): no tunneling of driveline Mean Age = 52.75 ± 16.3 Male = 36 (90%) BMI = 26.49 ± 4.58 HeartWare = 40 (100%) DT- not reported Group 2 (*n*=41): Double tunneling of driveline. Mean Age = 51.34 ± 16.4 Male = 31 (75.6%) BMI = 27.34 ± 4.63 HeartWare = 41 (100%) DT- not reported	Rate of DLI: 20/81 = 24.7% Decreased Risk of DLI: Double-tunneled driveline group ($p < 0.001$)	II/B
28	McCandless et al (2014)[17]	Retrospective analysis	*N* = 57 LVAD implants between 2008-2012 Exposed Velour Group (*n*=15): Mean Age = 56 ± 14 Sex Ratio (M/F) = 13/2 BMI = 25.1 ± 2.9 HMII = 100% DT = 21% Silicone-Skin Interface Group (*n* = 42): Mean Age = 56 ± 15 Sex Ratio (M/F) = 37/5 BMI = 27.5 ± 5.5 HMII = 100% DT = 26%	Rate of DLI: Velour group: 3/15 = 20% Silicone-Skin Interface group: 1/42 = 2.4% Decreased Risk of DLI: Silicone-Skin Interface (*p*=0.026).	II/B
29	Cagliostro et al (2016)[22]	Prospective cohort	*N* = 286 Old Dressing Management Group (A): Age = 58.71 ± 13.24 Male = 80 (74.8%) BMI = not reported HMII *n* = 106 (99.1%) HW *n* = 1 (0.9%) DT = 29 (27.1%) New Dressing Management Group (B): Age = 57.81 ± 13.78 Male = 133 (83.6%) BMI = not reported HMII = 132 (83.1%) HW = 27 (16.9%) DT = 60 (37.7%)	Rate of DLI: 29/286 = 10.1% Old Dressing Management: 17/107 =15.9% New Dressing Management: 12/159 = 7.5% Decreased Risk of DLI: Relative risk reduction of 62.5%, absolute risk reduction of 11% in new dressing protocol group Decrease in readmission rate for DLI from 0.08 (Group A) to 0.03 (Group B) event per patient year.	II/A
30	Stahovich et al (2016)[26]	Multi-center, prospective, self-controlled	*N* = 50 Mean age = 62 ± 11 years Male *n* = 46 (92%) BMI = not reported HMII = 100% DT = not reported	Rate of DLI: 3/50 = 6% Freedom from DLI at 180 days was 93% ± 4% Most found the kit extremely comfortable (*n* = 37 (80%)) and were extremely satisfied (*n* = 41 (89%) with the kit. Did not examine risk of DLI or the effects of the kit on DLI rates.	II/C

(*continued*)

Table 1 (*Continued*)

	Author	Study Design	Sample, Demographics, HF and LVAD Characteristics	Key Findings	Evidence Quality
31	Menon et al (2015)[21]	Retrospective analysis	*N* = 40 (sample size unclear due to discrepancies between text and figures) Merbromid group *n* = 17 Octinidine *n* = 31 Mean age = 58.1 ± 11.8 years Male *n* = 26 (65%) BMI = Not reported HMII = 100% DT = 9 (22.5%)	Rate of DLI: 2/40 = 5% Decreased Risk of DLI: Merbromid use ($p = 0.043$)	II/C
32	Wus et al (2015)[25]	Retrospective analysis	*N* = 68 Mean age = 57 ± 11.4 years Male *n* = 55 (80.9%) BMI = 28.6 ±5.9 HMII = 100% DT = not reported	Rate of DLI: 0 No driveline infections were found in the study population during the 30-day post-op follow-up period. Since there were no DLIs found, no difference was seen in driveline infection between daily, weekly, or M/W/F dressing change frequencies.	II/B
33	Aslam et al (2016)[23]	Retrospective Analysis	*N* = 88 Group 1 (*n* = 24) - Old dressing protocol: Mean age = 58.25 ± 14.9 years Male *n* = 17 (70.8%) BMI = 26.6 ± 4.3 HMII = 24 (100%) DT = 18 (75%) Group 2 (*n* = 64) - New dressing protocol: Mean age = 58.2 ± 14 years Male *n* = 54 (84.4%) BMI = 26 ± 0.7 HMII = 40 (62.5%) HW = 24 (37.5%) DT = 30 (46.9%)	Rate of DLI: 14/88 = 15.9% Decreased rate of DLI: Group 2 with new dressing change practices had significantly lower rates of DLI ($p < 0.0001$) New driveline management strategy was significantly associated with decreased risk of infection in multivariate analysis (OR 0.09, 95% CI 0.02-0.4, $p = 0.002$)	II/B
34	Zainah et al (2016)[24]	Prospective anlaysis	*N* = 42 Intervention = Acticoat Silver Dressing Mean age = 60.3 ± 8.8 years Male *n* = 15 (75%) BMI = 28.7 ± 5.6 CF-LVAD = 100% DT = not reported Control = Standard Dressing Mean age = 48.6 ± 14.8 years Male *n* = 15 (68.2%) BMI = 28.6 ± 5.5 CF-LVAD = 100% DT = not reported	Rate of LVAD Infection: 10/42 = 23.8% No statistically significant difference in LVAD infection rate between the intervention and control dressings.	II/C

that reported driveline infection specifically either used a consensus definition of driveline infection, provided their own criteria, or did not report a definition of infection at all. The consensus definitions for driveline infection used included those from INTERMACS and ISHLT. Two other definitions were adapted from the Hospital Infection Control Practices Advisory Committee [HICPAC] and the Cleveland Clinic. Table 2 summarizes these definitions and the number of articles utilizing them. Due to the diversity of infection types and definitions reported, this review will refer to "LVAD-related infection" unless driveline infection was specified.

The average sample size across the 34 studies was 215 (SD ± 348) patients, with a range of 27 to 2006 patients. The average rate of LVAD-related infection among the studies was 24% (SD ± 17.3%) with a range of 0% to 93% of the study sample. Most centers reported rates close to the average rate. One outlying institution reported an infection rate of 93% amongst 27 consecutive LVAD patients within 12 months after implantation.[13] The authors were unable to identify variables that may be responsible for this high infection rate; however, it may have been related to factors unique to the center, its protocols, or practice during that time.

Fig. 2 shows a summarizes the articles' evidence level and quality. We found no Level I studies and the majority of articles were either III/B or III/C, meaning they were non-experimental studies of either "good" or "low" quality.

Few clinical characteristics other than BMI and age describe the vulnerable host

The majority of studies focused on the "vulnerable host", or the demographic and clinical characteristics of LVAD patients and whether they were associated with risk of LVAD-related infection. Twenty-one of the 34 articles found a statistically significant association between one or more clinical and demographic variables and risk of LVAD-related infection. In these 21 articles, we found 19 different variable associations that were statistically significant (Fig. 3). However, only two patient characteristics, increased BMI and

Table 2
Definitions of LVAD-related infection utilized in the literature examined.

	Definition of driveline/LVAD infection	Number of articles
INTERMACS	*Percutaneous site and/or pump pocket infection: positive culture of the driveline site or pump pocket, the need for antibiotic therapy, and clinical presentation of pain, fever, discharge, or leukocytosis.*[64]	*9*
ISHLT	*Percutaneous driveline infections are divided into proven, probable, and possible. Proven driveline infection involves documented involvement of superficial tissues to the facia and muscle layers, positive skin culture, increased temperature at site, purulent discharge and/or erythema at the site.*[5]	*8*
HICPAC	*Adapted from HICPAC definition of surgical site infection: Infection occurring within 30 days after procedure that involves skin or subcutaneous tissue (superficial) or facial and muscle layers (deep) and presents with purulent drainage from site, or positive culture, or symptoms such as pain, localized swelling, redness or heat.*[65]	*1*
Cleveland Clinic	*Defined as LVAD-related infection and divided into three classes. Class I involves positive culture from site, bloodstream infection with same organisms, and no other clear etiology of infection. Class II has positive culture from site, local or systemic symptoms of infection (febrile, purulent discharge, and pain/swelling/redness at site), and no bloodstream infection. Class III is simply local or systemic signs of infection, response to antibiotic therapy and/or removal of the device, no culture evidence or bloodstream infection, and no other obvious etiology of infection.*[66]	*1*
Other definition	Criteria defined by specific institution	*8*
Not reported	No definition of infection was provided	*7*
Total		*34*

younger age, were associated with increased risk of infection in more than one study.

The driveline exit site is the primary portal of entry

Surgical implantation of the device and the driveline exit site are important "portals of entry" for infectious microorganisms. A small number of articles evaluated surgical technique of implantation and the formation of closed tissue around the driveline exit site. These studies examined the effect of exposed vs. buried driveline velour, an external anchoring suture at the driveline exit site, conventional vs. double-tunneled drivelines, and implantation of different device types on the risk of driveline infection. The only technique that showed a statistically significant increase in risk of driveline infection, and was reported in more than 1 study, was exposure of the driveline velour outside the body at the driveline exit site.[14–17] Three studies found conflicting evidence whether HeartMate II or other continuous flow devices have lower risk of infection.[18–20]

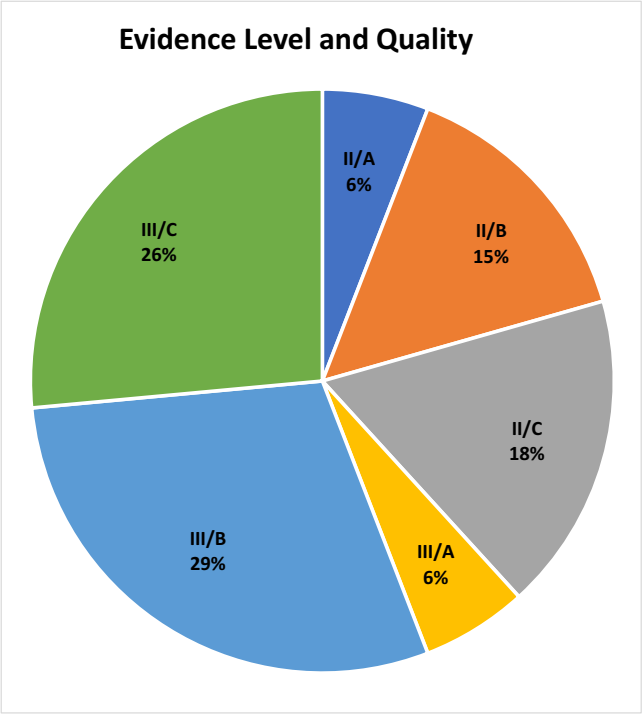

Fig. 2. Each article was evaluated using the Johns Hopkins Nursing Evidence-Based Practice Model and assigned an evidence level and quality rating.[11] Shown here are the percentage of the articles found to be a specific evidence level and quality. No articles of levels IV and V were included, and no articles of Level I were found that met our inclusion criteria. Legend: evidence level (I, II, or III)/evidence quality (A, B, or C). Level I studies: either randomized controlled trials or experimental studies. Level II: quasi-experimental studies with some manipulation of an independent variable, no random assignment, and may or may not have a control group. Level III studies: non-experimental studies that are descriptive or examining correlations or comparing groups and they do not manipulate an independent variable.

Some literature investigated the care of the driveline exit site, a critical portal of entry for infection. However, the interventions and outcomes measured varied amongst studies. Four studies addressed the materials used to change driveline dressings.[21–24] Menon et al[21] compared their standard driveline antiseptic cleansing to a new method using a merbromid antimicrobial product (2% merbro- min solution, 30 mL; Co. New FaDem SRL Farmaceutici & Chimici, Giugliano, Campania, Italy). They saw a statistically significant decrease in driveline infection, however, merbromid is currently illegal in many countries due to its mercury content. Cagliostro et al,[22] saw a statistically significant reduction in driveline infection (including a notable 11% absolute risk reduction) with the introduction of a new driveline dressing management protocol utilizing a standardized kit and a silver-impregnated gauze. Aslam et al[23] also utilized a silver-impregnated gauze as part of their intervention and saw a statistically significant reduction in driveline infections rates. Conversely, a study by Zainah et al[24] saw no difference in driveline infection rates utilizing silver. One study, by Wus and colleagues,[25] compared driveline infection rates between dressing changes performed daily, weekly, and three times per week. They found no infections during their pre-implementation and 30-day follow-up period. Therefore, they could not determine if there was a difference in infection rates with different dressing change frequencies. One article by Stahovich et al[26] examined levels of patient satisfaction with a new driveline dressing change kit which found that patients were significantly more comfortable using the new kit ($p < 0.001$). They did not compare pre-intervention and post-intervention driveline infection rates. Table 3 summarizes the different driveline dressing change kit components (if a kit was used) or the materials used in the driveline dressing change protocol.

Determining the organism of infection

The microbiology of LVAD-related infection was an additional focus of some studies. Sixteen out of 34 articles reported the causative

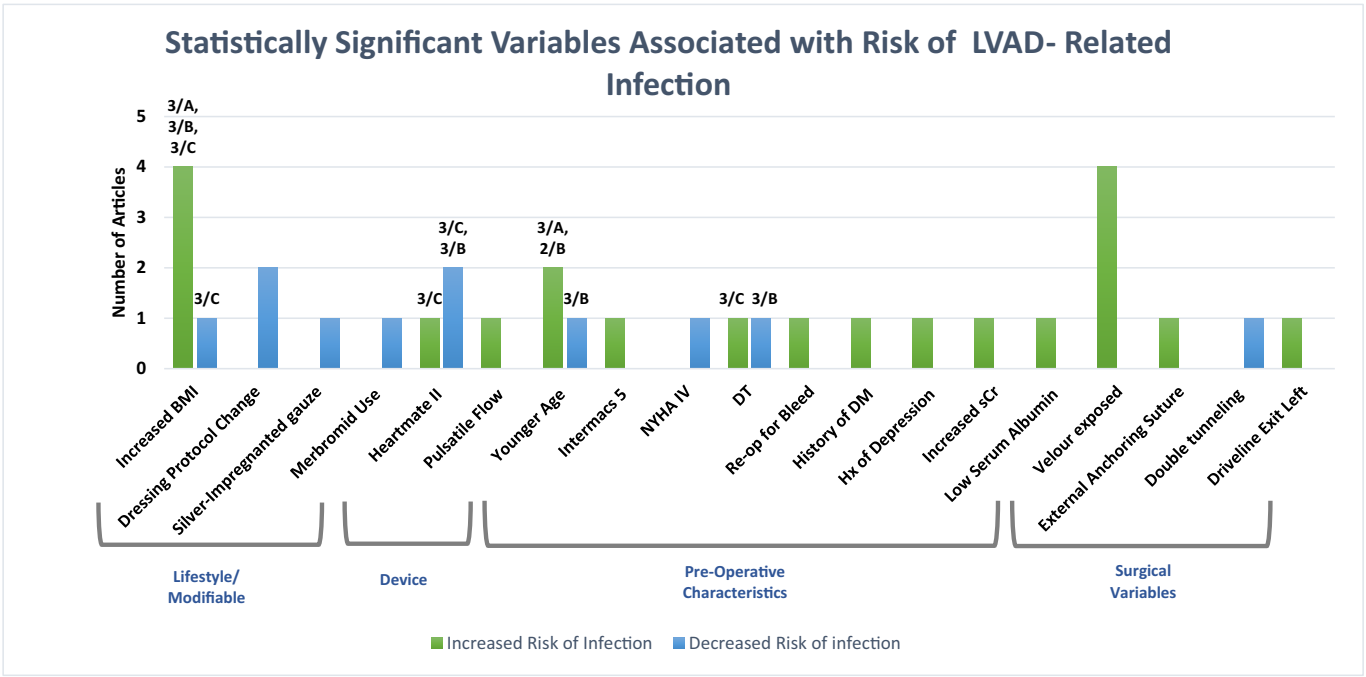

Fig. 3. Summary of statistically significant variables associated with risk of LVAD-related infection. X-axis shows individual variables with article citations in parentheses. These variables are divided into categories including: lifestyle/modifiable, device, pre-op characteristics, and surgical variables. Y-axis shows the number of articles that found a particular variable to be significantly associated with increased or decreased risk of LVAD-related infection. Green indicates an increased risk of infection, while blue indicates decreased risk of infection. Evidence level and quality grades are shown above variables with divergent finding. Evidence level and quality seem to suggest that when results are conflicting, findings reported by >1 article are, in general, of higher evidence level and quality. Increased BMI,[14,27–29] Dressing Protocol Change,[22,23] Silver-Impregnated Gauze,[23] Merbromid,[25] Heartmate II,[18–20] Pulsatile Flow,[49] Younger Age,[16,28,31] INTERMACS 5[46], NYHA IV,[54] Destination Therapy (DT),[14,53] *Re*-op for Bleed,[46] History of Diabetes Mellitus (DM),[27] History of Depression,[48] Increased Serum Creatinine,[48] Low Serum Albumin,[30] Velour Exposed,[14–17] External Anchoring Suture,[58] Double-Tunneling (of driveline),[59] and Driveline Exit Left.[16] (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

microorganisms of infection in their patient populations. The organism most frequently reported as the most common cause of LVAD-related infection was *Staphylococcus aureus* – methicillin sensitivity not specified - (33%), followed by *Staphylococcus* species – individual species not reported - (28%), methicillin-resistant *Staphylococcus aureus* [MRSA] (17%), coagulase negative *Staphylococcus* species – individual species not reported- (5%), and *Pseudomonas aeruginosa* (17%) (Fig. 4). One study, Koval et al. collected serial cultures from infected drivelines over time and found that in 18% of infections the original organism cultured was subsequently replaced by a different superinfecting organism, all of which were gram-negative.[27]

Discussion

We have discovered that current LVAD driveline infection literature has focused primarily on the vulnerable host, portal of entry, and causative organism aspects of the chain of infection. Though divergent findings between studies were shown in multiple risk factors, the evidence suggests that increased BMI,[28–30,14,31] younger age,[29,32,16] and exposed driveline velour[14–17,33] are associated with increased risk of infection and driveline dressing protocol change[22,23] is associated with lower risk of infection. Evidence remains conflicting regarding the effect of implant strategy (bridge-to-transplant vs. destination therapy) and device type. All other variables that were found to be statistically significant were reported by only one study, highlighting the need for multi-center studies to examine risk factors in adequately powered samples.

Fig. 5 shows the chain of infection and how it relates to LVAD driveline infection based on our synthesis of the literature. Our review shows that the current literature has not adequately examined the host reservoir, portal of exit, and mode of transmission. These aspects, with the addition of the portal of entry, appear to be the most modifiable and potentially promising for patient-centered intervention due to their integral relationship with LVAD driveline dressing change practices. Some evidence addressed driveline dressing practices, however, only two articles showed a statistically significant reduction in driveline infection and their dressing interventions were different (i.e. dressing change frequency, use of kit, or use of new antimicrobial products). There were additional quality improvement articles that addressed the topic of driveline dressing change practices that found conflicting evidence on the impact of driveline dressing practice change on rates of driveline infection. Hozayen et al. found no difference between two different dressings and Iseler et al. even found an increase in driveline infection rates. Variation of intervention and limited available high- quality evidence makes it difficult to recommend specific dressing change practices, frequency, and materials from existing data.

Human skin as the host reservoir for infection

Our review showed that the most common causes of LVAD-related infection are *Staphylococcus aureus, MRSA*, *Pseudomonas aeruginosa,* and coagulase-negative *Staphylococcus* species. Understanding the organisms of infection is important not only for selection of antibiotic therapies for treatment but can also give insight into the potential origin of infection. The human skin is a complex organ that protects against pathogens but also serves as host to diverse communities of bacteria, viruses, and fungi essential to developing the human immune response.[34,35] Through metagenomic analysis, there is evidence that the composition of microbes

Table 3
Summary of driveline dressing change materials and frequency.

Article	Use of Kit	Dressing materials	Dressing change frequency
Stahovich et al (2016)[26]	Yes	1. 70% isopropyl alcohol swab 2. Chlorascrub Maxi Swabstick and Swab 3. No Sting Barrier Film 4. Silverlon Wound Pad Dressing 1.5 × 1.5 inch 5. SorbaView Ultimate Dressing 6. Foley anchor 7. Sterile nonlatex gloves 8. Hair cover 9. Face mask 10. Sterile saline Styrofoam tray	Every 7 days
Menon et al[21]	No	1. Octenisept (0.1% octenidine dihydrochloride, 2% 2-phenoxyethanol) 2. Merbromid (2% merbro- min solution) 3. Metalline compress (for dry wounds) 4. 5 sterile gauze sheets 5. Fixomull patch 6. Hollister plate	Daily during early pre-operative period (no timeframe provided). Every 5–6 days after early pre-operative period.
Wus et al (2015)[25]	No	1. Chlorhexidine 2. Occlusive dressing 3. Personal Protective equipment 4. Stabilization device No further detail was provided about the components of the driveline dressing or the materials used for the dressing change.	Daily (standard care) OR Weekly (intervention)
Cagliostro et al (2016)[22]	Yes	Standard Care (No Kit): 1. Gauze with sterile water (cleansing) 2. Gauze with Chlorhexidine Solution 2% (cleansing) 3. Gauze pad (dressing) 4. Bio-occlusive dressing 5. Abdominal binder OR Bio-occlusive dressing OR STAT lock (for driveline anchoring) Intervention (Kit): 1. ChloraPrep 1 step swab (cleansing) 2. Silver Gauze, Gauze pad (dressing) 3. Bio-occlusive dressing 4. Centurion anchor (driveline anchoring)	Not reported
Aslam et al (2016)[23]	No	Group 1 – Standard Dressing 1. Chlorhexidine cleansing 2. Sterile 4 × 4 gauze 3. Abdominal Binder Group 2 – Intervention Dressing 1. Chlorhexidine cleansing 2. Silver-impregnated foam 3. Clear Dressing 4. Driveline anchor	Group 1 Daily Group 2 Every 3 days
Zainah et al (2016)[24]	No	Acticoat- Silver Dressing vs. Traditional Dressing No further details were provided about dressing change practices or other materials used for the dressing or stabilization.	Not reported

found on a particular skin site is highly influenced by the physiology of that site.[34] Skin sites can be classified as either moist, dry, or sebaceous.[35] In LVAD patients, the driveline exit site is located relatively near the umbilicus, in an area considered a physiologically "moist" region of the skin due to its partial occlusion from clothing, skin folds, and increased temperature. Organisms of "moist" skin regions appear to be the predominating causes of LVAD infection, thus suggesting that the skin and its microbial burden is a reservoir of infection. Additionally, the organism of LVAD infection may change over time, with one study suggesting that organisms may shift from gram-positive to gram-negative as infection progresses.[36] Gram-negative organisms are particularly difficult to treat due to their thick capsule, unique cell wall components, and increasing antimicrobial resistance. Since the human skin serves as host to both gram-positive and gram-negative bacteria, we assert that reducing microbial bioburden and maintaining sterility at the driveline exit site is an essential method for infection prevention.

Reducing microbial bioburden at the portal of exit

The "portal of exit" is the site from which pathogens are transmitted, which for LVAD driveline infection includes contaminated hands of the patient/caregiver/provider performing dressing changes, non-sterile dressing materials, environmental contaminants, or the surrounding skin microflora. Driveline dressing change practices such as hand hygiene, aseptic technique, skin cleansing around the driveline, and use of sterile dressing materials all influence these crucial portals of exit. Our analysis showed limited evidence regarding driveline dressing changes. However, some clinical centers from our review based some aspects of their dressing change practices on principles from the Central Line Associated Bloodstream Infection [CLABSI] literature extended to the LVAD context.[37] LVADs and central lines have significant similarities, including their penetration of the skin barrier and direct access to the heart. Additionally, pathogens in vascular access device infections

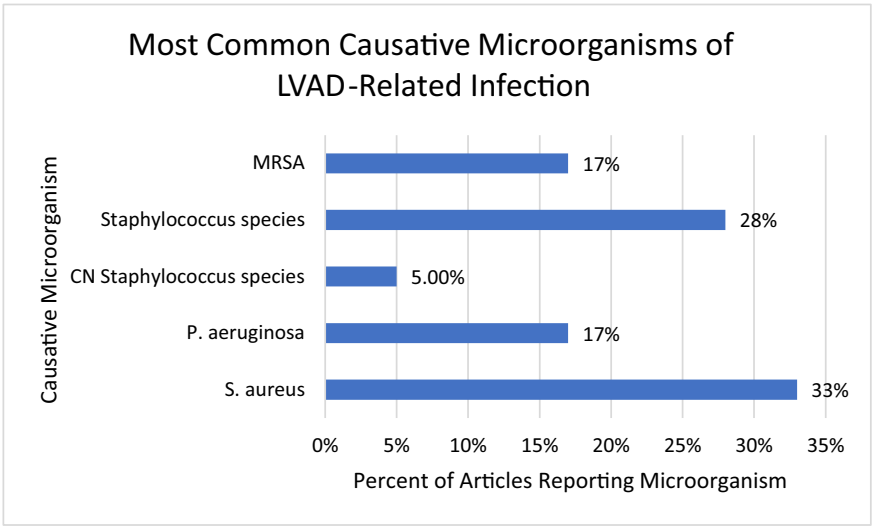

Fig. 4. Percentage of articles that found a particular organism to be the most common cause of LVAD related infection. *N*=16 articles. The most common organisms causing LVAD-related infection in the current literature are *Staphylococcus aureus* (*S. aureus,* methicillin sensitivity not specified), *Staphylococcus* species (individual species not specified), and Methicillin-Resistant *Staphylococcus aureus* (MRSA). *Pseudomonas aeruginosa* (*P. aeruginosa*) caused the lowest number of infections.

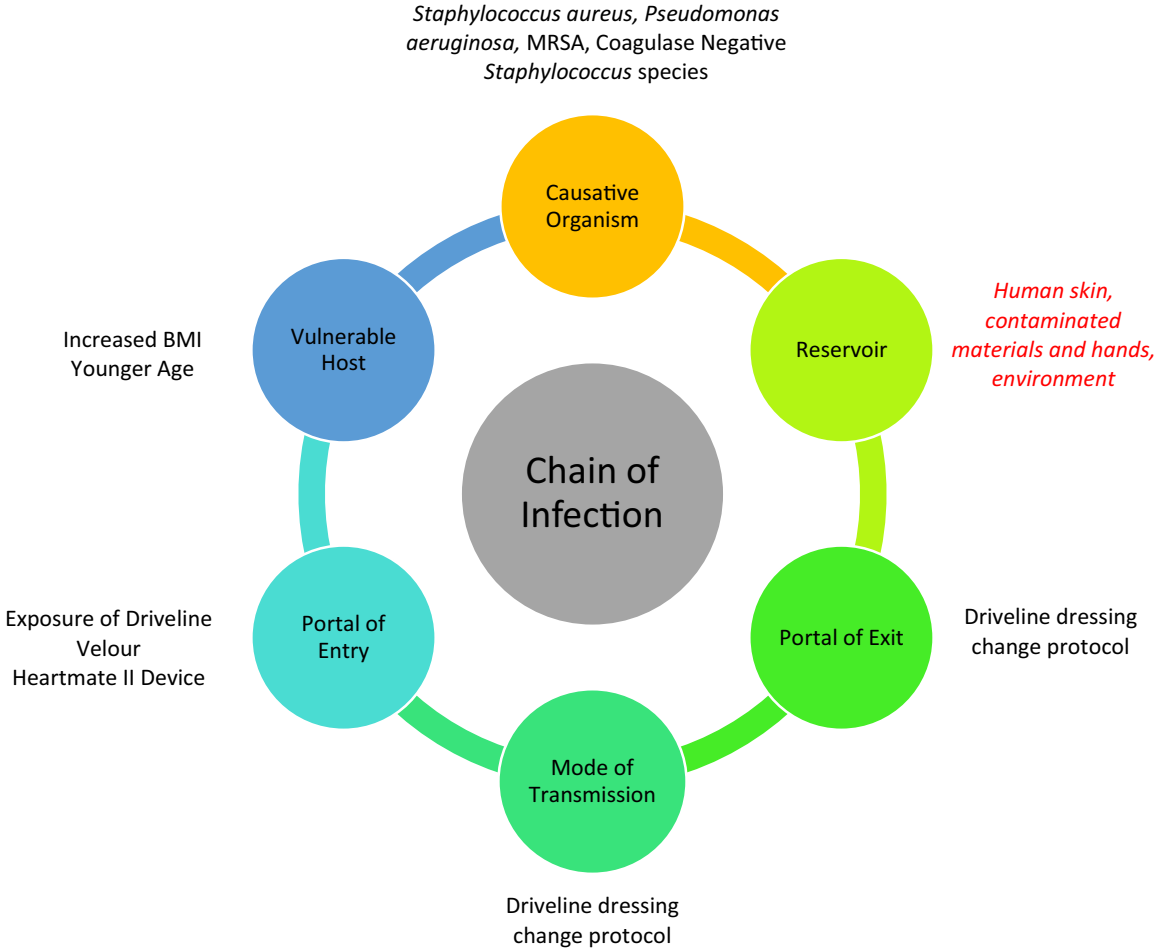

Fig. 5. The Chain of Infection, the epidemiologic model of infectious disease transmission, and how it relates to the current LVAD driveline infection literature. Adjacent to each part of the chain of infection are the variables found to be significantly associated with either increased or decreased risk of infection. The literature primarily focuses on the organism of infection, vulnerable host, and some aspects of the portal of entry. Only one article examined the effects of driveline dressing practices on infection rates with statistically significant results, leaving little evidence on which to base current practice. Those variables indicated in red have been extended to the LVAD context from the central line associated blood stream infection literature. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

are similar to those found in LVAD-associated infections.[37]According to the Centers for Disease Control and Prevention's guidelines for preventing intravascular catheter-related infection, the top two routes of transmission are migration of skin flora from around the site of the catheter and direct contact with the catheter by contaminated hands or materials.[37] Therefore, like with central lines, reducing microbial bioburden at the driveline exit site and preventing introduction of bacteria from non-sterile or contaminated materials and hands through proper sterile technique is critically important for preventing LVAD-related infection. Though we only found a few articles that demonstrated a statistically significant reduction in driveline infection with changes to driveline dressing management practices, these findings are promising and warrant further investigation through multi-center trials.

Consensus recommendations: central venous catheter vs. LVAD driveline dressings

Guidelines for the prevention of intravascular catheter-related infections draw from current literature to provide recommendations for the care of intravascular catheters, including central venous catheters.[37] Relevant recommendations from these guidelines can be divided into a few categories: staff education and assessment of competence, hand hygiene and aseptic technique, dressing change materials, and dressing change practices.[37] Table 4 summarizes these recommendations. Additionally, the Joint Commission recommends the use of "care bundles" to standardize insertion practices and ongoing maintenance of central venous catheters.[38,39] Adherence to such bundles have been shown to increase implementation of evidence-based practices and reduce rates of central line associated bloodstream infection.[38,40,41]

The ISHLT has similarly published guidelines for the prevention of infection in LVAD patients.[2] However, their recommendations lack significant detail and often defer to institutional policy. General recommendations included the use of sterile technique, cleansing the exit site with an antiseptic solution, most commonly chlorhexidine, and covering it with a protective dressing.[2] They make no strong recommendation about type of dressing supplies or frequency of dressing changes due to limited evidence. Additionally, the authors of the ISHLT guidelines make it clear that more research is necessary to determine specific product recommendations and the frequency of driveline dressing changes.

There is a dearth of literature focused on driveline dressing protocols and management, which appears to be one of the most modifiable variables in nursing care of LVAD patients to prevent driveline infections. Driveline dressing protocols have also fallen mostly into the realm of quality improvement rather than research. We found five quality improvement articles but they did not meet our inclusion criteria.[42–44,27,45] This appears to reflect the current quality of evidence regarding driveline dressings and shows that there is a lack of higher-level evidence on which to base practice recommendations. We recommend that the guidelines for the dressing change practices of central venous catheters (standardization of dressing change practices and nurse education, utilization of sterile kits) be adapted and applied to the LVAD context in order to develop a standardized driveline dressing change kit and protocol. The introduction of this kit to inpatient practice may influence patient and caregiver education and serve as a testable intervention with the goal of reducing rates of driveline infection.

While successful infection prevention strategies are under development for the inpatient setting, where there is a high degree of investigator control and intervention fidelity, the outpatient setting remains understudied. To ensure continuity from inpatient to outpatient, many centers are using similar standardized kits for home driveline maintenance and impatient dressing changes. They teach the patient and caregiver(s) using these kits, starting in the inpatient setting, and with reinforcement in the outpatient setting. Additionally, many centers utilize resources such as instructional videos, handouts, return demonstration, and host annual re-education sessions. Some LVAD centers utilize home nursing services, however, the skill and knowledge of each home nursing service varies, especially when not using a standardized dressing kit. Best practices for teaching patients and caregivers for the home setting have not been developed and there is little evidence on which to base any recommendations.

Nurses are integral in the care of the LVAD driveline and patient and caregiver education making them essential to the development and implementation of interventions to reduce rates of driveline infection. It is clear, though, that the prevention of driveline and all LVAD-related infection is an interdisciplinary effort and we cannot do so without collaboration amongst physicians, surgeons, nurses, pharmacists, physical therapy and other members of the care team. Sterile technique during implant in the operating room, proper care of the driveline dressing by nursing staff and the patient/caregiver dyad, prophylactic antibiotics before dental procedures, identifying patient barriers to caring for LVAD and driveline, and rapid diagnosis of early infection are just a few examples of how an interdisciplinary care team work together to prevent infection in patients with LVADs.

Table 4
Summary of relevant guidelines for the prevention of intravascular catheter-related infections.[35]

Category	Recommendations
Healthcare Personnel Training	1. Educate healthcare personnel on the care and use of intravascular catheters. 2. Provide education about infection prevention measures to prevent catheter-related infections. 3. Periodically assess healthcare personnel knowledge. 4. Only trained personnel who have been evaluated as competent to care for and use intravascular catheters should do so.
Hand Hygiene and Aseptic Technique	1. Perform hand hygiene with soap and water or alcohol-based hand rub before and after inserting, replacing, accessing, repairing, or changing the dressing of an intravascular catheter. 2. Use aseptic technique for the insertion of catheters.
Dressing Materials	1. Use sterile gauze or a sterile, transparent, semi-permeable dressing. 2. If the site is bleeding or the patient is diaphoretic, gauze should be used until bleeding and/or sweating has resolved. 3. No recommendation is made for use of chlorhexidine impregnated dressings.
Dressing Change Practices and Frequency	1. Use an antiseptic solution to clean the skin during dressing changes. Chlorhexidine should be used for the care of central venous catheters unless the patient has an allergy. Then iodine or 70% alcohol can be used. 2. Antiseptics should be allowed to completely dry. 3. If the dressing becomes visibly soiled, wet or loose, it should be changed. 4. When using gauze dressings, they should be changed every 2 days. 5. When using transparent dressings, they should be changed every 7 days. 6. The catheter should be secured with a securement device to prevent dislodgement.

Finally, current literature has not explored how well patients and caregivers understand not only the techniques for dressing change, but also the rationale for the techniques. Low health literacy has shown to be associated with higher rates of hospitalizations, poorer health outcomes, and higher mortality among heart transplant patients, indicating a likely vulnerability among LVAD patients as well.[46] It is likely that few LVAD patient resources meet the 5th grade reading level recommended for healthcare education. Also, studies should consider standardized approaches to nurse education, nurse-led teaching of patients and caregivers, appropriate monitoring of patient adherence to protocols and skills refreshers for patients. Despite the limited evidence for sociodemographic predictors of infection, issues of health disparities, health literacy, and access to resources should continue to be a point of focus in the care of LVAD patients in addition to readily modifiable factors such as driveline dressing change practices.

Limitations and strengths

We acknowledge that there are limitations to our literature review. Our search strategy may not have completely captured all related literature. There was significant heterogeneity in study design and measures, preventing meta-analysis. Further, there are inherent challenges with studying the LVAD population due to such small sample sizes, making it difficult to capture statistical significance and generalize results. Several articles that identified additional variables associated with LVAD infection were excluded, particularly due to year of publication and inclusion of pulsatile devices. These articles identified correlates of LVAD infection such as malnutrition,[47] device associated T-cell dysfunction,[48] longer ICU stay,[49] and prolonged duration of support.[49,50] However, these variables from older studies have not surfaced in recent literature. Finally, nursing care was rarely the focus of these studies, limiting our ability to identify best practices. This literature review makes a meaningful contribution to the literature by synthesizing findings related to risk for driveline infection according to the Chain of Infection, highlighting the key role of nursing, as a member of the interdisciplinary care team, in improving patient outcomes for people with advanced heart failure and an LVAD.

Conclusions

The purpose of this systematic literature review was to explore clinical characteristics of LVAD patients associated with risk of driveline infection and to identify ways to improve nursing care within the context of the Chain of Infection. Though divergent findings between studies were shown in multiple risk factors, the evidence suggests that increased BMI, younger age, and exposed driveline velour are associated with increased risk of infection and driveline dressing protocol and standardized kits including the use of silver-impregnated gauze are associated with lower risk of infection. Most studies focused on the vulnerable host, portal of entry, and causative organism aspects of the Chain of Infection. Future studies are needed to establish best practices for materials for driveline dressing care, techniques for driveline management and approaches to educating healthcare providers, patients and families to improve LVAD patient outcomes.

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