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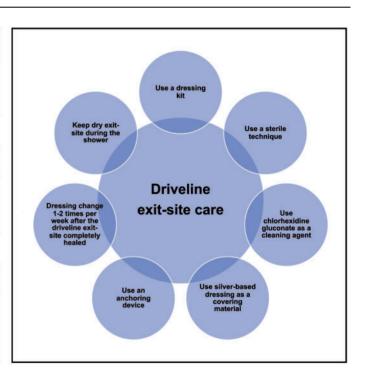
# Driveline exit-site care protocols in patients with left ventricular assist devices: a systematic review

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# Key question Is there a standardized left ventricular assist device (LVAD) driveline exit-site care protocol? Key finding(s) This systematic review reveals a marked variability in driveline exit-site care protocols without a standardized driveline dressing technique. Take-home message The LVAD driveline exit-site care protocols that include chlorhexidine, silver-based dressing and anchoring device might be best in reducing driveline infection rates.



# **Abstract**

**OBJECTIVES:** Driveline infections continue to be a significant complication following left ventricular assist device (LVAD) implantation. Driveline exit-site care is crucial for the prevention of infections; however, there are no uniform guidelines. The goal of this study was to provide an overview of the currently published driveline exit-site care protocols in patients with LVAD.

**METHODS:** A systematic literature review was performed. Studies before 15 December 2020 were included if the number of driveline infections was a primary outcome and the driveline exit-site care protocol was explained.

**RESULTS:** Eleven articles were included in the systematic review, including 1602 patients with LVADs. The median of the frequency of driveline infections in the articles was 13.8% with a range of 0-52.6%. There was a marked variability in the methods of care of driveline

exit sites, without a standardized driveline dressing technique in patients with LVADs. The frequency of driveline infections was 6–7.5% in studies using a dressing kit that included chlorhexidine, a silver-based dressing and an anchoring device. Furthermore, there was variability in the anchoring devices and the frequency of dressing changes, which varied from daily to weekly. No specific anchoring device or change frequency was found to be superior.

**CONCLUSIONS:** Based on this systematic review, driveline exit care protocols that included chlorhexidine, a silver-based dressing, the use of an anchoring device and dressing kits might be best in reducing driveline infection rates. However, prospective studies with larger cohorts are needed to establish the optimal protocol for driveline exit-site care.

**Keywords:** Left ventricular assist device • Dressing • Driveline • Driveline infection • Protocols • Care

### **ABBREVIATIONS**

CHG Chlorhexidine gluconate

HM HeartMate HW HeartWare

LVAD Left ventricular assist device

# INTRODUCTION

Driveline infections continue to be a significant complication following left ventricular assist device (LVAD) implants and are a limiting factor to successful long-term LVAD support [1, 2]. The International Society for Heart and Lung Transplantation Registry for Mechanically Assisted Circulatory Support reported driveline infection rates as high as 29% after LVAD implantation for 3 months [2]. The Interagency Registry for Mechanically Assisted Circulatory Support reported that driveline infections occur in  $\sim$ 19% of recipients of LVAD by 12 months after implant [3].

The driveline exit site is frequently the entry site of pathogens that may cause local infection, and these infections could track to the pocket and the pump. Therefore, driveline infections increase the risk for pump/cannula, pocket and bloodstream infections [2]. We know that care of the driveline exit site is paramount for the prevention and treatment of driveline infections [4, 5]. Despite the importance of its care, there are few specific recommendations for the management of the LVAD driveline exit site [4, 6–8]. Research on driveline exit-site care has shown that driveline exit-site management is not standardized, resulting in a wide variety of management protocols among LVAD centres [9]. The goal of this systematic review was to provide an overview of the currently published driveline exit-site care protocols in patients with an LVAD.

# **MATERIALS AND METHODS**

# Search strategy

This systematic literature review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines [10]. The search strategy was developed with a librarian for inclusion sensitivity. A literature search was performed using Embase, Medline Ovid, Cinahl EBSCOhost, Web of Science Core Collection, Cochrane Central register of trials and Google scholar databases using the following search terms: 'left ventricular assist device', 'ventricular assist device', 'heart assist device', 'driveline', 'wound care', 'infection prevention', 'driveline infection', 'device infection', 'exit site', 'wound infection', 'wound care', 'care', 'wound management', 'dressing', 'protocol'.

# Study selection

Two reviewers (Z.O.K. and Y.C.Y.) independently reviewed potentially eligible studies for evaluation. Titles and abstracts were examined for possible inclusion before the full-text versions of the remaining articles were obtained. All authors were involved in the final selection of and data extraction from included articles. Any discrepancies among the authors regarding inclusion were resolved by consensus among all authors. Full-text clinical research articles written in English and published before 15 December 2020 were included in the systematic review. Studies were included if a driveline exit-site care protocol was explained, and if driveline-related and specific infections were a primary outcome. Case reports, review articles, animal studies and conference abstracts were excluded. In addition, studies were excluded if they only discussed surgical interventions for care management, if they examined pulsatile flow devices or if fewer than 30 patients were included.

# Data extraction

Data that were extracted included study and LVAD characteristics, sample size, follow-up time, device type and strategy, definition criteria of driveline infections and perioperative antibiotic prophylaxis. The primary outcomes reported in the studies were driveline care protocols and driveline infections. We also evaluated time to first infection, infection relapse rates and microorganisms causing driveline infections.

# **Quality assessment**

The quality of each article was appraised using the Strengthening the Reporting of Observational Studies in Epidemiology Statement checklist (Table 1). A higher score from the checklist indicates higher quality [19].

# Statistical analyses

Data from the articles were analysed with SPSS 22.0 (SPSS Inc., Chicago, IL, USA). Categorical variables were presented in numbers and percentages. Continuous variables were presented as median and mean. A meta-analysis could not be performed due to the substantial heterogeneity of the exit-site care methods reported in the studies.

## **RESULTS**

A total of 846 articles were identified through the literature search after duplicates had been removed and were assessed by

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Article/country	Study design	Study period	Sample size	LVAD characteristics	Patient characteristics	Definition of LVAD infection	Perioperative antibiotic prophylaxis	STROBE
Schlöglhofer <i>et al.</i> (2020) Austria [11]	Retrospective analysis, single centre	January 2013– July 2017	Cohort <i>n</i> = 183	Device: HM II, HM 3, HW Device strategy: BTC: 35.5%, BTT: 32.8%, DT: 27.9%, BTR: 0.5%	Mean age: 58.0 years BMI: 26.6 DM: 32.7% Length of support: N/R	ISHLT	Z/R	19
Lander <i>et al.</i> (2018) USA [8]	Retrospective cohort study, single centre	January 2010- October 2015	Intervention $n = 92$ Control $n = 61$	Device: HM II, HW Device strategy: BTC: 59%, DT:41%	Mean age: 58 years 1 BMI: 29.7 DM: 43.8% Length of support: N/R	INTERMACS ISHLT	N/R	20
Aburjania <i>et al.</i> (2017) USA [12]	Retrospective cohort study, single centre	November 2006– September 2015	Intervention $n = 120$ Control $n = 163$	Device: HM II Device strategy: N/R	Mean age: 59 years BMI: 29.1 DM: N/R Length of support. 713 days	Institution's standard definition	Yes	20
Durand <i>et al.</i> (2017) USA[13]	Retrospective cohort study, single centre	August 2005– December 2014	Intervention $n = 65$ Control $n = 19$	Device: N/R Device strategy: BTT: 82%, DT: 18%	Mean age: 55 years BMI: 25.8 DM: 22% Length of support: 370 days	ISHLT	Yes	20
Cagliostro <i>et al.</i> (2016) USA [14]	Prospective cohort study, January 2009- single centre December 2013	January 2009– December 2013	Intervention $n = 159$ Control $n = 107$	Device: HM II, HW Device strategy: BTT: 67%, DT: 33%	Mean age: 58.2 years BMI: N/R DM: 34.2% Length of support: N/R	INTERMACS	N/R	8
Son et al. (2017) USA [15]	Retrospective analysis, single centre	January 2009– December 2013	CHG group $n = 37$ PVP-I group $n = 7$	Device: HM II Device strategy: N/R	Mean age: 60 years BMI: 25.0 DM: 36.4% Leneth of support. 521 davs	INTERMACS	Yes	19
Stahovich <i>et al.</i> (2016) USA [7]	Prospective study, multicentre	Z Z	Cohort n = 50	Device: HM II Device strategy: N/R	Mean age: 62 years BMI: N/R DM: 25% Length of support 496 days	N/R	N/R	18
Menon <i>et al.</i> (2015) Germany [16]	Retrospective cohort study, single centre	January 2008– April 2011	Intervention $n = 31$ Control $n = 17$	Device: HM II Device strategy: BTT/BTC/ BTR = 77.5%, DT = 22.5%	Mean age: 58.1 years BMI: 27.2 DM: 29% Length of support: 198 days	The Cleveland Clinic Classification	Yes	20
Stulak <i>et al.</i> (2013) USA [17]	Retrospective cohort study, single centre	February 2007– September 2011	Intervention $n = 144$ Control $n = 141$	Device: HM II Device strategy: BTT 59%, DT 41%	Mean age: 54 years BMI: N/R DM: N/R Length of support: N/R	Z/R	Yes	
Sharma <i>et al.</i> (2012) USA [4]	Retrospective analysis, single centre	January 2007– January 2011	Cohort <i>n</i> = 143	Device: HM II Device strategy: BTT 39%, DT 61%	Mean age: 61.3 years BMI: 30.8 DM: 33.6% Length of support: N/R	ISHLT	Yes	18
Hozayen <i>et al.</i> (2012) USA [18]	Retrospective cohort study, single centre	N/ N	Utah protocol n = 16 Minnesota protocol n = 47	Device: HM II, HW, VentrAssist Device strategy: N/R	Mean age: 57.1 years BMI: 29.7 DM: 39.6% Length of support: 483 days	ISHLT	N/R	15

Categorical values are reported as n (%).

BMI: body mass index (kg/m²); BTC: bridge to candidacy; BTR: bridge to recovery; BTT: bridge to transplant; CHG: chlorhexidine gluconate; DM: diabetes mellitus; DT: destination therapy; HM: HeartMate; HW: HeartWare; INTERMACS: Interagency Registry for Mechanically Assisted Circulatory Support; ISHLT: International Society for Heart and Lung Transplantation; LVAD: left ventricular assist device infection; N/R: not reported; PVP-I: povidone-iodine; STROBE: Strengthening the Reporting of Observational Studies in Epidemiology Statement.

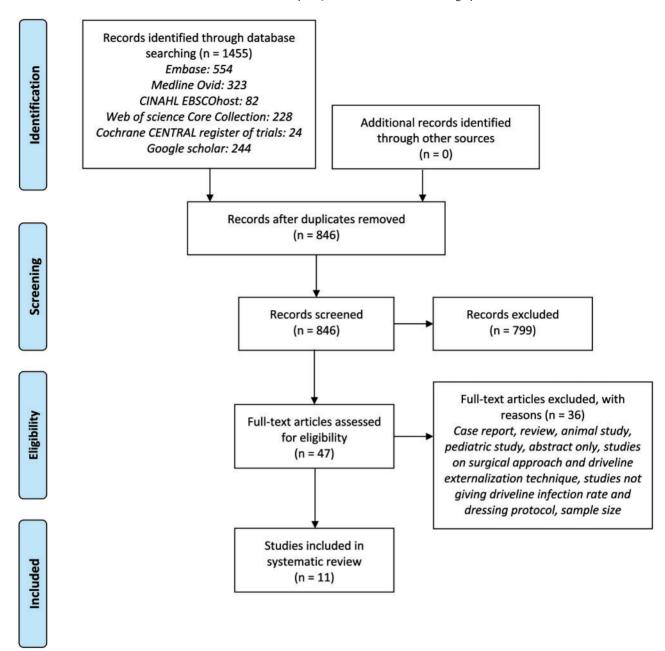


Figure 1: Flow diagram summarizing the review process.

title and abstract for the review. The full texts of 47 articles were reviewed based on the selection criteria, and 36 were excluded based on full manuscript assessment. Eleven articles fulfilled the inclusion criteria, underwent quality assessment and were included in the final review (Fig. 1).

Nine articles included studies conducted in USA: one study was conducted in Germany and one in Austria. The definitions of LVAD driveline infections used in the article are shown in the Supplementary Table 2. Nine articles were retrospective cohort studies and 2 were prospective studies (Table 1). There was a substantial range in types of dressing methods and of management care methods discussed in the articles (Table 2). Three of the studies evaluated the entire care protocol, whereas others compared cleaning agents, covering materials, showering properties and the use of a dressing kit (Table 3). There was no obvious change over time in the driveline exit-care protocols that made a

substantial difference. Interagency Registry for Mechanically Assisted Circulatory Support and International Society for Heart and Lung Transplantation criteria were used for definitions of driveline infections in 7 of the articles. Table 1 summarizes the final articles and the Strengthening the Reporting of Observational Studies in Epidemiology Statement scores. The mean number of patients described in the 11 articles was 145 patients with LVAD (range 44-285 patients). The LVAD strategies mentioned in the articles were bridge to transplant/candidacy/ recovery (63%) and destination therapy (37%). The median of the driveline infection frequencies reported in the articles was 13.8%, with a range of 0-52.6% in a follow-up of 6-44 months in this cohort. The causative microorganisms of driveline infections were reported in 8 out of 11 articles. The organisms reported as the most common causes of driveline infections were Staphylococcus aureus and Pseudomonas aeruginosa (Table 3). The types of the

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Article	Cleaning agent	Dressing closure	Anchoring device	Dressing change frequency	Showering	Sterile technique	Use of a dressing kit
Schlöglhofer <i>et al.</i> (2020) [11]	Octenidine solution	Absorptive non-adherent slit compress (Askina Pad $5 \times 5 \text{ cm}$ )	Secutape Nanoplast fixation	Twice or 3 times weekly	N/R	Yes <sup>a</sup>	N/R
Lander <i>et al.</i> (2018) [8]	CHG and saline solution	Control: sterile gauze pad dressing (the Telfa island occlusive sandwich dressing) Intervention: the Kendal fenestrated foam dressing	Control: Centurion Foley holder Intervention: Centurion secure view port window	Weekly	N/R	Yes <sup>b</sup>	Z R
Aburjania <i>et al.</i> (2017) [12]	CHG PVP-I (if there is a skin irritation)	Z,Z	N/R	Z/R	Not allowed, exit site must be kept dry (using a hand-held shower attachment to wash their hair and lower extremities)	Yes <sup>c</sup>	Z R
Durand et al. (2017) [13]	Polymyxin-trimethoprim so- lution (polymyxin B 10000 units/ml + trimethoprim 1 mg/ml)	Z/Z	N/R	Once or twice weekly	Allowed once per week when the exit site has healed	N/R	Z Z
Cagliostro <i>et al.</i> (2016) [14]	Control: CHG 2% Intervention: CHG 2% and 70% isopropyl alcohol	Control: sterile gauze pad dressing Intervention: silver-based dressing	Control: bio-occlusive dressing, binder or StatLock device Intervention: centurion Foley holder	<b>≅</b> Z	Z/Z	N/R	Yes
Son et al. (2017) [15]	CHG group: CHG 2% PVP-I group: povidone-iodine 10%	Sterile gauze sponge dressing	Centurion Foley holder	Three times weekly	Allowed with occlusive covering of the driveline exit site	Yes <sup>c</sup>	Yes
Stahovich <i>et al.</i> (2016) [7]	CHG 3.15%, saline solution and isopropyl alcohol 70%	Silver-based dressing SorbaView ultimate dressing	Centurion Foley holder	Weekly	Allowed with occlusive covering of the driveline exit site	Yes <sup>d</sup>	Yes
Menon <i>et al.</i> (2015) [16]	Control: octenidine dihydro- chloride 0.1% Intervention: merbromin 2%	Silver-based dressing and sterile gauze pad dressing	Hollister plate stabilizer	Every 5-6 days	N/R	Yes <sup>b</sup>	N/R
Stulak <i>et al.</i> (2013) [17]	CHG 4%	N/R	N/R	N/R	N/R	Yes	N/R
Sharma <i>et al.</i> (2012) [ <b>4</b> ]	CHG and saline swabs	Sterile gauze pad dressing	Abdominal binder	Daily	N/R	Yes <sup>b</sup>	N/R
Hozayen <i>et al.</i> (2012) [18]	Utah protocol: N/R Minnesota protocol: soap and antimicrobial spray	Utah protocol: foam-based dressing Minnesota protocol: sterile gauze pad dressing	Z/R	Utah protocol: every third day Minnesota protocol: daily	N/R	Yes <sup>c</sup>	X X
Erasmus University Medical Centre	CHG 4%	Silver-based and sterile gauze	Hollister plate stabilizer	Two times a	Allowed once per week when	Yese	No No

 $^a$ Using sterile dressing closure, face mask, hair cover and sterile gloves.  $^b$ Using sterile dressing closure, face mask and sterile gloves.

<sup>c</sup>Using sterile dressing closure.
<sup>d</sup>Using sterile dressing closure, face mask, hair cover and non-latex gloves.
<sup>e</sup>Using sterile dressing closure and sterile gloves.
<sup>e</sup>Using sterile dressing closure and sterile gloves.
CHG: chlorhexidine gluconate; N/R: not reported; PVP-I: povidone-iodine.

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Article	Intervention/implementation	Median follow-up time (months)	Driveline infection rate	Time to first infection (days)	Infection relapse rate	Microorganisms
Schlöglhofer <i>et al.</i> (2020) [11]	To characterize risk factors for DLI readmission 2 years postimplant	24	27.3% (50/183)	N/R	Z/R	S. aureus 56% (32/57)³ P. aeruginosa 12% (7/57)³ Others 32% (18/57)³
Lander <i>et al.</i> (2018) [8]	Control: historical LVAD patients (using Telfa Island dressing) Intervention: fenestrated hydrophilic foam dressing	Control: 23.8 Intervention: 39.1	Control: 21.3% (13/61) Intervention: 7.6% (7/92) (P = 0.032)	N/R	45% (9/20)	MSSA 32%, <sup>a</sup> MRSA 11% <sup>a</sup> P. aeruginosa 14%, <sup>a</sup> Proteus 11% <sup>a</sup> CoNS 7%, <sup>a</sup> Others 25% <sup>a</sup>
Aburjania <i>et al.</i> (2017) [12]	Control: historical LVAD patients Intervention: no conventional showers and keep the exit site dry while bathing	Control: 44.4 Intervention: 13.2	Driveline infection (P = 0.06) Control: 42% (69/163) Intervention: 14 % (17/120) Pseudomonas infection (P = 0.077) Control: 9% (15/163) Intervention: 1% (1/120)	347 (entire sample)	Z/ \Z	P. aeruginosa Control: 17% (15/86) Intervention: 1.1% (1/86)
Durand <i>et al.</i> (2017) [13]	Control: no topical antibiotics Intervention: topical polymyxin trimethoprim solution	12.3	Control: 52.6 (10/19) Intervention: 13.8% (9/65) (P = 0.001)	Control: 164 Intervention: 320	37% (7/19)	P. aeruginosa: 37% (7/19) MSSA 16% (3/19) Skin flora: 26% (5/19) Others: 21% (4/19)
Cagliostro <i>et al.</i> (2016) [14]	Control: historical LVAD patients (using gauze pad dressing and not using a standard kit) Intervention: using a standard kit for dressing (includes silver-based gauze dressing and a standard anchoring device)	Control: 8.7 Intervention: 11.6	Control: 15.8% (17/107) Intervention: 7.5% (12/159)	Control: 154 Intervention: 181	Control: 65% (11/17) Intervention: 50% (6/ 12)	w Z
Son et al. (2017) [15]	CHG group: using CHG for cleaning PVP-1 group: using povidone-iodine in patients with CHG intolerance for cleaning	17.3	CHG group= 5.4% (2/37) PVP-I group= 42.9% (3/7) (P = 0.02)	336 (entire sample)	Z//Z	CHG group: Acinetobacter 50% (1/2) Stenotrophomonas 50% (1/2) PVP-I group: S. aureus 100% (3/3)
Stahovich <i>et al.</i> (2016) [7]	Using the percutaneous lead management kit for dressing	9	6% (3/50)	180	N/R	N/R
Menon <i>et al.</i> (2015) [16]	Control: using octenidine solution for cleaning Intervention: using Merbromin solution for cleaning	Control: 6.7 Intervention: 6.5	Control: 11.8% (2/17) Intervention: 0% (P = 0.043)	Control: 130.5 Intervention: infection free	N/R	S. aureus 100% (2/2)
Stulak <i>et al.</i> (2013) [17]	Control: sterile dressing changes without continued (long-term) prophylactic antibiotics Intervention: sterile dressing changes with continued (long-term) prophylactic antibiotics	Control: 11 Intervention: 12.3	Control: 13% (19/141) Intervention: 18% (26/144) (P = 0.15)	Z/R	N/R	<i>Staphylococci</i> (no rate)
Sharma <i>et al.</i> (2012) [4]	Experience with the management of driveline infections (sterile dressing changes with CHG and saline application, without prophylactic oral antibiotics)	11.3	12% (18/143)	182	22% (4/18)	CoNs: 44.5% (4/9 <sup>b</sup> ) S. aureus: 33.3% (3/9 <sup>b</sup> ) P. aeruginosa: 22.2% (2/9 <sup>b</sup> )
Hozayen <i>et al.</i> (2012) [18]	Utah protocol: foam-based dressing Minnesota protocol: Gauze-based dressing	18	Utah protocol: 19% (3/16) Minnesota protocol: 13% (6/47) (P = 0.68)	N/R	N/R	N/R

<sup>&</sup>lt;sup>a</sup>The study reported cultures with multiple organisms.

PThe study reported microorganisms for 9 cases.
CHG: chlorhexidine gluconate; CoNS: coagulase-negative staphylococci; DLI: driveline infection; LVAD: left ventricular assist device; MRSA: methicillin-resistant Staphylococcus aureus; MSSA: methicillin-sensitive Staphylococcus aureus; N/R: not reported; PVP-I: povidone-iodine; P. aeruginosa: Pseudomonas aeruginosa; S. aureus: Staphylococcus aureus.

devices were HeartMate (HM) II and 3, HeartWare (HW) and VentrAssist in the included articles; HM II in 6, HM II and HW in 2, HM II, 3 and HW HVAD in 1 and, HM II, HW and VentrAssist in one study. In one study, the device type was not reported (Table 1). Readmission for a driveline infection was evaluated according to the device type in one study. Those authors reported that patients with an HM 3 had a higher risk for driveline infection readmissions compared to those with an HW HVAD or an HM II [11].

# Driveline exit-site cleaning agents

The most frequently used cleaning agent was chlorhexidine gluconate (CHG) (n=7) (Table 2) [4, 7, 8, 12, 14,15, 17]. CHG was used with the saline solution in 3 studies [4, 7,8]. CHG characteristics (saline or alcohol-based) were not reported in the articles. In 2 studies, if the patient had a skin irritation or CHG intolerance, povidone-iodine was used as an alternative cleaning agent [12, 15]. Driveline infection frequency differed among the studies, with a range of 5.4-21.3% in the studies using CHG as a cleaning agent (Table 3). Studies using CHG and a silver-based dressing for the care of driveline exit sites reported a driveline infection frequency of 6-7.5% [7, 14]. In the studies using CHG and a sterile gauze dressing for exit-site care, driveline infection frequencies were between 5.4% and 21.3% [4, 8, 14, 15]. Son et al. [15] reported a higher driveline infection frequency when povidoneiodine was used as an alternative cleaning agent in patients intolerant to CHG (42.9%). Durand et al. [13] evaluated the effect of topical polymyxin-trimethoprim (poly) solution on driveline infections. The driveline infection rate was reported in 9 patients (13.8%) in the group using the poly solution and in 10 patients (52.6%) in the non-poly group (P = 0.001). Menon et al. [16] compared merbromin with octenidine solutions for cleaning the driveline exit site. The frequency of driveline infections in patients using octenidine was 11.8%; no infections were found in patients using a merbromin solution. In the study by Schlöglhofer et al. [11], octenidine was used as a cleaning agent and the driveline infection frequency was reported to be 27.3%. Hozayen et al. [18] reported a driveline infection frequency of 13% when soap and antimicrobial spray were used to clean the driveline exit site.

# Dressing materials for the driveline exit site

Sterile gauze pads (n = 5) and silver-based dressings (n = 3) were the most commonly used covering materials for dressing the driveline exit site (Table 2). Cagliostro et al. [14] compared driveline dressing protocols using silver-based dressings with those using a sterile gauze dressing. The frequency of driveline infections (7.5%) in the silver-based group was lower than that in the group using sterile gauze (15.8%). In the study by Stahovich et al. [7], silver-based dressings and CHG were used for the care of the driveline exit site. With this protocol, driveline infection frequency and the time to first infection were 6% and 180 days, respectively. Two studies evaluated driveline exit-site dressing protocols that included foam-based dressings [8, 18]. Hozayen et al. [18] compared foam and sterile gauze dressings for covering the driveline exit site. Driveline infection frequency was reported to be 19% for foam-based dressings and 13% for sterile gauze dressings (P = 0.68). Lander et al. [8] used foam-based dressings and CHG for dressings; the frequency of driveline infections was 7.6%. Schlöglhofer et al. [11] reported a driveline infection rate of 27.3% when absorptive non-adherent compresses and octenidine were used to care for the driveline exit site.

# Anchoring devices used for stabilization of the driveline

For immobilization of the driveline, the Centurion Foley holder, Hollister plate stabilizer, abdominal binder, Centurion secure view port and Secutape Nanoplast fixation were used (Table 2). The most frequently used anchoring device for stabilization of the driveline was the Centurion Foley holder in 4 studies [7, 8, 14, 15]. In 2 studies, the driveline exit-site dressing protocol included the Centurion Foley holder, a silver-based dressing and CHG. These studies reported a driveline infection frequency and a time to first infection of 6-7.5% and 180 days, respectively [7, 14]. The driveline care protocol in 2 studies included the Centurion Foley holder, sterile gauze dressing and CHG. These studies reported driveline infection frequencies 5.4-21.3% [8, 15]. The Hollister plate stabilizer was used to immobilize the driveline in one study; the reported frequency of driveline infections was 0-11.8% [16]. The study that used an abdominal binder for immobilizing the driveline reported a driveline infection rate of 12% [4]. In the study of Schlöglhofer et al. [11], Secutape Nanoplast fixation was used; the reported driveline infection frequency was 27.3%.

# Frequency of driveline exit-site dressing change

The frequencies of dressing changes differed among the studies and varied from daily to weekly (Table 2) [4, 7, 8, 11, 13, 15, 18]. Two studies reported weekly dressing changes in driveline exitsite care protocol. Stahovich et al. [7] evaluated the effect of using a dressing kit and a weekly dressing change in their study; they reported 6% driveline infection frequency and 180 days to first driveline infection. Lander et al. [8] compared weekly fenestrated foam dressings and weekly occlusive sterile gauze dressings. Whereas the driveline infection frequency in the weekly fenestrated foam dressing group was 7.6%, an infection frequency of 21.3% was reported in the weekly occlusive sterile gauze dressing group. In 2 studies with daily dressing changes, driveline infection frequencies of 12-13% were reported [4, 18]. Hozayen et al. [18] reported a 3-times-weekly foam-based dressing change and a 19% driveline infection frequency in their study. In the study of Son et al. [15], a 3-times-weekly dressing change protocol that included CHG and povidone-iodine as the cleaning agent was evaluated. The study reported a driveline infection frequency of 5.4% in the CHG group and 42.9% in the povidone-iodine group. In the study of Schlöglhofer et al. [11], a 2- to 3-times-weekly dressing change with octenidine solution and 27.3% driveline infection frequency were reported.

# Showering strategies for patients with left ventricular assist devices

Showering strategies in the driveline exit-site care protocols were reported in 4 studies (Table 2) [7, 12, 13, 15]. Aburjania et al. [12] investigated the effect of abstaining from conventional showers and keeping the driveline exit site dry. Driveline infection frequency and *Pseudomonas* infection frequency were 14% and 1% in the intervention group and 42% and 9% in the control group, respectively. An occlusive covering over the driveline exit-site dressing during showering was used in 2 studies; the driveline infection frequencies reported were between 5.4% and 42.9% [7, 15].

# Using a kit for driveline exit-site dressing

The utilization of a kit for driveline exit-site dressing was reported in 2 studies (Table 2) [7, 14]. Cagliostro *et al.* [14] compared a group that used a standard kit that included a silver-based dressing and an anchoring device with an historical control group. Driveline infection frequency and time to infection were 7.5% and 181 days in the standard dressing kit group and 15.8% and 154 days in the historical control group, respectively. In the study of Stahovich *et al.* [7], the use of a percutaneous lead management kit for dressing was evaluated. They reported a driveline infection frequency and time to infection of 6% and 180 days, respectively.

# **DISCUSSION**

In this systematic review, we found a marked variability in the care protocols for LVAD driveline exit sites and no standardized driveline dressing technique. But, driveline exit care protocols including chlorhexidine, silver-based dressings, the use of an anchoring device and dressing kits might be the best for reducing driveline infection rates.

CHG appeared to be the most commonly used cleaning agent for driveline care. CHG has a broad spectrum of activity against gram-positive, gram-negative non-spore-forming bacteria, yeast and selective lipid envelope viruses [20, 21]. Furthermore, CHG is considered to be advantageous in the care because of poor absorption from the skin and no evidence of systemic accumulation and adverse events [20]. Additionally, CHG has already been proposed as an effective agent for the prevention of surgical site infections [20, 21]. Unfortunately, data on the concentration of CHG, time of evaporation and whether it was saline or alcoholbased or not, were not available in the included studies. In case of CHG intolerance, povidone-iodine was used for driveline care [12, 15]. Povidone-iodine is an effective bactericidal solution against gram-positive and gram-negative organisms and does not delay healing. However, the absorption of iodine from the skin is a disadvantage [22]. Studies comparing the efficacy of CHG and povidone-iodine in surgical site cleaning and prevention of infections show the superiority of CHG [23, 24]. The use of merbromin in driveline exit-site care is controversial because it is a toxic agent due to the brome and mercury content and is therefore prohibited in many countries [16, 25]. Octenidine, which has been used frequently as an antiseptic in recent years, is another cleaning agent used in driveline care. It is recommended for use in prophylactic antisepsis because it is not absorbed by the skin and mucosa, and it is well tolerated and suitable for topical use [26, 27]. In addition, a polymyxin-trimethoprim solution was effective in the prevention of driveline infections. However, no other studies suggested the use of either of these solutions in LVAD care. Based on the foregoing discussion, the standardized driveline care protocol should include CHG as the main cleaning and antiseptic agent, because it is advantageous over other solutions in terms of both cost and effectiveness [23]. Alternatively, the use of octenidine or povidoneiodine solutions in CHG-intolerant patients may be suggested.

In this systematic review, sterile gauze and silver-based dressings were the most frequently used materials to cover the driveline exit site. The use of sterile gauze dressings in a non-infected dry exit site that completed the healing process can be cost-

effective in the driveline exit-site care protocol [28]. In our analysis, the silver-based dressing was more effective. The use of a silver-based dressing was recommended for preventing colonization and improving healing [29, 30]. However, some researchers assumed the evidence for silver-based dressings in the prevention of infections to be insufficient and the costs too high [31, 32]. Foam-based dressing is generally recommended for exudate wounds due to its absorbent property and is not recommended for use in dry wounds [28, 33]. According to the results of our study and those reported in the literature, wound characteristics should be taken into consideration when choosing the covering material in driveline care protocol. Therefore, the use of a silverbased dressing only in the first 6 months after LVAD implantation may be (cost) effective in preventing driveline infections [34]. Silver or foam-based dressings may be preferred depending on whether the exit site has infection or exudate.

An anchoring device is one method for preventing driveline exit-site trauma and is thereby effective in reducing the driveline exit-site infections [34–37]. In our study, there was great variability in the anchoring devices used for the driveline stabilization. However, no clear data for the superiority of any one of the anchoring devices were found.

The frequency of changing a driveline exit-site dressing varies considerably according to the institution [9, 36, 38]. None of the particular dressing change frequencies was more effective than another in the prevention of driveline infections. The study by Wus et al. [6], not included in the systematic review because of the short follow-up time and inclusion of hospitalized patients, reported that dressing change frequency had no effect on driveline infection frequencies. In determining the optimal dressing change frequency, driveline exit-site features and whether there is infection should be taken into consideration [34, 36]. Daily dressing change is recommended until the driveline exit site heals completely for effective exit-site cleaning and preventing wet dressings. Once the driveline exit site has healed and there is no drainage, a lower dressing change frequency may be feasible and safe and also increases caregiver and patient satisfaction [18, 36].

In the management of driveline exit-site care, keeping the driveline exit site dry should be considered in the prevention of driveline exit-site infections. Therefore, showers are recommended only after the driveline exit site has healed completely in patients with LVAD [34, 36]. Keeping the driveline exit site as dry as possible during the shower and changing the dressing immediately after the shower may be effective in preventing driveline infections, in particular *Pseudomonas* infections.

The driveline care protocol requires the use of many different materials. This systematic review suggests that using a dressing kit might be effective in reducing the driveline infections. The use of a dressing kit in driveline care can be effective in increasing patient compliance and reducing infection frequency [7].

# Clinical implications

Taking the findings of this systemic review into account, driveline exit-site care is best performed within a standardized protocol, using sterile dressing materials and sterile gloves and a dressing kit (Fig. 2, Supplementary Table 1). CHG should be used for driveline exit-site cleaning; octenidine or povidone-iodine should be used in case of CHG intolerance. The properties of the exit site should be taken into consideration when choosing the covering material. A silver-based dressing can be used, particularly in the first months after

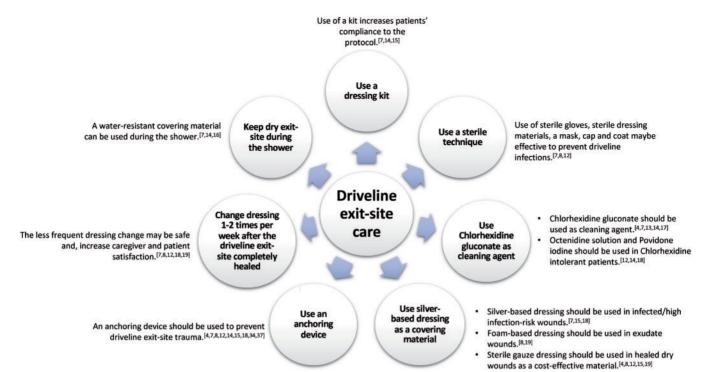


Figure 2: Recommendations based on the systematic review.

implantation. An anchoring device should be used to prevent driveline exit-site trauma. The driveline exit site should be kept as dry as reasonably possible. The dressing change frequency can be based on the properties of the exit site. For a dry exit site that has completed the healing process, the dressing change frequency can be once or twice a week. The proposed changes, despite the increased cost for materials and agents (e.g. silverbased dressings), may significantly reduce frequent readmissions and long hospitalizations.

# Limitations

This systematic review has limitations that should be considered when interpreting the results. The studies included in the systematic review were mostly retrospective cohort studies. In addition, the studies had small sample sizes and did not compare the same exit-site care protocols. Due to the substantial heterogeneity in the exit-site care methods of the studies, a meta-analysis could not be performed, and the centre-specific findings of the systematic review are perhaps not generalizable. Furthermore, the studies had fewer destination therapy patients and hence may under-represent these patients.

### CONCLUSION

Based on this systematic review, driveline exit-site care protocols including chlorhexidine, silver-based dressings, use of an anchoring device and dressing kits might be best in reducing the frequency of driveline infections. However, no strong evidence for a standardized driveline exit-site protocol exists. Prospective studies with larger cohorts are needed to establish the optimal protocol for LVAD driveline exit-site care.

# SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

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# **Author contributions**

Zeliha Ozdemir Koken: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Resources; Software; Validation; Visualization; Writing—original draft; Writing—review & editing. Yunus C. Yalcin: Investigation; Methodology; Resources; Software; Writing—original draft. Diana van Netten: Investigation; Methodology; Resources; Supervision; Writing—review & editing. Chantal C. de Bakker: Investigation; Resources; Writing—review & editing. Maaike van der Graaf: Investigation; Resources; Writing—review & editing. Methodology; Resources; Supervision; Writing—review & editing. Nelianne J. Verkaik: Conceptualization; Methodology; Resources; Supervision; Writing—review & editing. Kadir Caliskan: Conceptualization; Data curation; Investigation; Methodology; Project administration; Resources; Software; Supervision; Writing—original draft; Writing—review & editing.

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