

Cite this article as: Koken ZO, Yalcin YC, van Netten D, de Bakker CC, van der Graaf M, Kervan U *et al.* Driveline exit-site care protocols in patients with left ventricular assist devices: a systematic review. *Eur J Cardiothorac Surg* 2021;60:506–15.

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

Zeliha Ozdemir Koken^{a,b}, Yunus C. Yalcin ^{a,c}, Diana van Netten^d, Chantal C. de Bakker^a,
Maaïke van der Graaf^a, Umit Kervan ^e, Nelianne J. Verkaik^d and Kadir Caliskan ^{a,*}

^a Department of Cardiology, Unit of Heart Failure, Heart Transplantation and Mechanical Circulatory Support, Erasmus University Medical Center, Rotterdam, Netherlands

^b Surgical Nursing Department, Faculty of Nursing, Hacettepe University, Ankara, Turkey

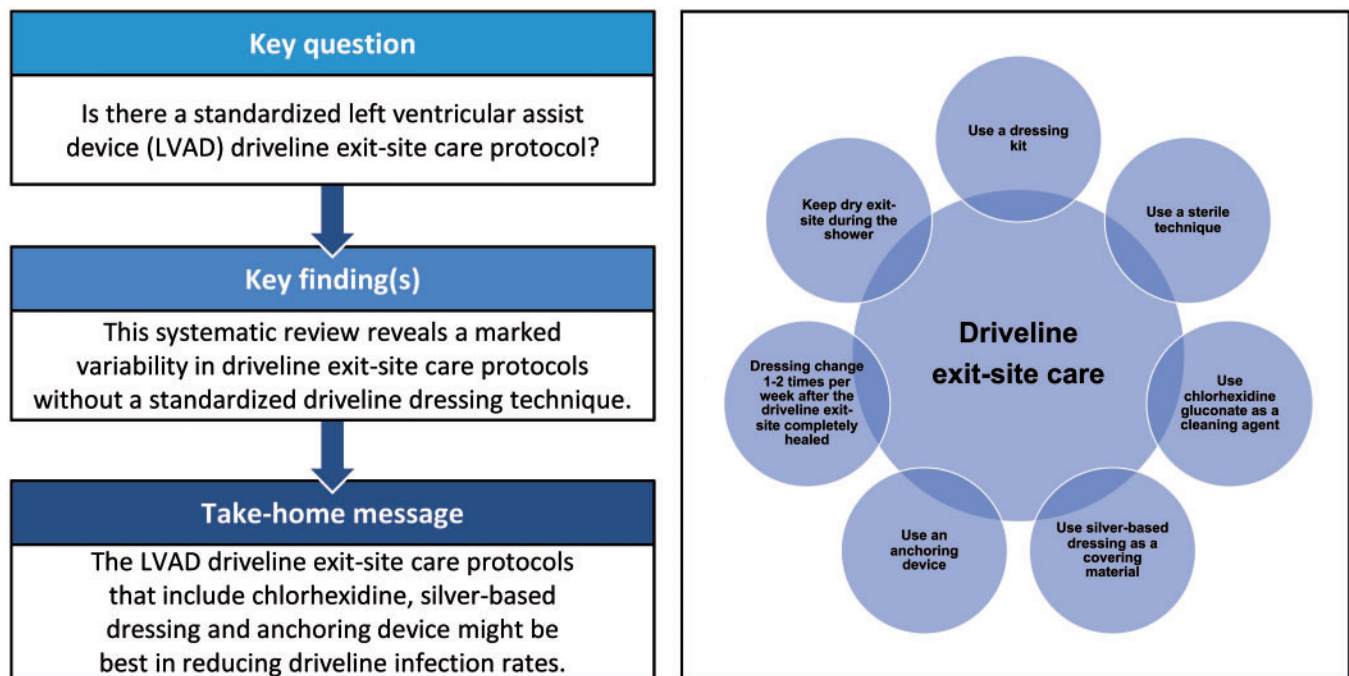
^c Department of Cardio-thoracic Surgery, Erasmus University Medical Center, Rotterdam, Netherlands

^d Department of Medical Microbiology and Infectious Diseases, Erasmus University Medical Center, Rotterdam, Netherlands

^e Department of Cardiovascular Surgery, University of Health Sciences, Ankara City Hospital, Ankara, Turkey

* Corresponding author. Thoraxcenter, Room RG 431, Erasmus MC, University Medical Center, Dr. Molewaterplein 40, 3015 GD Rotterdam, Netherlands. Tel: +31-654937133; e-mail: dr.kcaliskan@hotmail.com (K. Caliskan).

Received 29 October 2020; received in revised form 14 February 2021; accepted 17 February 2021



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 ~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

Table 1: Summary of baseline characteristics of the articles in the systematic literature review

Article/country	Study design	Study period	Sample size	LVAD characteristics	Patient characteristics	Definition of LVAD infection	Perioperative antibiotic prophylaxis	STROBE score
Schlöglhofer <i>et al.</i> (2020) Austria [11]	Retrospective analysis, single centre	January 2013–July 2017	Cohort n = 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	N/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, single centre	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	18
Son <i>et al.</i> (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% Length of support: 521 days	INTERMACS	Yes	19
Stahovich <i>et al.</i> (2016) USA [7]	Prospective study, multicentre	N/R	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	N/R	Yes	18
Sharma <i>et al.</i> (2012) USA [4]	Retrospective analysis, single centre	January 2007–January 2011	Cohort n = 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/R	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.

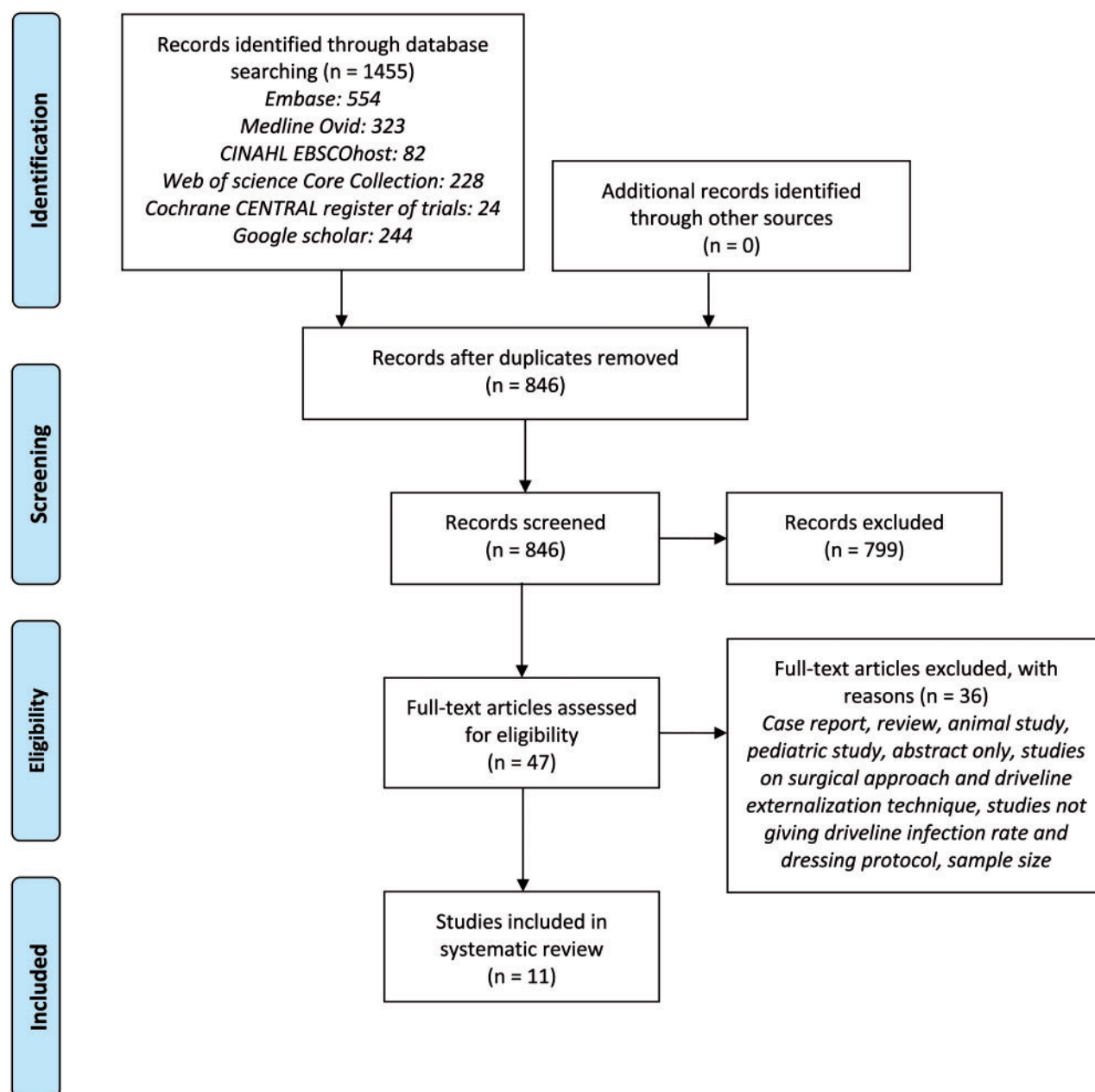


Figure 1: Flow diagram summarizing the review process.

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

Table 2: Summary of driveline exit-site dressing change methods described in the articles and at the Erasmus University Medical Center

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 × 5 cm)	Secutape Nanoplast fixation	Twice or 3 times weekly	N/R	Yes ^a	N/R
Lander <i>et al.</i> (2018) [8]	CHG and saline solution	Control: sterile gauze pad dressing (the Telfa island dressing) Intervention: the Kendal fenestrated foam dressing	Control: Centurion Foley holder Intervention: Centurion secure view port window	Weekly	N/R	Yes ^b	N/R
Aburjania <i>et al.</i> (2017) [12]	CHG PVP-I (if there is a skin irritation)	N/R	N/R	N/R	Not allowed, exit site must be kept dry (using a hand-held shower attachment to wash their hair and lower extremities)	Yes ^c	N/R
Durand <i>et al.</i> (2017) [13]	Polymyxin-trimethoprim solution (polymyxin B 10 000 units/ml + trimethoprim 1 mg/ml)	N/R	N/R	Once or twice weekly	Allowed once per week when the exit site has healed	N/R	N/R
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	N/R	N/R	N/R	Yes
Son <i>et al.</i> (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 ^c	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 ^d	Yes
Menon <i>et al.</i> (2015) [16]	Control: octenidine dihydrochloride 0.1% Intervention: metbromin 2%	Silver-based dressing and sterile gauze pad dressing	Hollister plate stabilizer	Every 5–6 days	N/R	Yes ^b	N/R
Stulak <i>et al.</i> (2013) [17]	CHG 4%	N/R	N/R	N/R	N/R	Yes ^c	N/R
Sharma <i>et al.</i> (2012) [4]	CHG and saline swabs	Sterile gauze pad dressing	Abdominal binder	Daily	N/R	Yes ^b	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	N/R	Utah protocol: every third day Minnesota protocol: daily	N/R	Yes ^c	N/R
Erasmus University Medical Centre	CHG 4%	Silver-based and sterile gauze pad dressing	Hollister plate stabilizer	Two times a week	Allowed once per week when the exit site healed	Yes ^e	No

^aUsing sterile dressing closure, face mask, hair cover and sterile gloves.^bUsing sterile dressing closure, face mask and sterile gloves.^cUsing sterile dressing closure.^dUsing sterile dressing closure, face mask, hair cover and non-latex gloves.^eUsing sterile dressing closure and sterile gloves.

CHG: chlorhexidine gluconate; N/R: not reported; PVP-I: povidone-iodine.

Table 3: Summary of results of the articles included in the systematic literature review

Article	Intervention/implementation	Median follow-up time (months)	Driveline infection rate	Time to first infection (days)	Infection relapse rate	Microorganisms
Schlöglhofer et al. (2020) [11]	To characterize risk factors for DLI readmission 2 years postimplant	24	27.3% (50/183)	N/R	N/R	<i>S. aureus</i> 56% (32/57) ^a <i>P. aeruginosa</i> 12% (7/57) ^a Others 32% (18/57) ^a
Lander et al. (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%, ^a MRSA 11% ^a <i>P. aeruginosa</i> 14%, ^a <i>Proteus</i> 11% ^a CoNS 7%, ^a Others 25% ^a
Aburjania et al. (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) <i>Pseudomonas</i> infection (P = 0.077) Control: 9% (15/163) Intervention: 1% (1/120)	347 (entire sample)	N/R	<i>P. aeruginosa</i> Control: 17% (15/86) Intervention: 1.1% (1/86)
Durand et al. (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)	<i>P. aeruginosa</i> : 37% (7/19) MSSA 16% (3/19) Skin flora: 26% (5/19) Others: 21% (4/19)
Cagliostro et al. (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)	N/R
Son et al. (2017) [15]	CHG group: using CHG for cleaning PVP-I 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)	N/R	CHG group: <i>Acinetobacter</i> 50% (1/2) <i>Stenotrophomonas</i> 50% (1/2) PVP-I group: <i>S. aureus</i> 100% (3/3)
Stahovich et al. (2016) [7]	Using the percutaneous lead management kit for dressing	6	6% (3/50)	180	N/R	N/R
Menon et al. (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	<i>S. aureus</i> 100% (2/2)
Stulak et al. (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)	N/R	N/R	<i>Staphylococci</i> (no rate)
Sharma et al. (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) ^b <i>S. aureus</i> : 33.3% (3/9) ^b <i>P. aeruginosa</i> : 22.2% (2/9) ^b
Hozayen et al. (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

^aThe study reported cultures with multiple organisms.^bThe 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 povidone-iodine 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 exit-site 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 alcohol-based 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 bromine 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 antiseptics 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 povidone-iodine 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 silver-based 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. silver-based 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.

ACKNOWLEDGEMENTS

The authors wish to thank Wichor Bramer from the Erasmus MC Medical Library for developing and updating the search strategies.

Conflict of interest: none declared.

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. **Maaïke van der Graaf:** Investigation; Resources; Writing—review & editing. **Umit Kervan:** 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.

Reviewer information

European Journal of Cardio-Thoracic Surgery thanks Massimiliano Meineri and the other, anonymous reviewer(s) for their contribution to the peer review process of this article.

REFERENCES

- [1] Kirklin JK, Pagani FD, Kormos RL, Stevenson LW, Blume ED, Myers SL *et al.* Eighth annual INTERMACS report: special focus on framing the impact of adverse events. *J Heart Lung Transplant* 2017;36:1080–6.
- [2] Hannan MM, Xie R, Cowger J, Schueler S, de By T, Dipchand AI *et al.* Epidemiology of infection in mechanical circulatory support: a global analysis from the ISHLT Mechanically Assisted Circulatory Support Registry. *J Heart Lung Transplant* 2019;38:364–73.
- [3] Goldstein DJ, Naftel D, Holman W, Bellumkonda L, Pamboukian SV, Pagani FD *et al.* Continuous-flow devices and percutaneous site infections: clinical outcomes. *J Heart Lung Transplant* 2012;31:1151–7.
- [4] Sharma V, Deo SV, Stulak JM, Durham LA 3rd, Daly RC, Park SJ *et al.* Driveline infections in left ventricular assist devices: implications for destination therapy. *Ann Thorac Surg* 2012;94:1381–6.
- [5] Hieda M, Sata M, Seguchi O, Yanase M, Murata Y, Sato T *et al.* Importance of early appropriate intervention including antibiotics and wound care for device-related infection in patients with left ventricular assist device. *Transplant Proc* 2014;46:907–10.
- [6] Wus L, Manning M, Entwistle JW 3rd. Left ventricular assist device driveline infection and the frequency of dressing change in hospitalized patients. *Heart Lung* 2015;44:225–9.
- [7] Stahovich M, Sundareswaran KS, Fox S, Hallinan W, Blood P, Chen L *et al.* Reduce driveline trauma through stabilization and exit site management: 30 days feasibility results from the multicenter RESIST study. *ASAIO J* 2016;62:240–5.
- [8] Lander MM, Kunz N, Dunn E, Althouse AD, Lockard K, Shullo MA *et al.* Substantial reduction in driveline infection rates with the modification of driveline dressing protocol. *J Card Fail* 2018;24:746–52.
- [9] Wilcox JE, Cameron KA, Harap RS, Shanklin KL, Grady KL, Cohen ER *et al.* Ventricular assist device driveline dressing-change protocols: a need for standardization. A report from the SimVAD Investigators. *J Card Fail* 2019;25:695–7.
- [10] Moher D, Liberati A, Tetzlaff J, Altman DG; PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Open Med* 2009;3:e123–30.
- [11] Schloglhofer T, Michalovics P, Riebandt J, Angleitner P, Stoiber M, Laufer G *et al.* Left ventricular assist device driveline infections in three contemporary devices. *Artif Organs* 2020;1–9. doi:10.1111/aor.13843.
- [12] Aburjania N, Sherazi S, Tchanchaleishvili V, Alexis JD, Hay CM. Stopping conventional showering decreases *Pseudomonas* infections in left ventricular assist device patients. *Int J Artif Organs* 2017;40:282–5.
- [13] Durand ML, Ennis SC, Baker JN, Camuso JM, McEachern KM, Kotton CN *et al.* Topical polymyxin-trimethoprim prophylaxis may decrease the incidence of driveline infections in patients with continuous-flow left ventricular assist devices. *Artif Organs* 2017;41:169–75.
- [14] Cagliostro B, Levin AP, Fried J, Stewart S, Parkis G, Mody KP *et al.* Continuous-flow left ventricular assist devices and usefulness of a standardized strategy to reduce drive-line infections. *J Heart Lung Transplant* 2016;35:108–14.
- [15] Son AY, Stein LH, DeAnda A, Katz SD, Smith DE, Reyentovich A *et al.* Impact of chlorhexidine gluconate intolerance on driveline infection during chronic HeartMate II left ventricular assist device support. *Int J Artif Organs* 2017;39:570–4.
- [16] Menon AK, Baranski SK, Unterkofler J, Autschbach R, Moza AK, Goetzenich A *et al.* Special treatment and wound care of the driveline exit site after left ventricular assist device implantation. *Thorac Cardiovasc Surg* 2015;63:670–4.
- [17] Stulak JM, Maltais S, Cowger J, Joyce LD, Daly RC, Park SJ *et al.* Prevention of percutaneous driveline infection after left ventricular assist device implantation: prophylactic antibiotics are not necessary. *ASAIO J* 2013;59:570–4.
- [18] Hozayen SM, Soliman AM, Eckman PM. Comparison of two ventricular assist device dressing change protocols. *J Heart Lung Transplant* 2012;31:108–9.
- [19] von Elm E, Altman DG, Egger M, Pocock SJ, Gotsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Lancet* 2007;370:1453–7.
- [20] Edmiston CE Jr, Bruden B, Rucinski MC, Henen C, Graham MB, Lewis BL. Reducing the risk of surgical site infections: does chlorhexidine gluconate provide a risk reduction benefit? *Am J Infect Control* 2013;41:S49–55.
- [21] Milstone AM, Passaretti CL, Perl TM. Chlorhexidine: expanding the armamentarium for infection control and prevention. *Clin Infect Dis* 2008;46:274–81.
- [22] Bigliardi PL, Alsagoff SAL, El-Kafrawi HY, Pyon JK, Wa CTC, Villa MA. Povidone iodine in wound healing: a review of current concepts and practices. *Int J Surg* 2017;44:260–8.
- [23] Lee I, Agarwal RK, Lee BY, Fishman NO, Umscheid CA. Systematic review and cost analysis comparing use of chlorhexidine with use of iodine for preoperative skin antisepsis to prevent surgical site infection. *Infect Control Hosp Epidemiol* 2010;31:1219–29.
- [24] Darouiche RO, Wall MJ Jr, Itani KM, Otterson MF, Webb AL, Carrick MM *et al.* Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. *N Engl J Med* 2010;362:18–26.
- [25] European Environmental Bureau Zero Mercury Working Group. Mercury in Products. 2019. <https://www.zeromercury.org/resources/> (15 December 2020, date last accessed).
- [26] Hubner NO, Siebert J, Kramer A. Octenidine dihydrochloride, a modern antiseptic for skin, mucous membranes and wounds. *Skin Pharmacol Physiol* 2010;23:244–58.
- [27] Koburger T, Hubner NO, Braun M, Siebert J, Kramer A. Standardized comparison of antiseptic efficacy of triclosan, PVP-iodine, octenidine dihydrochloride, polyhexanide and chlorhexidine digluconate. *J Antimicrob Chemother* 2010;65:1712–19.
- [28] Dhivya S, Padma VV, Santhini E. Wound dressings—a review. *Biomedicine (Taipei)* 2015;5:22.
- [29] Sibbald RG, Contreras-Ruiz J, Coutts P, Fierheller M, Rothman A, Woo K. Bacteriology, inflammation, and healing: a study of nanocrystalline silver dressings in chronic venous leg ulcers. *Adv Skin Wound Care* 2007;20:549–58.
- [30] Leaper D. An overview of the evidence on the efficacy of silver dressings. *J Wound Care* 2011;20:8–14.
- [31] Storm-Versloot MN, Vos CG, Ubbink DT, Vermeulen H. Topical silver for preventing wound infection. *Cochrane Database Syst Rev* 2010;CD006478. doi:10.1002/14651858.CD006478.pub2.
- [32] Michaels JA, Campbell B, King B, Palfreyman SJ, Shackley P, Stevenson M. Randomized controlled trial and cost-effectiveness analysis of silver-donating antimicrobial dressings for venous leg ulcers (VULCAN trial). *Br J Surg* 2009;96:1147–56.
- [33] Lee SM, Park IK, Kim YS, Kim HJ, Moon H, Mueller S *et al.* Superior absorption and retention properties of foam-film silver dressing versus other commercially available silver dressing. *Biomater Res* 2016;20:22.
- [34] Kusne S, Mooney M, Danziger-Isakov L, Kaan A, Lund LH, Lyster H *et al.* An ISHLT consensus document for prevention and management strategies for mechanical circulatory support infection. *J Heart Lung Transplant* 2017;36:1137–53.
- [35] Potapov EV, Antonides C, Crespo-Leiro MG, Combes A, Farber G, Hannan MM *et al.* 2019 EACTS Expert Consensus on long-term mechanical circulatory support. *Eur J Cardiothorac Surg* 2019;56:230–70.
- [36] Bernhardt AM, Schloglhofer T, Lauenroth V, Mueller F, Mueller M, Schoede A *et al.*; Driveline Expert STAGInG and carE DESTINE Study Group, a Ventricular Assist Device Driveline Infection Study Group. Prevention and early treatment of driveline infections in ventricular assist device patients—the DESTINE staging proposal and the first standard of care protocol. *J Crit Care* 2020;56:106–12.
- [37] Baronetto A, Centofanti P, Attisani M, Ricci D, Mussa B, Devotini R *et al.* A simple device to secure ventricular assist device driveline and prevent exit-site infection. *Interact Cardiovasc Thorac Surg* 2014;18:415–17.
- [38] Schloglhofer T, Robson D, Bancroft J, Sorensen G, Kaufmann F, Sweet L *et al.* International coordinator survey results on the outpatient management of patients with the HeartWare(R) ventricular assist system. *Int J Artif Organs* 2017;39:553–7.