Turkish Journal of Thoracic and Cardiovascular Surgery 2018;26(2):328-335
http://dx.doi.org/doi: 10.5606/tgkdc.dergisi.2018.14982

*Review / Derleme*

# Wound care of the driveline exit site in patients with a ventricular assist device: A systematic review

*Ventrikül destek cihazı uygulanan hastalarda driveline çıkış yeri yara bakımı: Sistematik derleme*

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***ABSTRACT***

***Background:*** This study aims to systematically define and analyze the studies on driveline exit site care methods for patients with a ventricular assist device.

***Methods:*** The studies related to driveline exit site care of the patients with a ventricular assist device published in English and Turkish between 2008 and 2017 were reviewed from the international Science Direct, PubMed, Web of Science, Scopus, and the national databases. Of a total of 83 articles, a total of seven research articles which met the inclusion criteria were included in the study.

***Results:*** Findings related to the agents used in the cleaning of the driveline exit site, dressing closures, dressing change frequency, and use of driveline anchoring devices were obtained from studies included in the research. It was found that chlorhexidine solution for skin cleaning and sterile gauze sheets and transparent covering for dressing closure were the most preferred methods for the driveline exit site care. Dressing change frequency varied considerably from center to center and anchoring devices were used in all studies.

***Conclusion:*** There is no gold standard method for the driveline exit site care of patients with a ventricular assist device and researches on the driveline exit site care seem to be limited. It is recommended that large-scale, randomized-controlled studies should be conducted which would provide a stronger proof of the driveline exit site care.

***Keywords:*** Care; dressing; driveline exit site; ventricular assist device.

***ÖZ***

***Amaç:*** Bu çalışmada ventrikül destek cihazı uygulanan hastaların driveline çıkış yeri bakım yöntemleri ile ilgili çalışmalar sistematik olarak belirlendi ve incelendi.

***Çalışma planı:*** 2008 - 2017 yılları arasında İngilizce ve Türkçe yayımlanan ventrikül destek cihazı uygulanan hastalarda driveline çıkış yeri bakımına ilişkin çalışmalar uluslararası Science Direct, PubMed, Web of Science, Scopus ve ulusal veri tabanlarında tarandı. Toplam 83 makaleden, dahil edilme kriterlerini karşılayan yedi araştırma makalesi çalışma kapsamına alındı.

***Bulgular:*** Araştırma kapsamına giren çalışmalardan driveline çıkış yerinin temizliğinde kullanılan ajanlar, pansuman kapama örtüleri, pansuman değiştirme sıklığı ve driveline kablo sabitleyici cihazlara ilişkin bulgular elde edildi. Driveline çıkış yeri bakımında cilt temizliğinde klorheksidin solüsyonunun ve pansuman kapama örtüsü olarak steril gaz spanç ile transparan örtü kullanımının en çok tercih edilen yöntemler olduğu belirlendi. Pansuman değiştirme sıklığı merkezlere göre oldukça farklılık gösteriyordu ve tüm çalışmalarda kablo sabitleyici araçlar kullanılmıştı.

***Sonuç:*** Ventrikül destek cihazı uygulanan hastalarda driveline çıkış yeri bakımına yönelik altın standart bir yöntem mevcut değildir ve driveline çıkış yeri bakıma ilişkin araştırmalar sınırlı sayıdadır. Driveline çıkış yeri bakımına ilişkin daha güçlü kanıtlar sunacak geniş kapsamlı randomize kontrollü çalışmaların yapılması önerilmektedir.

***Anahtar sözcükler:*** Bakım; pansuman; driveline çıkış yeri; ventriküler destek cihazı.

*Received:* June 14, 2017 *Accepted:* February 06, 2018

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***Cite this article as:***

Özdemir Z, Şenol Çelik S. Wound care of the driveline exit site in patients with a ventricular assist device: A systematic review. Turk Gogus Kalp Dama 2018;26(2):328-335.

Ventricular assist devices have become important treatment options as the bridge to destination therapy or transplantation for end-stage heart failure patients. These devices considerably increase the functional capacity, quality of life, and duration in this patient population.[1-3] Despite favorable results, device-related infections following implantation are challenging and increase the risk of morbidity and mortality in these patients.[4,5] Ventricular assist device-related infections are reported at rates up to 30 to 50 and the most common ones are pneumonia (23%), sepsis (20%), and driveline exit site infections (19%).[6] A center in Turkey has reported the driveline exit site infection rate as 22.9% and 50% depending on the device used.[7]

The ventricular assist devices consist of a pump connected to the ventricle, a small external control unit after the pump (controller), a cable connecting the pump to the control unit (driveline: power transmission line), and the power sources (batteries) operating the pump and the control unit. The driveline is extended from the pump implanted to the ventricle, passes through the skin, and is connected to the control unit.[8,9] The driveline exit site on the skin poses a huge risk of infections for patients undergoing ventricular assist device implantation. Therefore, the surgical techniques used for securing the driveline and the care of the driveline exit site play an important role in post-implantation infection control.[8,10,11] The surgical technique preferred in securing the driveline, the incision and suture materials used, and the minimization of tissue damage are reported to decrease the risk of developing driveline exit site infection.[11,12] The solution used in the cleaning of the site, the materials used to secure the driveline, the dressing materials and their change frequency are the important factors in driveline exit site care. Materials used in driveline exit site care vary according to the preferences of the institution performing the implantation. A review of the studies in the international literature reveals that a gold standard method for driveline exit site care has not been yet identified.[10,13-18] Local infections at the driveline exit site can be controlled with wound site care and the importance of such care, and the importance of patient training in this matter has been emphasized in the Cardiology-Cardiovascular Surgery Consensus Report for the use of ventricular assist devices in Turkey.[19] On the other hand, we did not find any study from Turkey on the care protocols, and the effectiveness of the method, material and solution used for care in Turkey. In addition, we observed that driveline care protocols differ between the centers where ventricular assist device implantation is performed in Turkey. Octenidine dihydrochloride, chlorhexidine, and povidone-iodine solutions are usually used in skin cleaning, while the dressing change frequency is daily or weekly. Sterile gauze can be also used for the closure of the dressing and adhesive plaster as an anchoring device.

Performing driveline exit site care within the scope of a standardized protocol or by developing a gold standard is thought to be effective in preventing or decreasing infections related to ventricular assist devices. In this review, we aimed to systematically define and analyze the studies on driveline exit site care methods for patients with a ventricular assist device. We believe that this review would guide healthcare professionals in developing a standard care protocol for the driveline exit site.

## MATERIALS AND METHODS

### Data sources and literature screening

The studies related to driveline exit site care in patients with a ventricular assist device were reviewed from the international Science Direct, PubMed, Web of Science, Scopus and national databases (National Turkish Medical Directory and National Thesis Center databases). The "ventriküler destek cihazları/ventricular assist device", "driveline/driveline", "bakım/care", "pansuman/dressing" search words were used in Turkish and English. *Inclusion criteria were as follows:*

- Articles published between 2008 and 2017;
- The driveline care protocol for patients with a ventricular assist device which is explicitly defined;
- Full text articles written in Turkish or English;
- Reviews and reports were excluded.

### Study selection and data analysis

A standard data summary form was developed for study selection and data analysis. The articles found in databases with the Turkish and English search words were examined nationally, internationally and under thesis titles. No studies were found in the National Database and National Thesis Center, while a total of 83 research articles and abstracts from the International Databases were evaluated with these search words. Of these 83 international articles, 12 were potentially related to the study and the full texts were accessible. Of 12 articles for which the full text was evaluated, seven research articles which met the inclusion criteria were included in the study and reviewed systematically (Figure 1). All articles included in the review based on the content of the data summarization form were classified and summarized under the titles *(i)* the

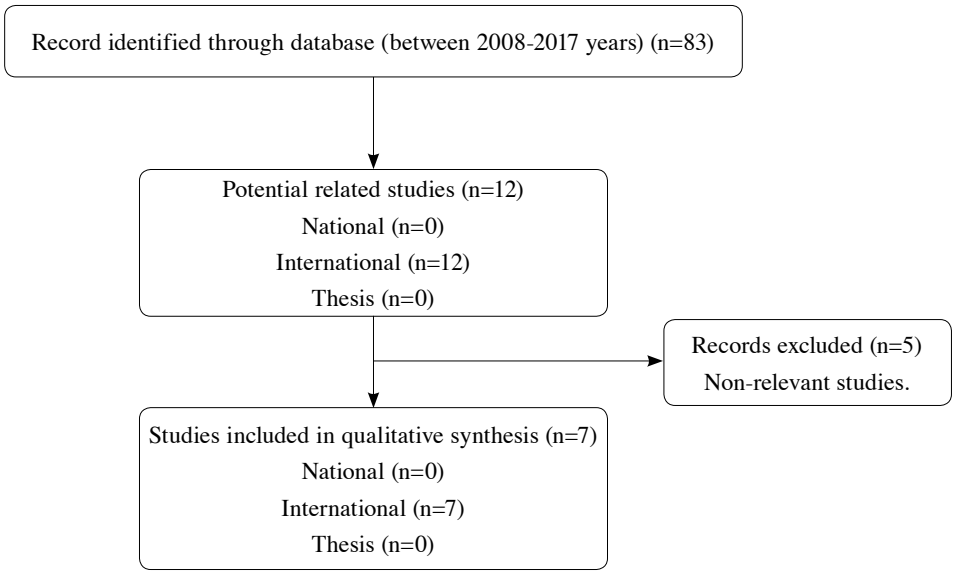


**Figure 1.** Study selection.

authors and year of the study, *(ii)* type of the study, *(iii)* subject/aim of the study, *(iv)* sample size of the study, *(v)* driveline infection diagnostic criteria, *(vi)* driveline dressing protocol, *(vii)* study findings, and *(viii)* study conclusion and recommendations (Table 1 and Table 2).

## RESULTS

A total of seven studies published between 2008 and 2017 were included in this study. All studies were international studies written in English. Six of these studies were cohort,[14,15,17,18,20,21] and one was an experimental study.[22] The studies included in the review compared the materials used in driveline exit site care and various methods in terms of care frequency, while reporting the standard driveline dressing protocols and driveline infection rates.

Table 1 presents the publication year and authors of the studies, study types, aims and sample sizes. The sample size was minimum 27 and maximum 266 with a total of 657. The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS),[14,17,20] Cleveland Clinic Classification of Ventricular Assist Device Infections,[15] International Society for Heart and Lung Transplantation Consensus,[18] and the Hospital Infection Control Practices Advisory Committee surgical site infection criteria[21] were used in the diagnosis of driveline infection. A physical evaluation was conducted for driveline infection and drainage material for culture was taken from the site in a study.[15,18,21,22] A driveline dressing protocol was used in all studies; the dressings were placed under sterile conditions and in accordance with aseptic technique in these protocols and sterile gloves and a mask were used,[14,15,17,18,20-22] and a surgical cap was also used in one of the studies (Table 1).[22] The following findings regarding the agents used in cleaning of the site, dressing closures, dressing change frequency and driveline anchoring device use were obtained from the studies included in the review (Table 1).

### Agents used in cleaning of the driveline site

Chlorhexidine was used to clean the driveline site in four of the studies included in the review (Table 1).[14,17,20,22] Driveline infection was not reported or seen only in a low rate in these studies where chlorhexidine was used for the cleaning of the driveline site.[14,17,20,22] Menon et al.[15] compared a control group where octenidine dihydrochloride was used for skin cleansing and a study group where 2% merbromin was used and showed a statistically significant decrease in driveline infections with the use of 2% merbromin. Driveline infection rates were reported to be low, when skin cleansing was performed with soap and antimicrobial spray in the study of Hozayen et al.[18] Chlorhexidine was used in four of five centers and hydrogen peroxide in the remaining one for skin cleaning of the driveline exit site and the infection rate was low in the study conducted by Stahovich et al.[22] aiming to develop a percutaneous lead care kit. Hydrogen peroxide was used in the study of Hieda et al.[21] and the infection rate at the driveline exit site at the post-implantation 12$^{th}$ month was over 90%.

## Table 1. Included studies in this review

| Author | Subject/aim | Type of study | Sample number | Infection evaluation method | Dressingmethod |
|---|---|---|---|---|---|
| Menon et al.,[15] | To investigate the efficiency of merbromin solution use in driveline wound care after LVAD* implantation in preventing driveline infection | Retrospective single-center cohort | 40 | "Cleveland Clinic classification of ventricular assist device infections" | *Control group:* The cleaning of driveline exit site with 0.1% Octenidine dihydrochloride by using a mask, sterile gloves, sterile sponge<br>Experimental group: A mask and sterile gloves were used; one or two drops of 2% merbromin solution were administered to the driveline exit site; when the site was dry, a Metalline compress was placed around the line and the driveline was covered with five sterile gauzes (a folded gauze on the left and right sides, one gauze under the line and two gauzes over the line) and stabilized with an anchoring device<br>*Dressing frequency:* The dressing was changed daily in both groups at the postoperative early stage and then every 6 to 7 days |
| Cagliostro et al.,[14] | To determine the effect of a standard driveline care kit use on the decrease of driveline infection rates | Cohort | 266 | INTERMACS infection diagnosis criteria | *Control group:* Cleaning with sterile water and 2% chlorhexidine using a gauze, closing with a transparent film dressing and using an anchoring device in accordance with aseptic technique (securement tape/band for stabilizing the driveline)<br>*Experimental group:* Cleaning with chlorhexidine gluconate, closure with bacteriostatic silver gauze dressing and transparent film dressing, and the use of a strong anchoring device in accordance with aseptic technique |
| Hozayen et al.,[18] | To reveal the effect of the standard protocol on the infection rate | Retrospective cohort | 63 | International Heart and Lung Association Transplantation Consensus | *Minnesota University protocol:* Cleaning of the driveline site with soap and an antimicrobial spray and closure of the area with gauze and securing with adhesive plaster in accordance with aseptic technique.<br>*Dressing frequency:* Daily change of dressing<br>*Utah Artificial Heart Program protocol:* The application of a foam based dressing 2x2 inches in size directly to the skin and a 4x4 inch foam based dressing over it and closure with transparent film dressing in accordance with an aseptic technique<br>*Dressing frequency:* Changing the dressing every three days |
| Wus et al.,[17] | To determine the effect of dressing changing frequency of inpatients with newly implanted LVAD on infection development | Retrospective cohort | 68 | INTERMACS infection diagnosis criteria | *Dressing protocol:* Skin cleansing with chlorhexidine, closure with sterile dressing, using an anchoring device in accordance with aseptic technique<br>*Dressing frequency:*<br>August 2008 - July 2011; daily dressing change<br>August 2011 - October 2012; weekly dressing change<br>November 2012 - September 2013; three times a week dressing change |
| Sharma et al.,[20] | To reveal the incidence and predictors of driveline infections developing in patients with LVAD for destination therapy | Retrospective cohort | 143 | INTERMACS infection diagnosis criteria | *Dressing protocol:* Cleaning an 8 cm area on the driveline exit site with chlorhexidine and distilled water while using a mask and sterile gloves, wrapping a cut gauze around the driveline, covering the driveline with 2x2 inch sterile gauze, use of an abdominal securement tape/band for stabilizing the driveline<br>*Dressing frequency:* Daily dressing |
| Stahovich et al.,[22] | To develop a percutaneous line care kit to keep the driveline exit site clean and to minimize driveline movement | Multi-center, prospective, non-randomized experimental | 50 | Physical evaluation and drainage culture from the area | *Dressing protocols:* Dressing placed in accordance with aseptic technique at all centers while using sterile gloves, a mask and a cap<br>1st center; cleaning of driveline exit site with hydrogen peroxide, closure with sterile gauze, use of an anchoring device and replacing the dressing every 2-3 days<br>2nd center; cleaning of driveline exit site with chlorhexidine or silver gauze solution, closure with transparent film dressing, use of an abdominal securement tape for stabilizing the driveline and replacing the dressing every 2- 3 days<br>3rd center; cleaning of driveline exit site with chlorhexidine, closure with sterile gauze, use of an abdominal securement tape for stabilizing the driveline and replacing the dressing daily<br>4th center; cleaning of driveline exit site with chlorhexidine, closure with sterile gauze or transparent gauze, use of an anchoring device and replacing the dressing every 2-3 days<br>5th center; cleaning of driveline exit site with chlorhexidine, closure with sterile gauze, use of an abdominal securement tape for stabilizing the driveline and replacing the dressing daily |
| Hieda et al.,[21] | To evaluate the incidence of infection-related complications in patients with LVAD*, interventions for LVAD*-related infections, and the early effects of the interventions | Retrospective cohort | 27 | Hospital Infection Control Practices Advisory Committee surgical site infection criteria (purulent drainage from the driveline exit area, culture from the area or drainage fluid, infection indicators detected with histopathologic, radiologic and physical evaluation) | *Dressing protocol:* Dressing with dilute hydrogen peroxide and antimicrobial occlusive dressing in accordance with aseptic technique<br>*Dressing frequency:* Daily 2-3 dressing changes |

INTERMACS: Interagency Registry for Mechanically Assisted Circulatory Support; LVAD: Left ventricular assist device.

**Table 2. Results Obtained From the Studies, Conclusions and Recommendations**

| Author | Results | Conclusion/Recommendations |
|---|---|---|
| Menon et al.,[15] | The decrease in driveline infection was found to be statistically significant in patients where Merbromin solution was used in the care of the driveline exit site after LVAD implantation (p=0.043). | The use of Merbromin solution in the continuous care of the LVAD driveline exit site can contribute to the decrease of driveline infections. Conducting multi-center cohort studies with larger samples to verify the results of this study are recommended. |
| Cagliostro et al.,[14] | A significant decrease was obtained in the risk of developing driveline infection with the use of bacteriostatic silver gauze dressing and a standard anchoring device (log rank=0.036). | The use of a standard kit containing silver gauze dressing and an anchoring device in driveline care after LVAD implantation decreases the risk of developing driveline infection by 11%. The routine use of this dressing technique is recommended in the prevention of driveline infections and infection-related complications. |
| Hozayen et al.,[18] | No difference was found between two techniques used as a result of 18 months of follow-up of two groups where the Utah and Minnesota care protocols were used (Log-rank p=0.58; Wilcoxon p=0.54). The satisfaction of the caregivers was significantly high with the Utah protocol (p=0.006) | Good results were obtained with the use of both techniques Instead of choosing one and using it for all patients, the technique most appropriate for the patient should be chosen and used. |
| Wus et al.,[17] | No driveline infection was found during hospitalization and in the 30 days after discharge in patient groups with dressing change performed daily, three times a week and weekly in the study sample. | Driveline infection development was not associated with the dressing frequency in this sample. There are only a few related studies and they do not provide strong evidence regarding the effect of dressing frequency in the prevention of infection. Larger prospective studies are recommended to determine and standardize the most appropriate dressing frequency. |
| Sharma et al.,[20] | Driveline infection was found to develop in 12% (n=18) of the 143 patients included in the study sample. Superficial infections made up 82% (n=15) and deep infections 18% (n=3). | Extending the ventricular assist device use duration increases the driveline infection risk significantly. Local wound care and anchoring of the driveline, patient training and close follow-up of the patient are recommended in the management of driveline infections. |
| Stahovich et al.,[22] | The use of a percutaneous lead management kit in driveline care was found to be quite comfortable and effective in the anchoring the driveline (p<0.001). The dressing change frequency was found to decrease (every 6-7 days or longer). Driveline infection was found in three patients among the patients using a percutaneous lead management kit. | The facilitation and development of dressing change technique decrease the risk of driveline infection. The use of a percutaneous lead management kit is recommended. |
| Hieda et al.,[21] | Infection was found at the driveline exit site in more than 90% of the patients in the 12 months after LVAD placement. | The results of this study emphasize the importance of wound care and antibiotic use in the prevention of infections related to ventricular assist devices and the authors recommend the implementation of these interventions at an early stage for their prevention. |

LVAD: Left ventricular assist device.

### Driveline dressing closures

The driveline exit site was reported to be covered with closure material in all studies included in the review.[14,15,17,18,20-22] The study of Cagliostro et al.[14] compared sterile gauze and a transparent film dressing with bacteriostatic silver gauze dressing and transparent film dressing use as a dressing closure and there was a significant decrease in driveline infections in the group, where bacteriostatic silver gauze dressing and a transparent film dressing was used (Table 2). Sterile gauze use was reported for dressing closure in the

Minnesota protocol and absorbent foam sponge dressing and a transparent film dressing in the Utah protocol by Hozayen et al.[18] (Table 1). Although favorable results were reported with the use of either technique, the satisfaction of the caregivers was significantly high with the Utah protocol where an absorbent foam dressing and a transparent film dressing were used.[18] Driveline infection was reported not to develop in the study of Menon et al.[15] where they used Metalline dressing pads for closure in their protocol (Table 1). Hieda et al.[21] reported that antimicrobial occlusive dressings were used to cover the site (Table 1).

**Driveline dressing change frequency**

The driveline dressing change frequency was seen to differ in the studies included in the review (Table 1). While the dressing on the driveline exit site was changed every day in the early postoperative period, it was changed every six to seven days later on in the study of Menon et al.[15] Dressing change was daily in the Minnesota protocol and every three days in the Utah protocol in the study of Hozayen et al.[18] (Table 1). No significant difference was found between the two protocols, one performed daily and the other every three days, and both techniques resulted in good results in this study (Table 2). The effectiveness of dressings changed daily, three times a week or weekly was evaluated and driveline infection was not reported in any patient; therefore, concluding that driveline infection development was not associated with the dressing frequency in the study of Wus et al.[17] Dressing change was reported to be made daily,[20] two to three times a day,[21] daily and every two to three days[22] in these studies (Table 2). While the driveline infection rate was low in two of these studies,[20,22] the rate was high in the study of Hieda et al.[21]

**Driveline anchoring device use**

Anchoring devices with adhesive properties such as a securement tape, belt, patch or tape were used to stabilize the driveline in six of the studies included in the review (Table 1). A care kit with a driveline anchoring device was used, and the risk for developing a driveline infection decreased by 11% in the study of Cagliostro et al.[14] The care kit containing an anchoring device was found to be significantly effective in the study of Stahovich et al.[22] conducted to develop a percutaneous lead management kit.

## DISCUSSION

Ventricular assist device implantation is an invasive intervention, as the driveline extends from the pump implanted to the ventricle to the skin. One of the most important problems encountered in the long-term follow-up of these patients is, therefore, driveline related infections.[4-6,10,15] It may be possible to prevent or minimize the development of this problem with standardized driveline exit site care. In this review, we evaluated a total of seven original study articles discussing driveline care in patients with a ventricular assist device and assessed the driveline area infection rates. Most of these studies were retrospective and no randomized-controlled studies specific to the subject with an adequate evidence level was found.

Converting driveline care into a protocol is important in terms of standardizing the care. It is, therefore, necessary to establish an institutional step-by-step protocol for the care process of the driveline exit site, and all healthcare staff should provide care accordingly. Driveline care was implemented according to a protocol in all the studies included in this review.[14,15,17,18,20-22]

All the procedures for driveline exit site care should be performed in accordance with an aseptic technique; patients and their relatives who will continue the care at home after discharge should be also trained.[8] All the studies in this review emphasize providing the care by using sterile gloves, mask, and cap and complying with asepsis rules.

One of the most important issues in driveline care is the choice of the agents used in cleaning the region and these agents differ according to the institutional protocols. Chlorhexidine, octenidine dihydrochloride, 2% merbromin solution, hydrogen peroxide, soap and antimicrobial spray were used in skin cleaning of the driveline area in the studies included in this review. Chlorhexidine solution, recommended to be used in the perioperative process to prevent surgical site infections,[23] was also the preferred solution for skin cleaning in driveline care protocols.[14,17,20,22] Reported driveline infection rates are quite low in studies where chlorhexidine is used in driveline exit site care.[14,17,20,22] In addition, 2% merbromin solution, hydrogen peroxide, soap and antimicrobial spray used in the care of the driveline exit site are also reported to contribute to decreased infection rates in other studies.[15,18,21,22] It can be concluded that the recommendations regarding the agent to be used in driveline skin cleaning are important based on the findings obtained from the studies included in the review, although they do not provide strong evidence.

Another issue to consider in driveline care is the dressing closures. Sterile gauze and transparent film dressing as well as bacteriostatic silver gauze dressing

and foam based dressing are reported to be used often as driveline dressing closures.[14,15,17,18,20-22] The routine use of a standard care kit including bacteriostatic silver gauze dressing is particularly recommended for driveline care.[14]

The dressing change frequency is also an issue in driveline care that varies from institution to institution and should be considered in the care protocol. Regarding dressing change frequency, implementations in the form of two to three times per day, daily, every two to three days, once a week, and three times a week were used in the studies.[14,15,17,18,20-22] When the results of these studies with different protocol are evaluated, it can be suggested that the dressing change frequency is not directly associated with driveline infection development and further studies are required to be performed to identify the most appropriate frequency.

Another implementation required in the driveline care protocol is the use of driveline anchoring devices. Driveline anchoring device use was reported in the majority of studies examined in this review and it was found to decrease the risk for developing a driveline infection.[14,15,17,18,20,22] Although various anchoring devices were used, however, there was no reported finding indicating the superiority of any one of these.

### Conclusion and recommendations

In conclusion, the findings of this systematic review show that driveline exit site care in patients with a ventricular assist device vary from institution to institution with no gold standard method, and the number of studies on such care is limited. The agent to be used in skin cleansing, the dressing closure, the dressing change frequency, and the driveline anchoring devices should be identified and included within the scope of a standardized driveline care protocol. However, further large-scale, randomized-controlled studies would provide stronger evidence.

**Declaration of conflicting interests**

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

**Funding**

The authors received no financial support for the research and/or authorship of this article.

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