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Characterization of injuries and dressings of left ventricular assist device drivelines

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ABSTRACT

Aim: To Identify and characterize driveline-related injuries among patients with HeartMate II® or HeartMate 3® and assess the dressings used during hospital stay. **Method:** Observational, cross-sectional study conducted between 2015 and 2023 at a large hospital in São Paulo, Brazil. **Results:** The sample consisted of 18 patients, with driveline injuries identified in 66.7%, categorized into stages one (83.3%), two (8.3%), and four (8.3%). Of these, 66.6% were diagnosed with driveline infection according to the Utah classification: stages two (50%), three (37.5%), and four (12.5%). A correlation was found between the occurrence of injuries and longer support time (p=0.035) and the presence of a diagnosis of driveline infections (p=0.013). The solutions most frequently used were Chloraprep™ (27.8%), Aqueous Chlorhexidine 0.5% (22.2%), and Saline 0.9% (22.2%), while the dressings were IV3000™ (72.2 %), Excilon™ (44.4%), and Biatain®Ag (33.3%). **Conclusion:** Driveline dressings are not standardized, indicating the need for new protocols and guidelines based on studies of high methodological quality and presenting robust evidence of the best solutions and dressings to prevent complications and promote better outcomes.

DESCRIPTORS: Heart-assist devices. Enterostomal therapy. Heart failure. Wounds and injuries.

Caracterização de lesões e curativos de *drivelines* de dispositivos de assistência ventricular esquerda

RESUMO

Objetivos: Identificar e caracterizar as lesões relacionadas ao *driveline* em usuários de HeartMate II® ou HeartMate 3® e avaliar os curativos utilizados durante a internação hospitalar. **Método:** Estudo observacional, transversal, com dados analisados entre os anos de 2015 e 2023, em um hospital de grande porte de São Paulo, Brasil. **Resultados:** A amostra foi composta de 18 pacientes, sendo identificadas lesões de *driveline* em 66,7%, categorizadas em estágio um (83,3%), dois (8,3%) e quatro (8,3%). Destes, 66,6% apresentavam diagnóstico de infecção de *driveline* com a classificação de Utah de estágio dois (50%), três (37,5%) e quatro (12,5%). Houve correlação entre a ocorrência de lesões e o maior tempo de suporte (p=0,035) e a presença do diagnóstico de infecção do *driveline* (p=0,013). As soluções mais frequentes foram Chloraprep™ (27,8%), Clorexidina Aquosa 0,5% (22,2%) e Soro Fisiológico 0,9% (22,2%), e as coberturas IV3000™ (72,2%), Excilon™ (44,4%) e Biatain®Ag (33,3%). **Conclusão:** Nota-se ausência da padronização de curativos de *drivelines*, destacando a necessidade de novos protocolos e diretrizes com estudos de alta qualidade metodológica e com evidência robusta das melhores soluções e coberturas, prevenindo complicações e promovendo melhores resultados.

DESCRITORES: Coração auxiliar. Estomaterapia. Insuficiência cardíaca. Ferimentos e lesões.

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Caracterización de lesiones y apósitos de drivelines de dispositivos de asistencia ventricular izquierda

RESUMEN

Objetivos: Identificar y caracterizar lesiones relacionadas con el *driveline* en pacientes con HeartMate II® o HeartMate 3® y evaluar los apósitos utilizados durante el ingreso hospitalario. **Método:** Estudio observacional, transversal, realizado entre 2015 y 2023, en un hospital de gran porte de São Paulo, Brasil. **Resultados:** La muestra estuvo conformada por 18 pacientes, identificándose lesiones de *driveline* en el 66,7%, categorizadas en estadios uno (83,3%), dos (8,3%) y cuatro (8,3%). De estos, el 66,6% fueron diagnosticados con infección de *driveline* con la clasificación de Utah en estadios dos (50%), tres (37,5%) y cuatro (12,5%). Hubo correlación entre la aparición de lesiones y el mayor tiempo de soporte (p=0,035) y la presencia del diagnóstico de infección del *driveline* (p=0,013). Las soluciones más frecuentes fueron Chloraprep™ (27,8%), Clorhexidina acuosa 0,5% (22,2%) y Salino 0,9% (22,2%), y los apósitos fueron IV3000™ (72,2%), Excilon™ (44,4%) y Biatain®Ag. (33,3%). **Conclusión:** Falta estandarización de los apósitos de *drivelines*, destacando la necesidad de nuevos protocolos y guías con estudios de alta calidad metodológica y con evidencia sólida sobre las mejores soluciones y coberturas, previniendo complicaciones y promoviendo mejores resultados.

DESCRIPTORES: Corazón auxiliar. Driveline. Estomaterapia. Insuficiencia cardíaca. Heridas y lesiones.

INTRODUCTION

Heart failure (HF) is a common final pathway of several cardiac diseases refractory to clinical treatments. The prevalence of HF tends to increase exponentially worldwide, in developed and underdeveloped countries, and it is the leading cause of hospitalization of Americans over 65. Additionally, HF is associated with high morbidity and mortality rates and frequent hospital readmissions, generating high costs to health systems[1].

Many patients with HF develop an advanced condition that is refractory to optimized clinical treatment. In this context, invasive therapeutic measures are adopted, such as the implantation of short-term or long-term left ventricular assist devices (LVADs)[1,2]. LVADs are used to provide circulatory support and stability, and function as a bridge to heart transplantation or, as a destination therapy for individuals with counter-indications. Such devices should be indicated for patients presenting minimal clinical stability and preserved systemic functions, to ensure a higher success rate.

Among the LVADs available in Brazil, HeartMate II® and HeartMate 3® are among the most frequently used devices[2]. HeartMate II® provides continuous flow implanted in the native heart, assuming the pumping function of the impaired left ventricle. It is positioned just below the diaphragm and is connected to the aorta, exerting all the energy necessary to propel the blood flow towards the systemic circulation, thus relieving the ventricular workload. The patient also uses an external vest containing a controller and batteries, connected to a small power-based monitor through a single power cable, the driveline. The exerted axial flow enables pumping up to 10 liters per minute, like a healthy native heart[3].

HeartMate 3® is intrapericardially implanted and has two tubes: inflow, positioned in the damaged left ventricle, and outflow, positioned in the ascending portion of the aorta. This levitated centrifugal continuous-flow device decreases blood shear during passage through the LVAD, thus reducing hemolysis. Its internal coating is composed of titanium micro particles, which reduces the thrombogenicity of the device, and a pulsatile flow, obtained by changing rotor speed every two seconds, allows the aortic valve to function, decreasing ventricular stasis. Two external lithium-ion batteries supply power to the device and are connected through a driveline with a non-single extension, i.e., it is divided into two parts that connect close to the patient's body, which facilitates the replacement of the device's external components whenever necessary. Like HeartMate II®, its maximum pumping capacity reaches 10 liters of blood per minute[4].

Although these devices reach high success rates, they are not exempt from complications. The primary events associated with LVADs include major gastrointestinal tract hemorrhages, right ventricular dysfunction, neurological events, infections on the insertion site or driveline, intrinsic or extrinsic pump malfunction, device thrombosis, hemolysis, arrhythmias, and arterial hypertension.[1] Pressure injuries at the driveline exit site are also seen in clinical practice, although such a complication is not yet widely discussed in the scientific literature.

The National Pressure Injury Advisory Panel (NPIAP)[5] has considered Medical Device Pressure Injuries (MDPIs) to be non-classical injuries, as they do not result from excessive pressure on bony prominences but result from the use of devices used for diagnostic or therapeutic purposes with direct local pressure. Note that such devices are usually composed of rigid inputs, which, when poorly adjusted or fixed or in the presence of local edema, favor the occurrence of injuries[6].

MDPIs usually leave a mark on the skin, which NPIAP classifies as:

- stage 1: nonblanchable erythema of intact skin;
- stage 2: partial-thickness skin loss with exposed dermis;
- stage 3: full-thickness skin loss;
- stage 4: full-thickness skin and tissue loss[7].

The UTAH classification is exclusively used to categorize MDPIs when associated with driveline infections, as follows:

- stage 1: skin is incorporated into the driveline, absent secretion, little or no hyperemia, and no sensitivity;
- stage 2: fissure or initial trauma, drainage, slight hyperemia, slight sensitivity;
- stage 3: skin away from the driveline, increased drainage, increased hyperemia, and sensitivity;
- stage 4: skin away from the driveline, large drainage volume, increased hyperemia, pain[1].

Although all patients with devices are susceptible to MDPIs, those with a critical condition are at high risk, as they are exposed to a large number of devices. Additionally, these individuals may present sensory impairment due to sedation and analgesia or other factors that contribute to the development of injuries, such as immobility[8]. In this context, nurses and the nursing team are the primary professionals providing care and managing patients to ensure and promote the integrity of the driveline outflow tract; most MDPIs result from a lack of knowledge, especially regarding prevention interventions[9].

Clinical nurses must identify and implement actions to prevent MDPIs and promote comfort. Inspecting the device site and applying clinical judgment are essential to recognize and diagnose risks; the literature recommends that such inspections be performed at least twice daily. Changes in the site should be considered, such as edema, humidity, and temperature, as such changes may lead to increased pressure and stress under the device, favoring skin rupture. Essential care includes keeping the skin under and around medical devices clean and dry, using the appropriate size of materials, alternating areas where devices are fixed, and padding/anchoring to relieve potential pressure on the skin. Additionally, films and adhesives should be applied and positioned with caution to prevent them from impeding and hindering inspection and visualization of the device[10].

OBJECTIVES

The objective was to identify and characterize driveline-related injuries among patients using HeartMate II® or HeartMate 3® and evaluate the dressings applied during hospitalization.

METHOD

This observational, cross-sectional study addressed a time frame from 2015 (the date of the first implant) to August 2023 and used data collected from medical records and institutional databases. The study settings include the cardiology

hospital units of the *Sociedade Beneficente de Senhoras do Hospital Sírio-Libanês*, a large philanthropic institution in São Paulo, Brazil.

PICO strategy[11] supported the definition of the guiding question, where P: patients using HeartMate II® or HeartMate 3®; I: not applicable; C: wound solutions and dressings; O: characterization of driveline-related injuries. The following research question was formulated according to the PICO: What is the relationship between the types of solutions and dressings used on HeartMate II® and HeartMate 3® drivelines and the development of injuries?

Adults over 18, both sexes, implanted with HeartMate II® or HeartMate 3® during the study period, regardless of the etiology of their HF, participated in this study. The inclusion criterion was incomplete medical records that would hinder the collection of information relevant to this study.

Two researchers collected data on the Electronic Patient Record (EPR) and Tasy HTML5 systems between June and August 2023, considering nurses' notes and analyses, driveline dressings, and other pertinent notes. The authors developed a semi-structured instrument to guide information retrieval from the medical records.

The following variables were addressed to characterize the sample and clinical profile: sex, age, race/color, height, weight, Body Mass Index (BMI), education, diagnosis that determined the device implantation, model (HeartMate II® or HeartMate 3®), support time (months), personal history (HF, systemic arterial hypertension, diabetes mellitus, dyslipidemia, obesity, others), the patient's current clinical outcome (death or alive), and cause of death (if applicable). The variables used to assess driveline exit site, MDPIs, and dressings were: appearance of the site, materials used in the driveline dressing, dressing change schedule, need for additional dressing changes, use of a driveline stabilizing/anchoring device; medical diagnosis of driveline infection (microorganism isolation), and the use of vacuum dressing at some point.

The authors developed spreadsheets to store data using Microsoft Excel version 365. Next, data were statistically analyzed, presenting summary measures such as mean, median, minimum and maximum values, standard deviation, absolute and relative frequencies (percentage), bar graphs, and one-dimensional scatterplots. Mann-Whitney and Fisher's exact tests were performed for inferential analysis; the significance level was 5% in all analyses. The analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 24 from International Business Machines Corporation (IBM) and R version 3.6.3

This study was initiated after the Institutional Review Board approved the project. All ethical guidelines provided by CNS Resolution No. 466, from December 12, 2012, were complied with, ensuring the anonymity and confidentiality of documentary sources and data disclosure and reliability. The study protocol underwent ethical review and was approved under opinion 6,420,266 and CAAE 74512223.8.0000.5461. There are no conflicts of interest regarding this study's content, and the authors assume full responsibility for the integrity of the results, emphasizing their commitment to not disclosing the participants' personal data. No information was recorded that would individually identify the individuals (e.g., name, ID number, contact number, or date of birth). Data collection was restricted to the variables essential for the research development.

RESULTS

This study's sample comprised 18 patients who met the inclusion criteria. Regarding their profile (Table 1), 55.6% were men and 44.4% were women. Most reported being White (55.6%), with higher education (50%), aged 58.8 years on average (±14.8), and with a mean BMI of 24.9 kg/m2 (±5.7).

The patients' clinical history before the device was implanted indicated distinct arrhythmias (55.6%), systemic arterial hypertension (50%), diabetes mellitus (33.3%), dyslipidemia (44.4%), ischemic stroke (ICVA), and acute myocardial infarction - AMI (22.2%) in addition to HF, which all the individuals presented. Other less frequent antecedents were neoplasms, serological positivity for human immunodeficiency virus (HIV), coronary artery disease, chronic kidney disease, obesity, dementia, and hypothyroidism. Regarding the clinical outcome, only 5 (27.8%) of the participants were alive up to the data collection period; 13 (72.2%) had died during the period of analysis. Among the causes of death, cardiopulmonary arrest (CPA) stood out at 30.8%, followed by septic shock (23.1%) and hemorrhagic stroke (HCVA) at 15.4%.

Table 1. Sample clinical and sociodemographic profile. São Paulo, 2023.

Variables	Description	n	%
Sex	Woman	8	44.4
	Man	10	55.6
	Total	18	100.0
Race/color	White	10	55.6
	Black	3	16.7
	Mixed	1	5.6
	Unknown	4	22.2
	Total	18	100.0
Education	Illiterate	1	5.6
	Middle School	5	27.8
	High School	2	11.1
	Higher Education	9	50.0
	Unknown	1	5.6
	Total	18	100.0
Age (years)	n	18	
	Mean	58.8	
	Median	57.5	
	Minimum	29.0	
	Maximum	82.0	
	Standard deviation	14.8	
BMI	n	18	
	Mean	24.9	
	Median	23.9	
	Minimum	17.3	
	Maximum	42.8	
	Standard deviation	5.7	
Clinical history	HF	18	100.0
	Arrhythmias	10	55.6
	Systemic Arterial Hypertension	9	50.0
	Diabetes ***mellitus***	6	33.3
	Dyslipidemia	8	44.4
	AMI	4	22.2
	ICVA	4	22.2
	Others	9	50.0
Clinical outcome	Death	13	72.2
	Alive	5	27.8
	Total	18	100.0
Cause of death	HCVA	2	15.4
	Refractory shock	1	7.7
	Septic shock	3	23.1
	Right ventricular failure	1	7.7
	Intraoperative complications	1	7.7
	CPA	4	30.8
	Pulmonary sepsis	1	7.7
	Total	13	100.0

Among the primary causes for indicating the devices, ischemic cardiomyopathy was the most frequent (44.4%), followed by post-chemotherapy cardiomyopathy (16.7%). Alcoholic cardiomyopathies, Chagas' disease, hypertensive, idiopathic, non-compacted, viral, and anabolic steroid-related cardiomyopathies were equally distributed in the sample (5.6%).

Regarding when the device was implanted, most (five devices) were implanted in 2017 (27.7%); four were implanted in 2018 (22.2%); two devices were implanted in 2015, 2019, and 2020 (11.1% per year); and only one device was implanted in 2016, 2021, and 2023 (5.6% per year). Regarding the LVAD model, HeartMate II® was implanted in 55.6% of the participants, and HeartMate 3® was the choice for the remaining 44.4%. The period the device provided support ranged from 1 to 79 months, with 20.4 months on average (±19.6).

Descriptions consistent with the MDPI concepts were found in the medical records of 12 patients (66.7%). According to NPIAP's general classification, these findings were categorized as MDPIs stage 1 (83.3%), stage 2 (8.3%), or stage 4 (8.3%). Among the patients among whom MDPIs were identified, 66.6% had a medical diagnosis of driveline-related infection. Therefore, the UTAH classification is applicable in these cases, with the following characterizations: stage 2 (50%), stage 3 (37.5%), and stage 4 (12.5%).

Eight patients (44.4%) received a medical diagnosis of driveline-related infections during the study period. Among the main microorganisms identified as the etiological agents, Staphylococcus aureus, Pseudomonas aeruginosa, and Candida parapsilosis were recorded, isolated in culture methods of driveline exit site secretion and/or fragments of the mediastinal region in solid and liquid media.

Using the Mann-Whitney Test, statistical analyses showed an association (Figure 1) between MDPIs and prolonged LVAD support (p=0.035). The Fisher Exact Test also showed a relationship (Figure 2) between MDPIs and a driveline-related infection diagnosis (p=0.013). No statistical association was found between the other study's variables, such as the dressings solution or materials, and the presence of injuries.

The records concerning the dressings used in the LVAD outflow tract region show that the dressing materials used in all participants can be divided into two groups: solutions and type of wound dressings. The solutions most frequently used to clean the exit site were Chloraprep™ (27.8%), Aqueous Chlorhexidine 0.5% (22.2%), and Saline Solution 0.9% (22.2%), and the dressings most frequently adopted were IV3000™ (72.2%), Excilon™ (44.4%) and Biatain®Ag (33.3%).

Table 2 presents the characterization of the MDPIs identified and the solutions and types of dressings used in the drivelines.

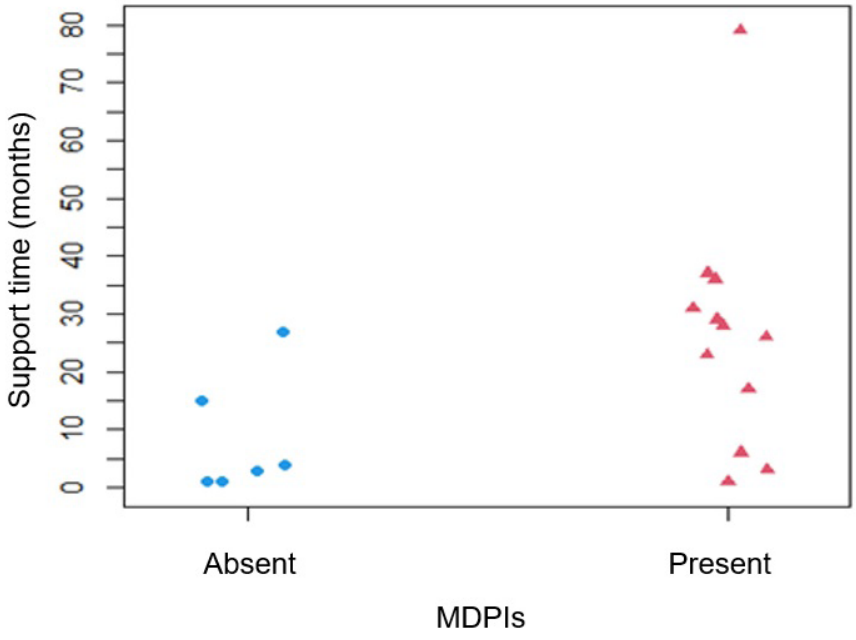

Figure 1. Relationship between the occurrence of MDPIs and LVAD support time. São Paulo, 2023.

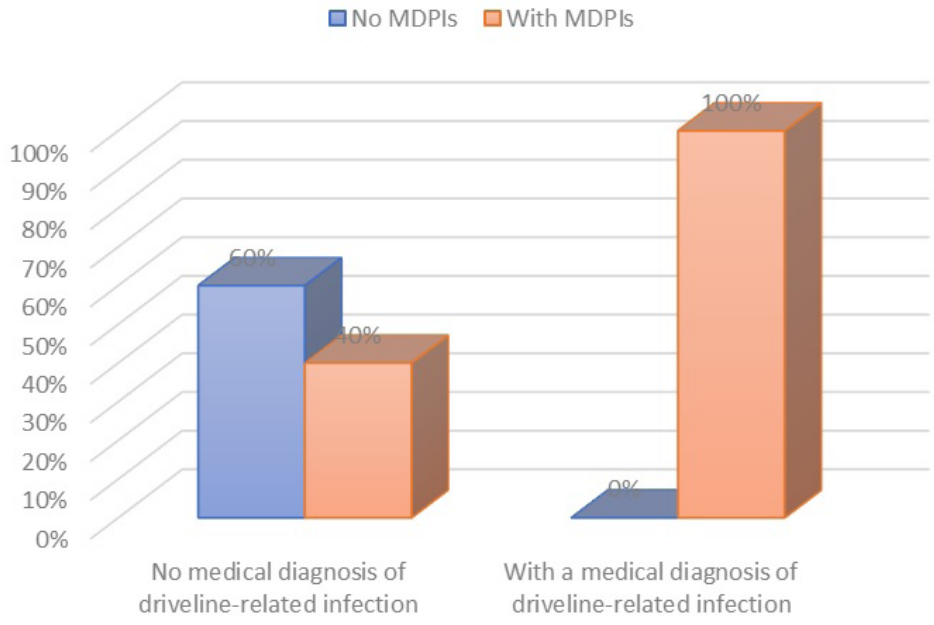

Figure 2. Relationship between the occurrence of MDPIs and driveline-related infections. São Paulo, 2023.

Table 2. Characterization of MDPIs and the types of solutions and dressings used in drivelines. São Paulo, 2023.

Variables	Description	n	%
MDPIs (General)	Absent	6	33.3
	Present	12	66.7
	Total	18	100.0
MDPI Stages (General)	1 – nonblanchable erythema of intact skin	10	83.3
	2 – partial-thickness skin loss with exposed dermis;	1	8.3
	4 – full-thickness skin and tissue loss	1	8.3
	Total	12	100.0
MDPI stages (UTAH)	1 – skin is incorporated into the driveline, absent secretion, little or no hyperemia, no sensitivity	0	-
	2 – fissure or initial trauma, drainage, slight hyperemia, slight sensitivity	4	50.0
	3 – skin away from the driveline, increased drainage, increased hyperemia, sensitivity	3	37.5
	4 – skin away from the driveline, large drainage volume, increased hyperemia, pain	1	12.5
	Total	8	100.0
Solutions	ChloraPrep™	5	27.8
	Aqueous Chlorhexidine 0.2%	4	22.2
	Saline Solution 0.9%	4	22.2
	Prontosan®	3	16.7
	Alcoholic Chlorhexidine 0.5%	2	11.1
Dressings	IV3000™	13	72.2
	Excilon™	8	44.4
	Biatain®Ag	6	33.3
	Blue Silicone Tape	3	16.7
	Allevyn™	2	11.1
	Aquacel®Ag	1	5.6
	Alginate Plate	1	5.6
	Mesalt®	1	5.6

According to the medical records, approximately 11 patients (61.1%) used the Hollister® plate stabilizer on the driveline as an anchoring device. Regarding the dressing change schedule, dressings were changed on an alternate-day basis (50%), daily (44.4%), or three times a day (5.6%). No additional changes were required in approximately 61.1% of the participants, while in 38.9% of the cases, the dressing needed to be changed more frequently than initially scheduled. Vacuum dressings were used in 22.2% of the patients at some point during the study period.

DISCUSSION

Studies indicate LVAD promotes increased survival by approximately 4 years among those implanted. However, research on the management of the driveline exit site shows that care has not yet been standardized, resulting in LVAD centers adopting a wide variety of protocols; driveline- or pump-related infections are the most common adverse events[12,13]. Although the incidence of these infections has decreased over time, such complications still affect 18.1% of patients during the first year after implantation and 11.9% in the following years.[14] Additionally, LVAD infections are associated with significant morbidity and mortality rates, primarily when related to bloodstream infections. Hence, early identification and treatment are essential for a better clinical outcome[15].

Literature reviews show that there are currently important discussions regarding driveline cleaning, dressing, and stabilization. These discussions highlight critical aspects of care that show a relationship with the occurrence of infections, such as the type of cleaning solution, type of dressing, the presence of an anchoring device, and the frequency of dressing changes. However, there are significant variations in the methods used. There is a significant deficit regarding guidelines for standardizing driveline exit site care, resulting in therapeutic approaches based on individual expertise and according to institutional protocols[17].

A systematic review analyzed cleaning agents for driveline exit sites, showing that chlorhexidine gluconate (CHG) was the solution most frequently used, while povidone-iodine was used as an alternative solution in cases where the patient had skin irritation or intolerance to CHG. The frequency of infection differed between studies, ranging from 5.4% to 21.3% among whom CHG was the cleaning agent; an infection frequency from 6% to 7.5% was reported among those whom CHG and a silver-based dressing were used on the exit site care. Studies that used CHG and sterile gauze dressing for exit site care showed infection frequencies equal to 5.4% and 21.3%, respectively. A higher frequency of driveline-related infections was found by one of the studies in which povidone-iodine was used as an alternative solution in patients intolerant to CHG (42.9%)[13]. Furthermore, studies in which 2% chlorhexidine-based products were used showed lower rates of driveline-related infections (5.4%)[12].

Considering the wound dressings, sterile gauze and silver-based dressings were the most commonly used in the exit site[12,13]. One study showed that the frequency of driveline-related infections in the silver-based group was lower than in the group that used sterile gauze (15.8%), and the frequency of infection and time up to the first infection when silver-based dressings and CHG were associated was 6% and 180 days, respectively. Another study compared foam dressings and sterile gauze and found that the frequency of transmission infection was 19% for foam-based dressings and 13% for sterile gauze dressings (p=0.68). Finally, another analysis, where foam-based dressings and CHG were used, found a frequency of driveline-related infections of 7.6%[13].

Traction injuries in the exit site are a significant risk for infection since part of the driveline has an interface section made of velvet designed for better internal adhesion; however, its exposure to the outside of the body may favor the occurrence of infections. Therefore, an anchoring device is a protective factor in preventing driveline infections[18,19]. A systematic review described the following anchoring devices for system immobilization: Centurion® Foley, Hollister® plate stabilizer, abdominal binder, Centurion® secure viewport, and Secutape® Nanoplastic fixation. The anchoring device most frequently used for stabilizing the transmission system was the Centurion® Foley support. It appears in four studies. The Hollister® plate stabilizer was used in the research field analyzed in this study, and another study analyzed the use of the same device and reported a frequency of driveline infections from 0 to 11.8%[13].

Although the frequency of dressing changes has not been shown to impact driveline-related infection rates directly, studies note that it may influence patient adherence to site care. There is no consensus in the literature regarding a standardized frequency of dressing changes, which may be daily, every two or three days, or weekly, depending on the drainage volume of the exit site[13,20].

CONCLUSION

The increased rates of HF in the global population and new technologies and therapies such as LVAD impose increasing challenges for nurses providing stoma therapy and managing patient injuries. This study characterizes MDPIs in patients implanted with HeartMate II® or HeartMate 3®, evidencing and corroborating scientific literature on the lack of standardized driveline dressings protocols, i.e., institutional protocols are used based on individual expertise. Hence, new guidelines are needed based on studies with high methodological quality and presenting robust evidence of the best types of solutions and dressings. Care provided to the device outflow tract is associated with complications contributing to higher hospital costs for health systems, more extended hospital stays, and worse patient outcomes. Future research is suggested to analyze and compare the best results among the different dressings available for LVAD drivelines.

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Authors' contributions: CMVS: Conceptualization, data curation, formal analysis, investigation, methodology, validation, visualization, writing – first draft, redaction – review, editing. NB: Conceptualization, data curation, formal analysis, investigation, methodology, validation, visualization, writing – review and editing. RBSP: Conceptualization, data curation, formal analysis, investigation, methodology, validation, visualization, writing – review and editing. DSG: Conceptualization, data curation, formal analysis, investigation, methodology, validation, visualization, writing – first draft, redaction – review, editing
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