

Home-care educational interventions to prevent complications in patients with Ventricular Assist Devices: a systematic review

G. Franceschini¹, G. Talevi¹, S. Maso², D. Comparcini³, M. Porfiri⁴, G. Cicolini⁵, V. Simonetti⁶

Received: 2023 July 28

Accepted after revision: 2023 October 16

Published online ahead of print: 2023 October 24

Key words: Heart-Assist Devices, Nurses, Education, Adverse Effects

Parole chiave: Dispositivi di assistenza cardiaca, infermieri, educazione, complicanze

Abstract

Background. The implantation of ventricular assist devices is the only effective alternative to cardiac transplantation in patients with chronic heart failure, in terms of survival and quality of life. However, their implantation can lead to physical and psychological complications, potentially preventable, especially in the long term, through patients' education. This research aimed to summarize the current best evidence on educational strategies towards patients after implantation of ventricular assist devices, in home-care setting, to reduce the major related complications, namely driveline infections, gastrointestinal bleeding and psychological complications.

Study Design. Systematic review.

Methods. Title and abstract selection, full-text screening, study quality assessment, and data extraction followed the PRISMA protocol and the Cochrane Handbook for Systematic Reviews of Interventions. The search was conducted through consultation of databases such as Medline, Scopus, EMBASE, and Web of Science, during the period from March 2022 to December 2022, in relation to English-language articles, from search strings processing and inclusion and exclusion criteria.

Results. Of the 1,231 items identified, 9 were selected because consistent with the inclusion criteria. The most effective educational interventions toward patients with ventricular assist devices were identified, delivered by multidisciplinary teams coordinated by a professional expert in management of ventricular

¹ Azienda Ospedaliero Universitaria delle Marche, Ancona, Italy

² Azienda ULSS3 Serenissima, Venezia, Italy

³ Interdisciplinary Department of Medicine, University of Bari "Aldo Moro", Bari, Italy

⁴ Department of Management, Università Politecnica delle Marche, Ancona, Italy

⁵ Department of Precision and Regenerative Medicine and Ionian Area - (DiMePRE-J), University of Bari "Aldo Moro", Bari, Italy

⁶ LUM University "Giuseppe Degennaro", Casamassima, Bari, Italy

assist devices, and regularly conducted. In particular, gastrointestinal bleeding and driveline infections could be prevented and reduced by complex, multimodal educational interventions, including telephone and app interventions. Educational strategies based on verbal instructions, hands-on demonstrations, innovative technologies, and active involvement of families/caregivers were particularly effective in preventing psychological complications.

Conclusions. Investing time and resources in educating patients with ventricular assist devices is mandatory, given the significant impact of educational outcomes on complications' reduction. Moreover, educational interventions geared towards patient's psychological well-being, brings positive outcomes on patient's compliance too, resulting in promising clinical outcomes. However, more in-depth research is needed, to support professionals in developing effective educational plans for such fragile and complex patients.

Introduction

Chronic heart failure (HF) is a growing global health challenge (1), with a worldwide prevalence of 65 million cases (2), and a high risk of death within 1 year, especially among older adults (3). Heart transplantation (HT), the gold-standard therapy for end-stage HF (4), is limited by insufficient donor supply (5) and by failure to meet selection criteria for HT surgery (6). Implantation of ventricular assist devices (VADs), which to date amount to >22,000 worldwide (7), as Right VAD (RVAD), Left VAD (LVAD), Biventricular VAD (BIVAD) (8) represents the only effective alternative to HT (9), in terms of survival (10) and quality of life (11, 12). Despite the benefits associated with their use, VADs involve a significant number of physical (13) and psychological (14) adverse events (AEs) (15), with clinical, economic and ethical implications (16, 17). Between the physical AEs (such as right heart failure, pump thrombosis, gastrointestinal bleeding, driveline infection, stroke, and aortic insufficiency) (13), bleeding is the most common one and the major cause of readmission (18), especially as gastrointestinal bleeding (GIB) that afflicts 15-30% of patients (13, 19). Additionally, local and systemic infection is a predictor of mortality (7), especially in critically ill, immune-compromised, or malnourished patients. In this regard, driveline infection is the most common one, occurring in 15.4% to 23.8% of cases (20).

As psychological AEs, almost half (47%) of the patients feel that VADs negatively affect their self-image, in terms of disgusting by own body and feeling of invasion (21). AEs occur at all time points (31% of survival patients is averagely readmitted within 30 days; 65%-80% within 1 year) regardless of risk factors (e.g. cardiogenic shock at time of implantation, preexisting severity of illness, organ dysfunction or need for anticoagulation (13)). A correct management of VADs, oriented to AEs prevention, is based on a comprehensive home-management care plan that incorporates therapeutic education, aimed to develop patients' and their caregivers' skills to care for and manage their conditions (22). In details, therapeutic education is related to improvements in health biomedical outcomes (23-25), such as AEs early identification and proper care (23), long-term adaptations to chronicity (24, 25), and to psychosocial outcomes (22), such as patient's self-efficacy and satisfaction (26). To obtain these goals, patients need knowledge and understanding disease processes, as well as specific disease management skills, achievable through a proper educational intervention (27). Recent studies (26, 28, 29) highlighted that educational interventions towards chronic patients should include a variety of educational strategies, from written materials and practical demonstrations to virtual, audiovisual, electronic media (26) and computer technology (28, 29). Moreover, literature (27) showed that educational

interventions towards chronic patients should be delivered by multidisciplinary teams, through a task-sharing approach (30). Thus, an allied healthcare staff can be defined as an excellent resource to deliver an optimal therapeutical healthcare intervention (30) and to foster the self-management competencies in chronic patients (31). Among healthcare professionals, nurses are directly involved in the patients' monitoring, treatment planning and in care delivery (32), as well as education and self-management promotion through the development of patients' empowerment (31, 33). At this regard, however, nurses could have a rather limited understanding and perception of knowledge and skills that patients develop regarding the proper management of diseases, restricted to the patients's 'adherence' to nursing recommendations (34); they often focus on disease management, putting attention on the adequate use of medication, ignoring sometimes the possible need of a psychosocial support (35). Regarding educational interventions towards patients affected by HF, literature showed contrasting results (36-37): nurse-led self-care educational interventions can improve clinical outcomes such as readmission and mortality (36) and increase patients' self-care (37), but not the quality of life and HF knowledge (36). Regarding the HF teaching-learning strategies mostly suitable for adults, available evidences are focused on hospitalized patients, excluding long term and home-based educational programs (25), relevant for reduction of AEs, such as bleeding (18), infections (7), and psychological complications (21). Even less is known referring to VADs patients, except that the development of effective educational strategies to foster their long-term adjustment to VADs could be affected by unexpected challenges for the home adaptation of patients and their families (transitions between settings of care, medication management and wound care, monitoring for AEs) (25). For these

reasons, tailoring educational methods for VADs patients (25) and their families and developing educational strategies for their self-management through supportive and sustainable techniques plays a pivotal role in the improvements of patients' care and outcomes (24), especially in homecare setting (25). The HF's burden (1), the impact of education on SM support in chronic patients (23), the potentialities of a home-based health education (38), and the contradictory results related to the role of nurses in the education of chronic patients (36,37), represent the motivations behind the present study. This systematic review aimed at evaluate and summarize current best evidence on educational strategies towards patients after VADs' implantation, in home-care setting, in terms of driveline infections, gastrointestinal bleeding and psychological AEs' reduction.

Methods

Design

The systematic review was conducted according to the methods defined in the Cochrane Handbook for Systematic Reviews of Interventions Section 8.5 (39) and reported according to The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (40). The review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO), registration No. CRD42023398368.

Search strategies and study selection

A systematic search was performed across four electronic databases: Medline (through Pubmed), Scopus, EMBASE, and Web of Science (WOS) were systematically examined, from March 2022 to December 2022 by two independent researchers. The search strategy included Medical Subject Headings (MeSH) and free text terms. The

main key search terms were: left ventricular assist device, education, drive line infection, gastrointestinal bleed, quality of life. The search strategy was adjusted for each database searched and was limited to peer-reviewed studies published in either Italian or English language from January 2012 to December 2021, to avoid the inclusion of obsolete educational techniques, without risking over-limiting the research. This time limit was set to include studies carried out in a period of significantly increased survival following VADs' implantation (41). Search strategies' details are shown in Table 1.

Two authors, independently, screened all titles and abstracts of potentially relevant

articles, based on the defined inclusion and exclusion criteria; duplicates were removed manually and through electronic tools (Zotero). Then, the abstracts or the full texts of the relevant articles were assessed independently by the two authors. Disagreements were resolved through consensus-based discussion or, when consensus was not reached, through consultation with an independent third author.

Inclusion and exclusion criteria

Articles were included if they met the following pre-determined inclusion criteria: studies carried out on educative interventions

Table 1. Search strategy

| Database | Search strategies | Number |
|----------|---|--------|
| PUBMED | (Left ventricular assist device OR Mechanical circulation support OR Mechanical hearts) AND (VAD education program OR VAD competence OR VAD training) AND (VAD competence OR VAD drive line infection OR Gastrointestinal bleed in VAD patient OR Lifestyle adjustment OR LVAD adherence OR LVAD self- efficacy OR LVAD self-management OR Quality of life OR Risk of left ventricular assist device driveline infection OR Readmission OR Survivor rate OR Vad complications) | 194 |
| SCOPUS | (ALL (left AND ventricular AND assist AND device) OR ALL (mechanical AND circulation AND support) OR ALL (mechanical AND hearts) AND ALL (vad AND education AND program) OR ALL (vad AND INTERVENTION AND PROGRAM) OR ALL (vad AND training) AND ALL (vad AND competence) OR ALL (vad AND drive AND line AND infection) OR ALL (gastrointestinal AND bleed AND in AND vad AND patient) OR ALL (lvad AND adherence) OR ALL (lvad AND self- AND efficacy) OR ALL (lvad AND self-management) OR ALL (risk AND of AND left AND ventricular AND assist AND device AND driveline AND infection) OR ALL (VAD AND patient AND quality AND of AND life) OR ALL (VAD AND readmission AND rate) OR ALL (survivor AND rate) OR ALL (vad AND complications AND reduction)) | 261 |
| WOS | ((((((((((((((((((ALL=(Left ventricular assist device)) OR ALL=(Mechanical circulation support)) OR ALL=(Mechanical hearts)) AND ALL=(VAD education program)) OR ALL=(VAD intervention program)) OR ALL=(VAD training)) AND ALL=(VAD competence)) OR ALL=(VAD drive line infection)) OR ALL=(Gastrointestinal bleed in VAD patient)) OR ALL=(LVAD adherence)) OR ALL=(LVAD self- efficacy)) OR ALL=(LVAD self-management)) OR ALL=(Risk of left ventricular assist device driveline infection)) OR ALL=(vad patient Quality of life)) OR ALL=(vad complication reduction)) OR ALL=(vad readmission rate)) OR ALL=(Vad Survivor rate)) | 223 |
| EMBASE | Left ventricular assist device OR Mechanical circulation support OR Mechanical hearts AND VAD education program OR VAD intervention program OR VAD training AND VAD late complications OR VAD drive line infection OR Gastrointestinal bleed in VAD patient OR LVAD adherence OR LVAD self- efficacy OR LVAD self-management OR Risk of left ventricular assist device driveline infection OR vad patient Quality of life OR vad complication reduction OR vad readmission rate OR Vad Survivor rate | 553 |

conducted by health care providers (without any limits or specification related to the type of educational strategies), as primary or secondary outcome 1), in adult VAD patients (Left or Bi-Ventricular Device) 2), in home-management context 3) related to primary literature and with any quantitative studies' design. Articles were excluded if they included terminal 1), oncological 2), pediatric 3), with cognitive impairment 4) patients; studies related to immediate post-surgery 5); including patients affected by COVID-19 6); studies implementing treatment protocols 7); studies related to VADs' caring in emergency departments 8); including exclusively educative interventions for caregivers as primary outcome 10) and considering only medical outcomes (INR, glucose rate, e.g.) 11); studies on economic assessment 12).

Quality appraisal

The methodological quality of the studies included was assessed using Cochrane tools: for the studies' assessment we used the Cochrane Handbook's supplement (RoB2) (42), developed by the EPOC group for the Cochrane Handbook: "Suggested risk of bias for EPOC reviews", The Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I). In details, ROBINS-I is structured into a fixed set of domains of bias, that leads to an overall risk-of-bias judgement. Based on answers to signaling questions, judgements for each bias domain, and for overall risk of bias, include the following risk of bias' levels: 'Low risk of bias', which indicates a study comparable to a well-performed randomized trial with regards to this domain (at low risk of bias for all domains); 'Moderate risk of bias', which stands for a study sound for a non-randomized study with regard to this domain but cannot be considered comparable to a well-performed randomized trial (at low or moderate risk of bias for all the domains); 'Serious risk of bias', that is related to a study that has some important problems

in this domain (at serious risk of bias in at least one domain, but not at critical risk of bias in any domain); 'Critical risk of bias', highlighting a study too problematic in this domain to provide any useful evidence in the effects on intervention (at critical risk of bias in at least one domain) (39); 'Unknown risk of bias', if not determined, applicable or reported.

The selected studies were independently appraised by two authors and any disagreements were resolved through consensus-based discussion or were discussed with a third author until a consensus was reached.

Synthesis

Data were extracted based on study's title and bibliographic details (authors, year and journal), study design and aim, country and study period; sample's details (participants and control group, when appropriate); inclusion/exclusion criteria; details about educational intervention; main results, outcomes assessment and time points of outcome assessment; limitations of the study and quality assessment total score. Each study was independently extracted by one author and validated by a second author. In this systematic review data were synthesized using a narrative approach. Due to high levels of heterogeneity among the included studies, a meta-analysis was not conducted.

Results

Study selection

The database search strategies yielded 1,231 articles. Between these studies, nine were included in the current review. Details related to studies' selection are shown in Figure 1.

Quality assessment of included studies

Based on ROBINS-I, a Cochrane Handbook's supplement (42), two studies

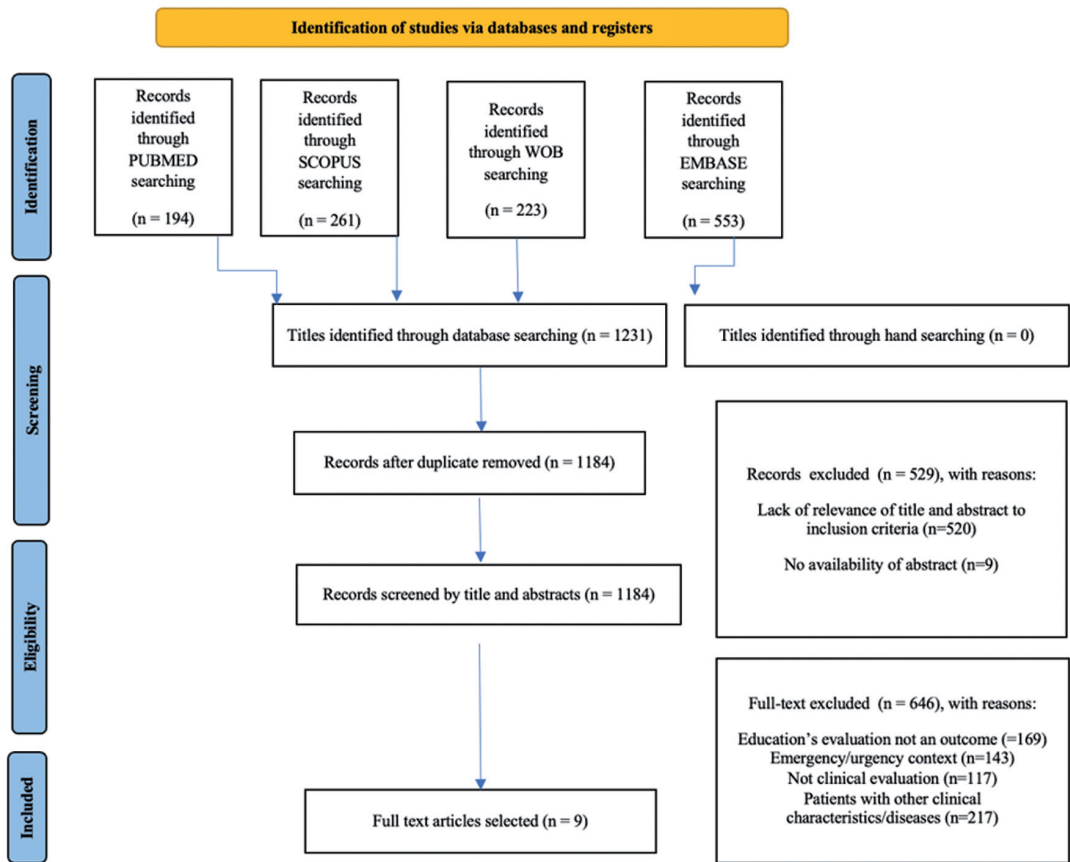


Figure 1. Flow diagram for systematic review

| | Bias due to confounding | Bias in selection of participants into the study | Bias in classification of interventions | Bias due to deviations from intended interventions | Bias due to missing data | Bias in measurement of the outcome | Bias in selection of the reported result | Overall risk of bias judgment |
|--------------------------------|-------------------------|--|---|--|--------------------------|------------------------------------|--|-------------------------------|
| Kugler et al. (2012) (45) | ● | ● | ● | ● | ● | ● | ● | ● |
| Nomoto et al. (2016) (43) | ● | ● | ● | ● | ● | ● | ● | ● |
| Asaka et al. (2017) (44) | ● | ● | ● | ● | ● | ● | ● | ● |
| Schlighofer et al. (2018) (50) | ● | ● | ● | ● | ● | ● | ● | ● |
| Casida et al. (2018) (1) (46) | ● | ● | ● | ● | ● | ● | ● | ● |
| Casida et al. (2018) (2) (47) | ● | ● | ● | ● | ● | ● | ● | ● |
| Hamed et al. (2019) (10) | ● | ● | ● | ● | ● | ● | ● | ● |
| Alam et al. (2020) (48) | ● | ● | ● | ● | ● | ● | ● | ● |
| Tovey et al. (2021) (49) | ● | ● | ● | ● | ● | ● | ● | ● |

Legend Critical ● Serious ● Moderate ● Low ● No information ●

Figure 2. Assessment of risk of bias using The Risk Of Bias In Non-randomized Studies of Interventions

were judged as at critical risk of bias (43, 44); six studies (10, 45-49), as at serious risk of bias, and one study, as at moderate risk of bias (50). Details related to quality assessment are shown in Figure 2.

General characteristics of the studies

Of the included studies, six were retrospective in design: one was conducted in Austria (50), three in United States (46-48), one in Germany (10), one in United Kingdoms (49); two were case-reports conducted in Japan (43, 44); one was a prospective, non-randomized study, conducted in Germany (45). Studies' characteristics are shown in Table 2.

Educational strategies analyzed by the studies

Effective educational strategies in reduction of gastrointestinal bleeding, driveline infection and psychological AEs were: 1) *telephone interventions*, alone or within an educational protocol, from three studies (45, 48, 50); 2) *interactive and cloud-based apps*, from four studies (43-45, 49); 3) *"Hands-on" instructions and practical skills demonstration*, alone or within an educational protocol, from three studies (10, 46, 48). Moreover, five studies described the *implementation of a complex, dynamic, holistic, and personalized set of different educational strategies*, to be implemented from the day before hospital discharge, until the follow-up ended, as a multidisciplinary intervention (10, 45-48). Of these, three involved *compliance and psychological interventions* (10, 46, 48). One added to the psychological intervention a *physical reconditioning program* (10). Three studies highlighted the relevance of *regular clinical or home visits* in strengthening educational results (10, 45, 48). All the studies analyzed showed a greater or lesser impact on gastrointestinal bleeding, driveline infection and psychological complications, as described in the following paragraphs.

Educational strategies and complications reduction

Gastrointestinal bleeding

Educational interventions effective in reduction of GIB episodes were defined by three studies (10, 43, 50). The implementation of "*The LAVD@home system*", a cloud information-sharing system, allowed the healthcare professionals (HCPs) to early detect hemorrhage's signs (HCPs), through pictures sent by patients (43). *The intensified follow-up protocol (IFUP) implementation*, composed by multi-disciplinary visits every 4–8 weeks, reinforcing patients' competencies in wound medication, driveline and device management (10) was related with a reduction of major bleedings (including GIB) of 19% ($p=0.01$). *Bi-weekly telephone interventions*, added to usual care, seemed to help the early detection of bleeding episodes (including GIB) (20.8% vs 36.4% of the patients subjected to usual care, $p=0.20$) (50).

Driveline infections

Four studies (10, 43, 44, 50) evaluated the impact of educational interventions in driveline infections prevalence. *The "LAVD@home system"* (43) and the *Social Networking Service (SNS)* (44) allowed patients to share pictures, related to wound site status, to HCPs, that were able to instruct patients in complications occurrence. *Bi-weekly telephone interventions* added to usual care, seemed to help the early detection of driveline infections (33.3% vs. 4.5% of the patients subjected to usual care, $p=0.02$) (50), as *IFUP implementation* (from 22 to 33%, $p=0.2$) (10).

Psychological complications

Five studies (43, 45-47, 49) evaluated the impact of educational intervention in psychological AEs. A *multi-modal protocol*, including a *counselling intervention*, compared to usual care, decreased the

Table 2. Summary of selected studies

| Study title and publication details | Study design | Aim(s) | Country and study period | Participants and inclusion/exclusion criteria | Type and nature of educational intervention | Outcome evaluation methods and time points of outcome assessment | Main results | Study limits |
|---|--|--|-------------------------------------|---|---|--|---|---|
| A multi-modal intervention in management of left ventricular assist device outpatients: dietary counselling, controlled exercise and psychosocial support. Kugler et al. (2012); European Journal of Cardio-Thoracic Surgery (45) | Non randomized, prospective, single center study | To report on <i>multi-modal</i> (nutritional, physical and psychosocial support) <i>intervention's results</i> in terms of body weight, exercise tolerance and psychosocial status | Germany; study period not mentioned | Intervention Group (IGr), n = 34 LVAD patients. Control Group (CGr-usual care), n = 36 LVAD patients. <i>Inclusion criteria:</i> patients followed-up at study center while being on LVAD support; ≥ 18 years old | Individualized intervention: 1) <i>nutrition management:</i> four individual educational sessions during consecutive outpatient clinical visits, written information, and scheduled telephonic follow-up; 2) <i>physical reconditioning program:</i> home-based, smartcard-guided training program, with regular phone calls; 3) <i>psychological counselling:</i> face-to-face contacts. | Body Mass Index (BMI), cardiopulmonary exercise tolerance, and Hospital Anxiety and Depression Scale Short Form (HADS-SF36); assessment at 6 weeks (baseline), and at 6, 12 and 18 months. | 1) Positive effect of nutrition management in BMI control: normal BMI in IGr ($p=0.35$); BMI's increase in CGr ($p=0.05$). 2) Significant differences regarding exercise tolerance in IGr patients ($p=0.04$); 3). A significant increase in anxiety in CGr, shown in psychosocial component HADS SF-36 (IGr: 4.95 ± 0.4 ; CGr: 6.6 ± 0.9 ; $p=0.03$). | Small sample size; limited generalizability of findings; study population treatment with two different pulsatile device types |
| A cloud-based home management system for patients with a left ventricular assist device: a case report. Nomoto et al. (2016); The International Journal of Artificial Organs (43) | Case report | To describe a <i>patient-centered cloud-based home management system</i> | Japan; 2014 | One 64-year-old patient with an LVAD. | LAVD@home system, a cloud computing system which allows patients to register vital signs, pump parameters and driveline status, through images/videos to health-care providers (HCPs) | Vital parameters, driveline exit site's images and text messages; assessment over 305 consecutive days during the study period | 1) Early detection of driveline infection and hemorrhage signs from HCPs; 2) Easy and rapid advice receipt from patients, regarding potentially serious issues, with enhancement of patients' sense of security | Related to case report design |
| Home Medical Care Support for Patients With Left Ventricular Assist Device Using Social Networking Service. Asaka et al. (2017); The Japanese Heart Failure Society (44) | Case report | To describe patients' experiences in <i>Social Networking Service (SNS)</i> 's utilization | Japan; study period not mentioned | 2 LVAD patients, needed treatment for driveline infection site | Patients take wound site status's pictures themselves, sending images to multidisciplinary medical staff, for sharing preventive and treatment strategies with patients | Pictures taken by patients themselves; time points of outcome assessment not mentioned | Enhanced patients' self-monitoring and HCPs' support, to maintain both safety and quality of life. | Related to case report design |

| | | | | | | | | |
|---|---|---|--|---|---|--|--|--|
| <p><i>A Standardized Telephone Intervention Algorithm Improves the Survival of Ventricular Assist Device Outpatients.</i> Schlöghofer et al. (2018); International Center for Artificial Organs and Transplantation and Wiley Periodicals (50)</p> | <p>Retrospective, single center study</p> | <p>To test the effect of telephone interventions performed by VAD Coordinators, in early identification of potential Adverse Events (AEs) and proper interventions</p> | <p>Austria; 2015-2017</p> | <p>IcGr n=25 LVAD patients, CGr n=71 LVAD patients (usual care). <i>Exclusion criteria:</i> death before hospital discharge, heart transplantation before hospital discharge, pediatric patients, follow-up in another center or lasted less than 12 months.</p> | <p>Bi-weekly standardized telephone interventions added to usual care</p> | <p>% of time in therapeutic range (TTR) based on the Rosendaal method (1993); structured inquiry composed by open-ended questions; 2 years after initial discharge</p> | <p>1) Major bleeding (including gastrointestinal bleeding) as the first cause of readmission in 36.4% of CGr (vs. 20.8% in IGr, p=0.20); 2) Driveline infections as the second cause of readmission in 33.3% of IGr (vs. 4.5% in CGr, p=0.02); 3) Hypertension in 31.8% of CGr (vs 9.1% of IGr, p=0.047), as result associated with telephone intervention; 4) Hospital readmission length of 32.9 days in CGr (vs 18.4 days in IGr, p=0.64)</p> | <p>Single center and non randomized study; small sample size</p> |
| <p><i>Ready, Set, Go: How Patients and Caregivers Are Prepared for Self-Management of an Implantable Ventricular Assist Device.</i> Casida et al. (2018) (1); Artificial Organ Research and Development (46)</p> | <p>Retrospective study; multicenter study</p> | <p>To explore the process of preparing patients and caregivers for VAD self-management (SM) before hospital discharge and to describe their experiences of the discharge process.</p> | <p>USA; study period not mentioned</p> | <p>102 VAD patients and 116 care-givers. <i>Patients' inclusion criteria:</i> ≥ 18 years old; educated at ≥ 5th grade; recipients of a continuous flow LVAD as a bridge to transplant or myocardial recovery, or destination therapy; discharged from hospital for at least 1 month; being treated by a VAD center in USA. <i>Caregivers' inclusion criteria:</i> ≥ 18 years old; educated at ≥ 5th grade; caring for patients with continuous flow LVADs at home for a minimum of days a week; caregiving role for at least 1 month at the time of recruitment; caregiver for a VAD patient treated in USA</p> | <p>Discharge preparation for patients and caregivers, as SM education and training, composed by "hands-on" instruction, videos, skill demonstration, and final evaluation quiz; validation of VAD SM competencies; provision of resource materials for the daily VAD SM</p> | <p>A self-administered demographic questionnaire and a VAD Hospital Discharge Survey; 2 months after hospital discharge</p> | <p>Patients and caregivers satisfaction related to discharge process > 70%, with no relation to educational sessions length; skill demonstration and quiz defined as appropriate VAD educational methods</p> | <p>Self-selection bias; self-administered questionnaires; convenient sampling; relatively restricted and minimal validity of the survey; online recruitment; no standard training/assessment curriculum across VAD centers</p> |

Table 2. Summary of selected studies (continued)

| Study title and publication details | Study design | Aim(s) | Country and study period | Participants and inclusion/exclusion criteria | Type and nature of educational intervention | Outcome evaluation methods and time points of outcome assessment | Main results | Study limits |
|--|------------------------------------|---|--------------------------|--|---|---|---|--|
| <i>Advancing the Science of Self-Management in Adults With Long-Term Left Ventricular Assist Devices.</i> Casida et al. (2018) (2); International Center for Artificial Organs and Transplantation and Wiley Periodicals (47) | Retrospective study | To test the applicability of the <i>individual and family self-management theory (IFSMT) to self-management (SM)</i> in LVAD patients | USA; 2015 | 100 LVAD patients, aged ≥ 18 years old; with a minimum education of 5 th grade; recipients of a second- or third-generation; with a LVAD as a bridge to transplant, myocardial recovery, or as destination therapy; with hospital discharge of at least 1 month | IFSMT included: evaluation of SM risks and protective factors, SM process; proximal outcome (actual engagement, as treatment adherence, or direct result of SM), and distal outcomes (as quality of life). | LVAD Patient Self-Efficacy Scale; LVAD Patient Home Management Adherence Scale; World Health Organization Quality of Life –BREF 20 | Direct influence of LVAD care self-efficacy and SM and LVAD care adherence, parallel to the IFSMT's assumptions, albeit with a small effect (beta=0.02) | Small sample size; secondary data analyses; observational research design; convenient sampling method used in the parent study; utilization of self-administered questionnaires. |
| <i>Implementation of an intensified outpatient follow-up protocol improves outcomes in patients with ventricular assist devices.</i> Hamed et al. (2019); Clinical Research in Cardiology (10) | Retrospective, single center study | To evaluate the effect of an <i>intensified follow-up protocol (IFUP)</i> on survival rates and VAD-associated complications. | Germany; 2015 | 57 VAD patients, that received the implantation at study center between February 2013-December 2017, were discharged home after VAD implantation and followed-up at study center. 30 patients were followed up according to the IFUP, compared to 27 patients in the pre-IFUP era. | IFUP was composed by: multidisciplinary (including VAD-coordinator) and scheduled visits every 4-8 weeks; defined protocol for routine diagnostics and test; intensified anticoagulation management; optimized wound and driveline management (repeated guidance every visit); reinforcement of patients' competencies on device management | Laboratory parameters, heart rate, blood pressure, medication and the occurrence of complications; 1 year after device implantation | IFUP patients showed: 1) A Major bleeding (including gastrointestinal bleeding) reduction from 19 to 0% (p=0.01); 2) A Driveline Infection increment from 22 to 33% (p=0.2); 3) An optimal HF medication use (p.value<0.02); 4) Not significant difference related to postoperative hospital stay length (day) (p=0.1); 5) Not relevant differences in MAP measurement (MAP <80 mmHg in 60% in both groups, p=0.3) | Single center, retrospective study; small sample size; inclusion of patients who survived to hospital discharge; missed quantification of other possible factors affecting survival; reports limited to the first year of follow-up. |

| | | | | | | | | |
|---|---|--|--|---|--|---|--|----------------------|
| <p>Protocol To Prevent 30 Day Readmission In Patients Who Receive A Heartmate LVAD with Pre Op Interventions Profile 1 – 3. Alam et al. (2020); Journal of Cardiac Failure (48)</p> | <p>Retrospective, single center study</p> | <p>To report on the results of a three phases protocol in terms of 30 days readmission rate</p> | <p>USA; study period not mentioned</p> | <p>IGr n=16 (LVAD implantation in the study center in 2019). CGr n= 27 (LVAD implantation in the study center 2017-2018; usual care).</p> | <p><i>Three phases rotocol: 1-at implantation:</i> multidisciplinary rounds led by LVAD coordinator; practical education on sterile techniques; review of medication plan the day prior to discharge, with patient and family; test from LVAD coordinator; <i>2-post-discharge:</i> phone call assessment the day after discharge; LVAD emergency management education; coordination of rehabs/home care agencies; weekly labs and phone calls to evaluate clinical, lab parameters and VAD equipment; <i>3-post-discharge:</i> scheduled multidisciplinary visits</p> | <p>Clinical and LVAD related characteristics (INTERMACS score; cardiomyopathy; pump) within 30 days from hospital discharge</p> | <p>Reduced hospital readmission patients within 30 days in IGr group (0% vs 29.6% in CGr)</p> | <p>Not mentioned</p> |
| <p>A Review of Ventricular Assist Device Patients Compliance in INR Reporting Using a New App-Based Program Compared with Telephone Surveillance. Tovey et al., (2021); The Journal of Heart and Lung Transplantation (49)</p> | <p>Retrospective, single center study</p> | <p>To compare the INR app-based program and the conventional method of telephone reporting, in improving patient's compliance and satisfaction</p> | <p>UK; study period not mentioned</p> | <p>IGr n = 17 patients. CGr n = 35 patients (usual care)</p> | <p>IGr and CGr reported their INR values, between 8am and 1pm on the day requested, via app or telephone to the VAD nurse specialist.</p> | <p>INR; satisfaction survey; compliance's assessment over a 15-day period</p> | <p>Increased compliance reported in IGr (96.5% vs 87% in CGr) ; high satisfaction level reported in relation to INR app (93.75% of respondent patients preferred using the app). Patients with previous issues with compliance preferred the app, defined from all patients easy to use and saving time.</p> | <p>Not mentioned</p> |

anxiety level (Mean and Standard Deviation at “SF-36 psychosocial component scores”: 4.95 ± 0.4 in Intervention Group; 6.6 ± 0.9 in Control Group; $p = 0.03$) (45). “*The LAVD@home system*” (43), such as other app-based systems (49), enhanced patients’ sense of security (43), satisfaction and compliance (49), because of the possibility of getting HCPs’ advice in potential troubles (43). A *complex educational process*, composed by “hands-on” instruction, videos, skill demonstration, evaluation quiz about competencies, and provision of materials for VAD management increased satisfaction levels in patients and caregivers (for 75 and 76% respectively), regardless of the duration of the educational session (46). An *approach involving patients and families (individual and family SM theory-IFSMT) in SM process*, evaluating its risks and protective factors, its proximal (e.g. treatment adherence) and distal outcomes (e.g. quality of life), increased sense of security and reduced anxiety, albeit with a small effect ($\beta=0.02$) (47).

Additional results from the studies analyzed

Some studies (10, 48, 50) reported results related to hospital readmissions length, mainly caused by bleeding (as GIB) and infection (51). Neither *bi-weekly telephone interventions* (50), nor *IFUP* (10) led to significant differences in hospital readmissions length, compared with usual care (18.4 days in vs 32.9 days, $p=0.64$; 55 days vs 43 days, $p=0.1$, respectively). A *three phase protocol*, including practical skills demonstration, hands on and verbal instruction, weekly telephonic calls, and clinical scheduled visits was related with absence of observed readmissions within 30 days, compared to usual care (0% vs 29.6%) (48). Moreover, some educational strategies seemed to have impact on patients’ compliance towards medications’ assumption. In fact, IFUP led to a *relevant increase in the use of optimal HF medication* (p . ranged between 0.0001 e 0.02) (10) and

the use of an *international Normalized Ratio (INR)-app* led to a compliance 9.5% greater, compared to usual care (telephone reporting) (49).

Discussion

This systematic review aimed to summarize current best evidences on educational strategies towards patients after VADs’ implantation, in home-care setting, in terms of driveline infections, gastrointestinal bleeding and psychological AEs’ reduction. The included studies showed heterogenous results that could be due to differences in study design, sample size, recruitment criteria, outcome evaluation method, follow-up duration, social and familiar patients’ support, patients’ health-literacy, demographic characteristics, severity of illness and sociocultural factors.

In relation to *gastrointestinal bleeding*, the studies analyzed showed effectiveness of complex and multidisciplinary educational protocol (10), telephonic interventions (50) and apps (43), with statistical significance only related to the complex and multidisciplinary educational protocol ($p=0.01$) (10).

In relation to *driveline infections*, two case reports (43, 44) showed the effectiveness of apps, with limits related to their low generalizability. It is interesting to note that patients subjected to a complex and multidisciplinary educational protocol (IFUP) (10), and to telephonic interventions (50), showed an increment in driveline infections despite only one study reported statistically significant results (50). These data were probably influenced by a more vigilant patient surveillance, rather than a failure of the management protocol (52).

In relation to *psychological complications*, several studies highlighted a relevant (45-47) and statistically significant impact (45) of a multimodal approach (composed by verbal and/or hands-on instructions, videos, practical demonstration). SM skills,

when enhanced, were beneficial not only in psychological terms (47), but also in AEs early identification and proper care (23). So, results related to SM could be interpreted as influential in proper clinical terms too, as happened for results related to QOL, a relevant predictor of treatment success and survival (53). Regularity in clinical or home visits, oriented to strengthen educational results, seemed to be relevant for AE's reduction (10, 45, 48).

The effectiveness of educational interventions in *hospital readmission rate reduction* was not clear; the positive impact of telephonic interventions (50) and of a complex multidisciplinary educational protocol (10) was not statistically significant. Moreover, three studies (10, 48, 50) between the nine analyzed, highlighted the relevance of the *VAD Coordinator*, a nurse highly specialized in VADs device management and care, providing SM support in outpatient setting. In fact, despite the relevance of a multidisciplinary team in curing and caring of such complex and frail patients, the VAD coordinator seemed to be essential for a proper management and an optimal coordination of the different services for VAD patients (10, 48, 50). The results derived from this systematic review are aligned with the most recent literature's findings related to HF (54-57). In details, the national and international HF Guidelines indicate as main component of HF treatment programs their multiprofessionalism: HCPs contribute, to the extent of their specific competencies (10), to the education of patients and caregivers, through face-to-face consultations, delivery of educational materials, telemonitoring and follow-up, to be implemented at inpatient and outpatient level (54, 55). Specifically, telephonic consultations, along with home visits (57, 58), and application of educational material (58), to be adopted through a personalized approach (56), were described by literature and by this systematic review, as relevant and effective educational approaches. Between these educative

strategies, telephone consultation, the use of apps and the application of educational material, could be considered feasible, because low-cost, and easy-to-apply, and could help to build a constructive interaction with patients, highly recommended by the literature (59). Since the literature showed that the results obtained from educational strategies in chronic patients could be difficult to maintain over time (60), the direct involvement of patients could help in increasing bond and trust between patients, family members and health professionals (57), premise of a successful educational strategy (59). On the other hand, telephonic interventions and apps could be effective toward patients/caregivers without cognitive impairment, able to use electronic devices, and, therefore, to understand the HCPs' advice and recommendations, highlighting the importance to invest in enhancing digital skills of patients and caregivers. Considering that a low disease-literacy is recognized as associated with a low self-care, readmissions and mortality (61, 62), efforts should be done towards the application of effective, feasible and up-to-date educational strategies. However, whether it could be deduced that the most effective educational strategies for VADs patients are similar to the ones applied to patients affected by HF, the results derived from this study and from recent literature (57) must be analyzed with caution, because evidence related to these themes are poor and scarce.

Overall assessment of quality

Overall, based on ROBINS-I risk of bias tool, the included studies demonstrated low scores across the considered criteria, showing a serious risk of bias, except for two, that received a critical risk of bias (43, 44), and one study (50), that received a moderate score. However, considering the few studies available in literature about this relevant theme, they were included in the review. A limitation of most of the studies concerned the adequacy of the study sample;

in fact, in one study only it was clearly described (45). Other risks concerned the studies' design (retrospective studies, case studies, integrative review, non-randomized studies): none of the studies included was an RCT. Moreover, outcomes measurements were not always clearly defined (43, 44).

Review strengths and limitations

This systematic review has several limits that need to be addressed. The first is due to the limited number of original researches conducted on the topic. The second one is related to the design of the included studies that limit the results generalizability: six retrospective studies (10, 46-50); two case reports (43, 44); one prospective, non-randomized study (45). Moreover, the studies analyzed were not fully comparable, in terms of tools for measuring the effects of educational interventions (questionnaires, vital parameters, scales, indexes, scores and surveys), sample sizes (related to study's designs), and of countries where the studies have been conducted. Moreover, it is worth pointing out that the clinical practice should be analyzed in the light of social-cultural factors (63), not assessable in this context. Afterwards, some databases (Cinhal and PsycInfo) were not consulted, so many eligible studies were not evaluated. However, the methodology related to the research conduction was clearly defined, to allow reproducibility and limit potential biases.

Implications for practice

Education offered by HCPs towards VAD patients can be considered an effective non pharmacological treatment to early detect and treat AEs. In details, composite, multiprofessional and technology-based educational strategies, with focus on theoretical and practical components of device management, seem to be associated with better outcomes. Their implementation involves strong collaboration between team members, availability of appropriate

technological tools, integration with patients and caregivers. Educating chronic patients, such as VADs patients, is today relevant and complex, presupposing a pathway tailored to a holistic dimension. This systematic review could be considered as a start-point, oriented to raise awareness of health systems to invest in the key-points highlighted: personalized care, multiprofessional and coordinated approach and technological support. However, more powerful studies, based on experimental designs, should be conducted to gain results' generalizability, and to make it possible to conduct correlation analysis with socio-demographical characteristics.

Conclusions

This review aimed to evaluate and summarize the current best evidence on educational strategies towards patients after VADs' implantation, in home-care setting, oriented to reduction of driveline infections, gastrointestinal bleeding, and psychological effects (three of the most frequent VAD complications). Despite the results' heterogeneity and limited statistical significance, we can assume that a complex, multimodal, holistic, and multidisciplinary intervention, of moderate intensity and regularly conducted, is crucial to correctly manage VAD system and prevent AEs (10, 43-50), regardless of its duration (46). The educational intervention should be oriented to develop patients' knowledge (22), skills (27), and psychological well-being (43, 45-47, 49), positively influencing patients' compliance towards medications' assumption (10). Further researches are needed to achieve a greater awareness about effective educational strategies, timing, actors and related roles, in order to optimize caring and curing time.

Funding: this work did not require funding

Conflict of interest: none declared.

Data availability: the data supporting the findings of this systematic review are from previously reported studies and datasets, which have been cited within the article. Further supporting data are available from the corresponding author upon reasonable request.

Conflict of interest: none declared.

Trial and Protocol Registration: PROSPERO registration ID: CRD42023398368 https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=398368.

Riassunto

Interventi educativi domiciliari per prevenire le complicanze nei pazienti portatori di dispositivi di assistenza ventricolare: una revisione sistematica

Premessa. L'impianto di dispositivi di assistenza ventricolare è l'unica alternativa efficace al trapianto cardiaco nei pazienti con insufficienza cardiaca cronica, in termini di sopravvivenza e qualità di vita. Tuttavia, il posizionamento di tali dispositivi può portare a complicanze fisiche e psicologiche, potenzialmente prevenibili, soprattutto nel lungo termine, attraverso l'educazione del paziente. Questa ricerca si proponeva di riassumere le migliori evidenze attuali sulle strategie educative nei confronti dei pazienti sottoposti all'impianto di dispositivi di assistenza ventricolare, in ambito di assistenza domiciliare, per ridurre le principali complicanze loro correlate, ovvero infezioni legate ai dispositivi stessi, emorragie gastrointestinali e complicanze psicologiche.

Disegno di studio. Revisione sistematica.

Metodi. La selezione di titoli e abstract, lo screening dei testi integrali, la valutazione della qualità degli studi e l'estrazione dei dati hanno seguito il protocollo PRISMA e il Cochrane Handbook for Systematic Reviews of Interventions. La ricerca è stata condotta tramite consultazione di banche dati quali Medline, Scopus, EMBASE e Web of Science, nel periodo compreso tra marzo 2022 e dicembre 2022, in relazione ad articoli in lingua inglese, a partire da elaborazione di stringhe di ricerca e da precisi criteri di inclusione ed esclusione.

Risultati. Dei 1231 articoli identificati, ne sono stati selezionati 9, in quanto coerenti con i criteri di inclusione definiti. Gli interventi educativi più efficaci nei confronti di pazienti portatori di dispositivi di assistenza ventricolare erano di tipo individualizzato, erogati da gruppi multidisciplinari coordinati da una figura professionale esperta nella gestione di tali dispositivi, e regolarmente condotti. In particolare, interventi educativi complessi e multimodali, comprensivi di interventi telefonici e app, sono risultati adatti a prevenire e ridurre le emorragie gastrointestinali e le infezioni legate ai

dispositivi di assistenza ventricolare. Strategie educative basate su istruzioni verbali, dimostrazioni pratiche, tecnologie innovative, e sull'attivo coinvolgimento dei familiari/caregivers, si sono invece dimostrate efficaci nel prevenire le complicanze psicologiche.

Conclusioni. È necessario investire tempo e risorse nell'educazione dei pazienti con dispositivi di assistenza ventricolare, dato il rilevante impatto dell'esito educativo sulla riduzione delle complicanze. Inoltre, l'erogazione di interventi educativi orientati al benessere psicologico del paziente, ha esiti positivi anche sulla compliance dei pazienti, con conseguenti risvolti clinici promettenti. Tuttavia, sono necessarie ricerche più approfondite, orientate a supportare i professionisti a elaborare piani educativi efficaci per pazienti così fragili e complessi.

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Corresponding author: Giancarlo Cicolini - PhD-MSc-RN, Professor of Nursing, Department of Precision and Regenerative Medicine and Ionian Area - (DiMePRE-J), University of Bari "Aldo Moro", Bari, Italy
e-mail: giancarlo.cicolini@uniba.it

ORCIDiS:

G. Franceschini: <https://orcid.org/0009-0005-4958-2640>

G. Talevi: <https://orcid.org/0009-0000-2708-4951>

S. Maso: <https://orcid.org/0009-0003-1271-8060>

D. Comparcini: <https://orcid.org/0000-0003-3622-6370>

G. Cicolini: <https://orcid.org/0000-0002-2736-1792>

V. Simonetti: <https://orcid.org/0000-0002-7185-4850>