Coronavirus disease 2019 (COVID-19) radically modified the organization of healthcare systems with shutdown of routine activities and outpatient clinics. Herein, we report our institutional experience with a Telemonitoring and Care Program (TC-Program) to monitor and support left ventricular assist device (LVAD) patients during COVID-19 outbreak. This single-arm cohort study analyzed 156 patients who entered the TC-Program at our institution between April and August 2020. The TC-Program was based on routine phone calls to patients and a 24/7 emergency line. In November 2020, patients were asked for feedback on the TC-Program and checked for survival, transplant, or explant. The primary endpoint was the rate of TC-Program-driven interventions. Patients (males: 82.8%) were 61 years old (interquartile range [IQR]: 53.0–67.5) and on LVAD support for 1,266 days (IQR: 475–2,211). Patients were included in the TC-Program for a median time of 99 days (min:15, max:120) and received a median number of six phone calls (min:1, max:14). Twenty-three patients (14.7%) were referred for clinical evaluation after phone contact. Two patients (1.27%) were diagnosed with COVID-19: one of them died after intensive care, and one remained pacemic symptomatic and recovered. Three patients asked to exit the program considering it not useful while the others gave high rates in terms of usefulness (median: 9, IQR: 8–10), information (median: 9, IQR: 8–10), good medical care (median: 9, IQR: 8–10), and psychologic support (median: 8, IQR: 7–10). A TC-Program based on the four ICSA principles (Inform, Care, Support, and Adapt) is feasible in LVAD patients and can be rapidly implemented during the COVID-19 pandemic. ASAIO Journal 2021; 67:973–981

Key Words: left ventricular assist device, mechanical circulatory support, heart failure, COVID-19, coronavirus, telemonitoring

Coronavirus disease 2019 (COVID-19) has been declared a pandemic on March 11, 2020 with a devastating effect on more than 200 countries. Its virulence, vector of transmission (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]), and its uncertainty have been exceptional and a real challenge for healthcare systems.1,2 The sudden need for a high amount of intensive care unit (ICU) beds and dedicated wards led to a drastic reduction of routine clinical activities to prioritize COVID-19 patients. In parallel, nonurgent outpatient visits and elective hospital admissions have been suspended to reduce the infection risk in patients and healthcare professionals. Accordingly, routine controls of patients supported with left ventricular assist devices (LVADs) have been canceled. Nevertheless, LVAD patients are in constant need of a tight connection with their referring centers to ensure an early diagnosis of LVAD-related complications and an adequate social and psychologic support for patients and families.3

Patients affected by COVID-19 share the same risk factors as patients suffering from cardiovascular diseases. Indeed, the effects of a SARS-CoV-2 infection involve the cardiac and vascular systems through imbalanced inflammatory and coagulation patterns.3,4 For these reasons, LVAD patients have been considered with particular attention during the COVID-19 outbreak to maintain their close connection to referring centers. Telemedicine and remote monitoring based on digitalized systems can surely help with this matter,5–12 especially when coordinated by specialists able to provide emotional support and triage medical problems.5 Notwithstanding, full digital telemanagement of LVAD patients is not yet available in every center.

Herein, we report our institutional experience with a Telemonitoring and Care Program (TC-Program) designed explicitly for LVAD patients during COVID-19 outbreak.

Methods

Study Design and Population

This single-arm cohort study analyzed prospectively collected data of patients who entered the LVAD TC-Program at Hannover Medical School (Hannover, Germany) from April 1,
2020 to August 1, 2020. All candidates were adults supported with a ventricular assist device (VAD) and included in our routine follow-up program. Data collection and analysis were approved by the institutional review board (Study ID number: 9326_BO_K_2020). Patients who prospectively entered the LVAD program at the study institution signed a consent form for data use for research purposes at the moment of LVAD implantation. Patients lacking the abovementioned consent were excluded from the study.

Demographic and clinical variables were collected. The primary endpoint was the rate of TC-Program-driven interventions. Secondary endpoints were the rate of COVID-19 diagnosis, rate of LVAD adverse events defined according to the interagency registry of mechanically assisted circulatory support (INTERMACS) definitions, patient’s compliance to the program and patient’s satisfaction.

The Telemonitoring and Care Program for Left Ventricular Assist Device Patients During Coronavirus Disease 2019 Outbreak

The TC-Program was developed at our institution during the first COVID-19 wave in spring 2020. Each LVAD patient routinely followed up at our center was initially screened through an intake phone call at the beginning of the COVID-19 outbreak, directly after the LVAD outpatient clinic shut-down on March 18, 2020. This first screening verified the homecare situation, recent or current hospital admissions, and open clinical problems, such as severe infections undergoing specific treatments. Moreover, the degree of patient’s education was tested to confirm his/her ability to independently and correctly perform driveline dressings, battery and controller exchange, blood pressure, fluids, and anticoagulation self-management. If the patient was deemed suitable for the TC-Program, a trained VAD coordinator established the first specific phone contact to educate the patient on COVID-19 guidelines regarding social behaviors and check the patient’s general status and LVAD parameters. At the same time, each patient was provided with surgical masks and driveline dressing kits through home delivery.

Subsequently, each patient was contacted through routine phone calls to identify a possible COVID-19 case or LVAD complication, educate on COVID-19 updates, answer patients’ questions, and provide psychologic support. The phone call was mainly developed based on a specific questionnaire (Supplementary Materials: Routine Questionnaire, Supplemental Digital Content 1, http://links.lww.com/ASAIO/A688) to investigate COVID-19 and heart failure (HF) symptoms. Simultaneously, the VAD-coordinator recorded all LVAD-specific data like flow, speed, power consumption, international normalized ratio values, weight, and status of the driveline site. If deemed necessary, the patient was asked to send a picture of the driveline site through e-mail or smartphone. According to the national guidelines, if a suspect of SARS-CoV-2 infection was identified, the patient was referred to a COVID-19 dedicated team. In case of a suspected LVAD complication, the appropriate action was taken. In parallel, a 24/7 LVAD emergency line managed by VAD coordinators was established as referral point for every patient requiring urgent assistance.

The full monitoring program with routine calls was suspended after reopening of the routine outpatient clinic on August 1, 2020. The 24/7 emergency line remained active also after the first COVID-19 outbreak. The phone monitoring program was considered concluded at the time of the first regular outpatient visit after the first COVID-19 outbreak or earlier in case of a referral to hospital/outpatient clinic, death, explant, or cardiac transplant. In November 2020, each patient was asked for feedback on the previous monitoring program (Supplementary Materials: Feedback Questionnaire, Supplemental Digital Content 1, http://links.lww.com/ASAIO/A688). Patients who received less than three phone calls were not asked to give feedback on the whole program. Follow-up for survival, transplant, explant, adverse events, or COVID-19 was completed in November 2020.

Statistical Analysis

Categorical and continuous variables were summarized as frequencies with percentages and median with interquartile range (IQR). All continuous variables were assessed for normal distribution using the Kolmogorov–Smirnov test. Missing values were not imputed. Analyses were performed using SPSS version 26.0 (IBM, Armonk, New York) and Prism version 8.0 (GraphPad Software, Inc., San Diego, CA).

Results

Baseline Characteristics and Inclusion in the Monitoring Program

A total of 156 patients supported with ongoing VAD therapy were included in the TC-Program (Table 1) over a total number of 170 patients followed up in our center. Patients living abroad (n = 3) were omitted. Further 11 patients were excluded because of prolonged hospitalization or chronic driveline infections requiring specific treatments.

The median age of the included population in March 2020 was 61 years (IQR: 53.0–67.5) and 82.8% of patients were males. The primary underlying HF etiology was dilated cardiomyopathy (49.0%), followed by ischemic cardiomyopathy (43.3%). The majority of patients were supported with a left ventricle assistant device (n = 155, 99.4%) and one patient was implanted with a right ventricle assistant device (RVAD) based on a diagnosis of arrhythmogenic right ventricular cardiomyopathy. At the moment of inclusion in the monitoring program, the median duration of LVAD support in the population was 1,266 days (IQR: 475–2,211). Significant comorbidities associated with higher cardiovascular or infection risks were chronic kidney disease (n = 33, 21.0%) and diabetes (n = 38, 24.2%). Overall, during the whole LVAD support time (127,715 patient/years), 50.3% of the patients were diagnosed with a driveline infection, 14.0% of patients experienced a neurologic event, and 10.8% (n = 17) of patients had a pump thrombosis which led to pump exchange in 15 patients (9.6%). Surprisingly, at the beginning of the COVID-19 pandemic, only 47.8% (n = 75) of patients declared a flu vaccination received in the months before.

Clinical Outcomes

Patients were included in the monitoring program for a median time of 99 days (min: 15, max: 120) and received a median number of phone calls of six (min: 1, max: 14). All
patients included in the TC-Program were asked about any typical COVID-19 or HF symptoms (Supplemental Materials, Supplemental Digital Content 1, http://links.lww.com/ASAIO/A688). The most frequently reported symptom was increased fatigue (n = 30, 19.1%), followed by headache (n = 26, 16.6%) and shortness of breath (n = 24, 15.3%). Eighteen (11.5%) patients reported having a persistent running nose, 12 (7.3%) suffered from limb pain, 11 participants (7.0%) had a persistent cough, and 10 (6.4%) suffered from diarrhea. Only five patients (3.2%) reported fever, and three (1.9%) reported a suspected loss of smell and taste (Table 2). Two patients included in the TC-Program were diagnosed with COVID-19, confirmed by laboratory tests. One of them died due to severe respiratory failure after admission to ICU at a peripheral hospital while the other one was referred to the general practitioner, experienced 3 days of mild respiratory symptoms and rapidly recovered. No other patient resulted positive at the SARS-CoV-2 test.

Ten more patients initially included in the program died before the end of the follow-up time. Two patients died due to lung carcinoma with metastasis; another patient suffered massive bleeding due to spleen rupture. Three patients died at home due to sudden death, and other three died at home under palliative care for deterioration of their health status and refusal of further therapies. One patient was admitted to the hospital due to kidney failure and infection and died during the same hospital admission. The median time between inclusion in the TC-Program and death was 183 days (min: 20, max: 263). Six more patients dropped out of the program because of heart transplantation after a median time of 146 days (min: 33, max: 152) after inclusion in the TC-Program. In all cases, transplantation was successful with a mean postoperative hospital stay of 33 days.

Overall, TC-Program-driven interventions were needed in 23 patients (14.7%) who were referred 28 times for further clinical evaluation after phone contact with the VAD coordinator. Over these 28 interventions, 13 patients were referred to the hospital (n = 10), outpatient clinic (n = 2), or general practitioner (GP; n = 1) due to LVAD related problems. Among these 13 patients experiencing LVAD complications, eight patients were referred for a driveline infection, two for nasal bleeding, one for gastrointestional bleeding, and one for fatigue due to anemia. One more patient was referred to hospital because of progressing dyspnea and decomposition due to a stenosis of the outflow graft requiring surgery. Cardiac decompensation or renal failure not due to LVAD complications occurred in six patients who were referred to the hospital (n = 3), outpatient clinic (n = 1), or GP (n = 2). Finally, seven patients were referred to the hospital (n = 6) or the general practitioner (n = 1) for other clinical reasons such as a checkup after a fall at home, respiratory infection, urinary infection, minor stroke, stenosis of the renal artery, and hematuria.

Evaluation of the Monitoring System

Over the 156 patients initially included in the monitoring system, 113 completed the feedback questionnaire. Eight patients were not asked to evaluate the program since they received three or fewer phone calls. Three patients asked to leave the program considering it not useful and refused to complete the feedback questionnaire. Six patients were admitted to hospital at the time of the feedback evaluation and further nine patients were not reachable by phone call after three attempts.

On average, the program received high evaluation rates from most patients, as reported in Figure 1. It was considered an excellent alternative to the standard outpatient clinic visits during the COVID-19 pandemic (median rate: 9, IQR: 8–10) and its usefulness was rated on median as nine (IQR: 8–10). Similar rates were assigned for the completeness of given information
the subjective feeling of adequate understanding of information (median: 9, IQR: 8–10), and the personal satisfaction about received information and advice (median: 9, IQR: 8–10). Most of the patients were satisfied with the medical and nursing management in this program’s context (median: 9, IQR: 8–10). Slightly lower rates were assigned to the questions investigating the psychologic support (median: 8, IQR: 7–10) and the feeling of being safer when included in the TC-Program (median: 8, IQR: 7–9). The majority of patients justified these slightly lower rates attributing a more assertive role to their families than the VAD coordinators in terms of psychologic support. All patients except nine correctly received the surgical masks and driveline dressing kits through home delivery.

**Discussion**

This study represents the first investigation demonstrating the feasibility, efficacy, and versatility of a Telemonitoring and Care Program for LVAD patients during the COVID-19 outbreak in Europe. The presented TC-Program was able to detect the need for urgent referral to further clinical evaluation in 14.7% of patients, identified a 1.27% rate of COVID-19 infections in 156 LVAD recipients, offered information and psychologic support with positive patients’ feedbacks and correctly provided surgical masks and driveline dressing kits through home delivery for 94% of patients. Moreover, commonly available technologies such as phone calls allowed the VAD coordinators to quickly reach and include most patients, avoiding any socioeconomic or educational disparities.

**COVID-19 and Left Ventricular Assist Devices**

Patients suffering from end-stage HF have been considered as a high-risk group for COVID-19 based on their many comorbidities and the specific interaction between SARS-CoV-2 and the cardiovascular system. Indeed, COVID-19 may act with direct cardiotoxicity, dysregulation of the renin-angiotensin-aldosterone-system, endothelial damage and thrombo-embolism, immune dysregulation, cytokine storm and oxygen demand-supply mismatch due to profound hypoxemia. Among HF patients, LVAD recipients are subjected to variations of the standard cardiovascular physiology due to a nonpulsatile blood flow, exposure of the blood to artificial surfaces, and risk of hemorrhagic and thrombotic events. Moreover, they suffer from compromised cellular immunity and cytokine imbalances leading to an increased susceptibility to infections.

Nevertheless, the interaction between LVAD and SARS-CoV-2 is still unclear. In our TC-Program, we monitored 156 LVAD patients from April to November 2020 during the first wave of COVID-19 outbreak, and we detected two COVID-19 cases (1.27%) with opposite outcomes: one patient required intensive care and eventually died while the second one remained paucisymptomatic and recovered. In this same period, Germany detected 1,076,553 COVID-19 cases and 16,248 COVID-19 related deaths in a population of 83 million people. The observed rate of SARS-CoV-2 infection in our LVAD population is thus comparable to the national statistics while the low incidence prevents every consideration on COVID-19 related outcomes in this specific population. Indeed, reports on SARS-CoV-2 and LVADs are still rare, and outcomes are conflicting, as depicted in Table 3. Few authors reported the development of a severe cytokine storm whereas Mahmood et al. hypothesized that LVAD might induce a protective immunomodulatory effect in COVID-19 disease. Birati et al. described a total of 40 LVAD patients diagnosed with SARS-CoV-2 in nine North American hospitals with a 20% fatality rate. Overall, based on the current paucity of data regarding LVADs and SARS-CoV-2, a structured and extensive monitoring program for this specific population is highly recommended and advocated.

The SARS-CoV-2 infection has been a concern for clinicians caring for LVAD patients since the very beginning. However,
Table 3. Published Reports of COVID-19 Infection in Patients With Ongoing LVAD Support

<table>
<thead>
<tr>
<th>Author</th>
<th>Cases (n)</th>
<th>Age (Years)</th>
<th>Sex</th>
<th>Device, Implant Date</th>
<th>Comorbidities</th>
<th>COVID-19 Symptoms</th>
<th>Therapeutic Approach</th>
<th>Clinical Course</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birati et al.</td>
<td>20</td>
<td>56 (IQR: 14 46–68)</td>
<td>females</td>
<td>HeartMate II (n = 5), HVAD (n = 9), HeartMate3 (n = 26) Implantation time: 16 months (IQR: 6–38)</td>
<td>ICM (n = 9), DM (n = 18), atrial fibrillation (n = 15), COPD (n = 3), history of stroke (n = 10)</td>
<td>Fever (n = 16), cough (n = 17), shortness of breath (n = 15), fatigue (n = 15), change in taste/smell (n = 9), nausea/vomiting/diarrhea (n = 10)</td>
<td>Supplemental oxygen (n = 8), mechanical ventilation (n = 6), hydroxychloroquine (n = 6), convalescent plasma (n = 3), tocilizumab (n = 2), remdesivir (n = 1), lepnomavir (n = 1), dexamethasone (n = 1), non-dexamethasone steroid (n = 6)</td>
<td>Death (n = 8), still hospitalized at the time of report (n = 3), discharged at home (n = 15), ongoing symptoms at home (n = 2), never hospitalized (n = 14)</td>
<td></td>
</tr>
<tr>
<td>Chau et al.</td>
<td>1</td>
<td>70</td>
<td>Male</td>
<td>HeartMate3, 2016</td>
<td>ICM, stage 3 CKD, obesity</td>
<td>Fever, flank pain, hematuria, myalgia, diarrhea, dyspnea</td>
<td>Hydroxychloroquine, tocilizumab (8mg/kg, 2 doses), mechanical ventilation, vasopressors, dexamethasone</td>
<td>Cytokine storm, severe ARDS, myocardial injury, vasodilatory shock</td>
<td>Expired on day 8</td>
</tr>
<tr>
<td>Dan et al.</td>
<td>2</td>
<td>74, 64</td>
<td>1 male, 1 female</td>
<td>Pt1: HVAD, 2017 Pt2: HVAD, 2012</td>
<td>Pt1: ICD, CKD, DM, morbid obesity, peripheral vessel disease, DLI Pt2: ICM, COPD, anemia, GI bleedings</td>
<td>Pt1: cough, shortness of breath, Pt2: cough, rhinorrhea, Pt1: NV, cefotaxime, spiramycin, oseltamivir, stop VKA/start parental heparin Pt2: supplemental oxygen, stop VKA/start parental heparin</td>
<td>Pt1: still hospitalized at the time of report (1 month) but recovering Pt2: discharged home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hodges et al.</td>
<td>1</td>
<td>44</td>
<td>Male</td>
<td>HeartMate3, 2019</td>
<td>ICM</td>
<td>Flu-like symptoms, intermittent fevers, dyspnea on exertion</td>
<td>Ceftriaxone, hydroxychloroquine → piperacillin-tazobactam, vancomycin, tocilizumab mechanical ventilation, norepinephrine</td>
<td>Elevated inflammatory markers, suspected arterial thrombosis, nasopharyngeal bleeding, hematuria, retroperitoneal hematoma</td>
<td>Recovery, discharged home on day 31</td>
</tr>
<tr>
<td>Korada et al.</td>
<td>1</td>
<td>48</td>
<td>Female</td>
<td>HeartMate II, n.r.</td>
<td>Hypertension, Type 2 DM, stage 3b CKD, morbid obesity</td>
<td>Fatigue, myalgia, intermittent productive cough, headache, fever</td>
<td>Lopinavir-ritonavir</td>
<td>Regular</td>
<td>Recovery, discharged home on day 8 → readmitted on day 37 for postviral subacute thyroiditis Paucisymptomatic at the time of report</td>
</tr>
<tr>
<td>Loforte et al.</td>
<td>1</td>
<td>55</td>
<td>Male</td>
<td>HVAD, 2016</td>
<td>DCM</td>
<td>Dry cough, PET-CT: multilobar and subpleural ground-glass opacities, consolidation</td>
<td>None</td>
<td>Regular</td>
<td>Recovery, discharged to nurse facility on day 5 Pt1: recovery, discharged home on day 8 Pt2: still in hospital at the time of report</td>
</tr>
<tr>
<td>Mahmood et al.</td>
<td>1</td>
<td>54</td>
<td>Male</td>
<td>HeartMate 3, 2017</td>
<td>ICM, HIV on ART, Type 2 DM, history of Kaposi's sarcoma, recurrent thrush</td>
<td>Fever, myalgia, cough, dyspnea</td>
<td>Hydroxychloroquine</td>
<td>Regular</td>
<td>Recovery, discharged to nurse facility on day 5 Pt1: recovery, discharged home on day 8 Pt2: still in hospital at the time of report</td>
</tr>
<tr>
<td>Piperata et al.</td>
<td>2</td>
<td>61, 72</td>
<td>Both males</td>
<td>Pt1: HeartMate3, 2020 Pt2: Jarvik 2000, 2016</td>
<td>Pt1: DCM, Type 2 DM, COPD, CKD, atrial flutter, CRT Pt2: ICM, Type 2 DM, CKD, atrial fibrillation, dyslipidemia, previous endocarditis, stroke previous, lymphocytic myocarditis, CKD on dialysis</td>
<td>Pt1: peripheral edema, severe dyspnea and increased weight, fever Pt2: fever, driveline infection</td>
<td>Pt1: dobutamine, levosimendan, furosemide Pt2: levofloxacin for driveline infection</td>
<td>Pt1: regular, Pt2: regular</td>
<td></td>
</tr>
<tr>
<td>Sikachi et al.</td>
<td>1</td>
<td>51</td>
<td>Female</td>
<td>HeartMate3, 6 months before</td>
<td>Increased chronic left pleural effusion*</td>
<td>Left-sided video-assisted thoracic surgery for decortication*</td>
<td>Acute fibrinous pleuritic*</td>
<td>N.r.</td>
<td></td>
</tr>
</tbody>
</table>

(Continued)
<table>
<thead>
<tr>
<th>Author</th>
<th>Cases</th>
<th>Age (Years)</th>
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<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sobol et al.</td>
<td>6</td>
<td>Range: 30−79</td>
<td>4 males, 2 females</td>
<td>HeartMate II (n = 2), HeartMate3 (n = 3), HVAD (n = 1)</td>
<td>ICM (n = 1), NICM (n = 5), hypertension (n = 4), DM (n = 2), obesity (n = 1), CKD on dialysis (n = 1)</td>
<td>Dyspnea and cough (n = 4), fever (n = 2), diarrhea (n = 1)</td>
<td>Hydroxychloroquine (n = 3), high-dose corticosteroids (n = 2), interleukin-1 receptor antagonist (n = 1), mechanical ventilation (n = 2), new dialysis (n = 1)</td>
<td>Severe cytokine storm (n = 1), asystolic arrest (n = 1), Fontan thrombosis (n = 1)</td>
<td>Death (n = 2), recovery (n = 4).</td>
</tr>
<tr>
<td>Singh et al.</td>
<td>1</td>
<td>66</td>
<td>Male</td>
<td>HeartMate II, n.r.</td>
<td>ICM, hypertension, atrial flutter, ischemic stroke</td>
<td>Fever, cough, and shortness of breath</td>
<td>Hydroxychloroquine 600mg BID, oseltamivir (75mg BID → lopinavir/ritonavir 400/100mg BID) → hydroxychloroquine 200mg BID, mechanical ventilation, vasopressors, continuous renal replacement therapy.</td>
<td>Progressive hypotension, right ventricular failure, acute kidney failure, ARDS, acalculous cholecystitis, septic shock.</td>
<td>Still in hospital and critically ill at the time of report.</td>
</tr>
</tbody>
</table>

*No further COVID-specific symptoms or treatments were reported.

ARDS, acute respiratory distress syndrome; ART, antiretroviral Therapy; BID, twice daily; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; DCM, dilative cardiomyopathy; DJI, driveline infection; DM, diabetes mellitus; GI, gastro-intestinal; HIV, human immunodeficiency virus; HVAD, HeartWare ventricular assist device; ICD, implantable cardioverter-defibrillator; ICM, ischemic cardiomyopathy; IQR, interquartile range; LVAD, left ventricular assist device; NICM, nonischemic cardiomyopathy; NIV, noninvasive ventilation; n.r., not reported; PET-CT, positron emission tomography–computed tomography; Pt, patient; VKA, vitamin K antagonist.

Several approaches to the same problem have been proposed with most of them concentrating on the use of technology and implemented in a few days to guarantee a prompt recognition of LVAD-related complications, misdiagnosis of COVID-19, impaired social and psychological well-being for patients and families. To address this problem, we developed a telemonitoring and care program during COVID-19, dedicated to COVID-19 patients. As a result, the tight connection between LVAD patients and their referring center became reduced to allow for a higher availability of intensive care beds. Moreover, due to the general reorganization in case of complications, as well as LVAD implantations, the modification of the general reorganization of healthcare systems and the modification of social behaviors related to COVID-19 prevention. On one hand, the routine outpatient visits have been suspended to prevent the spread of SARS-CoV-2 among healthcare professionals and patients. On the other side, the measures that patients with chronic conditions who are at higher risk for COVID-19, should practice social distancing may have consequences for those with chronic conditions who are at higher risk for COVID-19, may have consequences for those who are at higher risk for COVID-19, may have consequences for those who are at higher risk for COVID-19. 

The TC-Program was developed based on planned phone calls and a 24/7 emergency LVAD line. While this organization allowed each patient to take active contact, it also developed with the implantation of the telephone when the patient was regularly reached out by the VAD coordinator who could check those patients who were afraid of a phone call made this TC-Program affordable and rapidly adaptable to each patient and LVAD center, including those with smaller LVAD programs. Indeed, the flexibility of this TC-Program could potentially allow its implementation in different cultures and in healthcare systems, also outside Europe. The TC-Program was developed based on planned phone calls and a 24/7 emergency LVAD line. While this organization allowed each patient to take active contact, it also developed with the implantation of the telephone when the patient was regularly reached out by the VAD coordinator who could check those patients who were afraid of a phone call made this TC-Program affordable and rapidly adaptable to each patient and LVAD center, including those with smaller LVAD programs. Indeed, the flexibility of this TC-Program could potentially allow its implementation in different cultures and in healthcare systems, also outside Europe.

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approach positively (Figure 1) and correlated it to their feeling of safety and support, especially in the lack of an established and supportive social network. On the other hand, those already included in a stable, familiar environment judged their families as their primary source of psychologic support during the lockdown, and they identified the TC-Program as integration to their social network.

Finally, the combination of routine calls and emergency phone lines guaranteed the continuity of care to most LVAD patients. The TC-Program was able to detect the need for further clinical referral in 14.7% of included patients, based on specialized VAD coordinators’ triage skills. Patients judged this system as a valid and useful alternative to routine outpatient visits and expressed positive feedbacks on how their clinical problems were addressed. This care management’s vital point was the dynamic interaction among VAD coordinators, general practitioners, home care services, peripheral hospital, and implanting center. Indeed, several patients were referred to GPs and peripheral hospitals when the detected problem was not requiring access to the referral center. In this way, LVAD patients were prevented from entering the implanting center, an extensive tertiary care hospital dealing with COVID-19 patients. At the same time, this allowed our tertiary care hospital to preserve free beds and create new COVID-19 isolated wards to prioritize COVID-19 patients. Moreover, our implanting center serves for a large territory, and the close network with GPs and peripheral hospitals allowed patients to be treated without long travels, when applicable.

Figure 2. The ICSA principles. Schematic showing the ICSA approach to a sustainable and adaptable outpatient care system during the COVID-19 pandemic. ICSA, Inform, Care, Support, and Adapt.
Resources Management and Program Implementation

A possible limitation of this TC-Program is the demand for specialized personnel. To correctly manage this large TC-Program including 156 patients and, in parallel, run the in-hospital clinical activities, five VAD coordinators were involved. No new VAD coordinator was hired for the TC-Program, but the time management was radically modified. During the first COVID-19 wave, the VAD coordinators’ team was divided into two in-hospital working groups which alternated themselves every 7 days. This strategy ensured all essential services for in-hospital patients and guaranteed a lower infection risk for healthcare professionals due to a 50% reduction in their in-hospital working time. Simultaneously, the team members working from home were able to perform the planned phone calls through mobile phones provided by the hospital. This dynamic management made this TC-Program very versatile and adaptable. This TC-Program can be considered an excellent answer to face the new needs of the COVID-19 era and a starting point for every clinic interested in developing telemonitoring strategies. However, it will surely benefit from a future integration with smart phone-transmitted data, virtual driveline site evaluations, use of fully implantable sensors, and other smart technologies able to reduce each VAD coordinator’s workload and ensure continuous monitoring of patients’ vital parameters. Nevertheless, based on the positive feedback received by this TC-Program, the ICSA principles should be considered as the fundamental goals of future telemonitoring programs with adequate integration of clinical and psychologic aspects.

Limitations

This study was a retrospective review of prospectively collected data. Therefore, the number of patients and study power is limited, and further generalizations should be considered carefully. Moreover, no historical control group was planned, and a comparison with patients followed-up without TC-Program was not possible. Indeed, based on the wide network with peripheral hospitals, many patients used to be referred directly to their closest hospital after GP consultation for minor or not LVAD-related problems. These accesses to peripheral hospitals or GPs were mainly self-reported by patients at the time of their visit to our outpatient clinic and a structured data collection able to capture all these events was not in place before the TC-Program. The study was performed at a single high-volume LVAD center with previous experiences on telemonitoring techniques. Thus, results might have been affected by the institutional experience. Moreover, the TC-Program did not include our patients living abroad due to the differences in national COVID-19 guidelines.

Conclusion

This study demonstrates the feasibility, efficacy, and versatility of a Telemonitoring and Care Program for LVAD patients based on the four ICSA principles: Inform, Care, Support, and Adapt (Figure 2). This complete but straightforward TC-Program based on regular phone calls, a 24/7 LVAD emergency line and sprawling network of VAD coordinators, GPs, home care services, peripheral and tertiary hospitals received a positive endorsement from patients from both clinical and psychologic point of view. Our TC-Program allowed follow-up of LVAD patients during the COVID-19 lockdown, confirming that telemedicine is becoming an essential tool in contemporary medicine. Future developments of this program with integrated smart technologies and sensors need to be investigated in the upcoming future.

References


