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ORIGINAL ARTICLE
Heart Failure

Usefulness of the LAVITA Telemonitoring System in Patients With Heart Failure

— A Feasibility Study —

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Background: Heart failure (HF) hospitalization is increasing in Japan's aging population. Current guidelines recommend daily biometric monitoring for patients with HF to facilitate early clinical intervention. However, promoting patient self-management remains insufficient. Therefore, we assessed the usefulness of the LAVITA telemonitoring system, which automatically obtains and stores the biometric data of patients with HF via wireless devices.

Methods and Results: This prospective, single-arm, multicenter cohort study enrolled patients with HF. Patients were introduced to the LAVITA telemonitoring system and trained to measure body weight, blood pressure, pulse rate, oxygen saturation (SpO_2), physical activity with activity trackers (AT), and electronic patient-reported outcomes (ePRO). The primary outcome was the measurement rate of each cetology at 9–12 weeks post-discharge. The secondary outcomes included the subgroup analyses by age, sex, and left ventricular function. Thirty patients continued to use the system at home. The measurement rates of patient data were as follows: body weight 92.4% (interquartile range [IQR] 83.3–97.8%); blood pressure 95.6% (IQR 84.8–98.5%); pulse rate 96.5% (IQR 86.5–98.8%); SpO_2 93.1% (IQR 76.6–97.9%); AT 88.4% (IQR 31.3–98.5%); and ePRO 76.9% (IQR 26.4–95.9%). The subgroup analysis did not significantly differ.

Conclusions: The LAVITA telemonitoring system had high measurement rates for the biometric data of patients with HF, including elderly patients. Hence, it can possibly improve patient self-management and facilitate early clinical intervention.

Key Words: Heart failure; Self-management; Telemonitoring system

Cardiac disease remains the second leading cause of mortality in Japan, with heart failure (HF) as a primary driver. The aging population has led to a steady increase in the HF hospitalization, with approximately 10,000 new cases recorded annually, projecting a nationwide increase in the number of patients with HF to approximately 1.3 million by 2030.[1,2] Factors such as poor adherence to dietary salt intake and fluid restrictions, inconsistent medication usage, care-related problems and excessive physical activity significantly influence HF exacerbation. This phenomenon leads to delays in essential treatment and increased mortality and hospitalization risks.[3–5]

Effective HF management requires active patient involvement and empowerment.[6–9] The current guidelines recommend that patients with HF should engage in daily monitoring of biometric data to facilitate early clinical intervention before disease progression.[10,11] However, efforts that promote patient self-management have been significantly insufficient.[12] This phenomenon is caused by knowledge deficits, inadequate social and clinical support, challenges in personal relationships,[13–15] and inaccuracies in home-based vital sign measurements.[16,17]

Information and communication technology has been proposed as a valuable tool for enhancing management of HF.[18] However, some studies did not show the efficacy of telephone- or internet-based interventions in reducing HF hospitalization among patients with chronic HF.[19,20]

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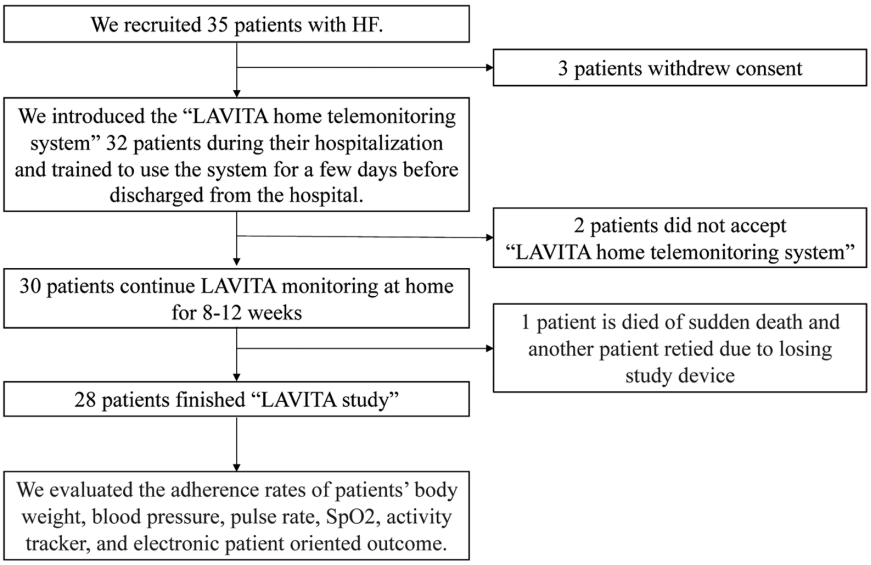

Figure 1. Study flowchart. HF, heart failure.

Patient engagement is important for the successful adoption of novel healthcare technologies.[21] The low utilization rates of these systems, often attributed to technical difficulties experienced by patients, are a significant barrier.[19,22] Therefore, the system's usability among technically unskilled individuals should be improved.[22]

The present study aimed to assess the efficacy of the LAVITA home telemonitoring system, which incorporates automatic vital sign recording via connected devices and allows data review by both patients and medical staff via an internet interface. The LAVITA home telemonitoring system does not require manual data recording and can be viewed anywhere with smartphones that they usually use via Wi-Fi. This system has been proven to reduce the burden of measuring vital signs when used on hospitalized patients with infection. We hypothesized that this system's user-friendly design could enhance patient proficiency, thereby improving adherence to vital and biometric data collection by reducing the burden on patients with HF.

Methods

Study Design and Overview

This prospective, single-arm, cohort study enrolled patients with HF who provided written informed consent from 2 facilities. Acute HF was defined as emergency hospitalization due to worsening HF. Meanwhile, chronic HF was defined as scheduled hospitalization due to HF. The LAVITA telemonitoring system was introduced to the participants, and comprehensive instructions were provided (**Figure 1**). The patients were trained to connect devices to a smartphone app via Bluetooth for data input and visualization. Biological data were measured and transmitted during hospitalization to a secured cloud system. The patients and research team could access these data via smartphones or personal computers (PCs). We instructed patients to measure their biometric data at least once at a specific time each day. Patients who were capable continued to use the system at home for 8–12 weeks post-discharge. Data were input into a dedicated smartphone or PC daily, and were presented to patients during regular outpatient visits. The equipment was reviewed and collected at the 12-week follow up, with provisions for replacement in case of malfunction.

The present study was conducted in accordance with the Declaration of Helsinki, the Ethical Guidelines for Medical and Biological Research Involving Human Subjects, and other applicable guidelines in Japan. The study protocol was approved by the Institutional Review Board of Kanazawa University and was registered with the University Medical Information Network Clinical Trial Registry (UMIN-CTR ID: UMIN000045259).

LAVITA Home Telemonitoring System

The LAVITA system was developed by Nihon Kohden Corp. (Tokyo, Japan), and used Wi-Fi networks for data upload. The daily biometric data of patients were recorded using a digital blood pressure monitor (UA-651BLE; A&D Medical, Tokyo, Japan), digital weighing scale (UC-352BLE; A&D Medical, Tokyo, Japan), pulse oximeter (KM-350/C; Kenzmedico Co., Ltd, Saitama, Japan), activity tracker (UW-204NFC; A&D Medical, Tokyo, Japan), and the LAVITA gateway (Nihon Kohden, Tokyo, Japan). Data were transmitted via Bluetooth through the LAVITA gateway to a secured cloud server. These data could be accessed by the patients and research team via smartphones or PCs (**Figure 2**). The patients received system training for >15 min before discharge, with additional support provided for those experiencing difficulties.

Outcomes

The primary outcome was the measurement rate of body weight, systolic and diastolic blood pressure, pulse rate, oxygen saturation (SpO_2), physical activity, which was assessed using activity trackers (AT), and electronic patient-reported outcome (ePRO) at 9–12 weeks post-discharge. The AT was used to measure the number of steps,

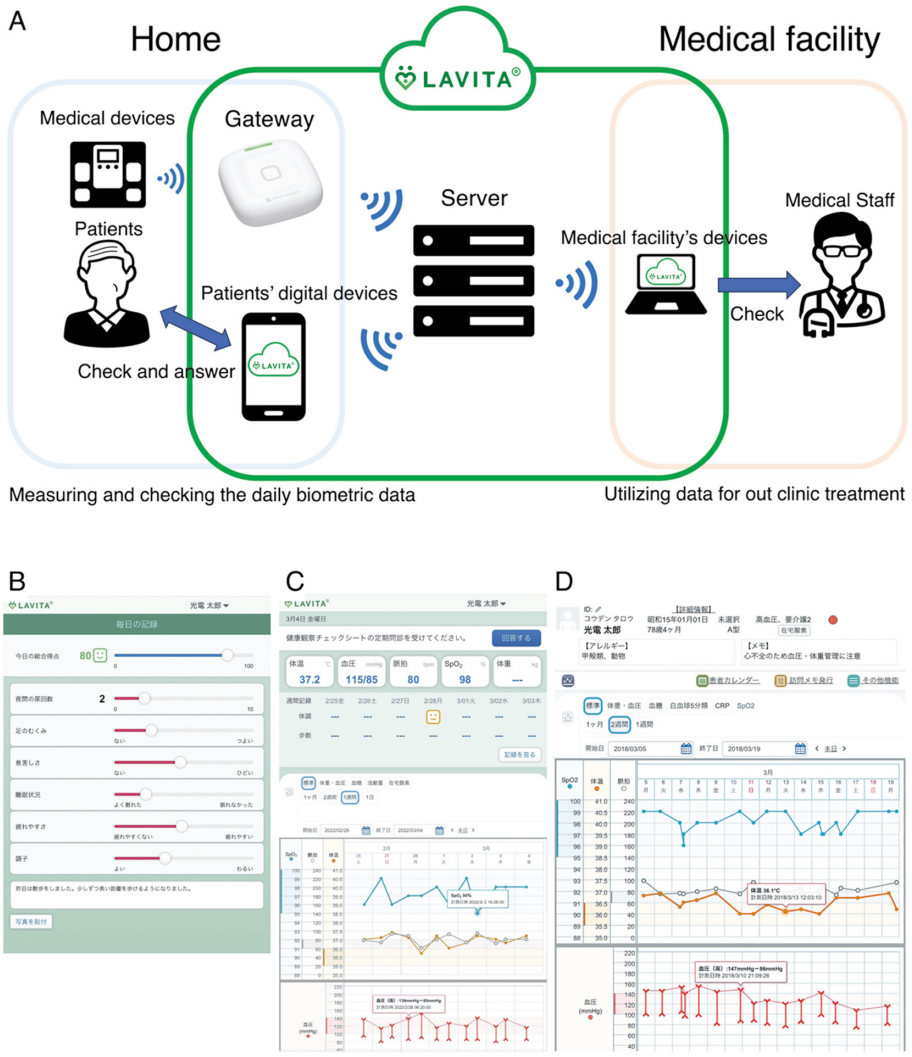

Figure 2. The LAVITA home telemonitoring system. Patients recorded their daily biometric data using the IoT devices connected to Wi-Fi networks for data upload. The data were transmitted to the cloud server via Bluetooth through the LAVITA gateway. Medical staff and patients can then access the data remotely via the LAVITA web application using their smartphones or personal computers (PCs). This system facilitates outpatient treatment and monitoring. (**A**) Overview of the LAVITA home telemonitoring system. (**B**) Heart failure (HF)-related questionnaire of electronic patient-reported outcome. (**C**) Viewing screen for patients via smartphone or PCs. (**D**) Viewing screen for medical staff via PCs.

walking time, and metabolic equivalent of tasks per hour during ambulation. The ePRO comprised 7 daily items assessing the overall physical condition, nocturia frequency, leg edema, dyspnea, sleep quality, fatigue, and general physical status via the LAVITA web application. The measurement rate was defined as the percentage of days with at least 1 data recording. The secondary outcomes included the results of the subgroup analyses of biometric data measurement rates, which focused on usability challenges for elderly individuals and were stratified according to age, sex, and left ventricular ejection fraction (reduced, mid-range, or preserved).

Patient Selection

The inclusion criteria were patients aged ≥20 years, HF hospitalization, ownership of a smartphone or PC with access to the LAVITA web application, ability to set Wi-Fi connectivity, and capacity to coordinate daily physiological data collection at home. The diagnosis of HF was inclusive of all conditions, regardless of left ventricular ejection fraction. The exclusion criteria included inability to use a smartphone, failure to use the system appropriately during hospitalization, lack of a home Wi-Fi environment, and cases considered inappropriate by the investigator team.

Statistical Analysis

Data were presented as median (interquartile range [IQR]) for primary outcomes, and frequency (%) for categorical variables. Descriptive statistical analyses were performed to summarize the collected biometric data and measurement rates. The Wilcoxon rank-sum test was used to per-

Table. Baseline Characteristics of the Participants

	All participants
n	30
Age (years)	65.3±12.3
≥65	20 (67)
Sex, male	18 (60)
Smoker	
Current	8 (27)
Former	7 (23)
Never	15 (50)
Heart failure	
Chronic	20 (67)
Acute	10 (33)
LVEF	
HFrEF	8 (27)
HFmrEF	6 (20)
HFpEF	16 (53)
Comorbidity	
Coronary artery disease	18 (60)
History of CABG	1 (3)
History of PCI	17 (97)
Hypertension	17 (52)
DM	5 (17)
Dyslipidemia	19 (63)
Atrial fibrillation	8 (27)
Medication	
ARNI/ARB/ACE-I	26 (87)
β-blocker	22 (73)
SGLT2 inhibitor	11 (37)
MRA	12 (40)

Unless indicated otherwise, data are presented as n (%), or median±SD. ACE-I, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor/neprilysin inhibitor; CABG, coronary artery bypass grafting; HFmrEF, heart failure with mid-range ejection fraction; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonist; PCI, percutaneous coronary intervention; SGLT2 inhibitor, sodium glucose cotransporter 2 inhibitor.

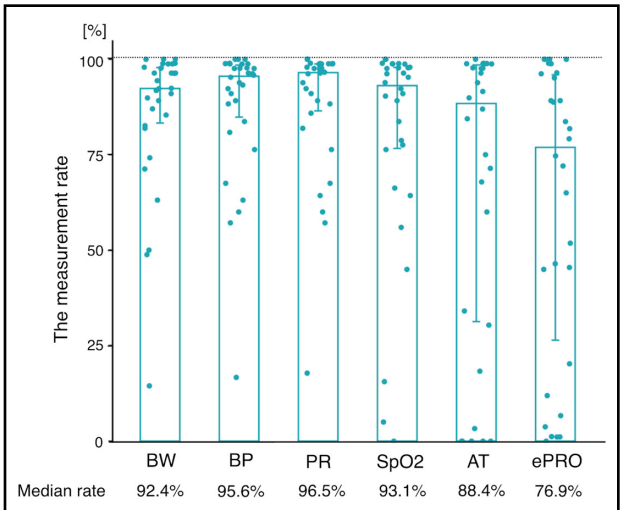

Figure 3. Bar plots showing the median measurement rates of each biometric component, with error bars indicating the interquartile range. The dot plots represent the measurement rates for individual patients. The median measurement rate of body weight (BW), home blood pressure (BP), pulse rate (PR), and SpO_2 were consistently high. In contrast, the median measurement rates for activity tracker (AT) data and electronic patient-reported outcome (ePRO) were low.

form between-group comparisons. A P value of <0.05 was considered statistically significant. The R software version 4.2.0 (R Foundation for Statistical Computing, Vienna, Austria) was used for all analyses.

Results

Patient Enrollment and Characteristics

Initially, 35 patients with HF were recruited. Three patients withdrew their consent, and 2 did not accept the LAVITA system during hospitalization. A total of 30 patients was included in this analysis.

Table shows the baseline characteristics of the participants. The median age of patients was 65.3±12.3 years, with two-thirds (n=20 [67%]) aged ≥65 years. In total, 18 (60%) patients were men. Chronic HF exacerbation was the primary cause of hospitalization (n=20 [66.7%]), and the remaining patients were admitted due to acute decompensated HF. Furthermore, 16 (53.3%) patients presented with HF with preserved ejection fraction (HFpEF), 7 (23.3%) with HF with mid-range EF (HFmrEF), and 7 (23.3%) with HF with reduced EF (HFrEF). Eighteen (60%) patients had a history of coronary artery disease, all of whom had undergone revascularization. The average follow-up period in the results is 83.2±10.4 days. The average number of daily measurements was 1.1±0.5 times in a day.

During the study period, 1 patient with stage D HF experienced sudden cardiac death. However, the patient was able to measure biometric data until the day before the event. Another patient was admitted for a hospitalization unrelated to HF; the patient used the monitoring device during hospitalization but forgot to take it home on discharge, resulting in withdrawal from the study. There were no HF-related hospitalizations during the observation period.

Primary Outcome

During the study period, all biometric components had consistently high measurement rates (**Figure 3**). The median measurement rates for body weight and home blood pressure were 92.4% (IQR 83.3–97.8%) and 95.6% (IQR 84.8–98.5%), respectively. The median measurement rate for pulse rate was 96.5% (IQR 86.5–98.8%), and the SpO_2 measurements were completed 93.1% of the time (IQR 76.6–97.9%). The measurement rates for AT data and ePRO were 88.4% (IQR 31.3–98.5%) and 76.9% (IQR 26.4–95.9%), respectively. The overall average rate of telemonitoring biometric data acquisition across all parameters was 78.1% (IQR 70.4–98.7%), which indicated a high level of patient engagement with the system.

Secondary Outcomes

In terms of sex, male patients achieved a slightly higher acquisition rate than female patients (92.4% vs. 81.2%; P=0.346; **Figure 4A**). Non-significant age-related differences were also observed, with individuals aged ≥65 years

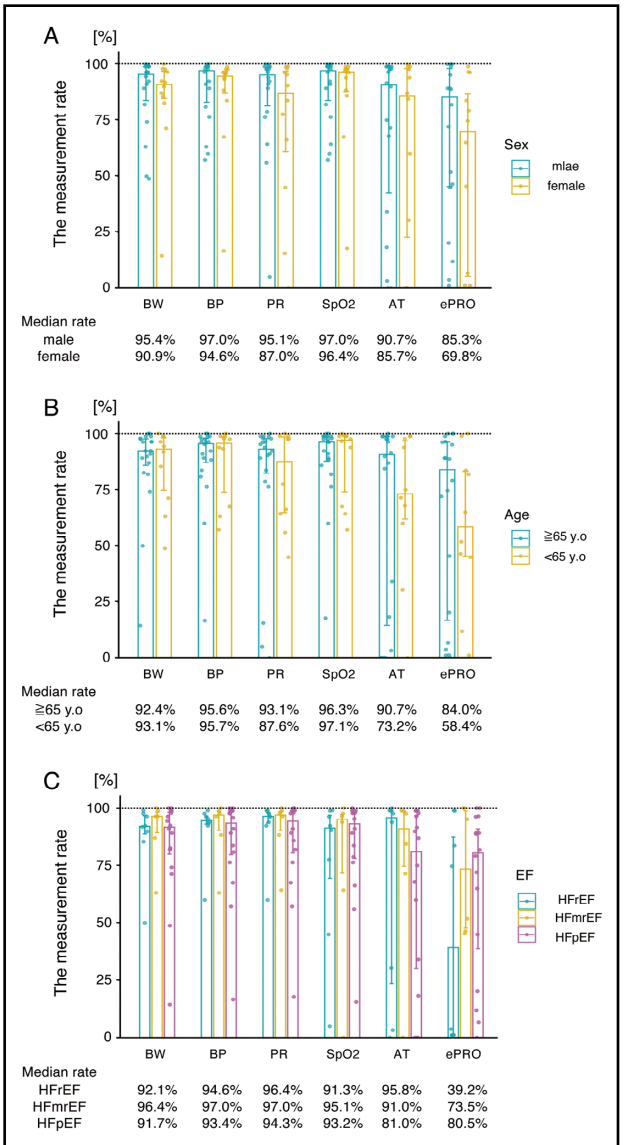

Figure 4. Subgroup analysis of measurement rates. (**A**) Stratification according to sex. No significant differences were observed between male and female patients. (**B**) Stratification according to age: ≥65 vs. <65 years. Patients aged <65 years had lower median measurement rates for AT and ePRO data than those aged ≥65 years. However, the results did not significantly differ between the 2 age groups. (**C**) Stratification according to ventricular function. Although the ePRO measurements varied, there were no statistically significant differences among the categories. The bar plots, error bars, and abbreviations in **Figure 4** are similar to those in **Figure 3**.

having a higher acquisition rate than those aged <65 years (90.2% vs. 84.0%; P=0.746; **Figure 4B**).

Further analysis according to HF categories, which were based on left ventricular EF, did not show significant differences. However, the acquisition rates varied across different biometric parameters (**Figure 4C**). Patients with HFrEF achieved an acquisition rate of 92.1% for body weight measurements. Meanwhile, patients with HFmrEF and HFpEF achieved acquisition rates of 96.4% and 91.7%, respectively. The blood pressure measurements presented with similar patterns, with acquisition rates of 94.6%, 97.0%, and 93.4% for patients with HFrEF, HFmrEF, and HFpEF, respectively. Interestingly, the ePRO completion rates varied more substantially across these groups, with rates of 39.2%, 73.5%, and 80.5% in patients with HFrEF, HFmrEF, and HFpEF, respectively.

Discussion

This study evaluated the measurement rate of home monitoring data in elderly patients with HF using the LAVITA home telemonitoring system. The following results were obtained. First, the measurement rates of 4 key biometric data (body weight, blood pressure, pulse rate, and SpO_2) were favorable. Second, the LAVITA home telemonitoring system could be used regardless of age. However, individual- and equipment-specific variations in measurement rates were observed. Third, some patients exhibited significantly low measurement rates for AT and ePRO. Hence, although the overall adherence to the telemonitoring system was high across various patient subgroups, engagement with specific components might vary based on patient characteristics and HF classification.

Furthermore, our study yielded the following findings. First, the acquisition rate of physiological data using the LAVITA home telemonitoring system was generally good, with median measurement rates among outpatients >90% for body weight, blood pressure, pulse rate, and SpO_2. This result is favorable compared with that of previous studies, which showed rates of <50% in patients who measured their weight regularly,[23] and up to 45% in patients who either did not use or inadequately used the assigned remote monitoring systems.[19] Although direct comparisons are limited by different study designs, the observed measurement rates are considered favorable.

Second, the results between individuals aged ≥65 years and those aged <65 years were comparable. Thus, even elderly individuals could effectively use remote monitoring devices and access their data online, often with family support. Previous research has emphasized the importance of user-friendly, intuitive systems for patients with low technical skills.[24] The LAVITA system's design, which primarily reflects biometric data obtained via measurements (except for AT and ePRO), may have decreased technical issues.[20] In addition, the involvement of caregivers, which is associated with improved HF management, may have contributed to the system's adherence.[25,26]

Third, the measurement rates of AT and ePRO were relatively lower than those of other biometric data such as body weight and blood pressure. This disparity could be caused by technological unfamiliarity leading to usage interruptions, particularly for AT, which requires continuous wear.[27] Recent studies have emphasized the potential of wearable AT for evaluating daily activity levels, which indicates that alternative devices might improve usability and measurement rates.[28] Moreover, the lower ePRO completion rates may reflect the additional burden of actively engaging with the web application, which can be particularly challenging for elderly patients. ePRO has been satisfactory in long-term decision-making for patients with HF.[29] However, our limited instruction time during hospitalization might have contributed to these suboptimal completion rates. The brevity of training could have resulted in reduced motivation and familiarity with the ePRO component, thereby ultimately affecting patient engagement.

Furthermore, several issues regarding compliance with digital devices were identified. Factors such as technical challenges, lack of motivation and acceptance, resistance among elderly or less tech-savvy patients, privacy concerns, and the need for ongoing support and training can affect system usability.[30–32] Our study showed the difficulty of maintaining device use at home and the need for strategies that can ensure consistent data recording.

Study Limitations

The strength of this study lies in its study design, which used a telemonitoring system, thereby showing that patients with HF, including those who are elderly, could generally use these devices effectively. However, this study also had several limitations. Selection bias could have existed due to the study's single-arm design and the exclusion of patients who did not accept the system during hospitalization. In addition, technical issues such as Bluetooth connectivity problems, network issues, battery life, and equipment malfunctions might have contributed to decreased measurement rates, as described in a previous study.[33] We only evaluated adherence with vital and biometric data collection, not early detection of worsening HF. Further research is considered necessary to demonstrate that self-monitoring of HF has an impact on early detection of HF and improvement in the prognosis.

Conclusions

The LAVITA telemonitoring system had a promising capability for acquiring good-quality biometric data from patients with HF, including those with advanced age. Hence, it can possibly enhance daily HF management after hospitalization. Nevertheless, future research should focus on optimizing user engagement, particularly for the AT and ePRO components, and addressing technical challenges to improve overall system efficacy.

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Disclosures

The present study was conducted under a collaborative research agreement with Nihon Kohden Corporation, which provided a joint research grant. The authors declare that although Nihon Kohden Corporation supported this study, the authors had full independence in reporting the study results.

IRB Information

The study protocol was approved by the Medical Ethics Committee of Kanazawa University and was registered with the reference number 2021-010 (713688).

Data Availability

The clinical and biometric data collected during this study are not publicly available due to patient privacy concerns and ethical considerations inherent in this research.

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