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RESEARCH ARTICLE

Physician-directed patient self-management in heart failure using left atrial pressure: Interim insights from the VECTOR-HF I and IIa studies

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Aims Haemodynamic monitoring using implantable pressure sensors reduces the risk of heart failure (HF) hospitalizations. Patient self-management (PSM) of haemodynamics in HF has the potential to personalize treatment, increase adherence, and reduce the risk of worsening HF, while lowering clinicians' burden.

Methods and results The VECTOR-HF I and IIa studies are prospective, single-arm, open-label clinical trials assessing safety, usability and performance of left atrial pressure (LAP)-guided HF management using PSM in New York Heart Association class II and III HF patients. Physician-prescribed LAP thresholds trigger patient self-adjustment of diuretics. Primary endpoints include the ability to perform LAP measurements and transmit data to the healthcare provider (HCP) interface and the patient guidance application, and safety outcomes. This is an interim analysis of 13 patients using the PSM approach. Over 12 months, no procedure- or device-related major adverse cardiovascular or neurological events were observed, and there were no failures to obtain measurements from the sensor and transmit the data to the HCP interface and the patient guidance application. Patient adherence was 91.4%. Using PSM, annualized HF hospitalization rate significantly decreased compared to a similar period prior to PSM utilization (0 admissions vs. 0.69 admissions over 11.84 months, $p = 0.004$). At 6 months, 6-min walk test distance and the Kansas City Cardiomyopathy Questionnaire overall summary score demonstrated significant improvement.

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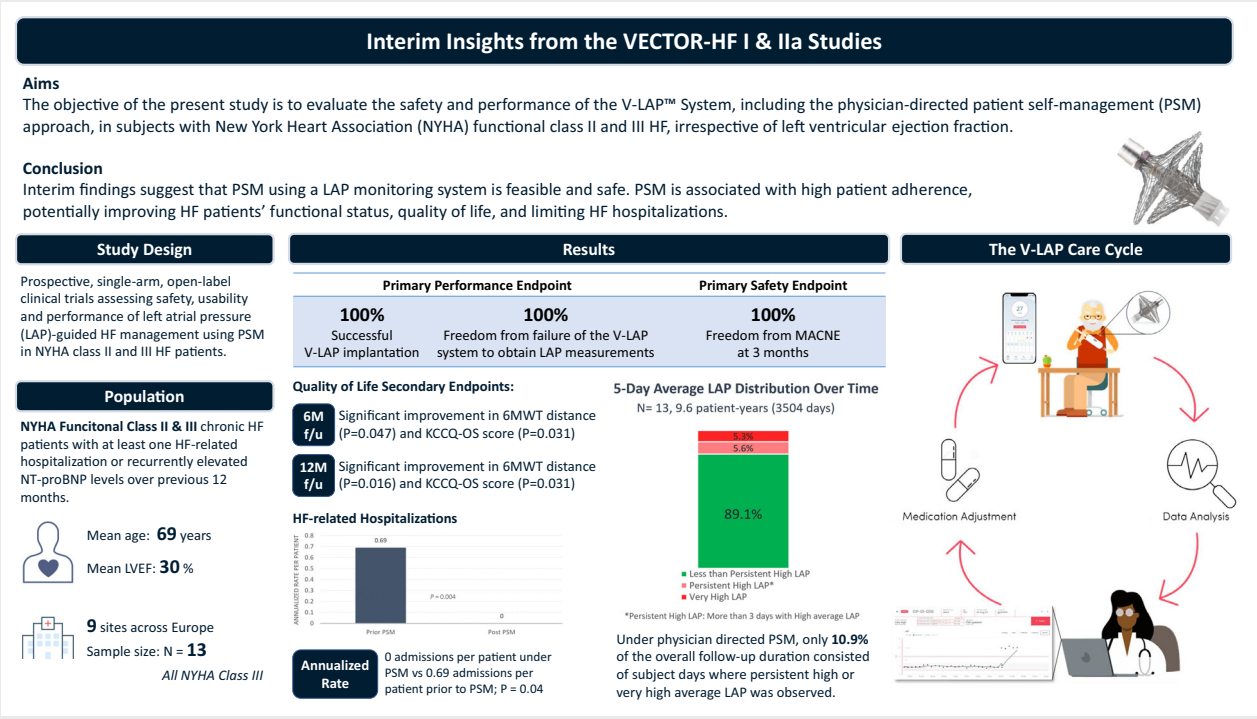
Conclusions Interim findings suggest that PSM using a LAP monitoring system is feasible and safe. PSM is associated with high patient adherence, potentially improving HF patients' functional status, quality of life, and limiting HF hospitalizations.

Graphical Abstract



Interim insights from the VECTOR-HF I and IIa studies. 6MWT, 6-min walk test; f/u, follow-up; HF, heart failure; KCCQ-OS, Kansas City Cardiomyopathy Questionnaire overall summary; LAP, left atrial pressure; LVEF, left ventricular ejection fraction; M, month; MACNE, major adverse cardiovascular and neurological event; NT-proBNP, N-terminal pro-B-type natriuretic peptide; NYHA, New York Heart Association; PSM, patient self-management.

Keywords Physician-directed patient self-management • Left atrial pressure monitoring • Heart failure

Introduction

Heart failure (HF) is a chronic condition characterized by significant morbidity and mortality. Worsening HF often manifests as deterioration of patient quality of life and HF hospitalization. With more than 26 million patients worldwide, it is one of the leading causes of hospitalizations and readmissions.[1–3]

The precipitation of hospitalization due to exacerbation of HF results from symptoms of volume overload, most commonly shortness of breath and peripheral oedema.[4] However, this cluster of symptoms is often the final step in a more prolonged process that involves fluid accumulation with associated elevations of intracardiac pressures, particularly left atrial pressure (LAP) or its surrogate, pulmonary capillary wedge pressure (PCWP).[5] This process develops over the course of days to weeks,[6] providing a substantial window for intervention and prevention of events.

Newly developed technologies enable remote haemodynamic monitoring using different sensing elements and have shown more promising results.[7–9] The most notable of these novel devices is the CardioMEMs™ System (Abbott, Sylmar, CA, USA), developed for use in HF management with a class IIb recommendation (level of evidence B) by the European Society of Cardiology (ESC) and the American Heart Association/American College of Cardiology/Heart Failure Society of America (AHA/ACC/HFSA) HF guidelines.[10,11] This recommendation is based on a reduction in HF hospitalizations as well as improved quality of life in symptomatic patients with HF. More recently, a meta-analysis assessing the impact of remote monitoring of pulmonary artery pressure

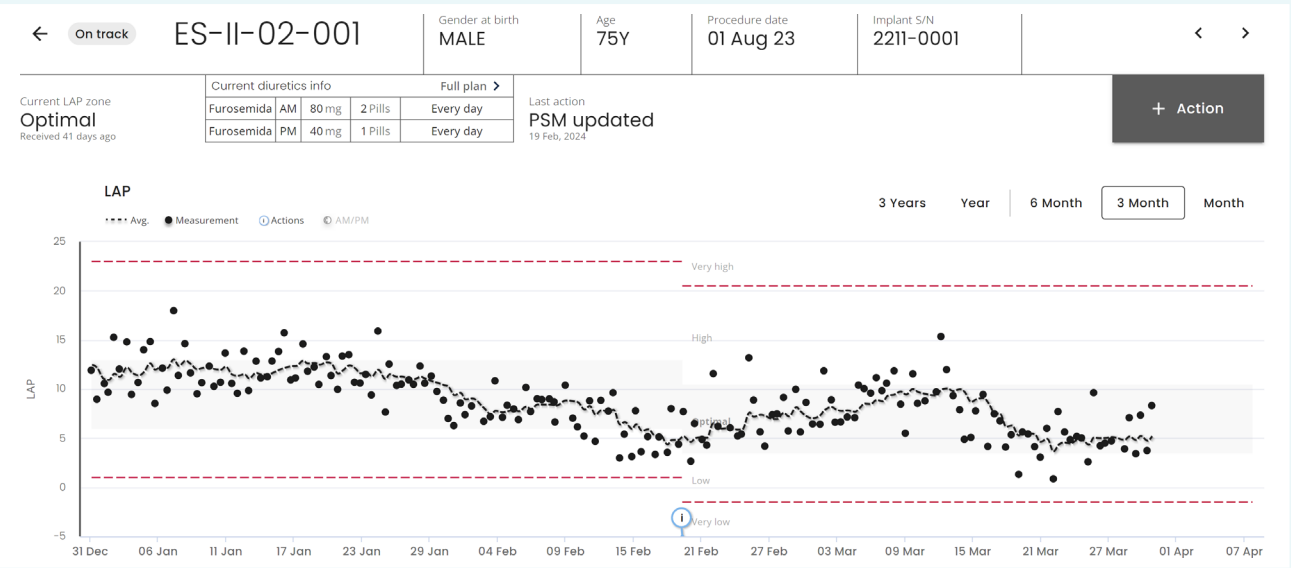


Figure 1 Healthcare provider interface: a secure web and mobile platform for healthcare professionals. It allows review of left atrial pressure (LAP) measurements, access to patient management tools, and adjustment of patient self-management (PSM) parameters.

(PAP) in three studies to guide treatment of patients with moderate to severe HF showed a reduction in episodes of worsening HF and subsequent hospitalizations.[12]

In its first in-human (FIH) study, the V-LAP™ system (Vectorious Medical Technologies, Ltd), a wireless implantable LAP monitoring system, demonstrated promising results as an intracardiac remote pressure monitoring device. These findings included a reduction in HF hospitalizations and an improvement in quality of life, with higher scores on the 6-min walk test.[13]

The aim of the present study was to evaluate the safety and performance of the V-LAP™ system, including the physician-directed patient self-management (PSM) approach, in subjects with New York Heart Association (NYHA) functional class II and III HF, irrespective of left ventricular ejection fraction.

Methods

System description

The V-LAP™ system consists of five components: an implantable LAP sensor, a transvenous (12 Fr) delivery system, an external belt-like reader unit, a secure healthcare provider (HCP) interface and a patient guidance application that displays LAP ranges and a personalized treatment plan to the patients. The LAP sensor is permanently implanted across the interatrial septum using a standard transseptal approach. The external reader is a wearable belt that is placed around the chest for 60 s and couples with the battery-free sensor implant to perform daily pressure measurements. The HCP interface is a secure web and mobile platform for healthcare professionals. It allows review of LAP measurements, access to patient management tools, and adjustment of PSM parameters (*Figure 1*). The interface aims to improve management efficacy by prioritizing patients based on LAP ranges and providing enhanced data for more effective treatment, placing the day-to-day HF management into the hands of patients, and minimizing the workload of

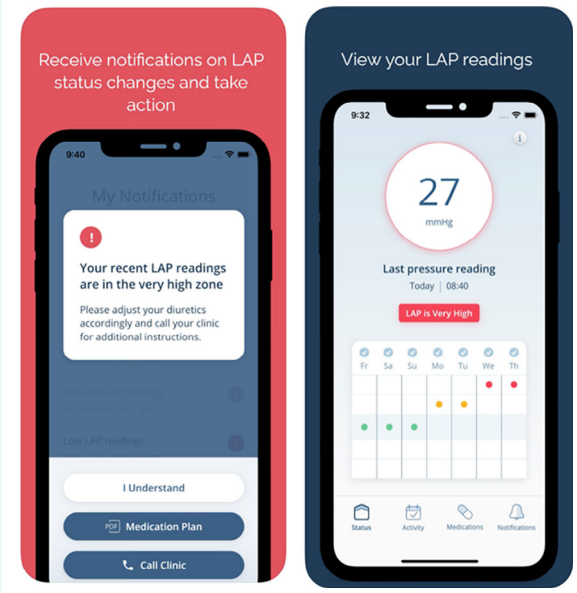


Figure 2 Patient guidance application: a smartphone application which provides notifications for self-adjustment of the treatment while allowing the patient to view recent left atrial pressure (LAP) readings and examine the prescribed diuretic treatment plan.

healthcare professionals. The patient guidance application is a smartphone application which provides notifications for self-adjustment of the treatment while allowing the patient to view recent LAP readings and examine the prescribed diuretic treatment plan (*Figure 2*). The readings are analysed and converted into actionable data in accordance with the physician-directed PSM paradigm, which may trigger medication adjustment accordingly (*Figure 3*).

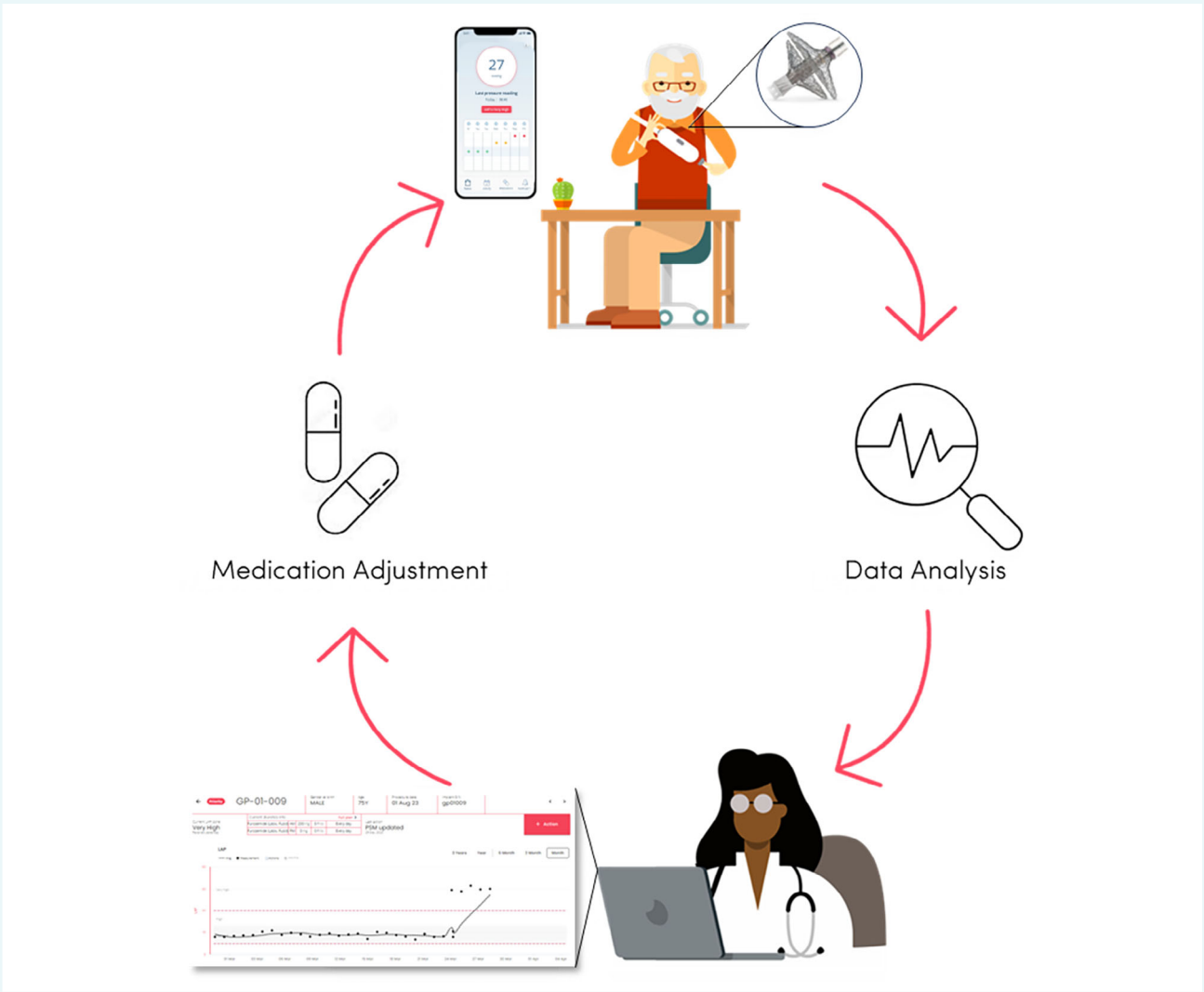


Figure 3 Flow of information between the V-LAP™ system components: the patient uses the external system daily for 1–2 min. Left atrial pressure (LAP) is measured, transmitted to the patient guidance application, and is accessible to the patient through the application and to healthcare professionals via the healthcare provider interface. The data are analysed and converted into actionable data in accordance with the physician-directed patient self-management (PSM) paradigm, which may trigger medication adjustment.

Study design

Following the completion of enrolment in the VECTOR-HF I FIH study,[9] in which pressure-guided therapy was managed solely by physician intervention, eligible subjects were transitioned to the physician-directed PSM approach and were instructed on the use of the patient guidance application. Once transitioned, eligible patients commenced adjusting medication in accordance with the physician-directed PSM approach for pressure-guided medical management.

To date, a total of 13 patients have used the physician-directed PSM approach (6 patients converted to PSM approach in the VECTOR-HF I study, and 7 patients enrolled in the VECTOR-HF IIa study). The VECTOR-HF I study was a FIH safety and feasibility study for the V-LAP™ system and the VECTOR-HF IIa was a study in a single geographic site (Tbilisi, Georgia), aimed at assessing the PSM approach with the system. Approvals from the respective regulatory authorities and ethics committees were obtained in all centres. The investigation conforms with the principles outlined in the Declaration of Helsinki.

Inclusion and exclusion criteria

In the VECTOR-HF I study, the main inclusion criteria were patients older than 18 years, with a diagnosis of AHA/ACC Stage C chronic HF in NYHA functional class III, who had at least one hospitalization for worsening HF within the past year or elevated levels of B-type natriuretic peptide, despite guideline-directed optimal medical and device therapy. Patients were included irrespective of left ventricular ejection fraction. Main exclusion criteria were life expectancy shorter than 12 months, estimated glomerular filtration rate <25 ml/min/1.73 m^2, untreated severe valvular lesions or pulmonary artery systolic pressure >70 mmHg or pulmonary vascular resistance >4.0 Wood units. Each patient provided written informed consent for study participation. This trial is registered with

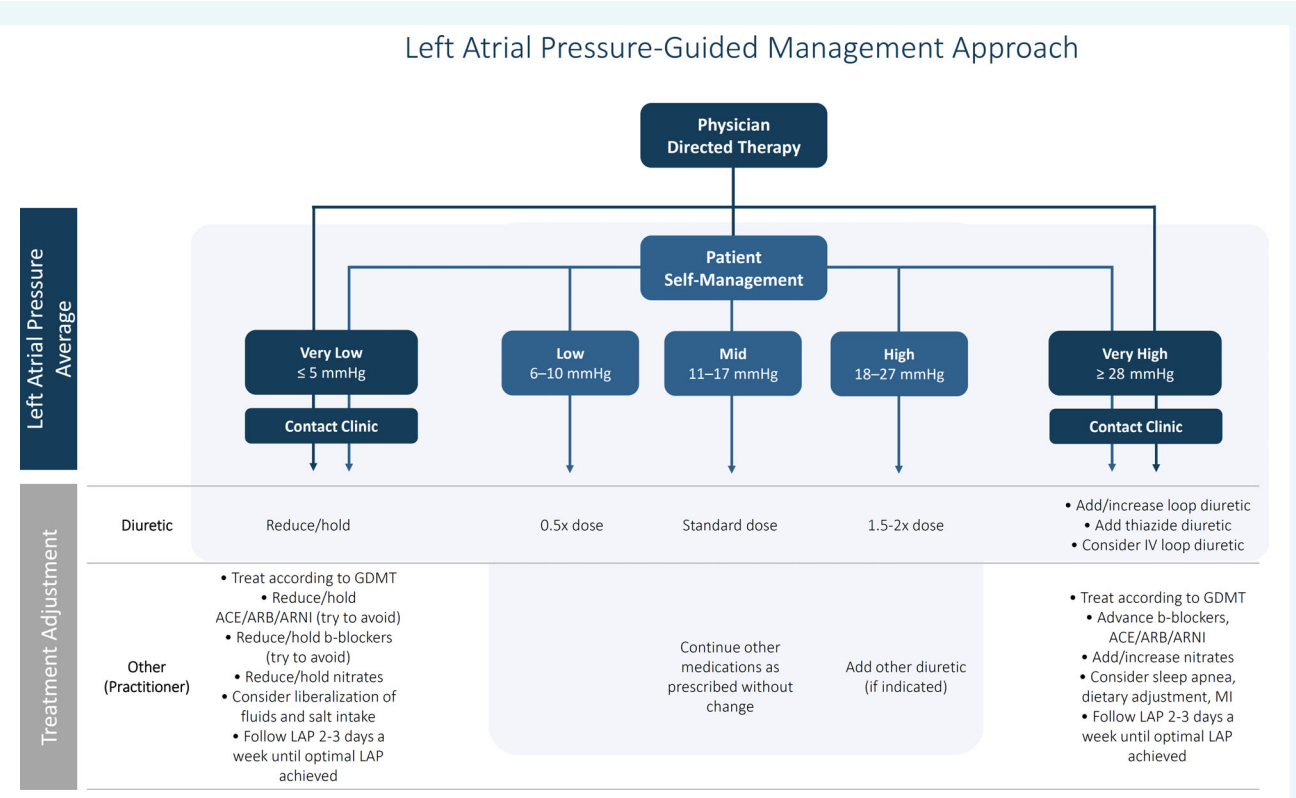


Figure 4 Treatment management approach: the data are analysed and converted into actionable data in accordance with the patient self-management paradigm, which may trigger medication adjustment. ACE, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor–neprilysin inhibitor; GDMT, guideline-directed medical therapy; IV, intravenous; LAP, left atrial pressure; MI, myocardial infarction.

ClinicalTrials.gov (NCT03775161). Inclusion and exclusion criteria were updated for the VECTOR-HF II studies to include both NYHA class II and III patients, an updated guideline-directed medical therapy definition and an added requirement of minimum technological knowledge of either the subject or the caregiver, with a smartphone or tablet for the use of the self-management application. Updated exclusion criteria included updated age – <22 or >88 years, intolerance to angiotensin receptor–neprilysin inhibitor, or an estimated glomerular filtration rate <20 ml/min/1.73 m^2. Intra-procedural exclusion criteria were also updated to include severe pulmonary hypertension at the index procedure >70 mmHg or pulmonary vascular resistance at the index procedure >4.0 Woods units (mmHg/L/min), that cannot be lowered with vasodilators.

Remote monitoring

Under physician-directed PSM, physicians defined thresholds that triggered self-adjustment of diuretic dosages when a 5-day moving average of LAP values deviated from the target range (initially set between 11 and 17 mmHg). When average LAP was lower or higher than pre-determined self-adjustment thresholds, the patient was notified by the patient guidance application to adjust diuretics accordingly, and when necessary, the physician was also notified. The collected LAP measurements are turned into actionable data by averaging the previous days of measurements and categorizing it into five different ranges from very low to very high (*Figure 4*).

The leading principles to the PSM approach are as follows:

- When the average pressure reading is very low (≤5 mmHg) or very high (≥28 mmHg): the patient self-adjusts medications immediately based upon the managing physicians pre-prescribed dosing algorithm, followed by a physician notification allowing for physician intervention at their discretion. The physician gets an alert when a single pressure reading is very low (<5 mmHg) or very high (>28 mmHg).
- When average pressure readings are low (6–10 mmHg) or high (18–27 mmHg): the application prompts medication self-adjustment, according to physician pre-defined dosages.
- When average pressure readings are mid (normal) (11–17 mmHg), the patient continues with the current treatment plan without adjustment.

The primary endpoints of the VECTOR-HF I and IIa trials were the successful deployment of the intracardiac sensor, the ability to perform initial measurements, and the freedom from study-related major adverse cardiac and neurological events (MACNE) up to 3 months post-procedure. Additional secondary endpoints were the rate of HF hospitalization, quality of life measures (changes in Patient Global Assessment) and Kansas City Cardiomyopathy Questionnaire overall summary (KCCQ-OS) score, changes in NYHA class, and changes in 6-min walk test distance, assessed at 6 and 12 months versus baseline. The KCCQ-OS score was used as a measure of the quality of life.

This score aggregates responses across multiple domains of HF-related symptoms, functional limitations, social interference, and quality of life. KCCQ-OS scores are scaled from 0 to 100 and are frequently summarized in 25-point ranges, where scores represent health status as follows: 0–24 for very poor to poor; 25–49 for poor to fair; 50–74 for fair to good; and 75–100 for good to excellent. Additionally, the adherence between patients treated by the physician-directed PSM approach and those treated by the physician-guided therapy in VECTOR-HF I study are described.

Statistical analysis

Categorical variables are presented as percentages, whereas continuous variables are presented as mean ± standard deviation in case of normal distribution and median (interquartile range [IQR]) for non-normal parameters. The paired sample *t*-test analysis was conducted to measure the changes in 6-min walk test, the number of HF admissions and KCCQ-OS. Changes in NYHA class were examined with the Wilcoxon signed-rank test. All statistical analyses were performed using IBM SPSS statistics, version 27 software (IBM Corp., Armonk, NY, USA). A p-value of <0.05 was considered statistically significant.

Results

Study population

Data from 13 NYHA class III chronic HF patients using the physician-directed PSM in nine different sites from four different countries are reported here. At the time of the writing of this manuscript, mean follow-up averaged 12.79 ± 4.92 months (389 days; range 101–523 days). The inclusion criteria of the VECTOR-HF I and IIa studies allowed for the enrolment of patients with NYHA functional class II and III. However, the entire subgroup of patients within the PSM cohort presented here were enrolled with NYHA functional class III. Six subjects were converted to the PSM approach from the VECTOR-HF I trial, and seven other subjects were enrolled in the VECTOR-HF IIa trial. Baseline patient characteristics are summarized in *Table 1*. At enrolment, the median age was 69.0 (IQR 67.0–74.0), with a prevalence of males (76.92%). Median body mass index was 29.65 kg/m^2 (IQR 26.29–31.64). Median left ventricular ejection fraction was 30.0% (IQR 25.0–39.0), median systolic PAP was 48.0 mmHg (IQR 39.0–52.0) and median PCWP was 15.0 mmHg (IQR 12.0–19.0). The number of subjects followed at each timepoint is shown in *Table 2*.

Table 1 Baseline patient characteristics ($n = 13$)

Characteristic	Median (IQR)
Age (years)	69.0 (67.0–74.0)
Male sex (%)	76.92
Female sex (%)	23.08
Body mass index (kg/m^2)	29.65 (26.29–31.64)
CRT or ICD (%)	30.77
Creatinine (mg/dl)	1.26 (1.05–1.59)
eGFR (ml/min/1.73 m^2)	44.90 (36.0–67.0)
Haemoglobin (g/dl)	14.10 (13.37–14.70)
6MWT (m)	295.10 (185.0–328.75)
SpO_2 (%)	98.0 (96.0–98.0)
LVEF (%)	30.0 (25.0–39.0)
Heart rate (bpm)	75.0 (68.0–85.0)
Diastolic blood pressure (mmHg)	78.0 (70.0–80.0)
Systolic blood pressure (mmHg)	130.0 (120.0–131.0)
RAP (mmHg)	7.50 (7.0–9.50)
PASP (mmHg)	48.0 (39.0–52.0)
PCWP (mmHg)	15.0 (12.0–19.0)
LAP by catheter	15.0 (11.0–19.0)

6MWT, 6-min walk test; CRT, cardiac resynchronization therapy; eGFR, estimated glomerular filtration rate; ICD, implantable cardioverter-defibrillator; IQR, interquartile range (25th–75th percentile); LAP, left atrial pressure; LVEF, left ventricular ejection fraction; PASP, pulmonary artery systolic pressure; PCWP, pulmonary capillary wedge pressure; RAP, right atrial pressure; SpO_2, oxygen saturation via pulse oximetry.

Table 2 Number of patients followed at each time point

Follow-up	
1-month PSM	13
3-month PSM	13
6-month PSM	10
12-month PSM	8

PSM, patient self-management.

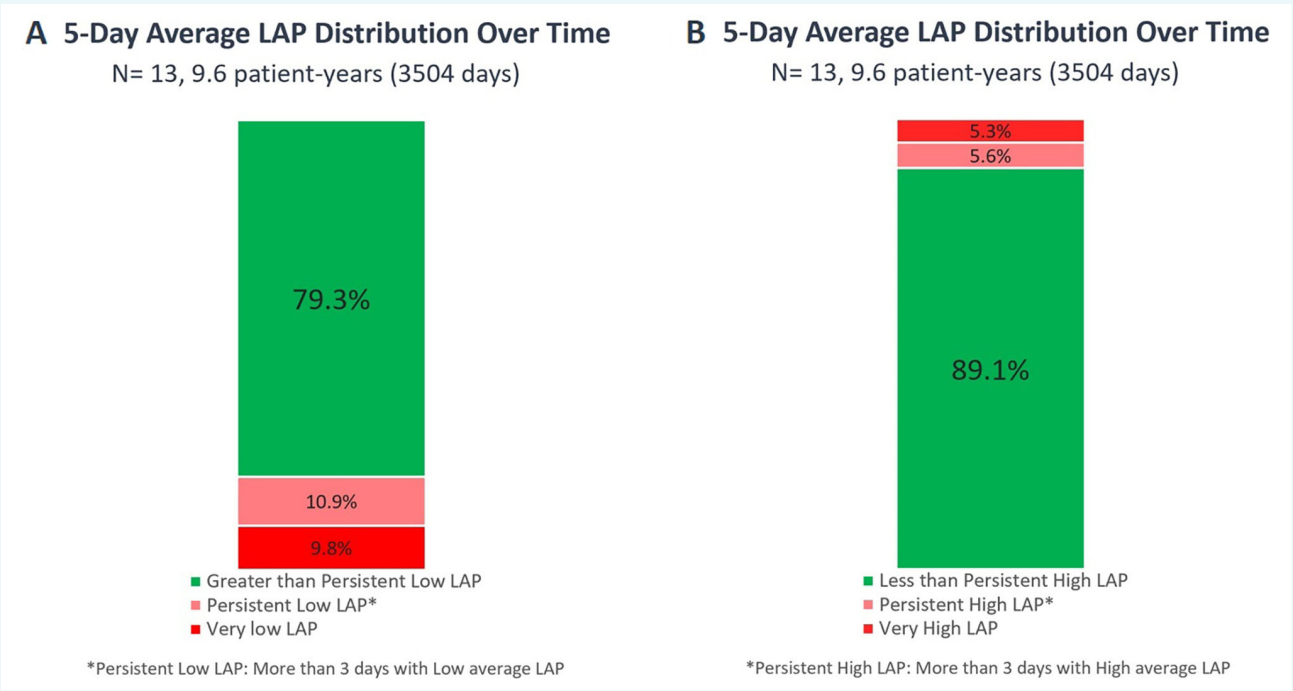
Study outcomes

There was 100% freedom from MACNE at 12 months post-implantation, indicating no complications occurred as a result of the implantation procedure, study device, or study protocol. At 12 months, there was 100% freedom of failure of the V-LAP™ system to obtain LAP measurements from the sensor and transmit the data to the HCP interface and the patient guidance application.

Regarding non-MACNE serious adverse events (SAEs), the event rates of patients included in the VECTOR-HF I study have been previously published.[9] Following the conversion of selected patients to the PSM approach, there has been a single SAE in the converted cohort (limb ischaemia), which was adjudicated by the Data and Safety Monitoring Board as unrelated to the device. In the VECTOR-HF IIa study cohort, where PSM was initiated at discharge following the implantation procedure, a total of five SAEs were reported. These included three cases of respiratory infection, as well as single reports of hypotension and pulmonary thromboembolism. All of these events were independently adjudicated as unrelated to either the device or the index procedure.

System adherence, measured as the taking of >5 measurements per week, tended to be higher at 6 months in the 13 subjects treated by the PSM approach, compared to 30 subjects evaluated under physician-directed LAP management in the VECTOR-HF I study (91.4 ± 15.2% vs. 79.3 ± 21.0%).

Under physician-directed PSM, only 10.9% of the overall follow-up duration (9.6 patient years; 3504 days) were subject days



Figures 5 (*A*, *B*) Five-day average left atrial pressure (LAP) distribution over time: under physician-directed patient self-management, only 10.9% of the overall follow-up duration consisted of subject days where persistent high or very high average LAP was observed. During 20.7% of the overall follow-up duration, subject days exhibited persistent low or very low LAP.

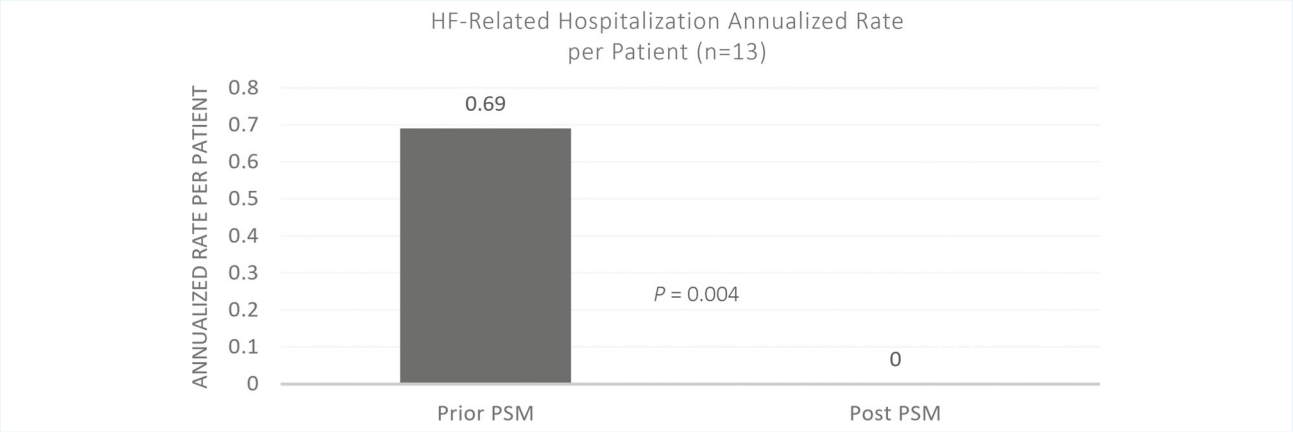


Figure 6 Heart failure (HF)-related hospitalization annualized rate per patient: using patient self-management (PSM), annualized HF hospitalization rate significantly decreased compared to a similar period prior to PSM utilization.

where persistent high (more than 3 days with high average LAP) or very high average LAP was observed (*Figure 5A*). Furthermore, 20.7% of the overall follow-up duration were subject days exhibiting persistent low (more than 3 days with low average LAP) or very low LAP (*Figure 5B*). Notably, persistent low LAP was not associated with signs or symptoms of dehydration in any of the patients.

Using the PSM approach, a significant decrease in the annualized rate of HF hospitalizations, calculated as the number of hospitalizations over individual patient follow-up duration, was observed compared to a similar period prior to PSM utilization (0 admissions vs. 0.69 admissions, over an average follow-up of 11.84 months, $p = 0.004$), as depicted in *Figure 6*. A significant decrease in the number of HF hospitalization days compared to a similar period prior to PSM use was shown as well (0 vs. 5.23 HF hospitalization days, $p = 0.004$). One case example involves a 70-year-old female Georgian subject with ischaemic HF and reduced ejection fraction (*Figure 7*), where reduced compliance led to a rise in LAP. The patient initially responded to the app's notifications to increase diuretics without physician intervention, after

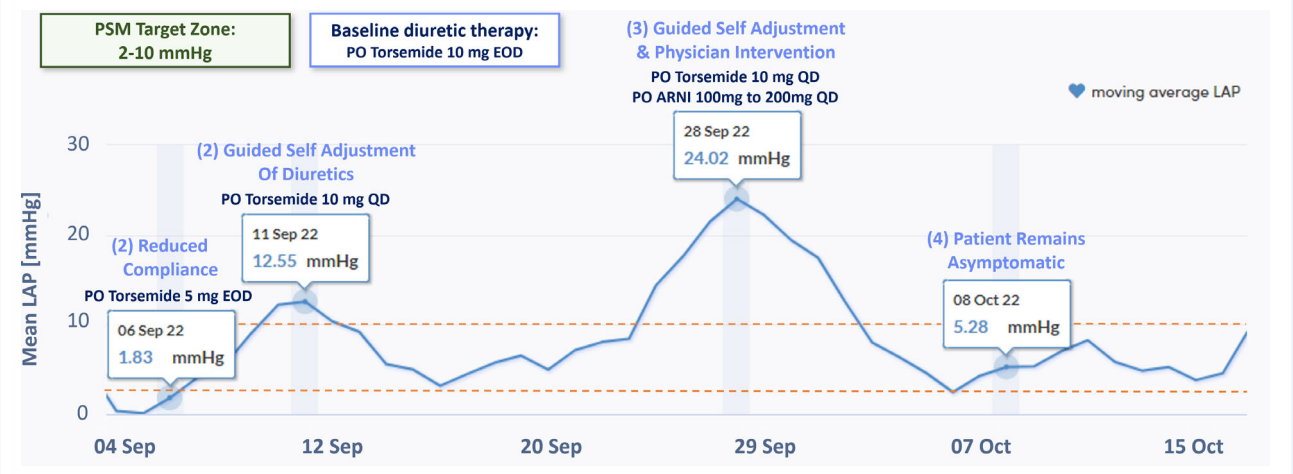


Figure 7 A 70-year-old woman with ischaemic heart failure and reduced ejection fraction demonstrated improved compliance and management of left atrial pressure (LAP) levels through app notifications prompting diuretic adjustments during the first rise in LAP values, and a physician intervention during the second rise in LAP values, resulting in increased angiotensin receptor–neprilysin inhibitor (ARNI) dosage and maintained medication adherence, preventing an episode of heart failure exacerbation. EOD, every other day; PO, orally; QD, once a day; PSM, patient self-management.

Table 3 Quality of life parameters at 6 and 12 months of follow-up

Parameter	Baseline	6-month follow-up	*p*-value	12-month follow-up	*p*-value
PGA (score), median (IQR)	0.00 (0.00–1.00)	0.00 (0.00–1.00)	0.766	0.00 (0.00–1.00)	0.5
6MWT (m), median (IQR)	187.00 (178.00–325.00)	325.00 (235.00–425.00)	**0.047**	312.5 (227.50–550.00)	**0.016**
NYHA class (score), median (IQR)	3.00 (3.00–3.00)	2.50 (2.00–3.00)	0.063	3.00 (2.00–3.00)	0.5
KCCQ-OS (score), median (IQR)	49.22 (36.4–52.08)	72.65 (55.86–86.89)	**0.031**	66.73 (63.02–86.07)	**0.031**
KCCQ-OS (score), mean (SD)	45.79 ± 7.94	71.73 ± 14.62	**0.031**	71.57 ± 11.53	**0.031**
KCCQ-OS (score) difference[a] from baseline, mean (SD)		25.94 ± 21.49		25.78 ± 19.30	

6MWT, 6-min walk test; IQR, interquartile range (25th–75th percentile); KCCQ-OS, Kansas City Cardiomyopathy Questionnaire overall summary; NYHA, New York Heart Association; PGA, Patient Global Assessment; SD, standard deviation.
[a]Difference = follow-up − baseline.

which LAP values returned to the target range. Upon a second rise in LAP values to the very high range, a physician notification prompted intervention. The physician increased the angiotensin receptor–neprilysin inhibitor dosage while ensuring the patient continued taking medications as prescribed. Subsequently, LAP values returned to the target range, once again avoiding a chronic HF exacerbation.

At 6 and 12 months, subjects demonstrated and maintained a significant improvement in the 6-min walk test (from median 187.00 m [IQR 178.00–325.00] to 325.00 m [IQR 235.00–425.00], $p = 0.047$ and to 312.50 m [IQR 227.50–550.00], $p = 0.016$, respectively). A significant improvement was noted at 6 and 12 months in the KCCQ-OS score as well (from median 49.22 [IQR 36.4–52.08] to 68.75 [IQR 53.91–86.46], $p = 0.031$, and 66.73 [IQR 63.02–86.07], $p = 0.031$, respectively). All quality-of-life analysis data are presented in *Table 3*.

Discussion

This pilot study demonstrated the safety and technical feasibility of physician-directed PSM using the V-LAP™ system. No periprocedural MACNE were reported and no device-related adverse events were observed during an average follow-up of 12 months. The V-LAP™ system stability was demonstrated with no device or reading failures. Sensor accuracy was maintained during the follow-up period using advanced technology that allows non-invasive drift detection and calibration. In addition, the safety and feasibility of the physician-directed PSM treatment paradigm were confirmed, with no adverse events related to the PSM paradigm, high compliance and improvement in clinical outcomes (*Graphical Abstract*).

The clinical benefits of physician-directed haemodynamic monitoring has been demonstrated, using pulmonary artery pressure

sensors.[8] Our findings, coupled with existing evidence on LAP monitoring,[9,14] suggest that this anatomical site of the sensor may offer significant theoretical advantages over PAP monitoring, allowing chronic HF patients to self-manage diuretics. In clinical practice, the use of PAP monitoring in HF patients requires careful consideration of its limitations and strengths. Increased pulmonary resistance, common in HF, can compromise the accuracy of PAP measurements in estimating left-sided filling pressure. The gradient between diastolic PAP and mean PCWP assumes crucial significance as it reflects pulmonary artery compliance, particularly in patients with lung disease or thromboembolism. Moreover, LAP monitoring provides valuable insights into conditions such as functional mitral regurgitation and cardiac ischaemia, enhancing the precision of management strategies, while it may be limited in the assessment of right ventricular failure. Nonetheless, an integration of left- and right-sided pressure sensors may offer a solution to this limitation. The unique intracardiac monitoring capabilities of the V-LAP™ system highlight the potential advantages of LAP monitoring. The HOMEOSTASIS FIH study, followed by the randomized LAPTOP-HF trial, pioneered the use of an implantable LAP monitoring device for HF management (HeartPOD, St. Jude Medical Inc, Minneapolis, MN, USA). A direct correlation between LAP measurements and prediction of clinical events has been demonstrated, particularly 30 days prior to HF exacerbation.[15] These studies were also the first to introduce an ambulatory physician-directed PSM approach, using a handheld patient advisor module, illustrating the potential to regulate LAP, improve haemodynamics, and enhance outcomes in advanced chronic HF patients.[15–17]

The clinical benefit observed in this study may be related to two key observations. First, the majority (90%) of PSM patients successfully avoided persistent or very high LAP values, a validated precursor to HF hospitalizations, as demonstrated in the VECTOR-HF I study.[9] Second, the physician-directed PSM paradigm may have added a behavioural component which contributed to the overall treatment effect. Patients were exposed to their LAP data and received immediate feedback, which in turn may have subsequently impacted their lifestyle choices. The behavioural aspect of PSM underscores the potential impact of patient engagement with health data, potentially leading to improved adherence and outcomes as demonstrated in previous studies.[14] This preliminary analysis indicates that providing patients with a decision-making tool through a smartphone-based application increases their motivation. This increase is suggested by the observed greater patient system adherence when compared with the physician-managed group in the VECTOR-HF I trial.

A noteworthy observation is the prevalence of very low average LAP values in some patients and the lack of adverse events associated with these values. The gold standard for assessing left-sided filling pressures is invasive measurement of PCWP through cardiac catheterization, typically performed in a supine position.[18] Consequently, pressure readings may not precisely reflect the haemodynamics of ambulatory patients who measure their left-sided filling pressures in various postures, particularly as postural changes have previously been correlated with haemodynamic changes.[19–21] In this trial, patients were instructed to measure their LAP while in an upright sitting position. The primary findings may indicate that supine filling pressures are significantly higher than sitting with legs down, which should be investigated further.

Shifting the fundamental haemodynamic monitoring paradigm and delegating some of the treatment responsibility to the patients has the potential to reduce the burden on the healthcare system. It enables physicians to prioritize severely unstable patients, ensuring they receive appropriate treatment to prevent significant deterioration or hospitalization. Non-adherence to recommended therapy is common in HF,[22] with reports indicating that up to 60% of patients do not adhere to their prescribed medication regimens, and as many as 80% fail to adhere to lifestyle recommendations.[23] Patient's empowerment, which plays an important role in treatment of chronic diseases, has the potential to significantly increase patients adherence to therapy and directly affect patients' lifestyle and clinical outcome.

The application of a monitoring system that allows the patient to maintain LAP and fluid volume within desired thresholds, rather than treating symptoms, may well shift the paradigm from crises to stability management.

Limitations

There are some significant limitations in this analysis. First, it combines patients from both the VECTOR-HF I and the VECTOR-HF IIa trials, both of which are prospective, single-arm, open-label studies. Although both studies had very similar inclusion and exclusion criteria, geographical differences may have led to variations in access to medications. Both trials were single-arm studies, and the analysis is based on a relatively small number of patients. Additionally, all patients in the PSM cohort were classified as NYHA functional class III during enrolment, and as such, the implications regarding patients with low to moderate levels of symptoms may be limited. In this early experience, the number of patient contacts, which would be elucidating for assessing the effectiveness and workload of LAP monitoring techniques, was unfortunately not systematically documented. Additionally, there are no specific data available on medication adherence. As such, future analyses of the VECTOR-HF I and IIa studies will also not provide this information. However, increased adherence to LAP measurement appears to serve as a surrogate measure for medication adherence, as suggested by the improved clinical parameters.

Conclusion

These interim findings are encouraging, suggesting that PSM using the V-LAP™ system is feasible and safe. It is associated with high patient adherence, may improve HF patients' functional status and quality of life, and has the potential to reduce the risk for HF hospitalizations.

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