The V-LAP System for Remote Left Atrial Pressure Monitoring of Patients With Heart Failure *Remote Left Atrial Pressure Monitoring*

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ABSTRACT

Objective: Patients with heart failure (HF) are at an increased risk of hospital admissions. The aim of this report is to describe the feasibility, safety and accuracy of a novel wireless left atrial pressure (LAP) monitoring system in patients with HF.

Methods: The V-LAP Left Atrium Monitoring systEm for Patients With Chronic sysTOlic & Diastolic Congestive heart Failure (VECTOR-HF) study is a prospective, multicenter, single-arm, open-label, first-in human clinical trial to assess the safety, performance and usability of the V-LAP system (Vectorious Medical Technologies) in patients with New York Heart Association class III HF. The device was implanted in the interatrial septum via a percutaneous, trans-septal approach guided by fluoroscopy and echocardiography. Primary endpoints included the successful deployment of the implant, the ability to perform initial pressure measurements and safety outcomes.

Results: To date, 24 patients have received implants of the LAP-monitoring device. No device-related complications have occurred. LAP was reported accurately, agreeing well with wedge pressure at 3 months (Lin concordance correlation coefficient = 0.850). After 6 months, New York Heart Association class improved in 40% of the patients (95% CI = 16.4%−63.5%), while the 6-minute walk test distance had not changed significantly (313.9 ± 144.9 vs 232.5 ± 129.9 meters; $P = 0.076$).

Conclusion: The V-LAP left atrium monitoring system appears to be safe and accurate. (*J Cardiac Fail 2022;28:963−972*)

Key Words: Invasive pressure monitoring, heart failure.

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The CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients (CHAMPION) trial demonstrated that in patients with heart failure (HF), medical management based on remote monitoring of pulmonary artery pressure (PAP) was associated with a reduction in hospitalizations due to HF when compared with medical management based solely on clinical signs and symptoms.[1] These findings were then confirmed in a real-world setting. Furthermore, in the subset of patients with reduced ejection fraction, PAP-guided therapy was associated with a reduction not only of HF hospitalization but also of mortality rates.[2,3]

Approximately 90% of patients admitted to the hospital for HF have pulmonary congestion related to elevated left atrial pressure (LAP).[4] Until now, only PAP sensors have been commercially available and approved for the management of HF. However, direct LAP monitoring may have distinct advantages in comparison to PAP monitoring. In patients with advanced heart failure, left- and right-sided filling pressures have frequently been found to be mismatched.[5,6] PAP also fails to correlate with left ventricular filling pressure in a variety of conditions, such as in patients with acute heart failure.[7,8] Secondary pulmonary hypertension is a common cause of PAP/LAP mismatch.[9] In addition, intracardiac pressure readings, as opposed to PAP sensors, may provide more sensitive assessment of important clinical events in patients with HF, such as the evaluation of diastolic function, atrial arrhythmias and left-sided valvular function (eg, the severity and progression of secondary mitral regurgitation). Finally, commercially available devices require the patient to remain stationary; the measurement is performed while the patient is lying in bed.

The V-LAP (Vectorious Medical Technologies, Tel-Aviv, Israel) wireless remote monitoring system measures LAP directly, enabling bidirectional communications with an external unit at rest and during ambulation. The ongoing V-LAP Left Atrium Monitoring systEm for Patients With Chronic sysTOlic & Diastolic Congestive heart Failure (VECTOR-HF) study, the first-in human clinical study, assesses the feasibility, safety, device performance, and usability of the V-LAP system in patients with New-York Heart Association (NYHA) Class III HF.

Methods

Study Design and Inclusion Criteria

VECTOR-HF (ClinicalTrials.gov Identifier: NCT03775161), the first in-human clinical study, is a prospective, multicenter, single-arm, open-label clinical trial that assesses the safety, performance and usability of the V-LAP system in patients with New-York Heart Association (NYHA) Class III HF. The investigation conforms with the principles outlined in the Declaration of Helsinki[10] and was approved by local ethics committees or institutional review boards. All participants provided written informed consent. Participating centers included the Rabin Medical Center (Israel); Shaare Zedek Medical Center (Israel); Gemelli University Hospital (Italy); Vivantes Klinikum im Friedrichshain and Am Urban (Germany); Rostock University Medical Centre (Germany); Marienhospital (Germany); CardioVascular Center Frankfurt (Germany); Queen Elizabeth Hospital (United Kingdom); Hammersmith Hospital (United Kingdom); Careggi University Hospital (Italy); Kaplan Medical Center (Israel); Rambam Medical Centre (Israel); and The Ohio State University (USA).

Briefly, eligible patients were men or women older than 18 years of age who had diagnoses of chronic American College of Cardiology/American Heart Association Stage C HF in NYHA functional class III who had histories of at least 1 hospitalization for worsening HF within the past year or elevated levels of brain natriuretic peptide (BNP $>$ 300 pg/mL or NT-proBNP $>$ 1500 pg/mL). Patients with both reduced and preserved ejection fraction were included and had to have been treated with optimal medical therapy, including guideline-directed device therapy, and to have been clinically stable for a minimum of 3 months prior to enrolment. Major exclusion criteria included: estimated glomerular filtration rate of $<$ 25 mL/min/1.73m^2; untreated severe valvular lesions; left ventricular end-diastolic diameter $>$ 80 mm; pulmonary artery systolic pressure $\geq$ 70 mmHg or pulmonary vascular resistance $>$ 4.0 Wood units; left atrial/ventricular or right atrial thrombus; active valvular vegetations; atrial myxoma; hypertrophic obstructive cardiomyopathy; acute myocarditis; large pericardial effusion; constrictive pericarditis; infiltrative cardiomyopathy; and inappropriate left atrial and interatrial septal anatomy (septal thickness $>$ 7 mm, fossa ovalis diameter $<$ 10 mm; and atrial septal defect or patent foramen ovale with more than a trace amount of shunting).

Study Device

As previously described,[11] the V-LAP system includes a sensory implant that measures and transmits LAP wirelessly to an external unit (reader). The implant is leadless and batteryless, receiving all its power from the reader. It is composed of a hermetically sealed tube that encases sensing elements and electronics. This includes an application-specific integrated circuit chip with inherent digital capabilities, such as error detection and correction, bidirectional

communication and transmission of several parameters, including pressure, body temperature and transmission power. Surrounding the tube, nitinol-braided anchors are attached. They consist of a distal and a proximal disc, and when the implant is fully deployed, they are positioned on the left and right sides of the interatrial septum, respectively, while the implant body traverses the septum (Fig. 1).

The system also includes an external unit that powers the implant and collects data via radio-frequency communication upon activation. It may be operated in all positions, including recumbent or upright, also permitting measurement during movement. Finally, the system includes a dedicated delivery system (Fig. 1, central illustration). Following implantation, the patient is instructed to take daily measurements at home. The data are then transferred via a gateway unit to a secured Cloud Storage database. This is reviewed and analyzed by the medical team using a dedicated data-display system (Fig. 1, central illustration).

Implantation of the V-LAP Left Atrial Remote Monitoring System

The procedure starts with a right-heart catheterization. Thereafter, transesophageal or intracardiac echocardiography is performed in order to assess for anatomy that is favorable for implantation and to rule out pathologies in the interatrial septum or thrombi in the left or right atrium. A dedicated 12-F transfemoral, trans-septal delivery system facilitates the implantation of the device at the interatrial septum under angiographic and echocardiographic guidance and using a dedicated delivery system (Fig. 2). At the end of the procedure, mean pulmonary capillary wedge pressure (PCWP) obtained invasively is correlated with simultaneous mean LAP obtained from V-LAP. All values represent mean values of measurements performed during brief breath-holding periods of 7−10 beats. Patients are treated with heparin to maintain Activated Clotting Time 250−350 during the procedure and thereafter with dual antiplatelet therapy: clopidogrel 75 mg with aspirin 75−100 mg for 3 months. For patients who are already being treated with oral anticoagulants, only clopidogrel is added.

Fig. 1. The V-LAP implant.

Follow-up and Endpoints

According to the study design, patients and their caregivers were not exposed to the LAP measurements during the first 3 months after the V-LAP implantation. After 3 months, a repeat right-heart catheterization was performed in order to measure mean PCWP invasively, which was correlated with simultaneous mean LAP obtained from V-LAP. After this, LAP measurements were used to guide patient management.

Primary endpoints included the successful deployment of the implant and the ability to perform initial pressure measurements as well as safety outcomes. Secondary endpoints included accurate pressure measurements and transmission of the LAP data to the V-LAP data display up to 3 months post-procedure, concordance of V-LAP measurements with PCWP at 3 months, as well as number of admissions due to HF (defined by the local HF team's assessment of the major cause for hospitalization of the patient), changes in NYHA Class, 6-minute walk test, patient global assessment by visual analog scale using a Likert scale composed of 7 points (−3 = much worse, −2 = worse, −1 = a little worse; + 3 = much better), Kansas City Cardiomyopathy Questionnaire, and NT-proBNP at 6 months.

Statistical Analysis

Continuous variables are presented as mean ± standard deviation in cases of normal distribution (according to the Kolmogorov-Smirnov test) and median (IQR) for non-normal distribution parameters. We present categorical variables as number (percentage). The Bland-Altman analysis and the Lin concordance correlation coefficient test were used to assess for accuracy of LAP measurements when compared with the Swan-Ganz catheter measurement of PCWP. The paired sample *t* test analysis was used for the comparison of the 6-minute walk test, the number of HF admissions and the Kansas City Cardiomyopathy Questionnaire before and after the procedure. The Wilcoxon signed-rank test was used for the analysis of NT-proBNP. NYHA and patient global assessment changes were demonstrated by test of proportions (P′ = X/n) in percentages and a 95% confidence interval. All statistical analyses were performed using IBM SPSS statistics, version 27

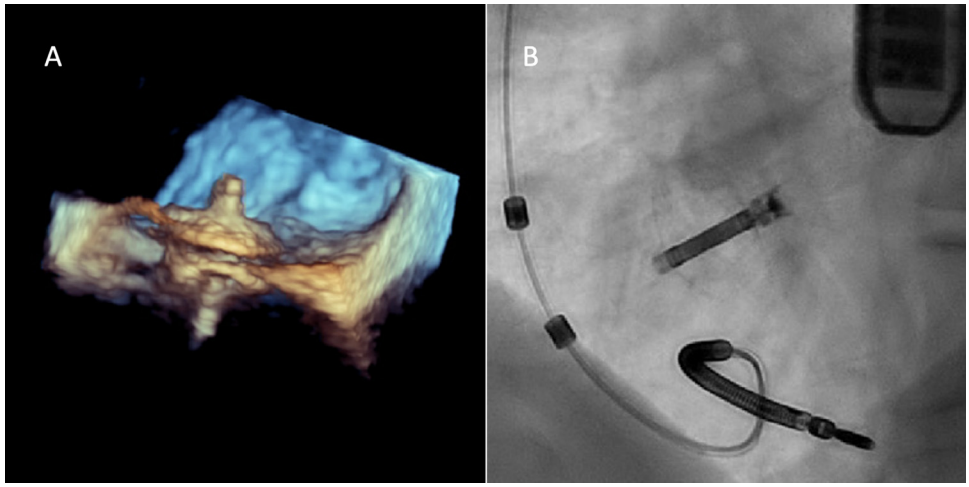

Fig. 2. A, Transesophageal echocardiography; B, fluoroscopy of the V-LAP following implantation at the interatrial septum.

software. A *P* value of < 0.05 was considered statistically significant.

Results

Between January 2019 and December 2020, 24 patients with NYHA Class III HF were enrolled in 11 sites (Supplementary Fig.). Of the patients, 22 (91.7%) experienced HF with reduced ejection fraction, and 2 experienced HF with preserved ejection fraction (8.3%). All were assessed by HF specialists and were treated according to guideline-directed medical therapy. The mean age was 67.4 ± 9.7; 4 patients (16.7%) were women; mean body mass index was 29.5 ± 3.3; and most patients were treated according to current guidelines (Table 1). As for echocardiographic and invasive hemodynamic data, median left ventricular ejection fraction was 30.7% (IQR 22.3%−37.5%), mean systolic pulmonary artery pressure was 45.0 ± 15.5 mmHg, and PCWP was 19.4 ± 7.3 mmHg (Table 1).

All 24 patients were successfully implanted with the V-LAP, fulfilling the primary outcome of the study. Total procedure time varied between 15 minutes and 2.25 hours (median 70.0 minutes). Mean LAP measured by the catheter was 18.6 ± 7.0 mmHg, and mean LAP measured by the V-LAP was 19.3 ± 5.7 mmHg. No device-related complications, defined as invasive treatment, device explant or death, occurred. One patient passed away during the follow-up period, having suffered a cerebrovascular accident, subsequent sepsis and multiorgan failure 2 months after device deployment. Another passed away due to the SARS-CoV-2 virus. Repeat transesophageal echocardiography demonstrated no evidence of device embolization, thrombi or infective endocarditis. No sensor failure occurred within the follow-up period. All devices transmitted accurate pressure measurements of the LAP data to the V-LAP data display up to 3 months postprocedure. These measurements consisted of high-resolution pressure waveforms. The V-LAP was compared to Swan-Ganz catheter measurement of PCWP at implantation in all patients and after 3 months in 21 patients at the time of the writing of this manuscript. Fig. 3 shows the concordance between the 2 measurements at the 3-month follow-up: a mean difference of −2.05 ± 3.33 mmHg (Lin concordance correlation coefficient = 0.850, 95% CI 0.676−0.934).

For the 20 patients who had reached the 6-month mark after implantation, improvement in the mean NYHA class was demonstrated in 8 of the patients (40.0%, 95% CI = 16.4%−63.5%); 7 (35.0%) were classified as NYHA class 2, and 1 (5.0%) was estimated to have NYHA class 1 symptoms. Furthermore, 6-minute walk test distance showed a trend toward improvement from mean 232.5 ± 129.9 m at baseline to 313.9 ± 144.9 m after 6 minutes ($P = 0.076$) (Fig. 4). Global assessment had improved in 11 patients (55.0%, 95% CI = 17.4%−94.6%) and had deteriorated in 1 (5.0%). NT-proBNP levels showed nonsignificant change (from median 1344.0, IQR 345.0−4339.0 to 1100.0, IQR 530.3−2238.5 pG/mL at 6 months; $P = 0.575$), as did the Kansas City Cardiomyopathy Questionnaire score (49.6 ± 19.4 at baseline vs 52.5 ± 20.6; $P = 0.403$), and the number of admissions due to HF at 6 months (0.5 ± 0.5 in the 6 months prior to implantation vs 0.3 ± 0.9 in the time interval between implantation and the 6M mark; $P = 0.634$).

In several cases, the data gathered from the V-LAP played a significant role in the care of patients during the COVID-19 pandemic. In 1 case in a center in Israel, both the patient and the medical team were blinded to the LAP measurement results in the first weeks after implantation. Incidentally, this period

Table 1. Patient Baseline Characteristics and Physiological Data

Parameter (n = 24)	Mean ± SD
Age (years)	67.42 ± 9.73
Female (%)	4 (16.67%)
Body mass index (kg/m^2)	29.52 ± 3.25
History of coronary artery disease (%)	13 (54.17%)
Diabetes mellitus (%)	17 (70.83%)
Hypertension (%)	19 (79.17%)
COPD (%)	4 (16.67%)
Atrial fibrillation (%)	12 (50.00%)
Beta-blockers (%)	23 (95.83%)
ACEi (%)	12 (50.00%)
ARNi (%)	11 (45.83%)
MRA (%)	17 (70.83%)
SGLT2i (%)	8 (33.33%)
Oral anticoagulants (%)	15 (62.50%)
CRT or ICD (%)	18 (75.00%)
Creatinine (mg/dL)	1.52 ± 0.50
eGFR (mL/min/1.73m^2)	54.62 ± 19.95
Hemoglobin (g/dL)	13.59 ± 1.59
6-Minute walk (m)	227.69 ± 132.63
Heart rate (beats per minute)	74.79 ± 11.88
Diastolic blood pressure (mmHg)	71.83 ± 9.05
Systolic blood pressure (mmHg)	115.21 ± 13.84
Left ventricular ejection fraction (%)	30.70 ± 10.17
LVEDD (mm)	65.20 ± 23.15
LVESD (mm)	44.45 ± 19.22
Left atrial area (cm^2)	32.02 ± 20.88
Mean RAP (mmHg)	9.29 ± 7.12
PASP (mmHg)	45.00 ± 15.53
Mean PCWP (mmHg)	19.38 ± 7.32
LAP by catheter (mmHg)	18.60 ± 7.52

ACEi, angiotensin converting enzyme inhibitor; ARNi, angiotensin receptor-neprilysin inhibitor; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; eGFR, estimated glomerular filtration rate; ICD, implantable cardioverter defibrillator; LAP, left atrial pressure; LVEDD, left ventricular end diastolic diameter; LVESD, left ventricular end systolic diameter; MRA, mineralocorticoid receptor antagonist; PASP, pulmonary arterial systolic pressure; PCWP, pulmonary capillary wedge pressure; RAP, right atrial pressure; SGLT2i, sodium-glucose cotransporter-2 inhibitors.

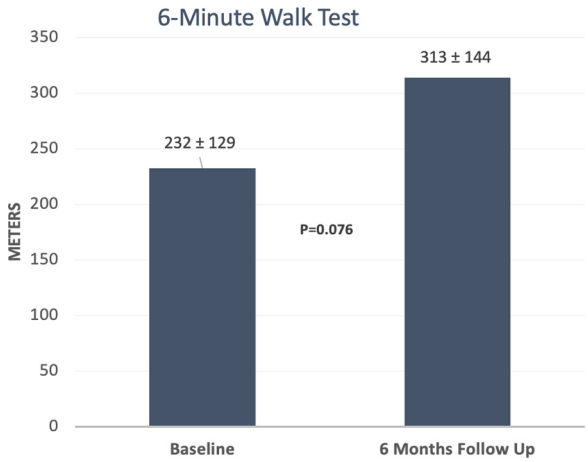

Fig. 4. Comparison of 6-minute walk test at baseline and 6 months after device implantation.

coincided with the first wave of the pandemic, resulting in self-isolation of the patient and reduced compliance with visits and medication. We were able to witness a gradual increase from a mean pressure of 6.6 to 19.4 mmHg during this time period, as well as prominent V waves before the data became available to the medical team, and the patient was treated accordingly.[12] In another case, a patient from Germany, placed in self-quarantine due to his multiple comorbidities and high risk of complicated and possibly lethal coronavirus disease, was instructed by the medical team to increase the dosage of diuretics (torsemide) after witnessing a rise in LAP remotely. In addition, temperature was measured using the V-LAP and showed normal values.[13] A final example from the same center is displayed in Fig. 5. In this patient, the team had responded to a rise in LAP by adjusting diuretic treatment, thereby maintaining pressures within the desired range, potentially preventing an event of HF exacerbation.

Discussion

VECTOR-HF is a first in human multicenter clinical study assessing the novel left atrial pressure V-LAP monitoring system. These initial results suggest that

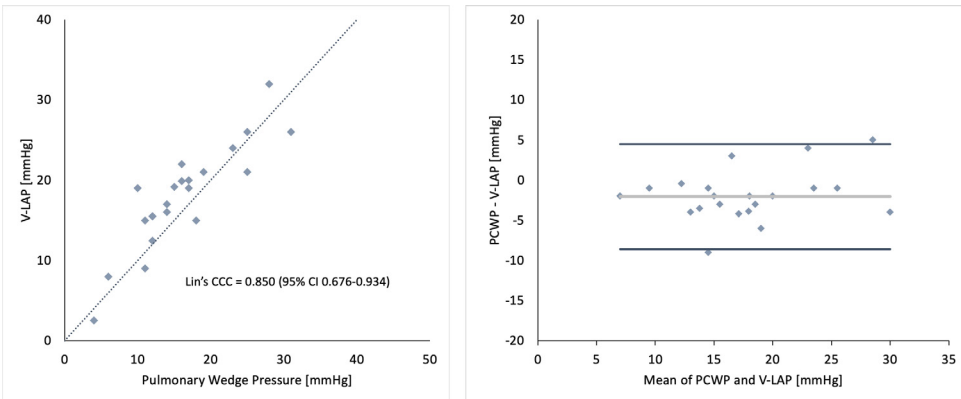

Fig. 3. Lin concordance correlation coefficient (left) and Bland-Altman (right) plots for mean LAP and PCWP. CCC, concordance correlation coefficient; LAP, left atrial pressure; PCWP, pulmonary capillary wedge pressure.

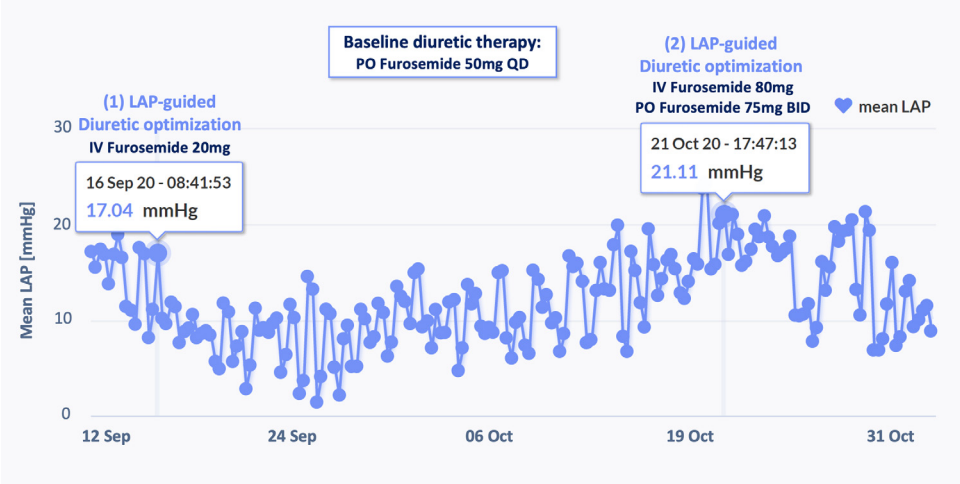

Fig. 5. The VECTOR-HF data display, demonstrating changes in LAP and the diuretics dosage adjustment in response. BID, bis in die; IV, intravenous; LAP, left atrial pressure; PO, per os; QD, quaque die.

the implantation of the V-LAP is feasible and safe and provides accurate LAP data remotely.

In patients with congestive HF, a rise in ventricular filling pressure typically occurs weeks before hospitalization.[14] The CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients (CHAMPION) trial showed the efficacy of a fully dedicated implantable HF monitoring system based on pulmonary artery pressure-guided management in reducing the risk of HF rehospitalizations.[1] However, devices assessing pulmonary artery pressure are hindered by their anatomic location within the right-sided circulation. This is especially relevant in patients with pulmonary artery hypertension. Among patients with HF and reduced left ventricular ejection fraction, the prevalence of pulmonary artery hypertension (based on right-heart catheterization) ranges between 40% and75%.[15,16] Initially, elevated pulmonary artery wedge pressure drives a reduction in pulmonary artery compliance. At later stages, pulmonary vascular resistance increases at the small-vessel level due to remodeling as well as to vasoconstriction and endothelial dysfunction, all affecting vessel distensibility and pulmonary vascular resistance calculation.[17,18] In addition, many patients may suffer from noncardiac causes of pulmonary artery hypertension. An important such condition is chronic obstructive pulmonary disease, which occurs in 27%–38% of patients with HF.[19] Even more prevalent are sleep-disordered breathing syndromes, existing in an estimated 50%–80% of the patients.[20,21] Both conditions contribute to pulmonary artery hypertension and increased vascular resistance.[22,23] Importantly, in patients with increased pulmonary vascular resistance, pulmonary pressure fails to estimate accurately left-sided filling pressures.[9] Therefore, right-sided pressure measurements may erroneously estimate increased left-sided values, leading to exaggerated medications for HF, thus risking adverse events, such as dehydration, renal failure and bradycardia, or lower pressures, reducing the efficacy of treatment. This was evident even in the CHAMPION trial, in which patients in the treatment arm suffered from a significantly higher number of dehydration events (n = 9) than patients in the control group (n = 5). Therefore, measurement of direct left-sided filling pressures potentially provides a more reliable form of hemodynamic assessment, enabling a more accurate estimation of the fluid status of patients with HF, a better prediction of exacerbations and a safer management scheme.

Pressure readings from within the left atrium may also assist in detecting important clinical events in this patient population. An example is diastolic dysfunction, present in HF with reduced ejection fraction as well as in HF with preserved ejection fraction. Measurements of left atrial pressure and left ventricular end-diastolic pressure are used to represent left ventricular filling pressure. The mechanisms of diastolic dysfunction include impaired relaxation, loss of restoring forces and increased diastolic stiffness.[24] As a compensatory mechanism to maintain cardiac output, there is elevation of left atrial pressure, which may be readily assessed using the V-LAP.

The HeartPOD (Abbott, formerly St. Jude Medical/Savacor, Abbott Park, IL) was a system that allowed for direct measurement of LAP in patients with ambulatory HF, based on an implantable pacemaker-like device composed of a sensor lead coupled to a subcutaneous antenna coil, a patient-advisory module, and remote clinician access via secure computer-based data management.[25,26] A prospective randomized trial aimed to assess the

safety and efficacy of the system in ambulatory NYHA functional class III patients.[27] However, enrollment in the trial was stopped early due to a perceived excess of implant-related complications. Preliminary results presented during a Late Breaking Clinical Trials Session at the 2016 Heart Failure Society of America meeting showed that when the results were analyzed using the CHAMPION trial endpoint of recurrent hospitalizations due to HF, the results of the HeartPOD were similar to those of CHAMPION.[28] Thus, although not a definitive evaluation of the efficacy of LAP-guided HF therapy, it suggested its potential and inspired ongoing technology development in this arena.

The V-LAP monitoring system requires no leads or batteries and is concurrently powered and interrogated via an external unit, sending data to a secure Cloud Storage. As opposed to other devices, patients may perform the measurement when in either a supine or a prone position, also enabling measurement during physical exertion, allowing for assessment of diastolic function. Another potential advantage is for patients with HF and functional (or secondary) mitral regurgitation, a potentially treatable condition. It has been shown that left atrial pressure is well correlated with the severity of mitral regurgitation during both angiography and surgery.[29,30] Left atrial pressure is a direct indication of the hemodynamic effects of mitral regurgitation, showing enhanced LAP V-waves, which may go unnoticed in the PAP waveform. Previous reports have shown the feasibility of trans-septal procedures following implantation of similar devices in a portion of the native septum, as recommended in the case of this relatively small implant or through the device in cases of larger implants.[31-33] Finally, left atrial pressure may detect atrial arrhythmias and myocardial ischemia-prevalent events[34] of important clinical significance in patients with HF.

There are 2 potential limitations in the system. The first is the need for a trans-septal procedure in order to implant the device. The second is the risk of thromboembolic events during and following implantation or, conversely, the need for antiplatelet treatment. Therefore, the V-LAP may hold advantages in cases of patients who may suffer from pulmonary hypertension, who may benefit from information regarding atrial arrhythmias, diastolic dysfunction and mitral regurgitation. On the other hand, for those who cannot tolerate a trans-septal procedure, a PAP sensor may be more suitable.

The ability to monitor patients with HF remotely has been especially important recently, during the unprecedented era of the COVID-19 pandemic, due to the patients' increased potential vulnerability to the effects of the virus.[35-37] During the COVID-19 pandemic, the V-LAP has shown the ability to monitor patients with HF remotely, enabling personalized and timely treatment while keeping these susceptible patients away from hospitals.[12,38,39] Importantly, this assumption was not proven in the recent randomized controlled GUIDE-HF trial, assessing PAP-guided therapy in patients with class 3 HF before and during the peak of the COVID-19 pandemic.[40] In that study, undertaken in 118 centers in North America, a prespecified pre-COVID-19 impact analysis showed a significantly lower rate of HF events in the treatment group before the pandemic (HR 0.81, 95% CI 0.66−1.00; $P = 0.049$) but not after the declaration of a national emergency in the USA on March 13, 2020, when a decrease in the rate of admissions was seen in the control group, possibly related to avoidance of hospitalization.[41] These disappointing results may also be driven by a relatively small change in mean pulmonary pressure, as compared with previous studies,[42,43] as well as the fact that the information acquired is right-sided pressure from the pulmonary artery, a surrogate for left-sided filling pressures. A final consideration to remember is that the potential advantages of the remote monitoring of patients with chronic disease, and HF in particular, are dependent on a health care system that adapts to the gathering of remote data and on the associated patient care based on such information. As the fourth industrial revolution enters the hospitals, data reported from remote sensors must be coupled with the appropriate infrastructure for large data acquisition, analysis and corresponding patient-management guidance.

Limitations

This report is an initial observation of an ongoing first in-human clinical study. Therefore, both primary and secondary outcomes need to be appraised cautiously. Also, the question of the true gold standard of left-sided pressure measurements remains. In our study, the V-LAP measurement was compared to a Swan-Ganz catheter measurement of PCWP at implantation and after 3 months. However, Swan-Ganz catheter measurement has previously been proven to suffer from several disadvantages,[44,45] limiting our ability to evaluate the device's accuracy and precision. Clinical endpoints were also compared to baseline, whereas medical changes based on the V-LAP measurements began after 3 months. Finally, this study is not powered to assess clinical endpoints, such as HF readmission rates or mortality.

Conclusions

Nevertheless, in this study we have shown that the implantation of the V-LAP is feasible and safe and provides accurate LAP data remotely. There were no device-related complications and no sensor-failure

events, and all devices transmitted accurate pressure measurements of LAP to the V-LAP data display 3 months after the procedure. In addition, some of the secondary endpoints suggest a potential benefit in reducing clinical signs and symptoms of HF. These initial promising results of the first 24 patients from the VECTOR-HF trial will be confirmed in future trials, including prospective randomized controlled ones.

Lay Summary

It has been suggested that ambulatory invasive hemodynamic monitoring of pressures may improve outcomes in patients with heart failure (HF). In this study, we describe our first experience with a novel wireless left atrial pressure monitoring system in HF patients. The system was implanted in 24 patients, and had demonstrated safe and feasible monitoring of left-atrial pressure remotely. These initial results support development of clinically powered, larger randomized trials assessing the efficacy of left-atrial pressure monitoring remotely, in reducing risk for HF readmissions and adjusting therapy in a personalized manner.

Supplementary Figure - Patient enrollment diagram.

Disclosures

LP owns stock options in Vectorious Medical Technologies; DM has received consulting fees from Vectorious Medical Technologies and owns stock options in the company; BA has received consulting fees from Vectorious and owns stock options in the company; GD has received consulting fees from Vectorious Medical Technologies; FL has received consulting fees from Vectorious Medical Technologies.

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Ethics or institutional review board approval

The investigation conforms to the principles outlined in the Declaration of Helsinki and was approved by local ethics committees or institutional review boards. All participants provided written informed consent.

Registration

https://clinicaltrials.gov/ct2/show/ NCT03775161

Proposed Tweet

The VECTOR-HF study assessed the ability of a novel left atrial pressure monitoring system to wirelessly measure pressures remotely in the first 24 patients. #HeartFailure #Innovation #Telemonitoring

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.cardfail.2021.12.019.

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