



## Brief Report

### First In-human study of a Novel Left Atrial Pressure Sensor: the Microtech LVAD Study

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**Key Words:** Cardiac hemodynamics, noninvasive intracardiac pressure monitoring, LVAD implantation.

## Introduction

Rates of heart failure hospitalization (HFH) are steadily increasing throughout the Western world. HFH negatively affects patients' prognoses and quality of life and carries a 2-year readmission rate of up to 83%, which accounts for much of the economic burden of the disease.<sup>1</sup> Signs and symptoms requiring admission often develop acutely, but an increase in cardiac pressure is evident starting weeks prior to clinical decompensation.<sup>2</sup>

Early identification of this preclinical stage of HF decompensation may enable augmentation of medical treatment and prevent HFH, but for this purpose, dedicated devices for continuous intracardiac pressure monitoring are required. Remote pulmonary artery pressure (PAP) monitoring using the CardioMEMS (Abbott) and the Cordella (Edwards) device are currently the only available options for remote invasive intracardiac pressure monitoring in clinical practice; the devices have received a class IIb (LOE B) recommendation in the European Society of Cardiology HF guidelines.<sup>1</sup> PAP monitoring using these systems has been shown to reduce HFH as well as mortality rates in patients with New York Heart Association (NYHA) class III HF,<sup>3</sup> but impact in a broader HF population has not been shown.<sup>4</sup> One possible explanation for the inconsistent effect of PAP monitoring is the mismatch between right- and left-sided intracardiac pressures in patients with HF.<sup>5</sup> Remote invasive left-sided intracardiac pressure monitoring may be superior to the current practice in terms of reducing HFH rates and optimizing long-term care.

To the best of our knowledge, the V-LAP (Vectorious, Tel-Aviv, Israel) device is the only dedicated device for direct LA pressure monitoring.<sup>6</sup> This device, implanted within the septum, can be actively charged and interrogated wirelessly through a wearable component that transmits LAP data via radio frequency communication.

Microtech (Tel-Aviv, Israel) has developed an implantable sensor platform to be used virtually anywhere in the body to measure most clinically relevant physiochemical parameters. The sensor is submillimeter in size, passive, contains no battery or antenna, is precalibrated during manufacturing, and is interrogated via ultrasound, much like a transthoracic echocardiography probe (Fig. 1). Functioning as an ultrasonic drum, the resonant frequency of the sensor is proportional to the quantity being measured (eg, pressure). The interrogation console (Fig. 1, C) includes barometric sensors that are then used to measure air pressure so as to derive the clinically relevant gauge pressure provided as the output. Uniquely, due to its size and passive nature, the sensor can be integrated into essentially all existing cardiac and noncardiac devices, converting them into "smart" devices.

As an initial clinical proof of concept, the sensor has been configured to measure pressure, mounted on a small cardiac-anchoring device and surgically implanted in the atria of patients undergoing implantation of left ventricular assist devices (LVADs). Pressures are then read using a dedicated home/clinic console operated by the clinical staff or by the patients themselves.

Here we report the first 4 cases performed at Rabin medical centre in Israel as part of the Microtech LVAD

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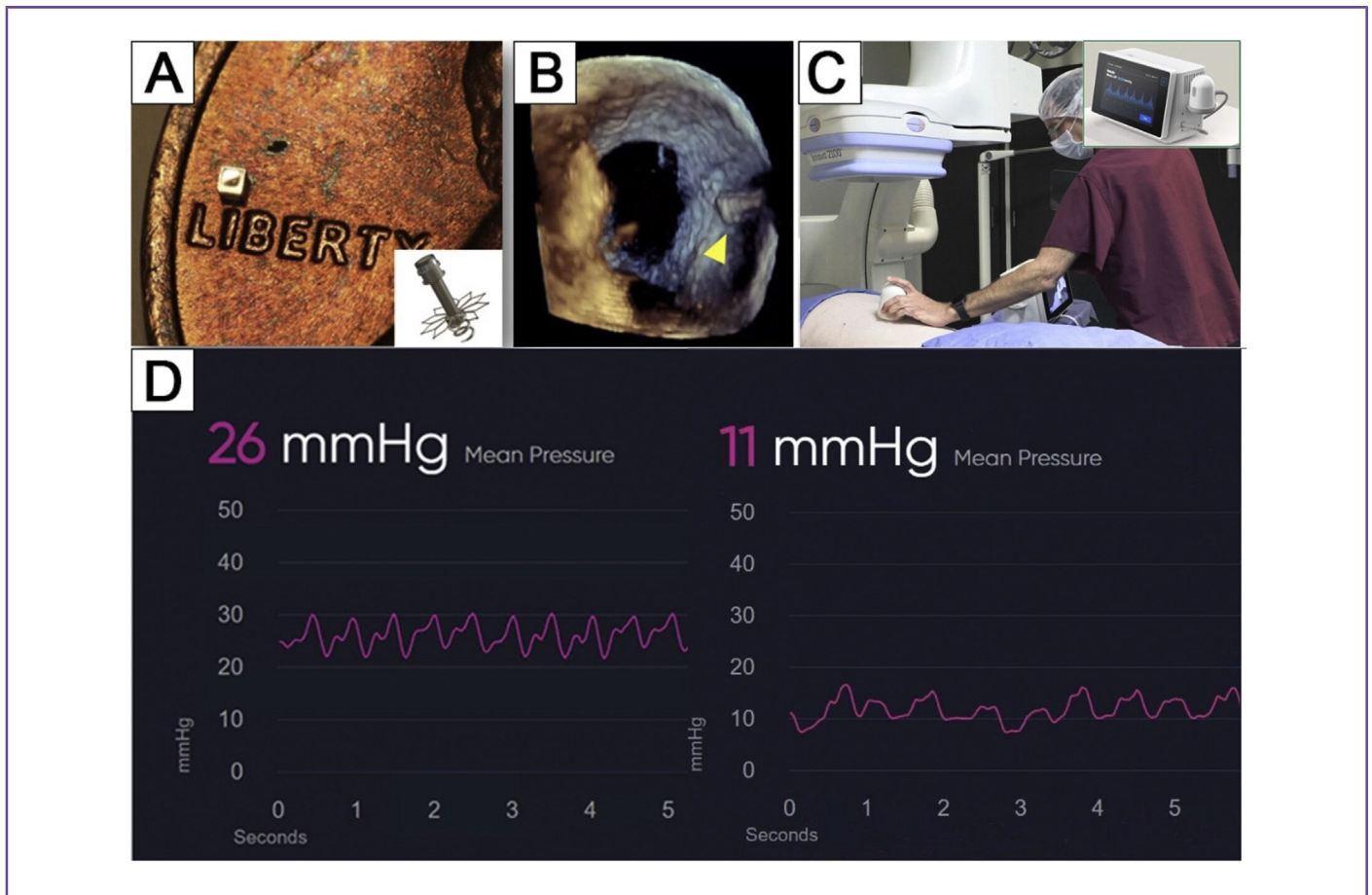
Manuscript received June 19, 2025; revised manuscript received September 4, 2025; revised manuscript accepted September 4, 2025.

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<https://doi.org/10.1016/j.cardfail.2025.09.008>



**Fig. 1.** A, The Microtech sensor is shown on top of a U.S. penny for reference and is mounted on a dedicated cardiac-fixation device (inset). B, Implantation in the right atrium is on the tricuspid valve plane between the septal leaflet and the atrial septum (arrowhead). C, Interrogation of the sensor in an animal experiment; the Microtech console (inset) is used to interrogate the sensor via ultrasound. D, The sensor produces high-fidelity pressure waveforms of the right atrial (left, taken from patient 2) or the left atrial (right, taken from patient 4) pressures.

study (NCT 06682910), a first-in-human, single-arm pilot study aimed to assess the anatomic stability, safety and usability of the Microtech system in patients undergoing LVAD implantation.

The study was funded by Microtech.

## Patients

The sensor was implanted in 4 patients suffering from advanced heart failure due to severely reduced ejection fraction, who underwent LVAD implantation. Patients' characteristics are detailed in Table 1. The sensor was implanted in the right atrium (RA) of the first 3 patients, between the septal leaflet of the tricuspid valve and the interatrial septum. In the fourth patient, the sensor was implanted in the left atrium (LA) on the mitral plane, just adjacent to the P2 segment. The sensor was fixed in place by "screwing" it in, using a dedicated implantation tool under direct visualization, and then the incision was closed with a purse-string suture. Pressure measurements through the sensor were attempted daily, starting on postoperative day (POD) 1 or as soon as possible, according to the patient's clinical status, to assess usability.

When an invasive reference measurement was available, either right-heart catheterization (RHC) or central venous pressure (CVP) was measured through a central line (for patients with right atrial implants). These readings were recorded simultaneously with sensor measurements to assess the system's accuracy. All patients were scheduled for RHC 1 month post implant, with simultaneous reading of the sensor to examine the accuracy of the sensor compared to RA/pulmonary capillary wedge pressure (PCWP) readings obtained through RHC. Subsequently, all patients will undergo follow-up with additional sensor measurements at 3–6, and 9 and 12 months. At least 1 of the follow-up time points (either 1 month or 3–6 months) will also include a remote patient monitoring (ramp) study to optimize pump parameters, while providing the opportunity to perform sensor measurements under changing hemodynamic conditions.

## Results

All 4 patients underwent surgical implantation of both the LVAD and the sensor without complications; sensor implantation added 5–10 minutes to the overall surgical procedure.

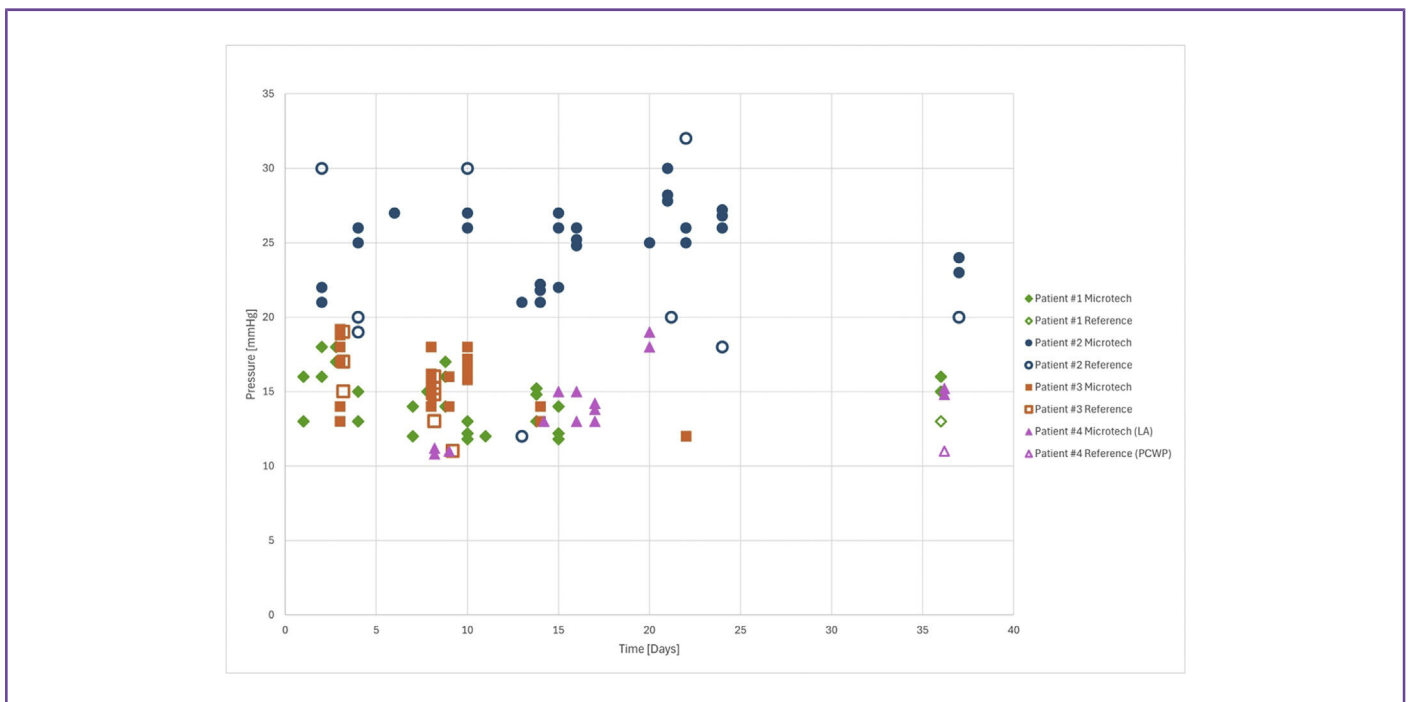
**Table 1** Patients' characteristics

	Patient #1	Patient #2	Patient #3	Patient #4
Age	51	64	71	67
Sex	Male	Male	Male	Male
Cause of HF	NICMP	ICMP	NICMP	ICMP
ICD/CRT-D	CRT-D	No	ICD	CRT-D
Previous revascularization	CABG	PPCI to LAD	No	LM PCI
Previous valvular surgery	MVR	No	No	No
Other cardiac interventions	Surgical LAAO, AVN ablation	None	No	CTI ablation
Other major comorbidities	COPD, silicosis	Morbid obesity, COPD	COPD, AF	DM
Ejection fraction (pre LVAD)	12%	30%	20%	10%
PAP pre LVAD (mmHg)	4	10	2	4
PCWP pre LVAD (mmHg)	14	12	12	15
Mitral regurgitation pre LVAD	None	None	Mild	Severe
Tricuspid regurgitation pre LVAD	Mild	Mild	Mild	Moderate
Mitral regurgitation post LVAD	None	Trivial	None	Mild
Tricuspid regurgitation post LVAD	Moderate	Mild-moderate	Mild	Mild

AF, atrial fibrillation; CABG, coronary artery bypass graft surgery; COPD, chronic obstructive pulmonary disease; CRT-D, cardiac resynchronization therapy device; CTI, cavo-tricuspid isthmus; DM, diabetes mellitus; HF, heart failure; ICD, implantable cardiac defibrillator; ICMP, ischemic cardiomyopathy; LAD, left anterior descending; LAAO, left atrial appendage occlusion; LM, left main; LVAD, left ventricular assist device; MVR, mitral valve replacement; PAP, pulmonary artery pressure; PCI, percutaneous coronary intervention; PPCI, primary percutaneous coronary intervention; PCWP, pulmonary capillary wedge pressure.

Patients 1, 3 and 4 experienced uneventful post procedural courses and were discharged home. There were no device-related adverse events. Patient number 2 (who suffered from significant lung disease) was reintubated and put on mechanical ventilation on POD 2; he was not able to be weaned from ventilation, underwent tracheostomy, and was discharged to a rehabilitation facility on POD 49. The patient died on POD 53 due to ventilator-associated pneumonia

Overall, 38 of 41 (92.7%) of reading attempts were successful: 12 of 12 (100%) for patient 1; 13 of 15 (87%) for patient 2; 7 of 7 (100%) for patient 3; and 6 of 7 (86%) for patient 4. All measurements were performed in the supine position by a physician/practitioner. A single self-measurement of the sensor was successfully attempted by patient 1 (on POD day 8); this was done in the sitting position. Measurements were also performed in patient 2 while intubated and ventilated, starting on POD 3. Right-



**Fig 2.** A scatter plot showing the sensor measurements for patients:1 (green), 2 (blue), 3 (orange), and 4 (pink). When simultaneous reference measurements were taken invasively (central venous pressure/right-heart catheterization; CVP/RHC), they are shown as open marks.

heart catheterization (RHC) was performed post-discharge for patients 1 and 4 (POD 35 for both). Results of simultaneous measurements of the sensor and right atrial/PCWP pressures obtained by RHC/CVP obtained through an indwelling jugular CVP monitor are shown in Fig. 2.

Patient 1 has completed his 3-month follow-up visit as an outpatient; his NYHA class was 2. Patients 3 and 4 have completed their 1-month outpatient follow-up visit; their NYHA classes were 3 and 2, respectively. All patients are scheduled for repeat follow-up visits at 3, 6, 9, and 12 months post implant.

## Conclusions

The Microtech sensor is a novel device that can be used to monitor intracardiac pressures, which offers several potential advantages over currently available remote-monitoring devices (size, location and its passive nature). The sensor is interrogated by the health care providers or by the patients themselves by using a console that communicates with the sensor via ultrasound. This first report demonstrates the safety of this system in patients undergoing LVAD implantation and provides encouraging initial data regarding its usability and accuracy. This includes measurements performed in multiple body positions, in close proximity to other implanted metallic objects. Three-quarters of patients have at least 1 cardiac device prior to LVAD surgery (see Table 1), and self-measurements were all in good agreement with invasive reference devices. The Microtech LVAD study (NCT 06682910) is ongoing and will enroll up to 15 patients to provide a more comprehensive assessment of the safety, usability and accuracy of the sensor in this population of patients.

A delivery system to enable percutaneous implantation of the sensor in the LA via a transseptal approach is under development. This will allow use of the sensor across the spectrum of patients with HF, with the ultimate goal of integrating the sensor into multiple existing intracardiac devices, which, it is hoped, will fulfill the potential of remote invasive monitoring to optimize care and improve clinical outcomes in the population of those with HF.



Guy Witberg

## CRedit authorship contribution statement

**BINYAMIN BEN-AVRAHAM:** Writing – review & editing. **EHUD JACOBSON:** Writing – review & editing, Investigation. **YORAM RICHTER:** Writing – review & editing, Funding acquisition. **GUY WITBERG:** Writing – original draft, Methodology, Formal analysis. **DANIEL BURKHOFF:** Writing – review & editing, Investigation. **NIR URIEL:** Writing – review & editing, Investigation. **TUVIA BEN-GAL:** Writing – review & editing, Investigation. **EREZ SHARONI:** Writing – review & editing, Investigation.

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