

CRT21 *Virtual*

Heart Failure Management Based on
LAP data with the world's first
in-heart microcomputer

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Jesselson Integrated Heart Center

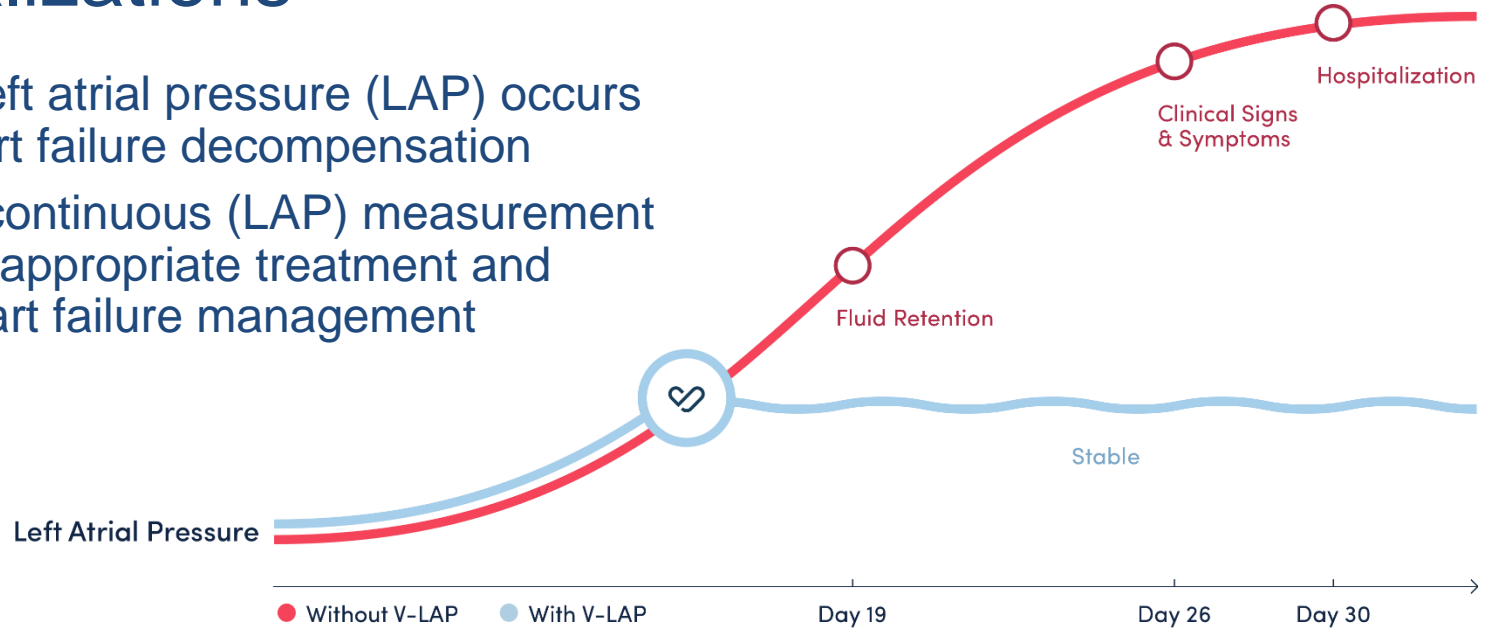
Shaare Zedek Medical Center, Jerusalem Israel

I have no relevant financial relationships

V-LAP based treatment to reduce HF hospitalizations

Increased left atrial pressure (LAP) occurs early in heart failure decompensation

Therefore, continuous (LAP) measurement may trigger appropriate treatment and improve heart failure management



Introducing V-LAP: The World's First In-Heart Microcomputer



- ✓ Battery-Free
- ✓ Wireless
- ✓ Digital
- ✓ Miniature

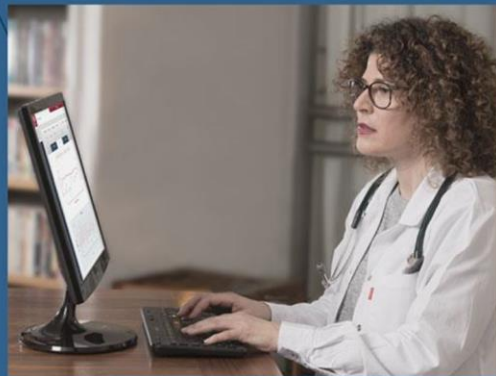
A Personalized, Patient-Centered Experience



Patient Transmits Data
at the tap of a button,
anywhere & anytime



AI Cloud Analyzes Data



Physician Adjusts Treatment
Real-time actionable data enables
remote adjustment of medications

VECTOR-HF Study



Design

Prospective, multicenter,
single arm, open-label
clinical trial



Subject Population

Chronic NYHA Class III
regardless of ejection
fraction, Hospitalization
for worsening HF or
elevated ambulatory
BNP/NT-proBNP



Primary & Secondary End-Point

Safety, usability, and
accuracy



Scope

45 patients



Participating Sites

11 sites
(Germany, Italy, UK, Israel)

Inclusion / Exclusion Criteria

INCLUSION CRITERIA:

1. Heart failure for at least 6 months
2. Stage C, NYHA Class III or ambulatory Class IV
3. Optimal heart failure therapy
4. HF hospital admission within 12-months
or NT-proBNP $\geq 1,500$ pg/ml

EXCLUSION CRITERIA:

1. NYHA class IV not ambulatory and ACC stage D.
2. **Recent Thrombosis** within the **last 6 months** intra-cardiac thrombus; stroke, transient ischemic attack; systemic or pulmonary thromboembolism; deep vein thrombosis
3. **Recent ACS**; cardiac or other major surgery within 90 days.
4. **Interatrial Septal Pathology.**
5. **Valvular Lesion** - untreated severe valve lesion
6. **Kidney Function** - eGFR < 30 ml/min/1.73 m².

VECTOR-HF Study Highlights

24

Enrolled
Patients

1 hour 20 min

Average
Procedure Time

28 months

Longest Followup
Time

< 6 min

Device Deployment
Time

Study Population Characteristics:

All patients NYHA Class III at enrollment

| Patient Characteristics (N=24) | | |
|--------------------------------|---|-------------------------------|
| | Attribute | Mean +/- SD |
| → | Age (years) | 67.42 ± 9.73 |
| → | Male (Y/N) % | 83.33 |
| | Body mass index (kg/m ²) | 29.54 ± 3.25 |
| | CRT or ICD (Y/N) % | 75.0 |
| | eGFR (mL/min/1.73m ²) | 54.88 ± 21.42 |
| | Hemoglobin (g/dL) | 13.60 ± 1.58 |
| → | 6-Minute walk (m) | 231.61 ± 130.27 |
| | spO ₂ (%) | 96.45 ± 2.28 |
| → | LVEF (%) | 30.71 ± 10.17 |
| | Heart rate (bpm) | 74.79 ± 11.88 |
| | Systolic / Diastolic blood pressure (mm Hg) | 115.21 ± 13.84 / 71.83 ± 9.05 |
| | Mean RAP (mm Hg) | 9.71 ± 7.27 |
| | PASP (mm Hg) | 45.62 ± 14.22 |
| | Mean PCWP (mm Hg) | 19.16 ± 6.92 |
| → | LAP by catheter | 18.56 ± 6.96 |

VECTOR-HF Study: Performance

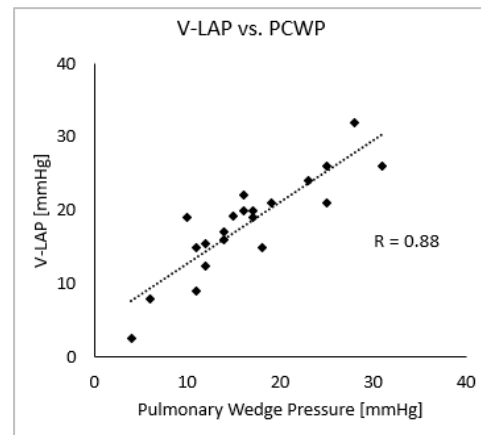
In first 21 patients LAP accuracy was demonstrated at 3 months visit, by comparing to the gold standard (PCWP).

Accuracy validation will be demonstrated in all remaining patients at the 3 months FU visit to be held during the upcoming 1-3 months.

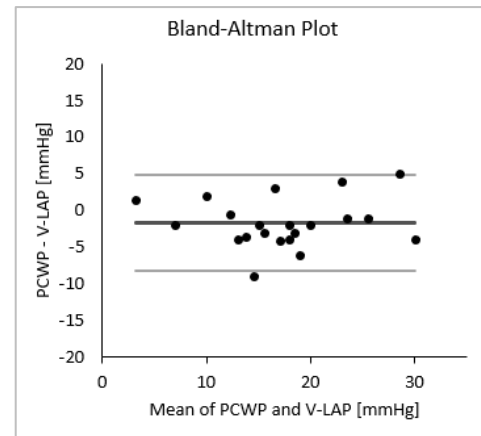
Excellent correlation between mean device-measured LAP and mean PCWP of $R=0.88$, significant at $P < .0001$

V-LAP vs. PCWP mean difference -1.69 ± 3.36 mmHg

Correlation
Graph

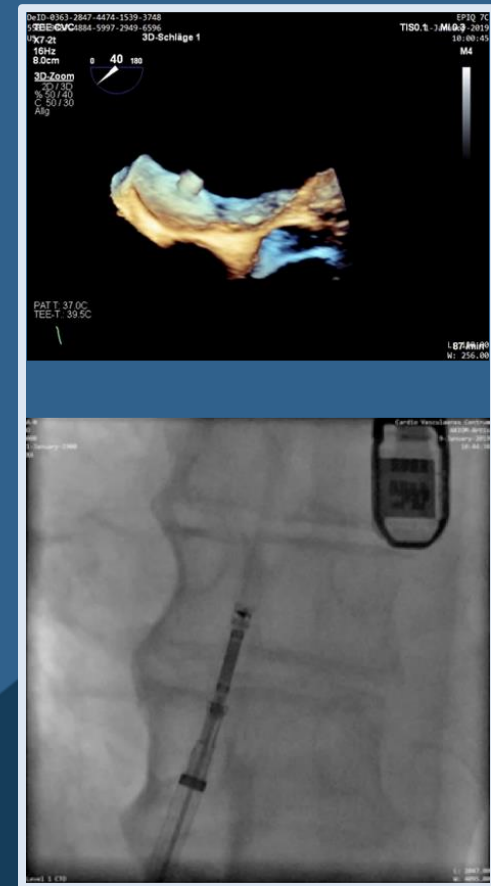


Bland Altman
Plot



Examples for Fluoroscopy and TEE

(H. Sievert, CardioVascular Center Frankfurt Germany)



Safety

30 serious adverse events

None were device or procedure related

Two deaths:

- CVA, sepsis and multiorgan failure two months after device deployment
- Complication of coronary intervention 3 months after deployment

| VECTOR-HF Study SAEs | |
|---------------------------------|------------------|
| Event term | Number of events |
| Heart Failure Hospitalizations | 13 |
| Hypertension | 3 |
| COVID-19 Infection | 2 |
| Dyspnea | 2 |
| CVA | 2 |
| Pneumonia | 1 |
| Hyperglycemia | 1 |
| Allergic Reaction to Medication | 1 |
| Weakness in Left Arm | 1 |
| Gastritis | 1 |
| Dizziness | 1 |
| Death | 2 |
| Total Events | 30 |

Patient DE-06-001

Optimization of therapy according to left atrial pressure

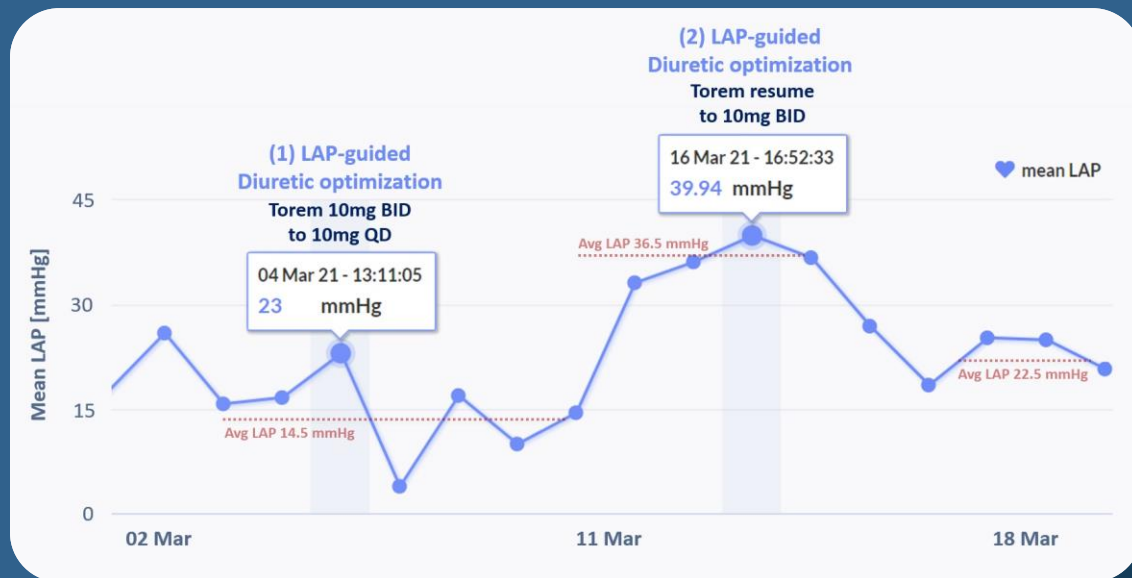
65 years old male

Implanted on 30 July 2019

Ischemic, HFrEF, Normal sinus rhythm

Changes in diuretics:

- **Baseline:** PO Torem 10mg BID
- **Mar 4th , 2021:** PO Torem 10mg QD
- **Mar 16th , 2021:** PO Torem 10mg BID



Patient IL-01-003

Hemodynamic elevation following COVID-19 infection

Each increase in LAP has been followed by hospitalization.

1/10/2020 - SARS-CoV2 infection and hospitalization

28/10/2020 - Hospitalization due to decompensation

26/11/2020 - Hospitalization due to decompensation

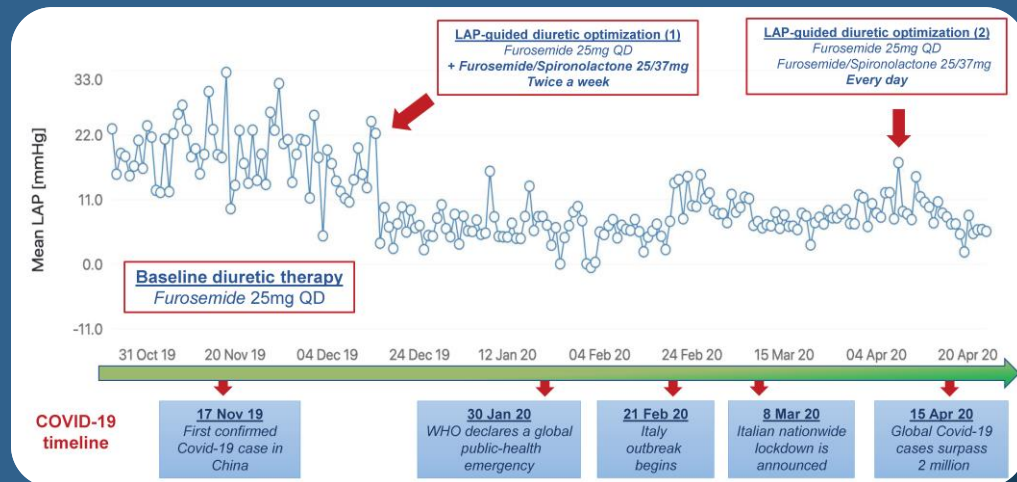


Patient IT-02-001

Experience of remote cardiac care during the COVID-19 pandemic: the V-LAP™ device in advanced heart failure

Published 19-May-20 | EJHF

LAP trends used to guide optimization of medical therapy, reducing patients' and health care providers' risk of exposure in the COVID-19 era.



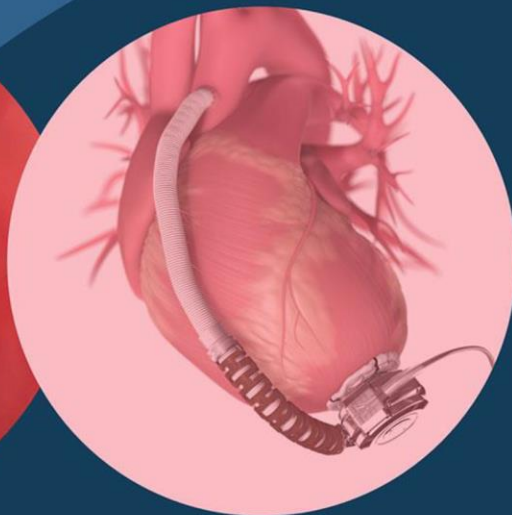
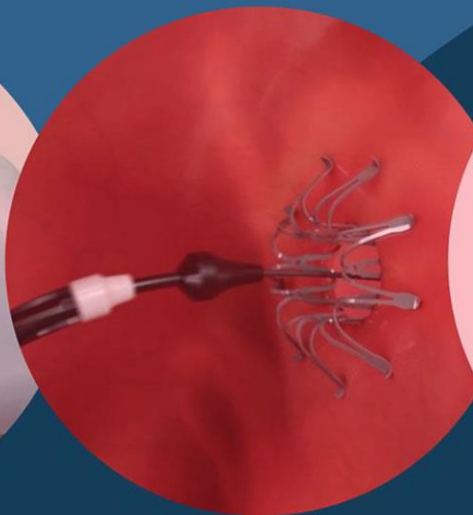
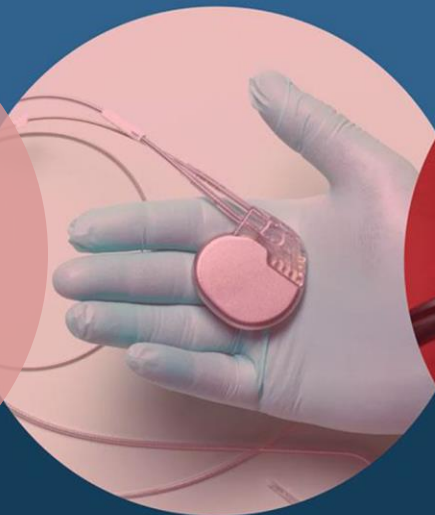
The timeline shows optimization of therapy according to LAP values measured with the V-LAP™ device.

What's Next?

Making Therapeutic Devices Smarter

V-LAP will be an enabler for combined diagnostic and therapeutic medical devices, which will provide optimal heart failure management and treatment.

Microsensors will be fitted across the cardiovascular system, gathering valuable physiological data remotely.



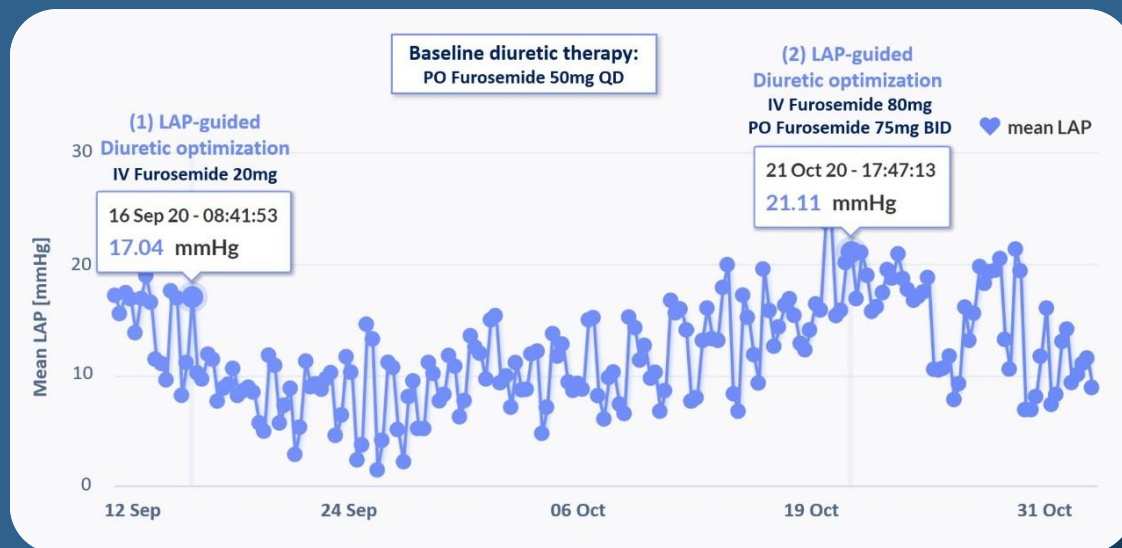
Patient IT-02-004

Optimization of therapy according to left atrial pressure

Each increase in LAP has been followed by therapy adjustment and subsequent decrease in LAP, preventing episodes of decompensation.

Changes in diuretics:

- **Baseline:** PO Furosemide 50mg QD
- **Sep 16th, 2020:** IV Furosemide 20mg
- **Oct 21st, 2020:** IV Furosemide 80Pmg, PO Furosemide 75mg BID



Patient DE-06-003

Optimization of therapy according to left atrial pressure

86 years old male

Implanted on 01 October 2020

Non-Ischemic, HFpEF, AF

Changes in diuretics:

- **Baseline:** PO Torsemide 20 mg BID
- **Dec 22nd , 2020:** PO Torsemide 60 mg QD
- **Dec 25th, 2020:** PO Torsemide 20 mg BID
- **Feb 10th , 2021:** PO Torsemide 30 mg QD
- **Mar 10th , 2021:** PO Torsemide 20 mg BID

