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A Novel Implantable Left Atrial Pressure Sensor in Two Heart Failure Patients

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Conflicts of interest
The authors have received institutional grant from Vectorious Medical Technologies. CDM and HS are members of the Scientific Advisory Board of the same company.

Classifications

Chronic heart failure, depressed left ventricular function, dilated non ischemic cardiomyopathy.

Short running title
LAP pressure sensor in heart failure patients

Monitoring pressure and adapting therapy to the rapid changes of left ventricular loading conditions is the cornerstone of treatment of acute heart failure in hospitalized patients. This approach has also been translated in the chronic setting as proved by the results of the only commercially available pulmonary pressure monitoring system (CardioMEMS, Medtronic, Minneapolis, USA) in terms of hospital admissions[1] and mortality[2]. We report the procedural results of a novel permanent sensor recording high fidelity pressure on the left side of the interatrial septum in two NYHA Class III patients with dilated cardiomyopathy.

The implant (Figure 1a) is composed of a microelectromechanical pressure sensor, positioned on the left-atrial side, and an electronic circuit and antenna positioned across the inter-atrial septum (antenna length 17 mm). These components are held in place by two braided nitinol hemidiscs (16 mm right atrial disc, 18 mm left atrial disc). The anchoring braid is crimped and loaded using a dedicated delivery system deployable through a 12F sheath and remains fully retrievable throughout the delivery process. The implantation procedure requires femoral venous puncture, transesophareal or intracardiac echocardiography guidance, trans-septal puncture centrally in the fossa ovalis and final simultaneous measurement of the pulmonary wedge and left atrial pressures. This digital intra-cardiac pressure sensor enables subsequently bi-directional communication with the external unit (Figure 1b) that also powers the implant and collects data via radio frequency communication. It is designed to operate with the patient both in supine and upright position and during exercise. The implant is designed to be operative and reliable for at least 10 years.

The implantations were performed in December 2018 in Frankfurt and January 2019 in Florence. The patients treated were 72 and 52 years old men with dilated cardiomyopathy (LVEF 32% and 35%, respectively). Both patients were on optimal medical therapy including loop diuretics.

TEE guidance was used in both cases, using deep sedation in one hospital and general anesthesia in the other (Figure 1c). Standard full heparinization with an activated clotting time of 250 msec is required during the procedure. The implantation procedure lasted 7 and 14 minutes, respectively, with high fidelity signals transmitted to the external unit showing good superimposition of the average pulmonary wedge and left atrial pressure (Figure 1d). Both patients were discharged home the day after the implantation on aspirin and clopidogrel or anticoagulation. No device-related adverse events were registered at follow-up up to 12 months.

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Figure legends

Figure 1: *(a)* The V-LAP™ implant; *(b)* The external unit; *(c)* TEE image of the implanted V-LAP™; (d) simultaneous V-LAP™ pressure tracings and pulmonary wedge pressure at the moment of the implantation

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