Safety, usability, and performance of a wireless left atrial pressure monitoring system in patients with heart failure: the VECTOR-HF trial (final results)

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Background: In heart failure (HF), implantable hemodynamic monitoring devices have been shown to optimize therapy, anticipating clinical decompensation and preventing hospitalization. Direct left-sided hemodynamic sensors offer theoretical benefits beyond pulmonary artery pressure (PAP) monitoring systems.

Aims: We evaluated the safety, usability, and performance of a novel left atrial pressure (LAP) monitoring system in HF patients (V-LAP).

Methods and Results: The VECTOR-HF study was a first-in-human, prospective, multicenter, single-arm, clinical trial enrolling 30 patients with HF. The device consisted of an interatrial positioned leadless sensor, able to transmit LAP data wirelessly. After three months, a right heart catheterization (RHC) was performed to correlate mean pulmonary capillary wedge pressure (PCWP) with simultaneous mean LAP obtained from the device. Remote LAP measurements were then used to guide patient management. The miniaturized device was successfully implanted in all 30 patients, without acute Major Adverse Cardiac and Neurological Events (MACNE). At 3 months, freedom from short-term MACNE was 97%. Agreement between sensor-calculated LAP and PCWP was consistent, with a mean difference of \(-0.22\pm4.92\) mmHg, the correlation coefficient and the Lin’s Concordance Correlation Coefficient values were equal to 0.79 (P<0.0001) and 0.776 (95% CI=0.582-0.886), respectively. Preliminary experience with V-LAP-based HF management was associated with significant improvements in NYHA functional class (32% of patients reached NYHA II class at 6 months, P<0.005; 60% of patients at 12 months, P<0.005) and 6-minute walk-test distance (from 244.59±119.59m at baseline to 311.78±129.88m after 6 months, P<0.05, and 343.95±146.15m after 12 months, P<0.05).

Conclusion: The V-LAP™ monitoring system proved to be safe and provided a good correlation with invasive PCWP. Initial evidence also suggests possible improvement in HF clinical symptoms that could be associated to a better outcome. Further studies are needed to test the efficacy of the device in heart failure patients.