Leadless LV Endocardial Stimulation for CRT: Final Outcomes of the Safety and Performance of Electrodes Implanted in the Left Ventricle (SELECT-LV) Study

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Introduction: Patients indicated for conventional CRT (CRT) do not always benefit due to CS lead issues both acute and chronic, inability to place the lead or not responding to CRT. LV endocardial pacing has been proposed as a potential solution. SELECT-LV assessed the safety and performance of a novel Wireless Stimulation of the Endocardium System, (WiSE), providing endocardial LV stimulation.

Methods: This non-randomized EU study of CRT included pts with either a failure of CRT, or requiring an upgrade and were unsuitable for CRT. WiSE includes a leadless pacing electrode implanted at the endocardial LV free wall. The electrode is activated by a submuscular ultrasonic transmitter, synchronized with RV pacing pulses from a co-implanted pacer/ICD. Primary end points of safety / performance and secondary endpoints for safety / performance / preliminary efficacy were at 1 and 6m.

Results: 39 were enrolled but 3 (8%) of pts did not have an adequate acoustic window, 1 withdrew pre-implant, and 1 had intra-operative VF precluding successful implantation; this pt died a few days later. There were successful implants in 34 of 35 pts (97%), and 34 (97%) pts completed 6m follow-up. Baseline data: age 65±8 yrs; 29 (85%) male; 44% ICM, 44% NICM and 12% both; EF 26.0±6.2; NYHA 2.6±0.6; and baseline intrinsic QRS 170±29 ms. There were 3 (8.5%) AEs peri-operatively and 8 AEs (22%) by 1 month. BiV pacing at 1 and 6m was demonstrated in 33 (97%) of 34 pts and in 31 (94%) of 33 pts respectively. Mean QRS reductions were 51 and 36 ms compared with baseline RV paced QRS and baseline intrinsic QRS respectively. At 6m, 63% of pts demonstrated ≥ 5% increase in EF at 6m; the mean increase was 7.1±8.0%. Compared with baseline, at 6m, 67% pts improved ≥1 NYHA class and 52% patients showed ≥15% improvement in LVESV. The clinical composite score at 6m showed that 28 (85%) improved, 3 (9%) unchanged, and 2 (6%) worsened.

Conclusion: This multicentre experience has demonstrated the feasibility of direct, wireless endocardial LV pacing to achieve CRT in patients with a previous CRT failure or previously unsuitable for CRT.