Safety and Performance of a Novel Two Lead Cardiac Resynchronization Therapy System

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Introduction: Novel two lead BIOTRONIK CRT-D (DX) devices provide a floating atrial dipole in lieu of a dedicated atrial lead to collect atrial sensing diagnostics and can offer several advantages compared to conventional three lead devices, including a reduction in procedural complexity and reintervention risk. When implanted with an LV lead, these combine for a two lead CRT system. The goal of the research presented herein is to evaluate CRT-DX system safety and performance compared with a conventional three lead CRT-D system at 3 months and 6 months post-implant.

Methods: A total of 126 subjects from the QP ExCELs study (NCT02290028), were selected to identify 63 matched pairs (each DX subject paired with a CRT-D control) with demographic characteristics based on age, gender, NYHA class, LVEF and heart failure etiology. All patients had a standard CRT-D indication with de novo implantation or an upgrade from an existing ICD or pacemaker. System performance data was obtained from routine, daily remote transmissions, and system performance differences were assessed by taking a 14-day average of the mean differences between each subject pair at 3 and 6 months post-implant. All adverse events utilized QP ExCELs case report forms and were evaluated through 6 months post-implant.

Result: Subjects were 65% male with a mean age of 67 years and LVEF of 25%. Sixty percent of the subjects were NYHA class III with the remainder NYHA class II. System performance characteristics are provided in the attached table. A total of 2 adverse events were identified as related or possibly related to the RA or RV lead in both the CRT-DX and in the conventional CRT-D cohorts. Two RV/RA lead dislodgements occurred in the CRT-D cohort, compared to 1 RV lead dislodgement in the CRT-DX cohort. One occurrence of oversensing in the RA dipole due to excess noise was identified in the CRT-DX cohort. All four of these events were resolved with a lead revision. Additionally, 4 implant-related events were identified as occurring in the conventional CRT-D cohort, compared with 2 implant-related events in the CRT-DX cohort. No pulse generator-related adverse events were identified in either cohort.

Conclusion: The results suggest similar safety and performance in both the CRT-DX and conventional three-lead CRT-D systems over a duration of 6 months post-implant, despite the DX lead utilizing one fewer lead.