Performance of a novel active fixation quadripolar left ventricular lead: Results from the Attain Stability Quad clinical trial

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Introduction: Dislodgements of left ventricular (LV) leads are still a challenging problem in cardiac resynchronization therapy (CRT). The Attain Stability Quad (ASQuad) MRI SureScan Model 4798 steroid-eluting, quadripolar LV lead has a side-helix to enable the lead to be actively fixated to the vessel wall. The uniquely designed active fixation can be advantageous in vessels that are wide or have short take-offs. Further, the helix easily elongates to allow for future extraction.

Methods: The ASQuad clinical study is a prospective clinical trial from 50 centers in 10 countries aimed at evaluating safety and effectiveness of the Medtronic Attain Stability LV lead. Lead implant related parameters were obtained. Reported adverse events were reviewed by an independent physician panel. Additionally, we compared ASQuad study results against data observed in the Attain Performa 4298 premarket study for implant experience and lead final placement.

Result: Of 440 enrolled patients (74.8% male, average age 70 ±11 years) who underwent an implant procedure, 426 (96.8%) were successfully implanted. The side-helix was mostly affixed in the mid to basal lateral position (62.0%), followed by mid to basal posterior position (29.0%). The lead tip placement was 90.6% non-apical; most often mid-lateral or mid-posterior (76.5%), and in a vein with diameter greater than the pacing electrode diameter (> 5.1 French) in the majority (60.4%) of procedures, which was 2X as that of the Medtronic Quadripolar Attain Performa Model 4298 (p<0.0001). The overall handling of the LV lead was rated as acceptable by implanters in 99.3% of cases. During implant, incidences of dislodgement during slitting was very low (0.45% vs 1.96% in Model 4298, p=0.0145). The mean PCT for all subjects at the final selected LV pacing vector was 1.15 ± 0.70 V at 0.5ms pulse width at implant and 1.07 ± 0.68 V at 6 months. Overall lead related complication free survival at 6 months was 97.6% (Figure 1). Three patients (0.7%) experienced LV lead dislodgement post implant, and these complications were resolved by repositioning of the lead (0 and 1-day post implant) in two and by lead replacement when noted at 90 days follow-up in one.

Conclusion: The Attain Stability Quad 4798 lead was implanted with a high rate of success (96.8%) and very low rate of dislodgment (0.7%), with lead placement mostly (90.6%) at non-apical locations.
Lead safety and effectiveness were demonstrated by 97.6% lead-related complication-free probability and low and stable PCTs. The active fixation mechanism enabled precise placement of the pacing electrodes at the desired target region. The novel fixation mechanism may further enhance the implanting physician's ability to deliver safe and effective CRT, and to potentially achieve desired CRT response in more heart failure patients.