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Implant procedure and lead handling characteristics of a novel active fixation quadripolar lead: Results from the Attain Stability Quad clinical trial

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Background: Dislodgements of left ventricular (LV) leads are still a challenging problem in cardiac resynchronization therapy (CRT). The Attain Stability Quad (ASQuad) MRI SureScan 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.

Purpose: To report on the handling, performance and safety of ASQuad LV lead in a large clinical study.

Methods: The ASQuad clinical study is a prospective clinical trial from 50 centers in 10 countries enrolling CRT candidates implanted with the ASQuad LV lead. Aside from evaluating safety and effectiveness of the LV lead, the trial specifically collected data on parameters related to lead stability during and post implant.

Results: Of 440 enrolled patients (74.8% male, average age 70±11 years) that underwent an implant attempt, 426 (96.8%) were successfully implanted. The helix was mostly affixed in the mid to basal lateral position (62%), followed by mid to basal posterior position (29%). The lead tip placement was most often mid lateral or mid posterior (77%), and in a vein with diameter greater than the pacing electrode diameter ($>$5.1 French) in the majority (60%) of procedures. Among all subjects (n=421) who underwent pacing capture thresholds (PCT) tests before and immediate after guide catheter slitting, 98% reported $\leq$1 V difference in PCT, and 86% were within 0.5 V. The interquartile range for the difference in PCT was –0.1 to 0.1 V. The mean PCT at implant for all subjects at the final selected LV pacing vector was 1.15±0.70 V at 0.5 ms pulse width. The average LV lead implant time was 16±21 minutes. Targeted pacing location was achieved in 97% of successful implants, and 98% of implanters reported good or fair stability after guidewire removal. The overall handling of the LV lead was rated as acceptable by implanters in 99% of cases. 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.

Conclusions: The ASQuad LV lead was implanted with a high rate of success and ability to achieve the targeted pacing location. Lead handling and stability following guidewire removal were rated as acceptable by nearly all implanters. The side-helix likely improved LV lead stability since 98% of the subjects had $\leq$1 V difference in PCT before and after catheter slitting during implant procedures, and by demonstrating a low post implant lead dislodgement rate.