Subclinical AF Detection with a Floating Atrial Sensing Dipole in Single-Lead ICD Systems: **Results of the SENSE Trial**

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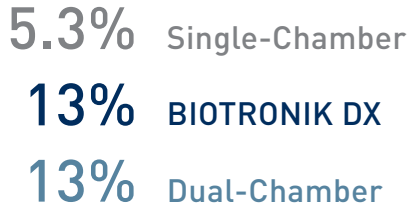
Study Design

- Prospective, multicenter, cohort-controlled study to determine the utility of the DX implantable cardioverter-defibrillator (ICD) system for subclinical atrial fibrillation (AF) detection.
- Eight centers in the United States, including 150 patients implanted with a BIOTRONIK DX ICD system, comparing data with historical single- and dual-chamber ICD cohorts derived from previous studies.
- Patients met standard indications for a primary or secondary prevention ICD, had no atrial pacing indication and no prior history of AF or atrial flutter.
- Cohorts were matched with regards to age, gender, and left ventricular ejection fraction.

Main Results

DX Superior to Single-Chamber and Comparable with Dual-Chamber



Patients with Atrial High Rate Episode (AHRE) Detections at 12 Months

1. AHRE detection was significantly higher in the DX cohort compared with the single-chamber cohort (p = 0.026).
2. It was not significantly different from the dual-chamber cohort (p = 1.00).
3. Multivariate regression showed use of DX was associated with AHRE detection (adjusted HR 2.40; 1.05–5.48; p = 0.038).

Clinical Relevance

- First study to assess efficacy of DX technology for subclinical AF detection in a prospective, multicenter, cohort-controlled trial.
- The results indicate that the DX ICD system may offer significant benefits for AHRE detection in ICD patients who do not have an atrial pacing indication, but are at high risk of developing subclinical AF.[1]

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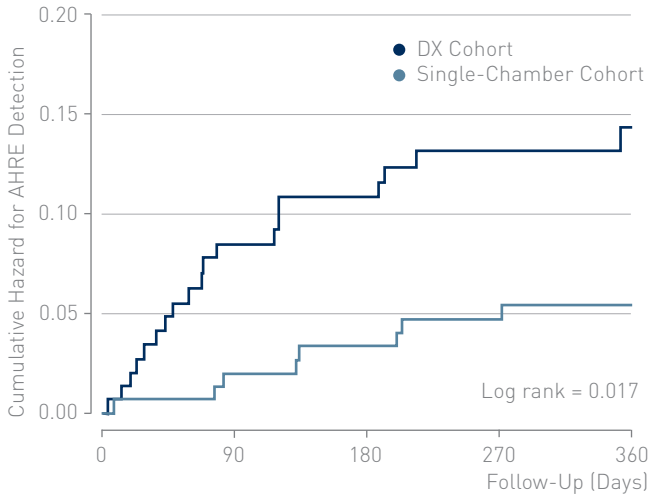
DX Cohort: Increased Detection of AHRE,[2] Zero Inappropriate Therapies and Reliable Atrial Sensing

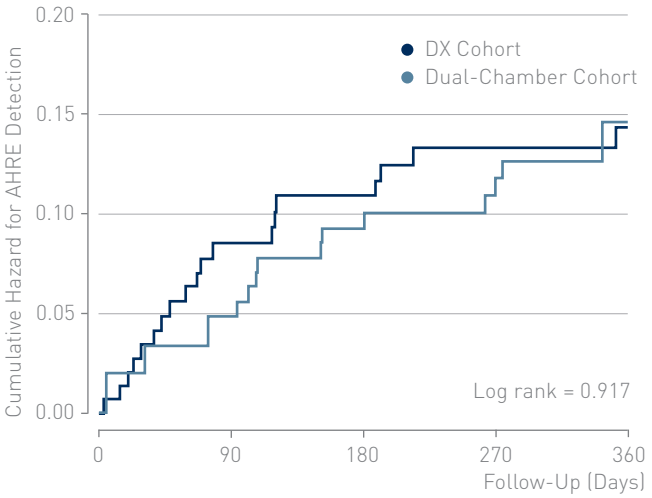
Time to First AHRE Detection

DX vs. Single-Chamber



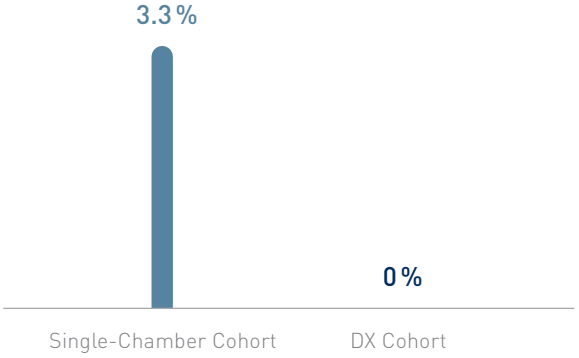
Increased AHRE detection in the DX cohort compared with single-chamber cohort (log rank p = 0.017)

DX vs. Dual-Chamber



No difference between DX and dual-chamber cohort (log rank p = 0.917)

DX Cohort Showed Zero Inappropriate Therapies



No patient experienced inappropriate therapies in the DX cohort.

Note: Single-chamber cohort includes device systems from multiple manufacturers. No data for dual-chamber cohort available.

Atrial Sensing in the DX Cohort: Stable and Reliable

8.0 mV

Mean sensed atrial amplitude **at implant**.[3]

7.3 mV

Mean sensed atrial amplitude **at 12-month follow-up**.[3]

0%

No patient required addition of an atrial lead due to inadequate sensing or sinus node dysfunction.

0%

No patients had clinical AF that was undetected by the DX system.

1 Author's conclusion extracted from publication.
2 Compared with single-chamber cohort.
3 Mean sensed atrial amplitude was 8.0 ± 5.0 mV at implant and 7.3 ± 4.8 mV at 12-month follow-up.

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