Research Article

Atrial sensing of Single-lead Implantable Cardioverter Defibrillator with DX Technology

Riccardo Mangione, MD[1], Antonio Greco, MD[2], Enrico Bertagnin, MD[3], Giuseppe Bottaro, MD[4], Paolo Zappulla, MD*, Daniela Dugo, MD[5], Angelo Di Grazia, MD[6], Valeria Calvi, MD[7]

1,2,3,4,5,6,7. Division of Cardiology, A.O.U. Policlinico "G.Rodolico – San Marco", University of Catania, Catania, Italy.

***Corresponding Author: Dr Paolo Zappulla, MD**, Division of Cardiology, A.O.U. Policlinico "G.Rodolico – San Marco", University of Catania , Via Santa Sofia, 78 - 95123 - Catania, Italy.

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Abstract

Introduction

Implantable cardiac defibrillator with DX technology (DX-ICD) consists of a single-lead system able to sense atrial signals via a floating atrial dipole.

This study aimed to assess the performance of the DX-ICD in terms of atrial sensing stability as compared to dual-chamber ICD (DR-ICD).

Methods

We included patients implanted with an ICD and followed-up at Policlinico "G. Rodolico – San Marco" of Catania. The primary outcome was the atrial sensing stability over time. Patients with DX-ICD were compared to those implanted with a DR-ICD in terms of atrial sensing at baseline, 1-year and 2-year follow-up.

Results

Out of 2,225 patients implanted with an ICD and followed-up at our facility, 47 patients fulfilled the eligibility criteria and represented the population of our analysis. Of them, 31 (66%) were implanted with a DX-ICD, while 16 (34%) with a DR-ICD. In the DX-ICD arm, the mean P wave sensing was 4.22±2.7 mV at baseline, 4.47±3.01 mV at 1 year and 4.73±2.94 at 2-year follow-up; in the DR-ICD arm, the mean P wave sensing was 3.73±1.21 mV at baseline, 3.5±1.44 mV at 1 year and 3.85±1.58 mV at 2-year follow-up (P-value >0.05). The mean atrial sensing amplitude did not show significant variations over a 2-year follow-up between the two arms, remaining in a clinically acceptable range.

Conclusion

DX ICD with an atrial floating dipole is a valuable option in patients not requiring atrial pacing, showing similar diagnostic performances to dual-chamber devices, but reducing the risks for procedural and lead-related complications.

Keywords: *Implantable cardioverter-defibrillator, atrial floating dipole, DX system, atrial sensing, cardiac implantable electronic devices.*

Introduction

Cardiac implantable electronic devices (CIEDs) encompass pacemakers (PMs), implantable cardioverter defibrillators (ICDs) and devices for cardiac resynchronization therapy (CRT).

CIEDs currently represent an important approach to provide life-saving therapy for the treatment of bradyarrhythmia, ventricular tachyarrhythmia and advanced systolic heart failure.

After ICD implantation, a sizeable proportion of patients develop atrial arrhythmias **(**1**)**; monitoring of atrial rhythm is of crucial importance for the detection and prompt treatment of atrial arrhythmias. An atrial lead is usually implemented to reach this goal. However, adding an atrial lead can increase the risk of procedural complications, as well as procedure-related times and costs.

A single-lead system able to sense atrial signals via floating atrial electrodes (VDD) was introduced several decades ago and was recently proposed as part of the Biotronik DX-ICD system in the early 2000s **(**2**)**. The modern DX system is the result of several improvements, consisting of a VR-T DX device and a Linox Smart DX active fixation lead, which is a single coil bipolar lead including two atrial ring electrodes spaced 15 mm from each other and 15-17 cm from the lead tip anchored to the right ventricle. Atrial electrodes are floating within the atrium, covering an area of 49 mm2, and have no atrial pacing capability.

The principal purpose of the DX-ICD system is to provide diagnostic information about atrial rhythm, reducing the risks for lead-related complications, such as lead dislodgment, infection, hematoma, and pneumothorax **(**3**)**.

Several studies have been conducted to demonstrate the advantages of the single-lead DX system compared to other devices with a dedicated lead for the atrium **(**4,5,6,7**)**. However, this issue remains a matter of debate and some clinical trials are still ongoing, such as the CRT-NEXT **(**8**)**, the BIO|REDUCE **(**9**)**, the BIOMASTER. Cor Family Study **(**10**)**.

Our study aimed to assess the medium-term reliability of the DX single-lead ICD in terms of atrial sensing stability as compared to dual-chamber ICD.

Methods

Eligibility criteria

Criteria for inclusion in our study are the following: 1) Patients have to be implanted with a dual-chamber or a single-chamber (with DX technology) CIED and followed-up at our center; 2) Active remote monitoring. To reduce the potential variability deriving from different manufacturers, patients with a Biotronik device were selected. No specific exclusion criteria were applied.

Study outcomes

The primary outcome of our study was the stability of DX lead atrial sensing, assessed by the evaluation of the variation of mean atrial sensing amplitude at 1 year and 2 years from ICD implantation.

Statistical analysis

Variables' distribution was explored using the Kolmogorov-Smirnov test. Normally distributed variables were described as mean and standard deviation (SD), while non-normally distributed variables were reported as the median and interquartile range (IQR). For non-normal parameters differences between baseline, first and second follow-up timepoint was explored by the Friedman test. Differences between means in the DX and the dual-chamber ICD cohorts were assessed with the Student t-test. All P values less than 0.05 were considered to be statistically significant. For multiple comparisons, Bonferroni correction was applied. Statistical analysis was performed with SPSS version 25 (SPSS, Chicago, IL, USA).

Results

Out of 2,225 patients who underwent ICD or PM implantation and are currently followed-up at our center, 388 patients are given remote monitoring, thus resulting eligible for inclusion in our study. To ensure the availability of active daily transmission of data with reliable quality, only patients implanted with a Biotronik device (270) were included. Of them, 47 were implanted with a single-chamber DX-ICD or a dual-chamber DR-ICD, therefore representing the population of our analysis (**Figure 1**). Of them, 31 (66%) were implanted with a DX-ICD, while 16 (34%) with a DR-ICD; 37 patients were males (78.7%) and 10 females (21.3%). The mean age at implantation was 64.95±12.07 years.

Patients underwent periodic outpatient follow-up visits in the first 2 years from implantation.

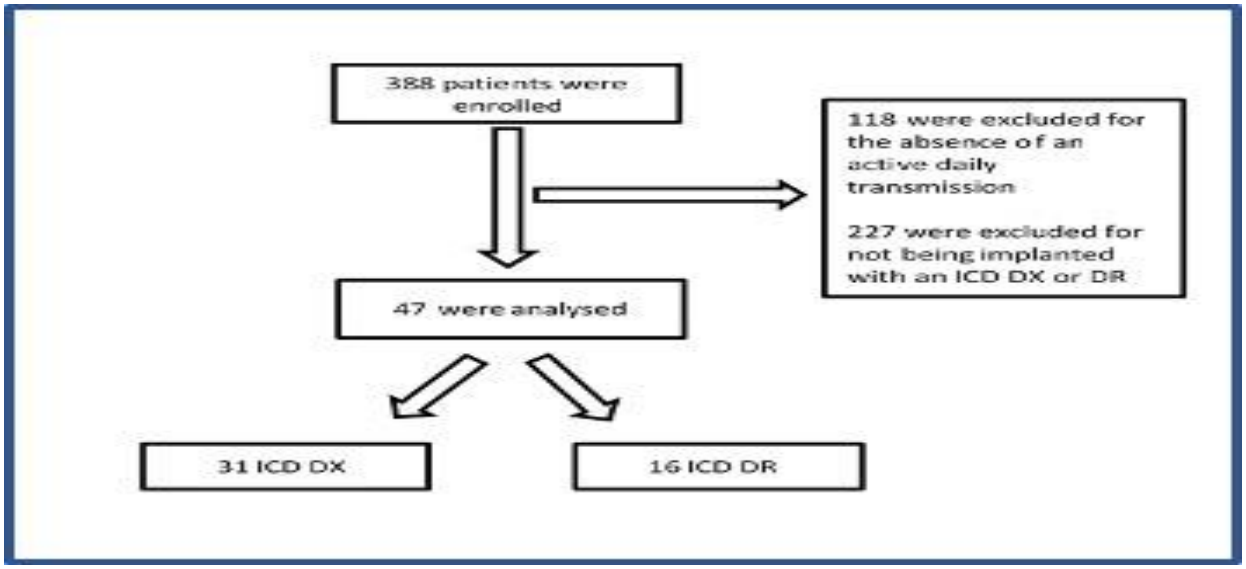

Figure 1

In the DX-ICD arm, the mean P wave sensing was 4.22±2.7 mV at baseline, 4.47±3.01 mV at 1 year and 4.73±2.94 at 2-year follow-up; in the DR-ICD arm, the mean P wave sensing was 3.73±1.21 mV at baseline, 3.5±1.44 mV at 1 year and 3.85±1.58 mV at 2-year follow-up. There was no between-groups difference (P value >0.05 for all comparisons) in mean P wave amplitude (**Figure 2**).

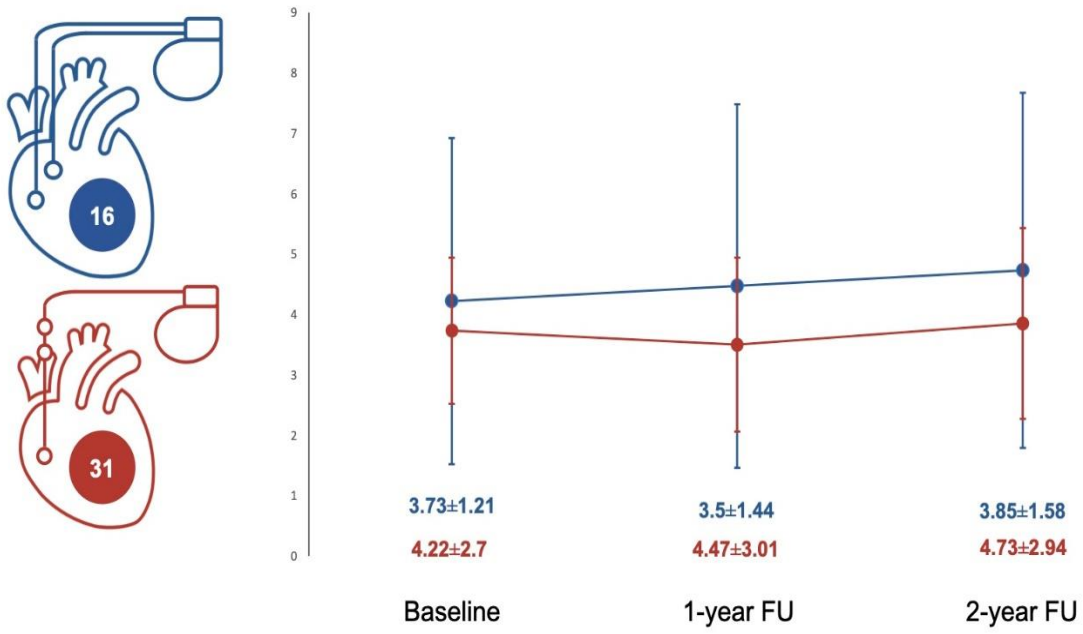

Figure 2

The median baseline P wave sensing of the DX-ICDs was 4.2 mV, ranging from 1.79 mV to 7.04 mV. This value was 3.96 mV (1.39 mV to 7.9 mV) at 1 year, 5.41 mV (1.47 mV to 7.87 mV) at 2-year follow-up, (P-value >0.05).

The median ventricular impedance value was stable as well: 518.16 Ω (447.6 Ω to 566.81 Ω) at baseline, 498.71 Ω (425.18 Ω to 554.59 Ω) at 1 year and 483.77 Ω (434.15 Ω to 552.51 Ω) at 2-year follow-up. These results are reported in **Table 1**.

Parameters	Baseline	1-year	2-year	P value
Median P wave sensing (mV)	4.2 (1.79-7.04)	3.96 (1.39-7.9)	5.41 (1.47-7.87)	>0.05
Minimum P wave sensing (mV)	3.21 (1.3-6.38)	3.1 (0.93-7.5)	3.92 (0.93-7.37)	>0.05
Median ventricular impedance (Ω)	518.16 (447.6-566.81)	498.71 (425.18-554.59)	483.77 (434.15-552.51)	>0.05

Table 1: Atrial sensing and ventricular impedance comparisons

Discussion

In this observational case series, we reported the results of a comparison between DX-ICD and DR-ICD in a population of patients implanted with an ICD at our facility. DX-ICDs take advantage of the DX system, equipped with an atrial floating dipole, able to detect atrial electrical signals, as described above.

An important advantage with these devices derives from the avoidance of a dedicated atrial lead, namely the reduction of lead-related complications such as lead dislodgment, infection, pneumothorax, hematoma, loose set screw at the ICD connector, lead insulation defect, lead fracture.

The main finding of this analysis was that the mean atrial sensing amplitude did not show significant variations over a 2-year follow-up, remaining in a clinically acceptable range.

Our results mirror those reported in previous literature. In a previous experience, 13 patients, implanted with a DX-ICD, were followed up for 200 days and their P-wave amplitude was collected daily; it was 3.9±2.2 mV at the implantation, whereas its mean value was 4.2±1.9 mV during the follow-up, showing reliable stability over time. A total of 95% of the P-wave measurements in the 200 days remained between ± 50% from the mean P-wave value **(**3**)**. Another study collected data from 32 patients implanted with Biotronik VR-T DX devices and followed them for a mean of 432±197 days after implantation. Atrial sensing stability was also found: starting from an average amplified P-wave amplitude of 8.7±0.77 mV during implantation, atrial sensing activity remained stable enough over time, within a range of 5.3-8.7

mV **(**11**)**. Similar results were found in a study of 116 patients with a shorter 6-month follow-up: mean P-wave amplitude varied from 5.0 to 6.1 mV, across different body positions **(**12**)**. Even the SENSE multicentre trial confirmed the stability, over a 12-month follow-up, of the DX single-lead ICD in the terms of atrial sensing amplitudes **(**5**)**, as explained above.

The stability of the atrial sensing is crucial because it allows the detection of atrial arrhythmias and to discern between supraventricular and ventricular arrhythmias through the SMART algorithm **(**2**)**. As such, it is possible to avoid shocking treatment of supraventricular arrhythmias, thus reducing the risk of inappropriate ICD therapies. A reliable atrial sensing capability is also necessary to early diagnose atrial high-rate episodes (AHREs). In fact, according to the results reported by the ASSERT study, in about one-third of patients implanted with PMs or ICDs, subclinical atrial tachyarrhythmia episodes occurred, and this was associated with an increased risk of ischemic stroke or systemic embolism **(**1**)**. Thus, prompt detection of these episodes may facilitate the prompt administration of anticoagulant and/or antiarrhythmic drugs to prevent further complications.

Until some years ago, atrial lead implantation was required to monitor atrial activity and most patients were implanted with a dual-chamber ICD, even in the absence of an established need for atrial pacing: the NCDR ("National Cardiovascular Data Registry", developed by the American College of Cardiology) ICD Registry recorded 64,489 dual-chamber ICD implantations in the United States of America between January 1, 2006, and December 31, 2007, but only 40.4% of them had a clear indication for pacing therapy **(**13**)**. A more recent study showed a similar trend: by the end of December 2013, it enrolled 205 patients, without a pacing indication, who were implanted with an ICD; of them, 36 (18%) and 169 (82%) received single- and dual-chamber ICDs, respectively **(**14**)**. Several studies showed that the risk of developing subsequent symptomatic bradycardia requiring atrial pacing was low: in the DAVID (The Dual Chamber and VVI Implantable Defibrillator) trial, only 3.9% of 256 patients assigned to VVI-ICDs arm needed for atrial pacing **(**15**)**; in Goldberger et al.'s study, in patients who received single-chamber ICDs the probability of upgrade to a dual-chamber ICD was of 7% **(**16**)**.

Importantly, implanting an additional lead implies a longer procedure time **(**4**)** and an increased risk of complications; in the NCDR ICD Registry, adverse events (such as cardiac arrest, lead dislodgement, pneumothorax, etc.) were more frequent with dual-chamber than with single-chamber device implantation (3.17% vs. 2.11%, $p<0.001$). Similar conclusions were drawn about the rate of in-hospital mortality (0.40% vs. 0.23%, $p<0.001$) **(**13**)**. Hence, based on these data, DX-ICD proves to have some important advantages over DR-ICD.

However, our study should be interpreted in light of several limitations. First, it was an observational retrospective study. Second, it involved a small number of patients, similar to the previous analysis in this area. Third, a selection bias was present because only patients implanted with Biotronik devices were analyzed. Fourth, the lack of clinical and therapeutic information prevented us from further analyses and considerations.

Conclusion

Atrial sensing is crucial for the management of atrial arrhythmias. Implanting a dedicated atrial lead ensures optimal atrial sensing, but conveys an increased risk for periprocedural and device-related complications. The atrial sensing with DX leads remained stable and comparable to DR-ICD atrial sensing for up to 2 years. DX leads with an atrial floating dipole are a valuable option in patients not requiring atrial pacing (**Figure 3**).

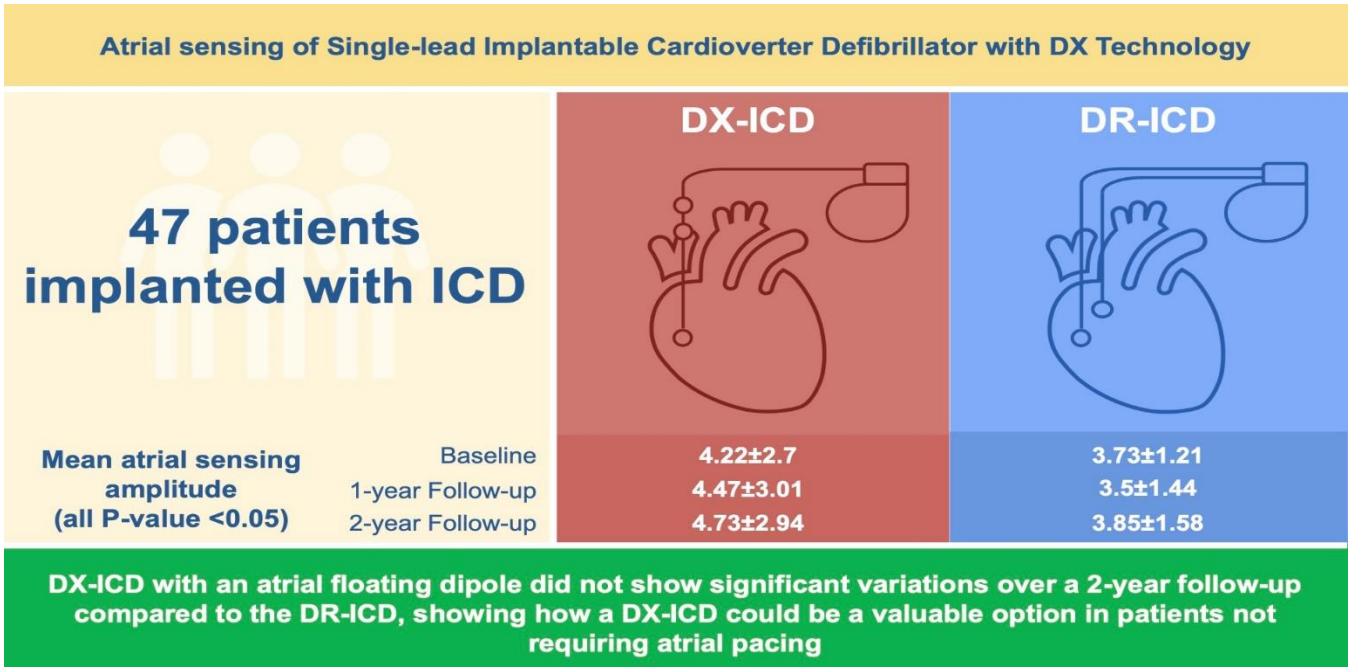

Figure 3

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