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The efficacy of the Linox^{Smart} DX ICD lead from a single center experience

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ABSTRACT

Purpose: The Biotronik Linox^{Smart} DX implanted cardioverter defibrillator (ICD) lead is a novel VDD lead with the advantage of integrated atrial sensing dipole combined with a special augmentation and filtering mechanisms. We sought to determine the efficacy of the Biotronik Linox^{Smart} DX ICD lead.
Methods: Non-randomized consecutive patients implanted with Biotronik Linox^{Smart} DX lead at Sheba Medical Center were included in this study. Electrical parameters and arrhythmic events were recorded during follow up of one year.
Results: Seventy-three patients (69 males (94.5%), mean age 61 ± 12 years) were included. All patients were successfully implanted with a Biotronic VR-T DX device and Linox^{Smart} DX ICD lead (DX-17 in 37% and DX-15 in 63% patients). Mean P wave amplitude at time of implantation was 3.66 ± 2.9 mV and improved significantly throughout the follow-up (5.29 ± 4.39 mV, $p = 0.009$). Appropriate atrial sensing (defined as P wave amplitude of ≥0.8 mV) rate of 100% at implantation significantly decreased to 89% ($p = 0.015$) at 12 months. Three out of 67 (4.5%) patients without a known history of atrial fibrillation had documented new onset paroxysmal atrial fibrillation. Appropriate shocks occurred in 4 (5.5%) patients. One patient with atrial sensing less than 0.4 mV had inappropriate shock.
Conclusions: Among patients implanted with the Biotronik Linox^{Smart} DX ICD lead in our single center, appropriate atrial sensing rate decreased over 12 months. Larger studies are needed to evaluate the reliability of long term appropriate atrial sensing.

1. Introduction

Single and dual chamber implanted cardioverter defibrillators (ICDs) are used for primary and secondary prevention of ventricular tachyarrhythmias and sudden cardiac death [1]. Dual chamber ICDs improve the ability to discriminate arrhythmias [2,3] and their advantage is counterbalanced by their higher complication rates [4].

The Biotronik Linox^{Smart} DX (Biotronik SE & Co, Berlin, Germany) is a novel VDD ICD lead, with the benefit of an integrated floating atrial sensing dipole harboring special augmentation and filtering mechanisms. A dedicated ICD device has a self-adaptive atrial input stage including a fourfold amplifier. The amplification, filtering, and adapted atrial input stages are located in the Biotronik ICD DX devices (Biotronik SE & Co, Berlin, Germany) [5]. This atrial sensing dipole has been shown to improve discrimination of arrhythmias obviating the need of additional atrial leads [6].

Concerns regarding the stability of atrial sensing of VDD leads over time were raised [7]. The present study sought to determine the efficacy of the Biotronik Linox^{Smart} DX ICD lead at our single center.

2. Methods

2.1. Patient population

Consecutive patients above the age of 18 years with an indication for a single-chamber ICD were recruited prospectively at Sheba

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Medical Center between May 2013 and November 2015 after providing a written informed consent. Exclusion criteria consisted of patients with permanent atrial fibrillation (AF). The study was conducted according to the Declaration of Helsinki and was approved by the local Institutional committee.

2.2. Biotronik DX ICD system

The Linox^{Smart} S DX steroid-eluting, single coil ICD lead system is designed to sense atrial and ventricular signals as well as deliver shocks. The lead is intended to be used specifically with two ICD systems - the Lumax 540 DX and the Lumax 740 DX (Biotronik SE &Co.) and is now available in newer Biotronik ICD models. These ICD systems are equipped with a SMART detection algorithm which proved to be safe and reliable for the detection of ventricular arrhythmias [8]. The lead is available in two subtypes; 15 cm subtype or 17 cm subtype according to the distance between the shock coil and the atrial dipole, chosen according to the discretion of the operator depending on the size of RV. Lead implantation was performed by standard technique as previously described [5].

2.3. Measurements

All the electrical parameters (atrial sensing, ventricular sensing, ventricular threshold, ventricular impedance) were recorded at implantation, before discharge, at 2 weeks, 3, 6 and 12 months follow ups. Appropriate atrial sensing was defined as P-wave sensing amplitude of at least 0.8 mV. This value was chosen as it is twice the value of the standard atrial sensing threshold (0.4 mV) programmed in the device.

2.4. Analysis of arrhythmic events

Atrial sensing was used for supraventricular and ventricular tachyarrhythmias discrimination. Atrial and ventricular arrhythmias, appropriate and inappropriate therapies were recorded during all follow up visits.

2.5. Statistical analysis

Continuous variables are reported as mean ± standard deviation and median. Nominal and ordinal variables are reported as frequencies and proportions. Student's *t*-test was used for comparison of continues variables. Chi square test was used to test categorical variables. Results were considered significant when $p < 0.05$.

3. Results

3.1. Study population

Seventy-three consecutive patients (69 males (94.5%), mean age 61 ± 12 years) were enrolled. Mean left ventricular ejection fraction was 31 ± 11%. Fifty-four patients (74%) received an ICD for primary prevention and 19 (26%) for secondary prevention. There was no significant difference in age, ejection fraction and the rate of atrial fibrillation among patients who received an ICD due to primary or secondary indications (Table 1). Five (7%) patients had a history of paroxysmal AF and 1 (1.37%) patient had persistent AF.

All patients were implanted with the Biotronic VR-T DX device and Linox^{Smart} DX ICD lead, without any significant complications. The 17-cm lead was implanted in 37% and the 15-cm lead in 63% of the cohort. The majority of leads (97.3%) were implanted at the RV apex compared with only 2 leads (2.7%) at the RV septum.

3.2. Measurements

Table 2 displays all measurements obtained at time of implantation and follow ups. Mean P wave sensing at implantation was 3.66 ± 2.9 mV and improved significantly during follow up at 12 months (mean P wave sensing 5.29 ± 4.39 mV, $p = 0.009$). Appropriate atrial sensing rate of 100% at implantation significantly decreased to 89% ($p = 0.015$) at 12 months (Fig. 1). Ventricular sensing improved during follow up (15.44 ± 5.61 mV at implantation and 17.84 ± 5.72 mV at 12 months, $p = 0.023$). Mean pacing threshold showed a trend for higher threshold at 1 year follow up (0.63 ± 0.26 V and 0.72 ± 0.26 V at 0.4 msec respectively, $p = 0.057$). Mean ventricular pacing impedance at implantation measured 704 ± 114 Ω and decreased to 527 ± 61 Ω at 2 weeks ($p < 0.0005$) and remained stable throughout 12 months follow up (517 ± 71 Ω, $p = 0.4$).

Table 3 compares measurements of the two different lead subtypes used (15-cm subtype and 17-cm subtype). No significant difference was observed in atrial sensing between the 2 subtypes at implantation. However, the mean P wave amplitude (mV) was higher among the 15-cm leads compared to the 17-cm leads at 1 day (7.67 ± 5.5 vs 5.01 ± 3.2, $p = 0.03$), 2 weeks (6.26 ± 5.8 vs 4.23 ± 2.72, $p = 0.04$) and 3 months after implantation (6.88 ± 5.2 vs 4.37 ± 3.74, $p = 0.03$), respectively. At 12 months these differences disappeared (6.015 ± 4.65 mV vs, 4.17 ± 3.7 mV, respectively. $p = 0.08$). Appropriate atrial sensing rate was non significantly higher among the 15-cm leads compared to the 17-cm leads at 1 year (93.5% vs 81.5%; respectively, $p = 0.11$).

3.3. Analysis of arrhythmic events

Notably, during follow up, 3 of the 67 patients without a known history of AF (4.5%) had documented new onset paroxysmal atrial fibrillation. Appropriate shocks occurred in 4 (5.5%) patients. One patient had an inappropriate shock and found to have a decline in atrial sensing from 4.8 mV at implantation to less than 0.2 mV after 1 year. In this case, other lead parameters were stable and the position of the lead was similar to implantation.

4. Discussion

The Linox^{Smart} S DX ICD lead offers AV discrimination with SMART detection algorithm for reducing inappropriate shocks and gaining information to optimize device programming. The SMART detection algorithm has proven to be safe and reliable for the detection of all ventricular tachyarrhythmias, with a specificity of 89% and a sensitivity of 100% [8].

The mean P wave sensing in our study was in agreement with the study of Iori et al. [9] who reported overall mean atrial sensing amplitude of 4.2 ± 1.9 mV, in 13 patients who received a DX ICD with the Linox^{Smart} DX ICD lead and followed for 200 days. In our cohort comprising 73 patients, mean P wave sensing improved significantly during a follow up of 12 months.

In the other hand, our study raises concerns regarding the long-term reliability of the Linox^{Smart} DX ICD lead atrial sensing ability. We observed a significant decrease in appropriate atrial sensing (defined as P-wave sensing amplitude of at least 0.8 mV) rate from 100% at time of implantation to 89% after 12 months. These findings contrast with a previous publication [5], which predefined an efficacy endpoint (calculated as the number of correct atrial sensing tests divided by the number of all atrial sensing tests conducted in patients lying in the dorsal position) to be higher than 90% and was reached in 93.8% of their patients up to 6 months of follow up. Furthermore, Worden et al. [6] reported long-term reliable recording of atrial signals of amplified atrial electrograms during

Table 1
Comparison of patients with primary or secondary prevention.

	Primary prevention (n = 54)	Secondary prevention (n = 19)	P value
Atrial fibrillation	5 (9.3%)	3 (15.8%)	0.43
Age (years)	60.6 ± 11.4	63.1 ± 14.2	0.4
EF (%)	30 ± 11.6	34 ± 10.4	0.19

Table 2
Measurements at time of implantation and follow ups.

	Implantation	1 day	2 weeks	3 months	1 year	P value
P wave (mV)	3.66 ± 2.9	6.65 ± 4.95	5.5 ± 4.9	5.89 ± 4.83	5.29 ± 4.39	0.009
R wave (mV)	15.44 ± 5.61	18.44 ± 6.05	17.89 ± 6.6	18.47 ± 5.84	17.84 ± 5.72	0.023
Impedance (Ω)	704.1 ± 114.7	611.1 ± 79.69	527.6 ± 61.98	533.7 ± 70.5	510.6 ± 68.5	P < 0.0005
Threshold (V)	0.63 ± 0.26	0.59 ± 0.2	0.8 ± 0.45	0.7 ± 0.28	0.72 ± 0.26	0.057

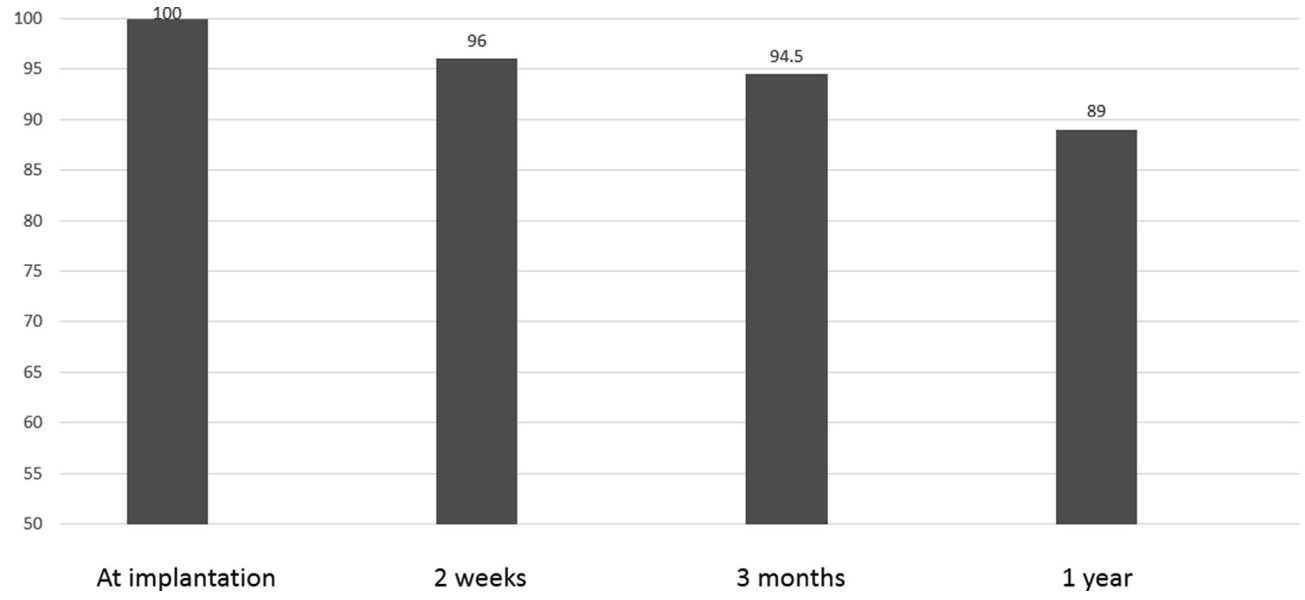

Fig. 1. Rate of patients (%) with appropriate atrial sensing (measured P wave amplitude ≥ 0.8 mV) during follow up. Appropriate atrial sensing rate of 100% at implantation significantly decreased to 89% (p = 0.015) at 12 months.

Table 3
P wave amplitude for the 15-cm lead and 17-cm lead at implantation and follow ups.

P wave amplitude (mV)	All patients	15-cm group	17-cm group	*p value
Implantation	3.66 ± 2.9	3.92 ± 3.04	3.22 ± 2.63	0.3
1 day	6.65 ± 4.95	7.67 ± 5.5	5.01 ± 3.2	0.03
2 weeks	5.5 ± 4.9	6.26 ± 5.8	4.23 ± 2.72	0.04
3 months	5.89 ± 4.83	6.88 ± 5.2	4.37 ± 3.74	0.03
1 year	5.29 ± 4.39	6.015 ± 4.65	4.17 ± 3.7	0.08

*P value for comparison of P wave amplitude for 15-cm vs 17-cm lead.

sinus rhythm and arrhythmias. However, this study included only 35 patients, of whom 32 patients followed for wide range of (56–765) days.

Notably, major difference in definition and length of follow up exist between our study and the latter 2 studies. Importantly, low atrial sensing (less than 0.8 mV) could cause atrial undersensing during atrial arrhythmias leading to inappropriate diagnosis of ventricular arrhythmia and inappropriate shock as was the case in one of our study patients. Another concern is that a reduction in atrial sensing threshold could cause QRS far field oversensing. This was tested by Safak et al. [5], who found that lower sensing thresholds caused a small increase in occurrence of QRS far field oversensing. Of note, such QRS far field oversensing was not observed in our study.

Comparing of available subtypes of Linox^{Smart} S DX ICD leads in our study revealed the 17-cm lead had a lower appropriate atrial sensing rate than the 15-cm lead, although not reaching significance. This finding is corroborated in a previous study were the rate of all evaluated atrial sensing tests showed appropriate atrial sensing in 96.4% of the 15-cm group and 91.5% of the 17-cm group (p < 0.05) [5]. Moreover, a significant higher mean P wave amplitude was found in our cohort amongst the 15-cm leads compared to the 17-cm leads for up to 3 months after implantation. This difference disappeared a year after the implantation. A similar finding was also reported by Safak et al. [5] with higher mean P wave amplitudes observed in the 15-cm lead (6.1 ± 2.2 mV vs 5.2 ± 2.7 in the 17-cm group, p < 0.05). From their experience they could say that the 15-cm leads fit better in smaller patients and in women, and the 17-cm leads deliver good P-wave amplitudes in very tall patients [5]. Interestingly, Michalak et al. [10] could not find any connection between height and atrial sensing. This latter study found that larger right atrium size and low sensing dipole location were related to lower atrial sensing amplitude.

In our study, appropriate shocks occurred in 4 (5.5%) patients. On the other hand, only 3 patients (4.5%) had documented new onset AF. This rate is lower than previously reported [5,9]. It could relate to differences in patients' characteristics studied. In addition, inappropriate atrial sensing could not be ruled out as a reason for lower rate of detected atrial tachyarrhythmias.

4.1. Study limitation

This is a non-randomized single center study. In addition, follow up periods are relatively short, and long-term performance of Linox^{Smart} ICD lead is lacking. Randomized studies comparing long term performance of dual chamber ICDs, VDD ICDs, and/or single chamber ICDs without atrial sensing with longer follow up are needed for definitive evaluation.

5. Conclusions

Mean atrial sensing of the Linox^{Smart} DX ICD lead agreed with previous studies. However, our study raises concerns on the reliability of the long term appropriate atrial sensing. Larger studies and longer follow up periods are needed.

Declaration of competing interest

The authors declare that they have no conflict of interest.

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