Prevalence of Sensing Abnormalities in Dual Chamber Implantable Cardioverter Defibrillators

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Background: The clinical efficacy of ICD therapy depends on accurate sensing of intracardiac signals and sensing algorithms. We investigated the occurrence of sensing abnormalities in patients with dual chamber ICDs.

Methods: The study group consisted of all patients with dual chamber ICDs enrolled in the LESS trial and patients implanted with dual chamber ICDs at a single center between January 1997 and July 2000. Electrograms of spontaneous ventricular arrhythmias requiring device intervention were analyzed.

Results: A total of 48 patients met the criteria for enrollment. Among the 244 episodes, 215 (88%) were due to ventricular tachycardia and 29 (12%) were due to ventricular fibrillation. Overall undersensing was infrequent with 12 (20%) patients exhibiting on average 2.2 undersensed beats during 26 episodes of ventricular arrhythmias. There was no delay in therapy due to undersensing. Oversensing occurred in 5 (10%) patients resulting in 13 (2.7%) episodes of inappropriate therapy. None of the patients had any lead abnormalities and oversensing resolved after device reprogramming in 4 patients while 1 patient required a separate rate sensing lead. Among patients with oversensing, 4 out of 5 were pacing before the index event while among patients with no oversensing only 5 out of 42 were pacing ($P < 0.001$).

Conclusions: Dual chamber ICDs demonstrate outstanding accuracy of sensing. However, because of the selection of patient population requiring more frequent pacing, oversensing occurs with a significant frequency. Meticulous evaluation in such patients is necessary to minimize the likelihood of oversensing and inappropriate shocks.

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Over the last two decades, implantable cardioverter defibrillators (ICDs) have become increasingly widespread as the treatment of choice for life-threatening arrhythmias.¹⁻³ Remarkable technological advancements continue to be made with the introduction of each generation of ICDs. The most advanced ICDs incorporate antitachycardia pacing, low-energy cardioversion, high-energy defibrillation, and dual-chamber antibradycardia pacing.^{4,5} These devices function as both dual chamber rate-adaptive atrioventricular pacemakers and defibrillators, and also provide simultaneous atrial

and ventricular sensing to optimize arrhythmia detection.

Sensing is the function by which an ICD determines the presence of electrical signals (electrograms) caused by cardiac depolarization. The clinical efficacy of ICD is critically dependent on accurate sensing of intracardiac signals and subsequent sensing algorithms. Since their inception, ICDs have reliably and accurately detected life-threatening ventricular arrhythmias despite the low amplitude of intracardiac signals during ventricular fibrillation (VF). With the advent of dual

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chamber defibrillators, pacing for sinus bradycardia and atrioventricular block occurs with a considerably higher frequency than in earlier generation single chamber defibrillators. In many ICDs, pacing increases the sensitivity gain, making oversensing more likely.⁶⁻⁸ In addition, the ventricular refractory period following pacing may decrease the sensing window, potentially increasing the incidence of undersensing. Several case reports and series have described sensing errors in single- and dual chamber ICDs.⁹ The purpose of this study was to investigate the occurrence of sensing abnormalities in a large multicenter series of patients with 4th generation dual chamber ICDs.

METHODS

Study Population

The study population consisted of two groups. The first group comprised all patients with dual chamber ICDs enrolled in the Low Energy Safety Study (LESS). The LESS trial was a multicenter study designed to examine the optimal safety margin for defibrillation in patients with ICDs. All study subjects in LESS received either a single- or dual chamber ICD with integrated bipolar lead systems from a single manufacturer (Guidant, St. Paul, MN). The second group consisted of consecutive patients from a single institution (New England Medical Center, Boston, MA) who had received a dual chamber ICD by the same manufacturer between January 1997 and July 2000. Patients with prior implants or separate rate-sensing leads were excluded.

Diagnosis of Sensing Abnormalities

Spontaneous episodes of arrhythmia that required therapy and had intracardiac electrograms available for review were selected. The stored electrograms before and after therapy delivery were analyzed. An electrophysiologist classified each arrhythmia based on atrial and ventricular rate, RR interval variability and electrogram morphology. Monomorphic ventricular tachycardia (MVT) was defined as a ventricular tachycardia with a single morphology on intracardiac electrogram and rate greater than 100 bpm. Tachycardia with no single dominant morphology and rate between 100 and 260 bpm was labeled as polymorphic ventricular tachycardia (PMVT), while ventricular fibrillation (VF) was defined as polymorphic tachycardia with a rate greater than 260 bpm.

The ventricular intracardiac electrogram recorded from the integrated bipolar sensing electrode and the corresponding ventricular channel markers were used in combination to identify ventricular undersensing and oversensing events. The presence of a ventricular intracardiac electrogram deflection without any corresponding ventricular marker was labeled as a ventricular undersensed beat. On the other hand, any electrical activity inappropriately sensed as cardiac depolarization as demonstrated by the presence of a ventricular marker without a corresponding intracardiac electrogram was diagnosed as a ventricular oversensed beat.

The amplitude of undersensed beat was compared to the previously sensed beat and also to the largest amplitude sensed beat in a time window up to 600 ms prior to the undersensed beat. The results were expressed as a change in absolute amplitude of the undersensed beat. The presence of pacing before the onset of arrhythmia also was noted.

Statistical Analysis

Continuous data were compared using paired *t*-test while the chi square and Fisher's exact test were used to compare data with nominal values. A P value of less than 0.05 was considered statistically significant.

RESULTS

There were 636 patients enrolled in the LESS trial. A total of 229 patients had a dual chamber ICD. Of these, 40 patients had spontaneous arrhythmia requiring therapy available for analysis. Among the 59 consecutive patients who received a Guidant dual chamber ICD at our institution between the specified time period, 8 patients had at least one episode of spontaneous arrhythmia requiring therapy. The baseline characteristics of patient population are given in Table 1.

The average duration of follow-up was 8.4 ± 5.3 months with the range between 1 month and 24 months and a median of 9 months. There were 29 patients who had Guidant Ventak model 1810 ICD, 9 had model 1831, 7 had model 1820, and 3 had model 1821. Of 48 patients, 39 had ventricular defibrillator lead model 0125, 3 had 0134, 2 had 0145 while the rest of the patients had 0155, 0144, 0095, and 0136 each. Information about the ICD and ventricular defibrillator lead for each patient with oversensing and undersensing events is

Table 1. Baseline Clinical Characteristics of the Two Groups of Patients Enrolled in the Study

		LESS Group (40)	NEMC Group (8)
Age	(mean $\pm$ SD)	65.3 $\pm$ 11.9	57.1 $\pm$ 12.2
Gender	Male	30 (75%)	8 (75%)
	Female	10 (25%)	2 (25%)
Indication	MADIT	4 (9.5%)	1 (12.5%)
	VT	26 (61.9%)	3 (37.5%)
	CA	12 (28.6%)	1 (12.5%)
	Other	0	3 (37.5%)
Disease	CAD	27 (67.5%)	3 (37.5%)
	IDCM	5 (12.5%)	5 (62.5%)
	Other	8 (20%)	0
NYHC	Class I	14 (35%)	3 (37.5%)
	Class II	19 (47.5%)	1 (12.5%)
	Class III	7 (17.5%)	4 (50%)
	Class IV	0	0
LVEF	(mean $\pm$ SD)	35.2 $\pm$ 14.8	25.5 $\pm$ 12.5

LESS = Low Energy Safety Study, NEMC = New England Medical Center, MADIT = Multicenter Automatic Defibrillation Implantation Trial, VT = ventricular tachycardia, CA = cardiac arrest, CAD = coronary artery disease, IDCM = idiopathic dilated cardiomyopathy, NYHC = New York heart failure classification and LVEF = left ventricular ejection fraction.

given in Tables 2 and 3. There was no particular ICD model or defibrillator lead that was associated with a higher incidence of ventricular oversensing or undersensing in our study population.

There were 475 episodes of spontaneous arrhythmia requiring therapy delivery among the 48 patients. Of these, 244 (51.4%) episodes were due to ventricular arrhythmia and 216 (45.5%) were due to supraventricular arrhythmia. Among the 244 episodes of ventricular arrhythmia requiring therapy, 215 (88.1%) were classified as ventricular tachycardia (VT) and 29 (11.9%) were diagnosed as VF.

Oversensing

There were 13 (5.3%) episodes of ventricular oversensing among 5 (10%) patients during which detection of extracardiac signals by the ICD resulted in inappropriate therapy (Table 2). In all patients the electrogram demonstrated low amplitude, fine electrical activity only on the ventricular channel that was inappropriately detected as VF by the device (Fig. 1). A thorough noninvasive electrophysiological evaluation was performed including measurement of R wave amplitude, pacing threshold, and lead impedance. Real-time intracardiac electrograms were monitored during pocket manipulation, isometric exercise of upper extremities, and valsalva maneuvers. A standard posterior-anterior and lateral chest roentgenogram was obtained in selected cases to rule out lead abnormalities. None of these patients were found to have any evidence of lead dysfunction including insulation break, lead fracture, or loose setscrew. The "noise" on the ventricular sensing channel was reproducible with valsalva or deep breathing maneuvers in all patients. In all the cases the sensing error was attributed to the oversensing of the skeletal myopotentials from the diaphragm because of its proximity to the lead. In four cases the oversensing cleared after reprogramming of device sensitivity from nominal to less, while one case required a new rate-sensing lead placement in the right ventricular outflow tract after induced oversensing persisted in the least sensitivity setting.

Among the 5 patients with ventricular oversensing, 4 were pacing 100% of the time just before the oversensing and inappropriate shock occurred. In contrast, among 44 patients with no ventricular oversensing only 5 patients were found to be pacing 100% of the time before their index arrhythmia ($P < 0.001$). Inhibition of pacing was observed during

Table 2. Summary Table of Patients with Spontaneous Ventricular Oversensing Episodes Leading to Device Therapy. Number of Patients Pacing Prior to Oversensing and Duration of Pause Resulting from Pacing Inhibition for Each Patient are Given

Patient No.	ICD Model	Vent. Lead	No. of Episodes	100% Pacing Prior to Oversensing	Pacing Inhibited by Oversensing	Longest Pause (s)	Sensitivity Setting*
1	1810	0125	9	Yes	Yes	12.2	Nominal
2	1810	0095	1	No	Yes	N/A	Nominal
3	1810	0125	1	Yes	Yes	6.8	Nominal
4	1831	0125	1	Yes	Yes	4.4	Nominal
5	1821	0125	1	Yes	Yes	3.9	Nominal

*Nominal setting is the most sensitive setting in Ventak AV defibrillator platform and corresponds to a sensing threshold of 0.15 mv.

Table 3. Summary Table of Patients with Undersensing on Ventricular Channel During Spontaneous Ventricular Arrhythmias

Patient No.	ICD Model	Vent. Lead	No. of Episodes	No. of Beats	Arrhythmia During Undersensing	Timing of Undersensing	Sensitivity Setting	Delay in Therapy
1	1810	0125	1	1	VF	Charging	Nominal	No
2	1810	0125	1	1	VF	Charging	Nominal	No
3	1810	0125	1	1	PMVT	Charging	Nominal	No
4	1821	0125	4	10	VF	8 detection 1 duration 1 charging	Least	No
5	1831	0134	1	2	MVT	Detection	Less	No
6	1810	0125	8	16	VF	8 detection 3 charging 2 reconfirmation	Least	No
7	1810	0125	4	10	PMVT	6 detection 2 duration 1 charging 1 reconfirm	Nominal	No
8	1831	0134	1	1	PMVT	Detection	Nominal	No
9	1810	0125	1	1	MVT	Detection	Less	No
10	1831	0145	1	1	MVT	Detection	Nominal	No
11	1820	0125	2	5	VF	1 detection 1 duration 3 charging	Least	No

VF = ventricular fibrillation, PMVT = polymorphic ventricular tachycardia and MVT = monomorphic ventricular tachycardia.

oversensing among the four patients who were pacing prior to it resulting in significant pauses of up to 12 sec. Oversensing was not associated with any other programmed settings or clinical parameters.

Undersensing

Undersensing of various degrees on the ventricular channel was identified in 11 (22%) patients during 25 (10%) episodes of spontaneous ventricular arrhythmias. Detailed information about these undersensing episodes is listed in Table 3. VF was the most common type of ventricular arrhythmia during which ventricular undersensing occurred (Fig. 2) followed by PMVT. Five patients had 16 (64%) episodes of VF demonstrating ≥ 1 undersensed beats. In four patients, three (12%) episodes of undersensing were noted during MVT and in three patients ≥ 1 undersensed beats occurred during six (24%) episodes of PMVT. Ventricular undersensing was extremely rare during supraventricular arrhythmias with only two patients having one episode each of ventricular undersensing during atrial fibrillation.

There was an average of 2.2 episodes of undersensing per patient. Ventricular undersensing oc-

curred most frequently during initial detection, representing 67.2% (39/58 beats) of all undersensed events, in comparison with 8.62% (5/58 beats) during duration window, 19.0% (11/58 beats) during charging, and 5.17% (3/58 beats) during reconfirmation. None of the undersensed events led to a delay or diversion in therapy.

Undersensed beats were of significantly smaller amplitude (7.6 ± 3.7 mm) relative to the previously sensed beats (16.9 ± 6.7 mm, $P < 0.0001$) and to the largest amplitude beat up to 600 msec prior (21.8 ± 4.3 mm, $P < 0.0001$). The mean decrease in amplitude of undersensed beats was 9.3 ± 6.7 mm compared to previous sensed beats, while the mean decrease in amplitude compared to the largest size beat up to 600 msec prior to undersensed beat was 14.2 ± 5.2 mm.

DISCUSSION

In our study of newer fourth generation dual chamber ICDs we found a low incidence of ventricular undersensing without a significant frequency of consequent delay or failure of therapy delivery during spontaneously occurring arrhythmias. Our study is in agreement with previous studies

Figure 1. Intracardiac electrogram from a patient with a dual chamber ICD showing the atrial, ventricular sense, and ventricular shock electrograms. Baseline rhythm is sinus with atrial sensing and ventricular pacing. "Noise" on the ventricular sensing channel leads to inhibition of pacing, spurious VF detection and inappropriate shock.

that showed low incidence of undersensing during induced and spontaneous ventricular arrhythmias episodes in the third generation single chamber ICDs and earlier devices.¹⁰⁻¹⁸ Mann et al. reported that 2 (2%) out of 98 patients with Ventritex Cadence defibrillator system had significant ventricular undersensing that led to delay or non-delivery of appropriate therapy during induced ventricular tachyarrhythmias.¹¹ Review of the stored electrogram from both cases revealed marked variability in electrogram amplitude that caused a failure of the amplifier gain sensitivity to increase adequately to detect each complex. Reprogramming of

sensing parameters corrected undersensing abnormality in both cases. Peralta et al. further studied the impact of undersensing on VF detection time and the relationship of undersensing to the programmed shock energy.¹² They found that undersensing was present in 44 (11.1%) of 398 episodes of induced sustained VF from 29 patients with Ventak P2 defibrillator systems.

From our investigation, we conclude that the dual chamber ICDs continue to have outstanding accuracy in the detection of spontaneous ventricular arrhythmias. The most common cause of undersensing was marked beat-to-beat variability

Figure 2. Intracardiac electrogram of a VF episode in a patient with dual chamber ICD. During initial detection of VF, two beats are undersensed (solid arrows). Both the undersensed beats are small in amplitude and immediately follow large amplitude beats. There are no channel markers corresponding to the undersensed beats and the next beat in each case falls out of VF zone (open arrows). There is no delay in detection. The device charges and delivers an 11 J shock that is unsuccessful, but the arrhythmia terminates spontaneously.

in electrogram amplitude resulting in fibrillatory signals falling out of range of the autogain sensing system.^{11,15,18} These episodes of undersensing were not clinically relevant because only rarely more than a few beats were undersensed and no delay in therapy was noted.

On the other hand, even though the overall incidence of oversensing was relatively low in our study it was still clinically significant as it led to delivery of inappropriate shocks. Inappropriate shock therapy results in unnecessary patient discomfort and extra health care costs. In the absence of lead abnormality, oversensing most com-

monly occurs due to diaphragmatic or abdominal myopotentials.^{19,20} In the majority of the patients this kind of oversensing can be corrected by reprogramming the device to a lower sensitivity setting. It is of note that in our study oversensing most commonly occurred in the setting of pacing. This observation is in agreement with previous studies in patients with single chamber ICDs, demonstrating that VVI pacing leads to a higher incidence of oversensing.^{6,7,19} As patients with dual chamber ICDs are more likely to be pacing than patients with single chamber ICDs, the incidence of clinically significant oversensing may create a

greater potential concern in this population. Oversensing was not associated with any other patient characteristics.

To better understand the causes of oversensing the normal functioning of automatic gain control (AGC) used by these devices should be considered. The objective of AGC circuitry is to establish a sensing threshold sufficiently sensitive to the smallest of signals (fibrillation) while avoiding saturation due to large signals. Following a sensed signal, the sensitivity threshold quickly begins to decrease from a level 75% of the signal amplitude down to the floor of the dynamic range currently in effect. The rate of decrease, or "attack rate," varies based on the rhythm and rate of the previous interval. If no activity is sensed after reaching maximum sensitivity, the pacing escape interval elapses and the device paces.

During pacing, the attack rate varies according to the paced interval such that maximum sensitivity is reached approximately 200 msec before the end of the escape interval. For safety, the AGC selects a more sensitive dynamic range during pacing to minimize the risk of mistaking fibrillation for asystole. Consequently, this increases the possibility of oversensing of shock or pace pulses and other non-physiological signals during pacing. Once a tachyarrhythmia episode is declared, the AGC switches to a faster attack rate. Like other sensed rhythms, the sensing threshold adjusts from a level that is 75% of the signal amplitude. In this case, the sensing threshold decreases approximately 25% faster, doubling its sensitivity every 150 msec.

Limitations

All patients who were studied did not undergo routine maneuvers to elicit diaphragmatic stimulation as the cause of oversensing and the true incidence of oversensing in these devices cannot be calculated. Radiographic data regarding the position of the lead was not available in all patients. The patients in our study had integrated bipolar leads that have a relatively large sensing "field of view." It is possible that true bipolar leads may have a lower incidence of oversensing than integrated bipolar leads.

CONCLUSIONS

Fourth generation dual chamber ICDs continue to demonstrate outstanding accuracy of sensing as

seen in previous single chamber devices. Undersensing does not occur with increased frequency compared to third generation devices. However, because of the selection of the patient population requiring more frequent pacing, oversensing occurs with a significant frequency. Thus, meticulous testing for oversensing is particularly important in a patient population that requires continuous pacing and is therefore at increased risk of inappropriate shock.

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