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Inappropriate cardioverter-defibrillator discharge continues to be a major problem in clinical practice

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Abstract

Background: *The purpose of this study was to determine the rate and causes of inappropriate rhythm detection, and to compare adequacy of ventricular arrhythmia detection by single-chamber and dual-chamber cardioverter-defibrillators (ICD).*

Methods: *We evaluated 190 patients (age 57.2 ± 11.2 years) with ICD. Follow-up: 34.3 ± ± 22 months. Dual-chamber ICD was used in 54 patients.*

Results: *We evaluated 2244 arrhythmia events recognized as of ventricular origin, including ventricular tachycardia and ventricular fibrillation. 431 events (19.2%) were recognized erroneously and resulted in an inappropriate ICD discharge. Most cases of inappropriate therapies (182 events, 42.23%) were due to atrial fibrillation or flutter. Overall, inappropriate arrhythmia detection was found in 64 (33.6%) of 190 patients. In terms of the number of affected patients, the most common cause of inappropriate ICD discharge was sinus tachycardia — 23 (12.1%) patients, followed by atrial fibrillation — 16 (8.4%) patients. Among 54 patients with dual-chamber ICD, inappropriate therapy was noted in 21 (38.8%) patients, (T wave oversensing, sinus tachycardia and atrial fibrillation etc.). No significant difference was seen in the rate of inappropriate therapy due to a rapid supraventricular rhythm between patients with single-chamber versus dual-chamber ICD. In contrast, patients with single-chamber ICD more often experienced inappropriate therapy due to atrial fibrillation (155* vs. *28 patients) and sinus tachycardia (66* vs. *9 patients).*

Conclusions: *Despite of introduction of new generations of ICDs, the problem of inappropriate ICD discharge could not be eliminated. The major problem is distinction between supraventricular arrhythmia and ventricular tachyarrhythmia.* (Cardiol J 2009; 16, 5: 432–439)

Key words: implanted cardioverter-defibrillator (ICD), inappropriate therapy

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Introduction

Major therapeutic advances in the management of ischemic heart disease and heart failure seen in the last decades resulted in an increased need for effective treatment of life-threatening cardiac arrhythmia [1, 2]. Ventricular tachycardia (VT) resulting in hemodynamic instability and ventricular fibrillation (VF) are the main causes of death among these patients [3].

In this regard, wide use of antiarrhythmic drugs is limited by their ineffectiveness during long-term treatment and numerous adverse effects including proarrhythmia [4]. The effectiveness of invasive treatment modalities, including radiofrequency (RF) catheter ablation and antiarrhythmic cardiac surgery, is also limited [5].

Implantable cardioverter-defibrillators (ICD) are established therapeutic devices used in the management of life-threatening cardiac arrhythmia, and their role has been well defined in the published guidelines [6]. Their advantage over the use of antiarrhythmic drugs in patients with a history of VF or VT, particularly in patients with reduced left ventricular ejection fraction (LVEF < 0.35), has been proven in major intervention trials such as the Antiarrhythmics Versus Implantable Defibrillators (AVID) study, the Cardiac Arrest Study Hamburg (CASH), and the Canadian Implantable Defibrillator Study (CIDS) [7–9]. In primary prevention, the effectiveness of ICD was documented in such clinical trials as the Multicenter Unsustained Tachycardia Trial (MUSTT), the Multicenter Automatic Defibrillator Implantation Trial (MADIT), the MADIT II study, the Sudden Cardiac Death in Heart Failure (SCD-HeFT) study, and the COMPArisoN of medical therapy, pacIng and defibrillatiON in heart failure (COMPANION) study [10–14].

Major arrhythmia-related parameters that are used by ICD to detect intracardiac signals include the rate of ventricular and atrial rhythm (in case of a dual-chamber ICD), sudden changes in these rates, and the stability of the cardiac rhythm. In addition, some devices may detect QRS width and morphology. Therapeutic options include antitachycardia pacing, defibrillation, and on-demand pacing in case of bradycardia. ICD devices may also store intracardiac electrograms recorded during an arrhythmia event for further retrieval and evaluation, thus allowing assessment of the adequacy of therapeutic activation and discharge.

Unfortunately, despite major technological advances since introduction of the first ICD model, these devices remain imperfect in terms of cardiac rhythm recognition [15–17]. Adequate rhythm detection is one of the major goals of ICD, and inappropriate arrhythmia detection, most often leading to an inappropriate therapeutic discharge, has many adverse consequences including impaired quality of life, more frequent need for ICD battery replacement, and proarrhythmia leading to induction of dangerous ventricular arrhythmia. All these effects result in more frequent hospital admissions and increased costs of therapy [18–21].

The purpose of this study was to determine the rate and causes of inappropriate rhythm detection, and to compare adequacy of ventricular arrhythmia detection by single-chamber and dual-chamber ICD.

Methods

We studied 190 patients with ICD implanted in 1997 through 2004 who were followed in the ICD outpatient clinic at the Department of Cardiology, Pomeranian Medical University, Szczecin, Poland. We only included patients with complete documentation of each arrhythmia event (including the programmator printouts), thus allowing assessment of the adequacy of the device therapy. The follow-up period was from 1997 to the end of 2005.

We analyzed the following patient baseline data at the time of first ICD implantation: age, gender, primary cardiac diagnosis, New York Heart Association (NYHA) class, LVEF as determined using echocardiography, the type of arrhythmia that was the indication for ICD implantation, other concomitant cardiac arrhythmia, the presence of intraventricular conduction abnormalities including left bundle branch block (LBBB) and right bundle branch block (RBBB), previous revascularizations, previous RF ablation procedures, any previous pacemaker implantation, and the model of implanted ICD device. Then, we analyzed clinical data and information from ICD programmator printouts collected during the follow-up period. Follow-up visits were scheduled at one month following ICD implantation, at 3 months and every 6 months thereafter, and also following ICD discharge events.

The study was approved by the bioethical committee and all patients gave their informed consent.

Statistical analysis

The significance of differences between patients with single-chamber and dual-chamber ICD was analyzed using Mann-Whitney U test for continuous variables and two-sided exact Fisher test for categorical variables. $P < 0.05$ was considered

statistically significant. All analyses were performed using the Statistica 7.1 software.

Results

We studied 190 patients, including 36 women and 154 men (mean age 57.2 ± 11.2 years, range 14–79 years) with ICD. Ischemic heart disease was diagnosed in 146 patients, including 123 patients with a history of myocardial infarction (more than one previous infarct in 14 patients). Postinfarction left ventricular aneurysm was found in 15 patients. Coronary artery bypass grafting was previously performed in 45 patients, and percutaneous coronary angioplasty in 47 patients. Other primary cardiac diagnoses included dilated cardiomyopathy in 22 patients, hypertrophic cardiomyopathy in 5 patients, long QT syndrome in 3 patients, arrhythmogenic right ventricular cardiomyopathy in 2 patients, previous repair of the tetralogy of Fallot in 2 patients, previous correction of the transposition of great arteries in one patient, and Brugada syndrome in one patient. No organic heart disease was found in 8 patients.

Overall, the mean NYHA class at the time of initial ICD insertion was 1.8 ± 0.7, and the study group included 51 patients in NYHA class I, 117 patients in NYHA class II, and 22 patients in NYHA class III. The mean LVEF was 37 ± 14% (range 15–80%).

Sustained VT was the indication for ICD implantation in 90 cases, and VF in 59 cases. In 29 patients, both types of ventricular arrhythmia were documented, and ICD was used for primary prevention in 12 patients.

Atrial flutter and/or fibrillation was present at the time of ICD implantation in 46 (24.2%) patients. LBBB was noted in 15 patients, and RBBB in 4 patients. Seven patients underwent previous pacemaker implantation, including 5 patients due to sick sinus syndrome, one patient due to atrial fibrillation with slow ventricular response, and one patient due to advanced grade II atrioventricular block.

The mean duration of follow-up was 34.3 ± ± 22 months (range 17 days to 89 months). During that time, patients were seen at on average 9.2 ± ± 5.6 (range 1–28) follow-up visits. Single-chamber ICD was used in 136 patients, dual-chamber ICD in 53 patients, and a combined ICD-cardiac resynchronization therapy device was implanted in one patients. We used devices manufactured by three companies: Biotronik (n = 115), Medtronic (n = 66), and St. Jude Medical (n = 9).

Clinical events during the follow-up

During the follow-up, 55 patients underwent device reimplantation, most commonly due to depletion of battery power, but also due to capacitor malfunction (resulting in prolonged device loading time) in 11 patients. Later, 4 patients underwent another device reimplantation, due to depletion of battery power in three cases, and in one patient due to exacerbation of heart failure that necessitated the use of a combined ICD-cardiac resynchronization device.

No ventricular arrhythmia event or inappropriate ICD therapy was noted in 72 (37.5%) of 190 patients. No ventricular arrhythmia was also noted in 23 (12.1%) patients who experienced inappropriate ICD therapy.

Overall, 2244 events occurred during the follow-up, including both adequate and inadequate ICD discharge. We found that 431 events (19.2%) could be considered inappropriate ICD activation. Table 1 shows the rate and causes of inappropriate ICD discharge. Most cases of inappropriate device activation were due to atrial fibrillation or flutter, followed by sinus tachycardia and oversensing of other signals than T wave. The latter included detection of muscle potential, R wave double counting, and far field sensing, when ICD lead damage could be excluded.

Inappropriate arrhythmia detection was noted in 64 (33.6%) patients, including 11 patients with two different causes of inappropriate ICD discharge. In terms of the number of affected patients, the most common cause of inappropriate arrhythmia detection and ICD discharge was sinus tachycardia, followed by atrial fibrillation and oversensing of other signals than T wave.

Comparison of single-chamber and dual-chamber ICD

In our study group of 190 patients, single-chamber ICD (ICD-VVI) was implanted in 136 (72%) patients, and dual-chamber ICD (ICD-DDD) in 54 (28%) patients. The two groups did not differ significantly in terms of any evaluated clinical parameter. The rate of inappropriate device therapy did not depend on the type of ICD (i.e. single-chamber versus dual chamber device). Inappropriate ICD discharge was found in 20.4% of all cases of therapeutic device activation in patients with single-chamber ICD, compared to 17.0% cases of device activation in patients with dual-chamber ICD (p = NS).

The most common cause of inappropriate ICD discharge in patients with dual-chamber ICD both

Table 1. Rate and causes of inappropriate device dicharge in 190 patients with implanted cardioverter--defibrillator (ICD).

Causes of inappropriate ICD therapy*	Number of inappropriate therapy events**	Number of patients***
Sinus tachycardia	66 (15.31%)	17 (27%)
Atrial fibrillation/flutter (AF/AFl)	182 (42.23%)	12 (22%)
Oversensing of other signals than T wave	66 (15.31%)	9 (14%)
T wave oversensing	61 (14.15%)	8 (12.5%)
Supraventricular tachycardia	2 (0.46%)	1 (1.5%)
Lead damage	40 (9.28%)	1 (1.5%)
Slow ventricular tachycardia (VT)	11 (2.56%)	5 (8%)
Unsustained VT	3 (0.7%)	0
Sinus tachycardia + other signal oversensing		4 (6%)
AF/AFl + slow VT		2 (3%)
AF/AFl + unsustained VT		2 (3%)
Sinus tachycardia + T wave oversensing		1 (1.5%)
Sinus tachycardia + lead damage		1 (1.5)
Unsustained VT + slow VT		1 (1.5%)
Overall	**431**	**64**

*Including the occurrence of two different causes of inappropriate ICD therapy in the same patient; **Percentage rate calculated for all inappropriate ICD therapy events; ***Percentage rate calculated for all patients who experienced inappropriate ICD therapy

in terms of the number of events (n = 57) and the number of patients (n = 8) was T wave oversensing, followed by sinus tachycardia (7 patients and 9 events), atrial fibrillation (5 patients and 28 events), oversensing of other signals than T wave (3 patients, 11 event), and slow VT and unsustained VT (1 event each).

Dual-chamber ICD implantation resulted in less frequent inappropriate device therapy in cases of atrial fibrillation and/or flutter and sinus tachycardia compared to patients with single-chamber ICD. Table 2 shows the rate and causes of inappropriate device therapy due to rapid supraventricular rhythms depending on the type of ICD used (single--chamber versus dual chamber device).

Discussion

Since the initial successful ICD implantation in 1980, numerous clinical trials showed benefits of ICD therapy in the prevention of sudden cardiac death [7–14]. ICD implantation is indicated in patients who survived cardiac arrest due to VF or hemodynamically unstable VT (unless the arrhythmia resulted from a reversible cause), and in whom further life expectancy exceeds one year in a good clinical condition. For some years now, major changes being introduced to the American and European guidelines in terms of wider indications for ICD implantation are mostly related to the primary prevention of sudden cardiac death and include patients at risk of life-threatening ventricular arrhythmia (e.g. Brugada syndrome, long QT syndrome, various cardiomyopathies), and patients with severely depressed left ventricular systolic function following a myocardial infarction, as manifested by low LVEF [6].

However, ICD implantation is associated with a range of problems. These include procedure-related complications (hematomas and surgical wound infections, infections involving ICD itself, lead dislocation or damage, and device damage) [22] and complications related to ICD functioning (inappropriate device activation, electrical storm). Numerous observations in patients with single-chamber ICD showed inappropriate device activation in approximately 20 to 30% of patients. The most common cause of inappropriate arrhythmia detection leading to inappropriate device discharge is supraventricular arrhythmia, and particularly atrial fibrillation [23–28]. Thus, dual-chamber devices that also use a signal from the atrial lead to recognize the type of cardiac arrhythmia were suggested to result in better discrimination of ventricular and supraventricular arrhythmia.

Benefits related to the use of dual-chamber ICD devices were shown in the Atrial Sensing To Reduce Inappropriate Defibrillation Study (ASTRID). In this study, algorithms using atrial and ventricular signal were associated with a reduced

Table 2. Rate and causes of inappropriate implanted cardioverter-defibrillator (ICD) therapy due to rapid supraventricular rhythms depending on the type of ICD used.

Causes of inappropriate therapy	Patients with single-chamber ICD (n = 136)		Patients with dual-chamber ICD (n = 54)		P for the difference in no. of inappropriate ICD therapy events	P for the difference in no. of patients experiencing inappropriate ICD therapy
	Inappropriate ICD therapy events	Patients	Inappropriate ICD therapy events	Patients		
Sinus tachycardia	57 (17.5%)	16 (11.8%)	9 (8.4%)	7 (13%)	0.029	NS
Atrial fibrillation and/or flutter	155 (47.5%)	11 (8.1%)	28 (26.2%)	5 (9.3%)	0.0001	NS
Supraventricular tachycardia	2 (0.46%)	1 (1.5%)	0	0		

number of inappropriate ICD discharge (0.04 ± ± 0.15 events/patient/month) compared to the devices that only used the ventricular rate criterion (0.58 ± ± 4.23 events/patient/month, p = 0.0425) [29].

Supraventricular tachyarrrhythmias as the major cause of inappropriate ICD discharge

The most common causes of inappropriate ICD therapy include rapid supraventricular rhythms such as sinus tachycardia, atrial fibrillation and flutter, and supraventricular tachycardia.

In our study, sinus tachycardia was the cause of inappropriate ICD therapy in the highest number of patients with inappropriate arrhythmia detection, as it was seen in 23 (36%) of 64 such patients. We noted 66 inappropriate ICD therapy events due to sinus tachycardia (about 15% of all such events). Sinus tachycardia is usually related to exercise, but it may also be associated with such clinical conditions as anemia, hyperthyroidism, respiratory failure or heart failure. The management should be directed at the treatment of the primary conditon, and may include appropriate use of drugs, mainly beta-blockers, to control the heart rate.

To avoid problems related to sinus tachycardia in patients with ICD, some centers routinely perform Holter monitoring and an exercise test during the same hospitalization after the device implantation. This allows objective confirmation of the adequacy of VT recognition zone set during ICD implantation. Such testing was not performed routinely in our center. Another way to prevent inadequate device therapy due to sinus tachycardia is the use of appropriate additional diagnostic criteria of ventricular arrhythmia, such as acute onset of arrhythmia, EGM width, and EGM morphology. The first of these criteria is based on the fact that the onset of ventricular arrhythmia is usually acute, whereas the heart rate increases more gradually in cases of sinus tachycardia. Some clinical situations, however, may render this algorithm inappropriate and result in the lack of ICD therapy despite the actual presence of ventricular arrhythmia (false--negative arrhythmia detection). For example, such a situation might occur when VT is preceded by a supraventricular arrhythmia, or VT cycle is initially longer than the VT recognition threshold set, but later gradually decreases below this value.

The two other criteria are based on differences of QRS width and morphology between supraventricular and ventricular arrhythmia. Some centers do not program these additional algorithms following ICD implantation due to reports that their use increases the specificity but decreases the sensitivity of VT recognition [30].

Instead, the acute onset of arrhythmia criterion is usually the only one that is initially programmed, and the other additional algorithms are only switched on after some events of inappropriate device therapy due to sinus tachycardia are recorded.

Antiarrhythmic drug may slow the VT rate below the maximum set rate of sinus tachycardia. On the other hand, decreasing the lower rate threshold of VT recognition may lead to an increased risk of inappropriate device therapy due to sinus tachycardia. The use of antiarrhythmic drugs to suppress ventricular arrhythmia in the context of inappropriate arrhythmia detection was discussed by Paul et al. [31]. These authors examined the effect of antiarrhythmic drug treatment on the rate of inappropriate ICD discharge. Among patients treated with class Ia drugs, the rate of inappropriate ICD discharge was 35% compared to 33% among patients treated with amiodarone, 41% among patients treated with class Ic drugs, and 63% among patients who received various combinations of antiarrhythmic drugs.

In a study by Królak et al. [32], sinus tachycardia was the main cause of inappropriate rhythm detection, noted in 227 (31%) of 725 events, while in our study 15% of inappropriate ICD therapy events were due to sinus tachycardia. This difference might have resulted from the fact that the additional algorithms differentiating between supraventricular and ventricular arrhythmia (eg. the acute onset of arrhythmia criterion) were not programmed initially but only after first episodes of inappropriate device therapy. Schaumann et al. [33] evaluated the efficacy of additional diagnostic algorithms (acute onset of arrhythmia and rhythm stability criteria) in preventing inappropriate ICD therapy due to sinus tachycardia and atrial fibrillation. The study included 124 patients, and the mean duration of follow-up was 20 months. Overall, inappropriate rhythm detection was noted in 13 (11%) patients, including two patients with inappropriate ICD therapy due to sinus tachycardia (15% of all patients with inappropriate rhythm detection).

In our study, the most common cause of inappropriate ICD therapy in terms of number of events was atrial fibrillation and/or flutter. These data are in agreement with most studies regarding inappropriate ICD therapy in which such a cause was identified in approximately 20% of all events.

In a study of 86 patients followed for 17 ± 9 months by Schmidt et al. [24], atrial fibrillation and/or flutter was the most common cause of inappropriate rhythm detection, noted in about 13% of patients. O'Nunain et al. [27] reported inappropriate ICD therapy due to atrial fibrillation and/or flutter in 21% of patients. Królak et al. [32] found that atrial fibrillation was the cause of 156 (5.6%) episodes of inappropriate rhythm detection and device activation, occurring in 14 (7.2%) patients. Rinaldi et al. [34] summarized 17 years of their experience with ICD and found inappropriate device therapy in 22 (14%) of 171 patients, with atrial fibrillation and sinus tachycardia being the most common causes (noted in 18 patients).

Did the introduction of dual-chamber ICD reduced the rate of inappropriate therapy due to rapid supraventricular rhythms?

As noted above, reducing the rate of inappropriate device therapy was the main rationale for introducing dual-chamber ICD.

In this regard, no conclusive data were obtained in a small group of patients (n = 21) reported by Fan et al. [35]. Similar results were presented by Hugl et al. [36].

In our study, dual-chamber ICD was implanted in 54 (28%) of 190 patients, and inappropriate device therapy was noted in 21 (38%) of these patients. The most common causes were T wave sensing, sinus tachycardia and atrial fibrillation, occurring with a similar rate compared to patients with single chamber ICD. However, the use of dual-chamber ICD resulted in better discrimination of rapid supraventricular rhythms and reduced number of patients with inappropriate device therapy due to atrial fibrillation and/or flutter and sinus tachycardia. Of note, patients in our study group were treated with various ICD models by different manufacturers, using various advanced algorithms to distinguish between supraventricular and ventricular arrhythmia, such as PR Logic (Medtronic), Smart (Biotronik), and AV Rate Branch (St. Jude Medical). Thus, our results may not necessarily apply to particular models of dual-chamber ICD. No difference in the number of patients with inappropriate device therapy due to supraventricular arrhythmia between groups with single-chamber and dual-chamber ICD, albeit with smaller number of such episodes in patients with dual-chamber ICD, may be explained by the the fact that additional algorithms to distinguish between supraventricular and ventricular arrhythmia were switched on only after the first event of inappropriate rhythm detection was recorded. Thus, only the number of events but not the number of patients with this problem could have been affected.

In contrast, Deisenhofer et al. [37] were not able to show benefits from the use of dual-chamber

devices in a group of 92 patients (including 45 patients with single-chamber ICD and 47 patients with dual-chamber ICD) in terms of reduced rate of inappropriate device therapy due to rapid supraventricular rhythms. The authors reported that most problems with inappropriate rhythm detection using additional diagnostic algorithms were related to atrial sensing malfunction (38 of 51 inappropriate therapy events).

Hintriger et al. [38] compared diagnostic algorithms used by various manufacturers to distinguish between supraventricular and ventricular arrhythmia during the electrophysiological study. None of the algorithms evaluated was shown to be 100% specific in detecting supraventricular arrhythmia. The devices proved to be most efficient at recognition of atrial fibrillation but fared worse in terms of detecting other rapid supraventricular rhythms (sinus tachycardia, atrioventricular nodal reentrant tachycardia etc.). The best results were obtained for GEM DR 7271 (Medtronic) and Defender IV (ELA) devices, while problems with detecting rapid rhythms resulting in stable ventricular rate were seen in case of Phylax AV (Biotronik) and Ventak AV III DR (Guidant) devices. The algorithms used by Medtronic and ELA devices are based on the analysis of PR intervals, sudden onset of arrhythmia and the ratio of atrial to ventricular impulses. Better results in terms of detection of supraventricular arrhythmia (specificity up to 89%) were reported by Kouakam et al. [39] who tested the usefulness of the Atrial View algorithm used in Guidant devices.

In summary, both our findings and data from the literature suggest that fast atrial rhythms continue to be the major cause of inappropriate ICD therapy that could not be eliminated despite significant technological advances in this area.

Conclusions

1. Inappropriate arrhythmia detection leading to inappropriate device discharge remains a major clinical problem in patients with implanted cardioverter-defibrillator.
2. The most common causes of erroneous rhythm detection and inappropriate therapeutic ICD discharge are sinus tachycardia and atrial fibrillation and/or flutter.

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