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Low rate of and rapid attention to inappropriate ICD shocks with remote device and rhythm monitoring: a qualitative study

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ABSTRACT

Objectives: Inappropriate shocks are unpleasant and painful. We hypothesise that remote monitoring and careful attention to known and incident atrial fibrillation (AF) can reduce inappropriate shocks to a very low level in clinical praxis.

Methods: Altogether 259 patients with implantable cardioverter defibrillator implanted for secondary (S, n=113) and primary (P, n=146) prevention were followed via remote monitoring. At implant, 42S (37%) and 54P (37%) patients had known AF.

Results: Inappropriate shocks, all but five due to AF, occurred in 7S (6.2%) and 11P (7.5%), and there were only inappropriate shocks in 5/7S and in 8/11P. They occurred in four of 42S (9.5%) with and in three of 71S (4.2%) without known AF, and in seven of 54P (13%) with and in four of 92P (4.3%) without known AF. The median time from shock to action was 5 and 1 day, respectively. Actions were medication with amiodarone, β blockers, β blockers+amiodarone or β blockers+digoxin (n=5), β blockers+insertion of an atrial lead (n=1), replacement of a fractured lead (n=2), reprogramming in combination with β blockers, digoxin or amiodarone (n=4), reprogramming (n=2) and none (n=4). After action, four further inappropriate shocks occurred during more than 2 years of follow-up, all due to AF.

Conclusions: Inappropriate shocks occurred at a low rate and most often because of AF known at implant. Remote monitoring enabled rapid action, after which few inappropriate shocks occurred over more than 2 years. Attention to known and incident AF was the most important action to reduce inappropriate shocks.

KEY MESSAGES

What is already known about this subject?

- Supraventricular tachyarrhythmias may cause inappropriate shocks.
- Implantable cardioverter defibrillator shocks in the awake state are unpleasant and only a few are needed to cause lasting distress and a reduced quality of life.

What does this study add?

- Inappropriate shocks are often caused by supraventricular tachyarrhythmias that are known at implant but not adequately treated.
- Remote monitoring enables early detection and treatment of arrhythmias that cause inappropriate shocks.
- Early action after detection reduces the risk of further inappropriate shocks.

How might this impact on clinical practice?

- Increased attention to atrial fibrillation (AF) known at implant can reduce subsequent inappropriate shocks.
- Early attention to new AF can reduce subsequent inappropriate shocks.
- More wide-spread routine use of remote monitoring may be justified.

INTRODUCTION

Implantable cardioverter defibrillator (ICD) therapy improves survival when prescribed for secondary[1] as well as for primary prevention.[2–4] However, ICD treatment may be either appropriate or inappropriate, and if given inappropriately to patients in the awake state, only a few shocks are enough to induce lasting psychological distress.[5 6] In addition, shocks can be arrhythmogenic.[7 8]

The incidence of inappropriate shocks varied from 9% to 11.5% in two studies over 2 years of follow-up,[9 10] and 13% in another trial with 3-year and 4-year follow-up.[11] A history of AF, smoking and antecedent-appropriate shock were predictors of inappropriate shocks.[9 11 12] Many programmable ICD parameters have an effect on the delivered device therapy, and studies on the efficacy and safety of ATP compared to shocks for fast ventricular tachycardias[13 14] are representative of current standard programming. In primary and secondary prevention patients, a reduction of both appropriate and inappropriate shocks was achieved by programming higher detection rates or prolonged detection

times.[15–17] New detection algorithms are under development and evaluation.[18 19] On the other hand, dual-chamber arrhythmia discrimination algorithms have not been proven to reduce the number of patients who experience inappropriate therapy, even if the number of inappropriately treated episodes is reduced.[20 21] Recommendations for optimal ICD programming are continually being published,[16 22 23] some of which were recently summarised and reviewed.[24]

Remote monitoring of device function and cardiac rhythm provides opportunities to early on detect malfunction or significant arrhythmias,[25–27] and enables prompt action when necessary. Remote monitoring may also be time-saving and cost-effective.[28 29] We hypothesised that remote ICD monitoring in combination with careful attention to known and incident AF would keep the incidence of inappropriate shocks at a low level, and we present our experience of remote monitoring of ICD treatment at a medium-sized Swedish hospital, according to SQUIRE publication guidelines.[30]

PATIENTS AND METHODS

This is a single-site retrospective observational study at a Swedish hospital with a catchment area of 300 000 inhabitants. Three physicians implanted the ICDs during the recruitment period. At outpatient visits two physicians and/or two trained device nurses routinely checked device properties, counters and histograms. The nurses independently performed tests and programming of stimulation thresholds and had access to a back-up physician, who also adjudicated rhythm strips and provided prescriptions for medication, when appropriate. The study was performed as part of the quality assurance programme. The purpose was to study the time to detection and action following arrhythmias resulting in shock, and how these actions affected the risk of further inappropriate or appropriate shocks.

All consecutive patients who received an ICD with remote monitoring (n=259) between 2004 and 2013 were included in this analysis, and there were no exclusion criteria. The devices were manufactured by Medtronic (Minneapolis, Minnesota, USA, n=177), Biotronik (Berlin, Germany, n=70) or St Jude Medical (Saint Paul, Minnesota, USA, n=12) at Halland's hospital, Varberg. Devices included single-chamber ICDs (n=77), dual-chamber ICDs (n=78) and cardiac resynchronisation therapy devices with defibrillation capabilities (CRT-D) (n=104). A CRT-D was usually prescribed to heart failure patients without any prior malignant arrhythmias (n=76), but the device was also chosen for secondary prevention patients with signs of heart failure or a low EF (n=28).

Device programming was performed on an individual basis. However, the most common ICD programming used for secondary prevention patients was a ventricular tachycardia (VT) zone ≥20 bpm slower than the slowest VT and NID (number of intervals for detection) 100, a fast VT zone 188–221 bpm via VF counter and a VF zone ≥222 bpm (NID 30/40). The corresponding limits for primary prevention patients were a VT zone ≥167 bpm (NID 100), a fast VT zone ≥188–221 bpm via VF counter and a VF zone ≥222 bpm (NID 30/40).

In the retrospective analysis, patients and their device-related data were retrieved through the remote monitoring system from the respective manufacturer, either CareLink, Home Monitoring or Merlin. In patients with Medtronic devices, shock therapy was identified via Discovery Link and, in case of device replacement, also via transmissions in CareLink. In patients with Biotronik or St Jude Medical devices, transmissions in each remote monitoring system were adjudicated. The follow-up period was from when the patient was connected to a remote monitoring system until the death of the patient (n=23), a move to another location (n=2), device explantation due to heart transplant (n=3), deactivation of device (n=1), or until the end of March 2014.

An inappropriate shock was defined as an episode starting with a shock not delivered for VT or VF, and ending if and when sinus rhythm was redetected by the device. Accordingly, it was possible for more than one shock to occur within the same episode. All device-registered episodes were counted, regardless of the time between episodes. Inappropriate shocks were categorised as to the cause, for example, AF, other supraventricular tachycardia, sinus tachycardia or abnormal sensing.

In all patients, the indication for ICD therapy, the LVEF, concomitant conditions and risk scores, presence of known AF, any rhythm and/or rate control medication and anticoagulation/antithrombotic treatment were recorded, as well as the programmed ICD settings including therapies for each zone, activated discriminators and if AF alert was activated. In addition, P and R sensed amplitudes were identified as well as the proportion of ventricular stimulation.

STATISTICAL METHODS

Continuous variables are reported as mean and SD. Selected proportions are reported with a 95% CI. For continuous variables, student's t test was used. For categorical data, Fishers exact test, χ^2 test and Mann-Whitney test were used. Two-tailed tests were applied. A probability value of <0.05 was regarded as significant. Data were processed and analysed using Microsoft Excel 2010 software.

RESULTS

From a total of 379 patients with an ICD, 259 patients, 202 of them men (78%), were equipped with remote monitoring. Their mean age at implant was 64.7 ±12 years. ICDs were implanted for secondary prevention in 113 and for primary prevention in 146 patients. The baseline demographics are shown in table 1. The

Table 1 Baseline demographics and comorbidities in primary and secondary prevention patients

Parameters	Secondary (n=113)	Primary (n=146)	p Value
Age, years	64.7±12	65±12	NS
Male	94 (83)	108 (74)	NS
Follow-up, months	39±24	30±22	<0.001
Ischaemic heart disease	69 (61)	73 (50)	NS
Left ventricular ejection fraction	40±14	29±10	<0.001
History of atrial fibrillation	42 (37)	54 (37)	NS
$CHADS_2$ score	1.6±1.3	1.8±1.1	NS
CHA_2DS_2-VASc score	3.0±1.7	3.1±1.6	NS
Single-chamber ICD	37 (33)	40 (27)	<0.001
Dual-chamber ICD	48 (42)	30 (21)	NS
CRT-D	28 (25)	76 (52)	NS

Values shown are mean±SD or n (%).
CRT-D, cardiac resynchronisation therapy+defibrillator; ICD, implantable cardioverter defibrillator; NS, not significant.

$CHADS_2$ and CHA_2DS_2-VASc scores were 1.7±1.2 and 3.1 ±1.7, respectively.

Appropriate shocks occurred in 24 (21.2%) secondary and in 15 (10.3%) primary prevention patients after a mean of 19.3±19.1 months. Sustained supraventricular tachyarrhythmias, specifically AF, were known at the time of ICD implant in 42 (37%) and 54 (37%) patients, respectively. The annual rates of appropriate shocks were 6.8% primary prevention patients and 18% secondary prevention patients.

Table 2 Basic demographics in patients with and without inappropriate shock (Inapp shock)

Patient characteristics	Inapp shock +(n=18)	Inapp shock– (n=241)	p Value
Age	61.6±14	64.8±12	NS
Male	16 (89)	186 (77)	NS
Primary prevention	11 (61)	135 (56)	NS
Single-chamber	5 (28)	72 (30)	NS
Dual-chamber	7 (39)	71 (29)	NS
CRT-D	6 (33)	98 (41)	NS
Ischaemic heart disease	10 (56)	132 (55)	NS
Left ventricular ejection fraction	33.3±13.4	33.9±13	NS
History of AF	12 (67)	84 (35)	0.007
CHADS2 score	1.8±1.0	1.7±1.2	NS
CHA2DS2VASc score	2.8±1.5	3.1±1.7	NS

Values shown are mean±SD or n (%).
AF, atrial fibrillation; CRT-D, cardiac resynchronisation therapy +defibrillator.

Inappropriate shocks during follow-up

Inappropriate shocks occurred in 7 (6.2%) secondary and 11 (7.5%) primary prevention patients after 14 ±19.9 months (range 0.33–55 months) and 9.7 ±14.1 months (range 0.07–46 months), respectively, all but five due to AF. The annual incidence of inappropriate shocks was 2.7% and 3.8% in secondary and primary prevention patients, respectively. Baseline demographics for patients with and without inappropriate shock appear in table 2.

Five of the seven secondary and 8 of the 11 primary prevention patients only had inappropriate shocks. Inappropriate shocks occurred in 5 of 42 (11.9%) secondary prevention patients with, and in 2 of 71 (2.8%) patients without, known AF. In primary prevention patients, inappropriate shocks occurred in 7 of 54 (13%) with, and 4 of 92 (4.3%) without, known AF at the time of ICD implant. The annual rate of incident AF was 5.3% in secondary and 5% in primary prevention patients. In the primary prevention patients, 10 of 11 had one, and one patient, two, inappropriate shocks before diagnosis and action. In secondary prevention patients, six had one, and one had two, inappropriate shocks before diagnosis and action. There were two further inappropriate shocks in each group during the remainder of the follow-up, for the two primary prevention patients at 5 and 11 months, respectively, after the first inappropriate shock, and for the two secondary prevention patients at 4.6 and 29 months, respectively. Five inappropriate shocks (two in primary and three in secondary prevention patients) were not caused by AF. Three of these were caused by sinus tachycardia, one by T wave oversensing and one by noise.

Prevalent versus incident AF

AF was known at implant in 37% of the patients in each group, and in total, 9.4% and 85.4% of these patients had pharmacological agents used for rhythm (n=9) or rate (n=82) control. In the secondary prevention group, 14% had rhythm control and 76% rate control agents, as compared with 6% and 93% in the primary prevention group, respectively. The proportions of patients with known AF who had inappropriate shocks were 11.9% in secondary and 13% in primary prevention patients. Rhythm or rate control therapy was equally prevalent in patients with and without inappropriate shocks.

A first-ever diagnosis of AF was obtained in 16.9% (12/71) of secondary and 13% (12/92) of primary prevention patients, representing an annual rate of 5.3% vs 5.0%, respectively. Among patients with known AF, 86.5% were already on anticoagulation at implant. A first ever diagnosis of AF led to initiation of anticoagulation in 75% of the patients.

Time to inappropriate shock and from shock to action

The time to the first inappropriate shock after ICD implantation appears in figure 1. In secondary

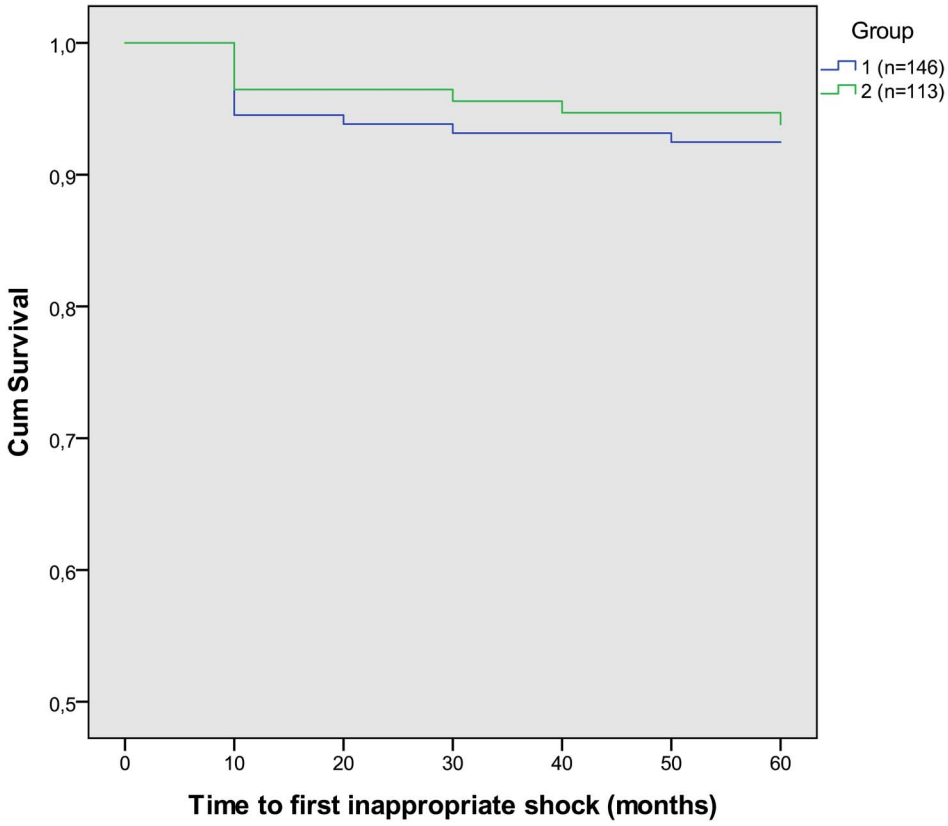

Figure 1 Kaplan-Meier curves showing the time in months to the first inappropriate shock from the start of remote monitoring in primary and secondary prevention patients. There was no statistically significant difference between the two groups. Group 1 (n=146) contains the primary and group 2 (n=113) the secondary prevention patients.

prevention patients with inappropriate shocks, the median time to the first inappropriate shock from the start of remote monitoring was 5 months, range 0.33–55 months. The median time from shock to action was 5 days, range 0–25 days (figure 2). In one patient, action occurred only after a second inappropriate shock, occurring 3 days after the first one. The remaining follow-up time was 43±29.7 months (range 5–88 months) and two

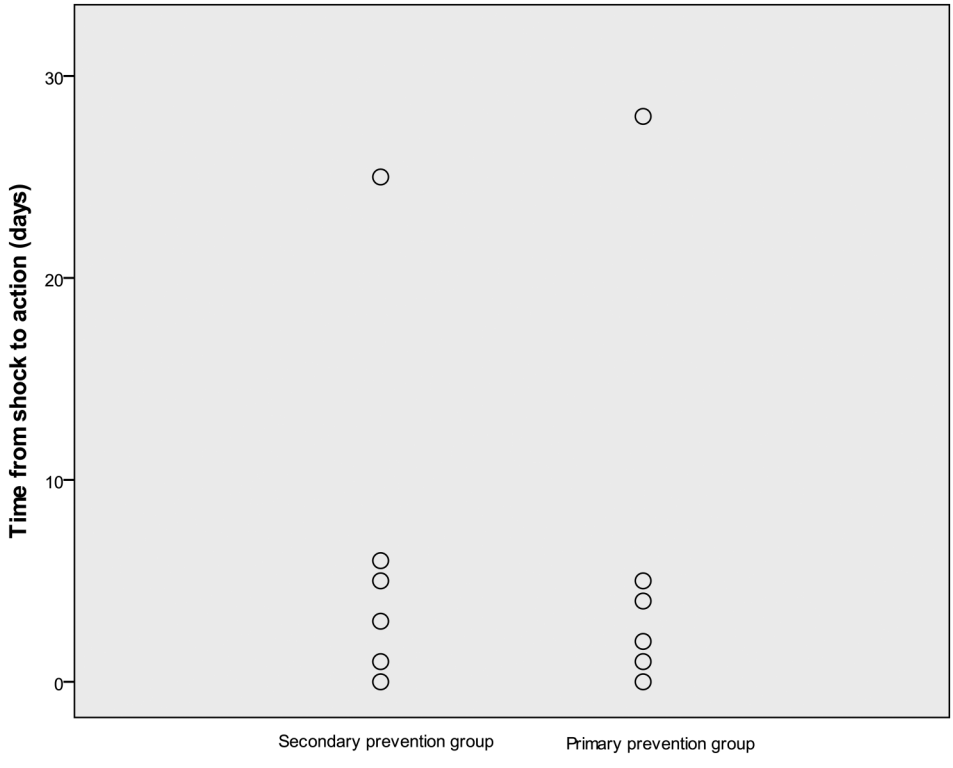

Figure 2 Time in days from inappropriate shock to action in primary and secondary prevention patients. There was no statistically significant difference between the two groups.

patients had one further inappropriate shock after 4.6 and 29 months, respectively, both due to recurrent AF.

In primary prevention patients with inappropriate shocks, the median time to the first inappropriate shock was 3 months, range 0.067–47 months (figure 1), and the median time from the first shock to action was 1 day, range 0–28 days (figure 2). In one patient, action occurred only after a second inappropriate shock, occurring 5 days after the first one. The remaining follow-up was 37.5±20.8 months (range 7–67) and two patients had one further inappropriate shock after 5 and 11 months, respectively, both due to recurrent AF.

Actions following inappropriate shocks

In the primary prevention group, eight patients with one inappropriate shock each, received an atrial lead due to intermittent AF+β blockers (n=1), β blockers+VF zone changed 222–250 bpm (n=1), amiodarone (n=2), new lead due to lead fracture (n=1) and no action (n=3). Three patients with two inappropriate shocks each, received β blockers (n=1), β blockers+amiodarone (n=1) and no action (n=1).

In the secondary prevention group, four patients with one inappropriate shock each, received β blockers+VT zone changed 150–167 bpm (n=1), amiodarone+VT zone changed 188–194 bpm+VF zone changed 230–250 bpm (n=1), VT2 zone changed 158–182 bpm+VF zone changed 200–222 bpm (n=1) and VF zone changed 207–222 bpm. Three patients with two inappropriate shocks each, received a new lead due to lead fracture (n=1), β blockers+digoxin (n=1) and β blockers +digoxin+VT2 zone changed 158–194 bpm+VF zone changed 194–222 bpm.

Gender aspects in inappropriate shocks

The number of inappropriate shocks was not significantly different between men and women, 7.9% and 3.5%, p=0.37, respectively. Small differences in the $CHADS_2$ scores were noted, 1.7±1.2 and 1.4±1.1, p=0.24, respectively, while the CHA_2DS_2-VASc scores were 3.0 ±1.6 and 3.3±1.7, p=0.19, respectively. Women with inappropriate shocks were younger than those without, 54.5±12.0 vs 62.2±14.1 years, p=0.53, and younger than men with or without inappropriate shocks, 62.4 ±13.9 years and 65.6±11.1 years, p=0.61, respectively.

DISCUSSION

Main results

Inappropriate shocks occurred at low and similar rates in patients with ICD treatment for secondary and primary prevention. AF was the dominant cause and was most often known at the time of ICD implant. A first-ever diagnosis of AF was established at a low annual rate, and remote monitoring enabled early detection of the cause of shocks, and after appropriate early actions recurrences were rare. Six of 18 patients received more than one shock, but none more than two shocks.

Reduction of inappropriate shocks by AF detection algorithms

Algorithms that identify non-malignant arrhythmias can prevent the ICD from delivering an inappropriate shock.[23 24] Studies have confirmed a reduction of the rate of inappropriate shocks, but the clinical problem is far from solved, since only a few shocks in the awake state are enough to produce long-lasting psychological distress and fear owing to negative expectations of another shock.[6 7 9] The most recent studies tested less aggressive programming, raising the threshold for shocks due to supraventricular tachyarrhythmia.[25 26] However, while saving the patient from some inappropriate shocks, this approach does not address the negative impact of the supraventricular arrhythmias.

Prevalent versus incident AF during follow-up

While AF was the most common cause of inappropriate shocks, only a minority of the patients with known or incident AF had shock delivery. Our results imply that patients without or with insufficient rhythm or rate control were those at the highest risk of recurrent arrhythmias and inappropriate shocks. Therefore, awareness of the arrhythmia history at implant and relevant therapy is an important clinical measure for reducing inappropriate shocks.

In patients without known AF, the first-ever AF is more difficult to predict. In our patients with first-ever AF, the risk scores at ICD implant were not statistically higher than in those without subsequent AF, with a mean $CHADS_2$ score of 1.8±1.5 vs 1.5±1.1, p=0.53, and a mean CHA_2DS_2-VASc 3.16±1.9 vs 2.8±1.6, p=0.33.

Remote monitoring and actions following inappropriate shocks during follow-up

The time to the first inappropriate shock was similar in patients with primary and secondary prevention with median times of 3 and 5 months. The causes of inappropriate shocks were immediately apparent in the remotely transmitted rhythm strips and led, with few exceptions, to action within 1-week. Adjustment of pharmacological treatment was the most common action, occasionally in combination with device reprogramming. True malfunction was detected once in each patient group, both times as a lead fracture leading to prompt and uncomplicated lead replacements. The fractured leads were of different kinds.

Predictors of inappropriate shocks

In the present analysis, the number of inappropriate shocks was too low to allow for a meaningful predictor analysis. However, no such analysis is needed to conclude that AF, whether prevalent or incident, was the main cause. Thus risk factors of AF are also potential risk factors of inappropriate shocks. Device-related problems are even harder to predict, and have also decreased with improved hardware and software.

Limitations

This is a single-centre report from a middle-sized Swedish hospital comprising the complete experience with ICD devices with remote monitoring. We cannot exclude the fact that the selection of patients may have differed from other sites, considering that the ICD implant rate is in the middle of the rates in Europe and far below that in the USA. In addition, the single centre nature of this report also means that ICD programming and response to inappropriate shocks may be biased and not always reproducible. However, this report supports the contention that ICDs can be implanted and adequately followed, and that remote detection of arrhythmias and other problems promptly leads to swift actions that solve the problems. Owing to its observational design, this report does not include a control group, which may be perceived as a limitation, but on the other hand, it allowed us to report our complete experience with remote monitoring.

CONCLUSION

Inappropriate shocks occurred at low and similar rates in patients implanted with an ICD for secondary or primary prevention, almost always due to AF that was known at implant. Remote monitoring enabled rapid attention and provision of medication, reprogramming or lead replacement, after which no further inappropriate shocks occurred during a follow-up of almost 3 years. Inappropriate ICD shocks remain an important clinical problem and may have various reasons, but prompt attention to known and incident AF appeared to be the single most important action to reduce the risk of inappropriate shocks.

Contributors ES, CR and NE designed the study. ES collected the data and provided the first draft of the manuscript. ES, CR, JE and NE participated in the analysis of data and provided critical reviews of the manuscript. All the authors have read and approved the final version of the manuscript.

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