"Natural Death" of a patient with a deactivated Implantable-Cardioverter-Defibrillator (ICD)?

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1 Abstract

A 66 year old patient with terminal heart insufficiency (NYHA IV) received maximum medical therapy, but was also in need of an ICD. The ICD functioned flawlessly for the whole duration of implantation. It reverted several ventricular tachycardias with anti-tachycardial pacing alone, whereas some needed cardioversion as well. The patient died on the 4th day of hospitalization for a routine check of his ICD.
The post-mortem examination revealed, that the ICD was deactivated, and that the data had been erased after the patient's death.
By reading off the raw data still stored within the ICD, the erased information could be restored. The stored EGMs showed traces of old ICD interventions as well as a permanent deactivation provoked by exposition to a magnetic field just hours before the patient's death.
The problem of archiving and documenting the volatile electronic data inside the ICD is discussed.
The need of a full autopsy after telemetric reading of the ICD data, including the explantation of the ICD aggregate and electrodes, as a means of quality assurance and under forensic aspects is emphasized.

Keywords

Implantable Cardioverter-Defibrilator (ICD), post-mortal diagnostics; pacemaker (PM); forensic diagnostics

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Abstrakt

Es wird der Fall eines 66-jährigen Patienten mit einer Herzinsuffizienz im Stadium NYHA IV vorgestellt, der neben einer maximalen medikamentösen Therapie auch einen ICD benötigte.
Über 1 Jahr funktionierte der ICD laut Angaben der behandelnden Kliniker problemlos. Er therapierte zahlreiche Tachycardien allein mit anti-tachycardem Pacing, einige mit anschließender Cardioversion. Am 4. Tag eines Klinikaufenthaltes wegen einer Routinekontrolle des ICD starb der Patient. Von den behandelnden Kardiologen wurde ein natürlicher Tod bescheinigt.
Im Rahmen der äußeren Leichenschau wurde der ICD explantiert. Eine Analyse der im ICD gespeicherten Daten ergab, daß der ICD von den Kardiologen nach dem Tode deaktiviert und die Daten gelöscht wurden.
Durch Auslesen der Rohdaten konnten die gelöschten Informationen rekonstruiert werden. Hierbei fand sich neben den noch nie ausgelesenen Protokollen alter Interventionen des ICD auch eine Deaktivierung durch einen externen magnetischen Einfluß (z.B. einem Permanentmagneten) in den frühen Morgenstunden des späteren Todestages.
Es wird auf die Beweismittelsicherung und die Beweismittelvernichtung bei flüchtigen elektronischen Daten innerhalb eines ICD aus forensischer Sicht eingegangen.
Die Notwendigkeit einer vollständigen Sektion nach telemetrischem Auslesen und Analyse der im ICD gespeicherten Daten, als Teil der Qualitätssicherung und unter forensischen Gesichtspunkten, wird betont.

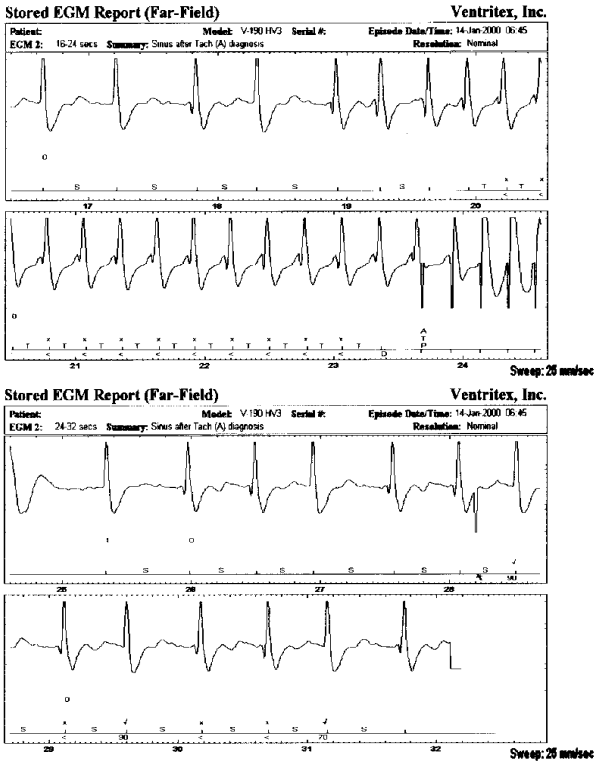


Abbildung 1: EMG of a ventricular tachyarrhythmia with successful termination by use of anti-tachycardial pacing (ATP) employing 5 bursts.

2 Introduction

We report on the case of a 66 year old patient suffering from terminal heart insufficiency (NYHA IV). Although he received maximum drug therapy, an Implantable Cardioverter-Defibrillator (ICD) was needed for sufficient therapy.[1]
The physicians reported, that the ICD worked flawlessly for over 1 year. There had been several successful interventions of the ICD using anti-tachycardial pacing (ATP, fig.: 1 [6]), as well as some, which needed a cardioversion (fig.: 2). The patient had regular checks on his ICD, and was said to be very compliant with regard to taking his drugs.

[1] An ICD is a device for the treatment of life-threatening ventricular tachycardias: Via intracardial electrodes, an EMG is constantly being analysed by the ICD. Anti-tachycardial pacing using 5-16 busts as well as defibrilation, when needed, is automatically applied by the ICD after detection of a ventricular arrhythmia.

All modern ICDs are a combination of pacemakers and ICD. Due to the mutual interference of the generators, special care must be taken in situations where an ICD as well as a PM are implanted [1][2].

In case of a diagnosis of a ventricular tachyarrhythmia, anti-tachycardia pacing (ATP) is used as a first attempt of treatment, depending on the programming of the genrator. The majority of tachyarrhythmias are based on a re-entry mechanism, in which the myocardial fibres are excited by a wavefront running in a circular fashion. Using multiple pacemaker impulses in such a way that the circular wavefront runs into refractory myocytes, this vicious cycle can be broken.

The heart is only cardiverted by the ICD in cases when the ATP is not successful or a hemodynamically unacceptable frequency of more than 200 beats/min is diagnosed. If this treatment does not result in a successful reversion the cardioversion is repeatedly applied—up to the maximum numer programmed (usually 6 times) or the battery is exhausted. Usually the battery will last 100-300 load cycles of the internal capacitor, depending on the ICD model [3][4][5].

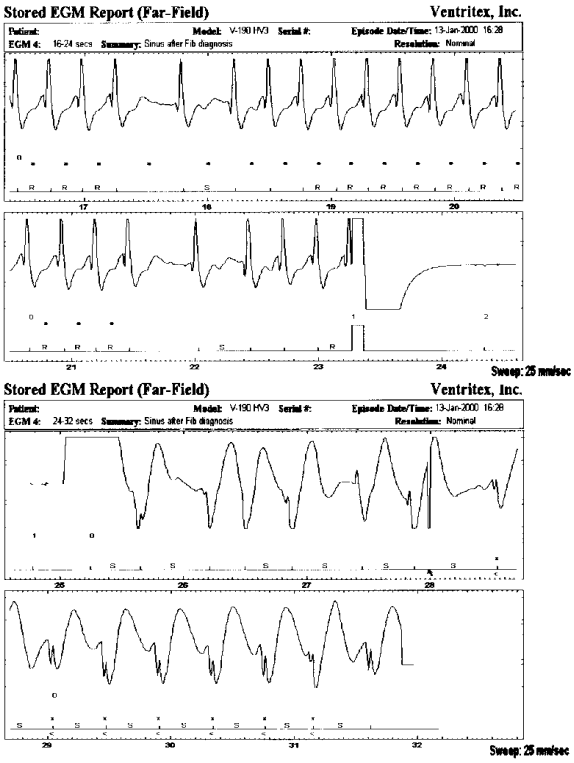


Abbildung 2: EMG of a ventricular tachyarrhythmia with successful termination by use of an ICD generated cardioversion. The last EMG-line has the shape of a typical post-shock waveform, with ICD-generated pacing impulses.

The patient died on the 4th day of hospitalization for a routine check of his ICD. The cardiologist in charge diagnosed a death of natural cause: acute cardiac failure on the grounds of chronic coronary heart disease.
The ICD was explanted on request of the relatives during the second external examination of the corpse before cremation. All electrical safety regulations were adhered to. An examination of the explanted ICD in the department of cardiology revealed, that the ICD had been permanently deactivated after the patient's death, and that all data was deleted.
However, most of the information stored within the ICD could be reconstructed by reading the raw memory data using a standard programmer in conjunction with the routine programmer back-up files. Thus, we could view the old intervention data, the corresponding EMGs, the timings, etc. To our surprise, the majority of the protocols of the old interventions had never been read from the ICD before. Furthermore, a deactivation of the ICD using a permanent magnetic field, like that from a strong permanent magnet was documented to have started in the early hours of the day, on which the patient later died.

2.1 Electronical Diagnosis

The ICD and PM[2]

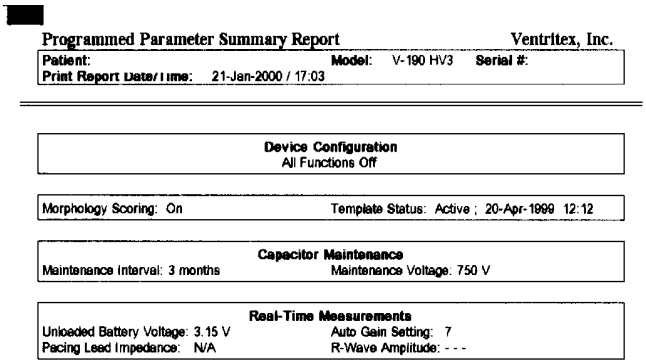
[2] PM abbr. Pace Maker.
A PM is a device for correction of the insufficient sinoidal rhythm generation and/or conduction by the use of direct electrical stimulation of the myocardium. are equipped with a telemetric capability for programming and follow-up.

An ICD can receive commands by the use of high frequency electromagnetic fields. The ICD responds to the commands by modulation of the external field. Thus, an ICD and the corresponding electrode system can be checked without the need of surgical explantation—even if the implant's carrier has died.
The large number of different telemetric programmers needed for the different ICD/PM has to be seen as the main obstacle to a routine post-mortem checking as there is no such thing as a universal ICD/PM programmer on the market. In some cases different programmers are needed, even within the same product line.
All modern PM/ICDs have an internal memory for the storage of EMGs sampled during interventions, as well as for a long-term EMG (mostly $24h$). All information about the interventions is stored, allowing for a post-shock diagnostic. The internal clock of the ICD is used as a time/date-stamp.
The internal clock of most ICDs is a free running counter which is set to the time and date of the programmer before every telemetric interrogation. The internal clock of the programmer is nothing but the standard computer clock, which is known for its notorious inaccuracy (commonly in the range of $\pm 2 min/month$ [7]). The time difference is only avaliable at the beginning of a telemetric session and will be lost after the correction of the time of the internal clock. Only the time and date of the internal ICD clock is changed—the time/date-stamp of the internally stored EMGs and intervention protocols are not changed accordingly. Thus the time difference can be of supreme importance in cases of accident reconstruction, etc., and therefore has to be documented very carefully.
The ICDs are not able to differentiate between a breakage in the electrode system and the patient's death. The internal structure of all ICDs is set in such a way, that the sensing sensitivity is increased, when no or only weak input signals are detected. Thus the noise immunity of the ICD is reduced, in favor of a possible compensation of an electrode breakage [8][9]. A further complication has to be seen in the overwriting of the internal $24h$ EMG after the patient passed away. Thus the internal ICD data should be read telemetrically as soon as possible. The general information about the state of the ICD and the protocols about past interventions can of course be accessed long after the patient's death [10].
The internal data of the PM/ICD will be stored, if the generator has been deactivated telemetrically. In such a state, the data will be quite resistant to external electromagnetic fields [11]. Another reason for deactivating the ICD has to be seen in the necessity to ensure the electrical safety of the persons handling the corpse.

3 The Case

The telemetric reading of the internal ICD data resulted in adaptation of the ICD's clock to the programmer's clock. The time difference was less than a couple of seconds. The

Indications for a PM implantation are: aquired AV-block, LV-dysfunction, bifascicular or trifascicular block, sinus node dysfunction, hypersensitive carotis node and neurovascular syndromes [3][5].



Programmed Parameter Summary Report — Ventritex, Inc.

Patient: — Model: V-190 HV3 — Serial #:
Print Report Date/Time: 21-Jan-2000 / 17:03

Device Configuration
All Functions Off

Morphology Scoring: On — Template Status: Active ; 20-Apr-1999 12:12

Capacitor Maintenance
Maintenance Interval: 3 months — Maintenance Voltage: 750 V

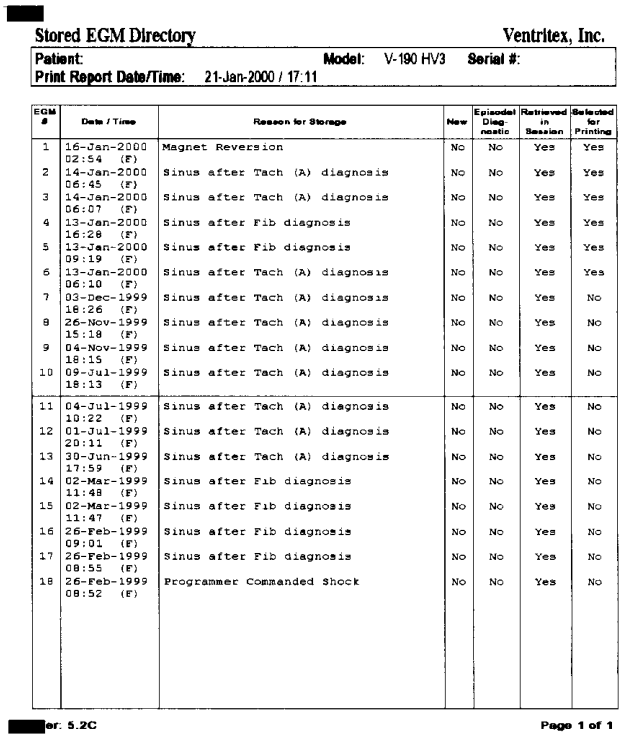
Real-Time Measurements
Unloaded Battery Voltage: 3.15 V — Auto Gain Setting: 7
Pacing Lead Impedance: N/A — R-Wave Amplitude: - - -

Abbildung 3: Facsimile of the 'Programmed Parameter Summary Report' showing implantation date, maintenance interval, functional state etc.

'Programmed Parameter Summary Report' is shown in figure 3.
The 'Stored EMG Directory' is shown in figure 4, detailing the ICD interventions.
The last 6 interventions occured during the patient's final hospital stay. Of the five instances in which a ventricular tachycardia was diagnosed, three were successfully treated by the use of ATP, two needed a cardioversion. The last intervention was a magnet reversion—the deactivation of the ICD by use of a permanent magnet—in the early hours (02:54am) of the last day of the patient's life. The application of the permanent magnet prohibited any further EMG recording of the ICD. Thus, the ICD's internal data could not be used for the analysis of the agonal period. The ICD's last 4 interventions had not once been read from the internal memory before our post-mortem examination. Due to software limitations of the programmer used, this information could not be printed—despite of being displayed on the built-in screen. After the patient's death, the ICD was deactivated by the cardiologist in charge, using a standard ICD-programmer.
In order to shed light into the mysterious circumstances of the death we requested permission for a scientific autopsy from the wife of the deceased .

3.1 Autopsy Results

A left ventricular dilatation, with a heart mass of 600g, was diagnosed during autopsy. Fibrosis was found in the papillary muscles, as well as some transmural fibrosis in the left ventricle, up to a size of $1cm \times 1{,}5cm$ with no histological signs of an acute infarction. Even though there was a high degree of atheriosclerosis in the aorta and the main arteries, with atheromatose plaques and ulcers, there was only minor coronar sclerosis, with a solitaire plaque in the proximal RIVA.
A massive edema of the lungs (2510g) pointed to a left ventricular failure.
There were no macroscopical or histological signs of an acute myocardial infarction. Due to the enlargement of the heart and a number of old myocardial scars cardial decompensation was taken to be a possible cause of death. The question of ventricular arrhythmia as the underlying cause of death, remains open.



Stored EGM Directory — Ventritex, Inc.

Patient: — Model: V-190 HV3 — Serial #:
Print Report Date/Time: 21-Jan-2000 / 17:11

EGM #	Date / Time	Reason for Storage	New	Episodal Diagnostic	Retrieved in Session	Selected for Printing
1	16-Jan-2000 02:54 (F)	Magnet Reversion	No	No	Yes	Yes
2	14-Jan-2000 06:45 (F)	Sinus after Tach (A) diagnosis	No	No	Yes	Yes
3	14-Jan-2000 06:07 (F)	Sinus after Tach (A) diagnosis	No	No	Yes	Yes
4	13-Jan-2000 16:28 (F)	Sinus after Fib diagnosis	No	No	Yes	Yes
5	13-Jan-2000 09:19 (F)	Sinus after Fib diagnosis	No	No	Yes	Yes
6	13-Jan-2000 06:10 (F)	Sinus after Tach (A) diagnosis	No	No	Yes	Yes
7	03-Dec-1999 16:26 (F)	Sinus after Tach (A) diagnosis	No	No	Yes	No
8	26-Nov-1999 15:18 (F)	Sinus after Tach (A) diagnosis	No	No	Yes	No
9	04-Nov-1999 18:15 (F)	Sinus after Tach (A) diagnosis	No	No	Yes	No
10	09-Jul-1999 18:13 (F)	Sinus after Tach (A) diagnosis	No	No	Yes	No
11	04-Jul-1999 10:22 (F)	Sinus after Tach (A) diagnosis	No	No	Yes	No
12	01-Jul-1999 20:11 (F)	Sinus after Tach (A) diagnosis	No	No	Yes	No
13	30-Jun-1999 17:59 (F)	Sinus after Tach (A) diagnosis	No	No	Yes	No
14	02-Mar-1999 11:48 (F)	Sinus after Fib diagnosis	No	No	Yes	No
15	02-Mar-1999 11:47 (F)	Sinus after Fib diagnosis	No	No	Yes	No
16	26-Feb-1999 09:01 (F)	Sinus after Fib diagnosis	No	No	Yes	No
17	26-Feb-1999 08:55 (F)	Sinus after Fib diagnosis	No	No	Yes	No
18	26-Feb-1999 08:52 (F)	Programmer Commanded Shock	No	No	Yes	No

[redacted]er: 5.2C — Page 1 of 1

Abbildung 4: Facsimile of the 'Stored EMG Directory' of the explanted ICD.

The long term EMGs stored in the patient's ICD revealed a strong tendency of his heart to develope ventricular arrhythmias: 5 interventions during the last 4 days of the patient's life (fig.: 4). Thus, an acute rhythmic occurence is judged to be the most probable cause of death [12].

3.2 Assessment

In the presented case, there are severe doubts about the naturalness of the cause of death: A machine, implanted to sustain and prolong the patient's life, was deactivated. On the other hand the patient suffered from severe heart insufficency (NYHA IV).

Furthermore, one has to discuss, whether there is such a thing as a natural cause of death, in a patient with an ICD. Even though the reliability of ICDs has been significantly raised during the last two decades [13][14], there is always the possibility of a generator or electrode failure [15]. From a forensic point of view, it seems very important to first read and analyse the telemetric data stored in the ICD, second test the system including the electrodes, third deactivate the ICD, and finally to explant the generator.

By use of the internal PM/ICD data, a tachycardia as a cause of death can be diagnosed—there are cases in which a tachycardia can even not be terminated by a fully functional ICD. Furthermore, insights into the exact timing of the death can be gained.

In our opinion the cause of death in an ICD patient has to be stated as '*unknown*' if no telemetric data has been gained and no autopsy has been performed.

4 Conclusion

In patients with ICDs or pacemakers, an assessment of the cause of death has to include an examination of the causal connection of the ICD/PM and the death. This examination is a necessary means of quality assurance, and has to include an analysis of the telemetrically accessible ICD/PM data as well as a full autopsy, with careful investigation of the ICD/PM system.

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