Pacemaker as a Cause of Death

Pacemaker Failure in a Patient with

'Sick Sinus Syndrome' and Bradycardia

Mirko Junge* www.DrJunge.de mj@DrJunge.de

Jörn Weckmüller† weckmuel@web.de

Herbert Nägele‡ naegele@uke.uni-hamburg.de

Klaus Püschel* ifrhh@uke.uni-hamburg.de

Wilfried Rödiger‡ roediger@uke.uni-hamburg.de

3rd January 2001

Contents

1 Abstract

We report on a patient who at the age of 78 consulted his doctor with the classical symptoms of a 'sick sinus syndrome': dizziness, confusion, fatigue, and syncope. The diagnosis of a bradycardic sinus node dysfunction was confirmed by a cardiologist. After implantation of an antibradycardia pacemaker, the patient made a full recovery. Due to a worsening of his medical situation, the patient was admitted to hospital 4 years later. A cardial decompensation with global cardiac insufficiency was diagnosed. When the patient died, he had been hospitalised for 8 weeks, his medical condition having been treated with drugs. The primary cause of death was stated as 'cardiac decompensation' in the death certificate.

An autopsy was performed by the resident pathologist; the pacemaker generator was left in place above the pectoralis muscle. During the required second post-mortem examination before cremation, the pacemaker was explanted. The electrode showed signs of stretching but was still connected to the generator.

Telemetric interrogation of the pacemaker generator showed the battery to be depleted (EOL). No electrical output could be measured from the generator terminals. The generator functioned flawlessly after battery replacement.

It is highly probable, that the pacemaker-battery was depleted for the last couple of weeks before the patient's death. Therefore, the absence of the cardiac pacing pulses has to be seen as the cause of the global cardiac insufficiency. Thus, the faulty pacemaker is the underlying cause of death; the death has to be classified as 'not natural'.

From a forensic point of view, a thorough investigation of an implanted pacemaker is of paramount importance in finding the precise cause of death.

Keywords

post-mortal diagnostics; pacemaker (PM); battery exhaustion

*Institute of Legal Medicine, University of Hamburg, Butenfeld 34, 22529 Hamburg, Germany

†Center for Biomedical Methods, Ruhr-University Bochum, Universitätsstr. 150, 44780 Bochum, Germany

‡Heart- and Vessel-Surgery, University of Hamburg, Martinistr. 52, 20246 Hamburg, Germany

2 Abstrakt

Es wird der Fall eines Patienten berichtet, der sich vor 4 Jahren, im Alter von 78 Jahren mit den typischen Symptomen des so genannten 'Sick Sinus Syndrome' bei seinem Hausarzt vorstellte: Abgeschlagenheit, Verwirrtheit sowie Schwindelanfälle mit Stürzen. Ein hinzugezogener Kardiologe bestätigte die Verdachtsdiagnose einer ausgeprägten Sinus-Bradycardie mit Synkopen bei Sinusknotenfehlfunktion und therapierte den Patienten durch Implantation eines Herzschrittmachers, worauf sich der Zustand des Patienten normalisierte.
8 Wochen vor dem Tode verschlechterte sich der Zustand des Patienten so dramatisch, das er zur stationären Behandlung eingewiesen wurde. Eine kardiale Dekompensation bei Globalinsuffizienz wurde diagnostiziert, woran sich ein 8 wöchiger, medikamentöser Therapieversuch anschloss, der mit dem Tod des Patienten endete. Als primäre Todesursache wurde von den behandelnden Ärzten die zu Beginn des Krankenhausaufenthaltes diagnostizierte kardiale Dekompensation in den Totenschein eingetragen.
Der Leichnam wurde von Pathologen obduziert, der Schrittmachergenerator wurde hierbei unberührt an typischer Stelle über dem M. pectoralis belassen. Im Rahmen der zweiten äußeren Leichenschau vor Kremierung wurde der Schrittmacher explantiert, zu diesem Zeitpunkt wies die Elektrode Zeichen einer Dehnung auf, war jedoch noch fest und elektrisch leitend mit dem Generator verbunden. Bei der telemetrischen Abfrage des Schrittmachers wurde der Batteriezustand als erschöpft (EOL) angezeigt, an den Generator-Elektroden konnte unter Last kein Signal gemessen werden. Durch Öffnen des Schrittmachergehäuses mittels einer Diamantsäge und Anschluss einer entsprechenden neuen Energiequelle konnte die Funktionsfähigkeit des Generators wieder hergestellt werden.
Der Herzschrittmacher war, unter Berücksichtigung des klinischen Verlaufs, höchstwahrscheinlich schon 8 Wochen vor dem Tod aufgrund der Batterieerschöpfung – nach nur 4 Jahren – bereits nicht mehr funktionsfähig und ursächlich für die Globalinsuffizienz des Patienten. Somit ist die Fehlfunktion des Herzschrittmachers todesursächlich gewesen und der Tod hätte als 'nicht natürlich' klassifiziert werden müssen.
Vom forensischen Gesichtspunkt aus ist die gründliche Aufarbeitung der in Herzschrittmachern gespeicherten Daten für die Bestimmung der Todesursache von größter Wichtigkeit.

3 Introduction

We report on the case of an 82 years old patient whose medical condition made the implantation of an anti-bradycardia pacemaker at the age of 78 necessary. After implantation, the patient made a full recovery.
The pacemaker generator was explanted as part of a two yearlong cross-section analysis of the post-mortem functional state of pacemakers (PM) and Implantable Cardioverter/Defibrillators (ICD) encountered during the second external examination before cremation in the crematorium Hamburg-Öjendorf [1].
The requirement of the German Batterieverordnung [2] (BattV, engl. battery directive) demands in §7 that all devices with embedded batteries must be returned to the manufacturer, or at least to the distribution channel, at the end of their lifes. All electrical safety regulations were adhered to.

3.1 Electronical Diagnosis

The modern pacemakers are equipped with a telemetric capability for programming and follow-up.
A PM receives commands by the use of high frequency electromagnetic fields and responds, using the same technology [3][4]. Thus, a PM, as well as the properties of the corresponding electrode system, can be checked without the need of surgical explantation—even when the patient is deceased [5][6].
The large number of different telemetric programmers needed for the different PM has to be seen as the main obstacle to a routine post-mortem checking, as there is no such thing as a universal PM programmer on the market. In some cases, different programmers are needed even within the same product line.

4 The Case

At the age of 78—4 years prior to his death—the patient consulted his physician with the classical symptoms of the 'sick sinus syndrome' (SSS): dizziness, confusion, fatigue, and syncope. The diagnosis of a bradycardic sinus node dysfunction was confirmed by a cardiologist. According to the current guidelines for SSS disease, an anti-bradycardia pacemaker was implanted [7][8]. After the healing-in period, the patient made a full recovery.
Due to a worsening of his medical situation, the patient was admitted to hospital, 8 weeks prior to his death. A cardial decompensation with a global cardiac insufficiency was diagnosed. The ECG showed no PM pulses, the heart rate was $40 bpm$. The patient was hospitalised for the last 8 weeks of his life. During this hospital stay attempts were made to treat his medical condition by sole use of anti-hypertensive drugs. In the death certificate, the primary cause of death was stated as 'cardiac decompensation' (fig.: 1§3).
An autopsy was performed by the resident pathologist. The pacemaker generator was left totally untouched in its place above the pectoralis muscle.
During the required second post-mortem examination before cremation the pacemaker was explanted and anal-

Figure 1: Facsimile of the confidential part of the death certificate.
In Lower Saxony, Germany, the result of an autopsy has to be documented in the death certificate (missing, in this case). Furthermore, the issuing institution is not declared on the certificate.

ysed. The electrode showed signs of stretching but was still connected—mechanically as well as electrically—to the generator.

4.1 Autopsy Results

At autopsy the following findings and diagnosis were stated by the investigating pathologist: High degree of atherosclerosis in the aorta as well as in the main arteries, with atherosclerotic plaques and ulcerated plots. Severe sclerosis of the coronary arteries with numerous atheromatous plaques some of which showed signs of calcification. A $1cm$ long stent was located in the arterial wall of the proximal section of the RIVA. Severe hypertrophy of the right ventricle.
The posterior papillary muscle showed signs of fibrosis. The scar of an old myocardial infaction, $1.5cm$ in diameter, was located in the posterior wall of the left ventricle.
Histological examination confirmed the old myocardial scars, no signs of fresh myocardial infarction could be found. The lung exhibited widespread fibrosis with numerous tight clusters of asbestos bodies coated with beaded or highly segmented bulbous macrophages.
In the pathologist's report a right ventricular decompensation was stated as the cause of death, based on the dilatation of the right heart and the significant fibrosis of the lung.
The pathologist's diagnosis was not documented in the death certificate, as required by law.

4.2 Technical Examination

After explantation and securing of the electrodes the pacemaker was checked using the telemetric programmer.
The internal clock of most PMs is a free running counter, set to the time and date of the programmer at the beginning of every telemetric interrogation. With the internal clock of the programmers being nothing but the standard

BIOTRONIK SWM 1000

Rel B-K00.0.A/2 22.09.2000 16:14

DROMOS SR SN. 858045

AUSTAUSCHINDIKATION ERREICHT!
PARAMETER (PERMANENT) 16:14

	VORHER	AKTUELL	
Mode		SSIR	
Grundfrequenz		60	ppm
Hysteresefrequenz		-----	ppm
Obere Grenzfrequenz		-----	ppm
Impulsamplitude		2.4	V
Impulsdauer		0.50	ms
Ven. Empfindlichkeit		0.5	mV
Atr. Empfindlichkeit		0.4	mV
Refraktärzeit		400	ms
Polarität Pace		UNIP	
Polarität Sense		BIPL	
Magneteffekt		ASYNC	
Sensor Simul.		-----	
Sensorverstärkung		6	
Sensorschwelle		mittel	
Frequenzanstieg		mittel	
Max. Sensorfrequenz		125	ppm
Frequenzabfall		mittel	

PATIENTENDATEN

Patient		
Symptom	B1	Synkope
Ätiologie	B1	Ätiologie unbekannt
EKG-Indikation	E4	SSS Bradykardie
Elektrode	BIPL	
Implantation	14.08.96	
Letzte Nachs.	17.01.00	

TRENDMONITOR	AKTIV
EREIGNISZAHLER	AKTIV

Figure 2: Facsimile of the 'Programmed Parameter Summary Report' outlining the most important pacemaker data: manufacturer and model, serial number, operational status, last check-up etc.

computer clock [9]—known for their notorious inaccuracy, commonly in the range of up to $\pm 15 sec/day$ being equal to $\pm 7.5 min/month$ [10]—large time-differences between the internal clock and the real-world time can accumulate. A further complication is due to the daylight-saving time, which is not handled in a standardized way and can result in abrupt $1h$ time-differences, when the internal clock is corrected. Thus, special attention has to be paid to the time-difference, as it is only available at the beginning of a telemetric session and will be lost after the correction of the internal clock's time. Only the time and date of the internal PM clock is changed—the time/date-stamp of the internally stored data is not changed accordingly [11]!
The observed time-difference was a couple of minutes, only.
All the acquired data were printed using the programmer to aid further study. The status report, termed 'Programmed Parameter Summary Report' is shown in figure 2.
The examined pacemaker—a Biotronik Dromos SR—has neither an arrhythmia detection function nor provisions for recording long-term EMGs. The only information provided is the battery depletion level as well as the electrode status (fig.: 3). The battery status was classified as EOL, i.e. depleted, by the telemetry data.
Thus, the presumed cause of death—a syncope with asystole—could not be proven by examination of the telemetric pacemaker data.

BIOTRONIK SWM 1000

Rel B-K00.0.A/2 22.09.2000 16:15

DROMOS SR SN. 858045

BATT./ELEKTR.-TELEMETRIE

Mode	S00
Batt. Status	EOL
Messwerte:	
Batt. Spannung	2.27 V
Batt. Strom	14 µA
Batt. Impedanz	22.5 kΩ
Imp. Spannung	----- V
Impulsstrom	----- mA
Impulsenergie	----- µJ
Impulsladung	----- µC
El. Impedanz	>3200 Ω

Figure 3: Facsimile of the 'Batteriestatus und elektronische Telemetrie': Detailed information about the battery status and state of the electrodes.

The electric measurements of the pacemaker's output signal resulted in a voltage value different from the programmed one ($0.5V$ at $10M\Omega$ vs. $2.4V$ at $3k\Omega$), whereas the frequency was still at the programmed $60ppm$.

By use of a diamond-bladed saw, the titanium casing of the pacemaker was opened and a new lithium battery was connected (fig.: 4). After this procedure, the PM functioned flawlessly, pointing towards the depleted battery as sole cause of malfunction.

4.3 Assessment

The battery of the pacemaker was depleted just 4 years after implantation. It seems very probable that the pacemaker was non-functional on admission to the hospital 8 weeks before the patient's death. Thus, the lack of pacing would be the cause of the global heart insufficiency.

The medical staff of the hospital overlooked the old pacemaker due to an unfortunate chain of events: The initial examination was performed by a junior student, there were no PM pulses in the ECG, the intern did not attend the x-ray demonstration, the radiologist did not mention the PM in his diagnosis.

The patient was still suffering from the sick sinus syndrome and therefore needed the pacemaker to treat his bradycardia. The cardial decompensation, which incidentally led to the global insufficiency, was a result of the bradycardia. Even using the most modern anti-hypertensive medication, a cardial recompensational mechanism could not be achieved. Implantation of an anti-bradicardia pacemaker is the treatment of choice for sick sinus syndrome [7][8]. An exchange of the pacemaker generator with its depleted battery for a new one would have cured the patient, even when taking into account the fibrosis of the patient's lung.

The failure of the pacemaker is the most probable cause of death; the death should have been classified as 'not natural'.

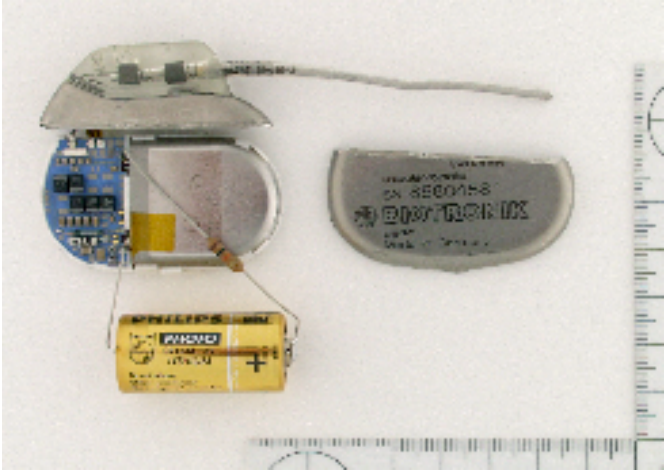

Figure 4: Cut open pacemaker with external replacement battery connected.
The internal resistance of the new battery was artificially increased by use of a resistor ($1k\Omega$, $125mW$), connected in series, to limit the maximum current flow. First, the negative, then the positive terminal of the replacement battery were connected to the depleted, built-in Lithium cell. Subsequently the positive terminal of the depleted battery was disconnected from the circuit, leaving the new battery as the sole power supply.
The pacemaker functioned flawlessly after connection of the new battery.

5 Conclusion

The case presented shows, that the cause of death was not correctly stated even though a detailed history was taken, and a clinical examination as well as an autopsy was performed—the pathologist didn't care for the pacemaker at all.
A telemetric examination of the pacemaker would have exposed the view to the depleted battery and its role in the patient's death.
Thus, one has to state that, in patients with an implanted pacemaker, an assessment of the cause of death has to include an examination of the PM's role in the death. This examination is a necessary means of quality assurance and has to include an analysis of the telemetrically accessible PM-data as well as a full autopsy, with careful investigation of the PM system.

References

[1] Junge M (2001) Eine Analyse von postmortal explantierten Herzschrittmachern (PM) und Implantierbaren Kardioverter-Defibrillatoren (ICD) (An analysis of post mortally explanted pacemakers (PM) and Implantable Cardioverters/Defibrillators (ICD)). Medical Dissertation, University of Hamburg. Available at http://www.DrJunge.de

[2] Verordnung über die Rücknahme und Entsorgung gebrauchter Batterien und Akkumulatoren (Batterieverordnung–BattV) (Directive about the taking back and waste disposal of used batteries and storage cells) (1998) Bundesgesetzblatt G5702, Nr. 20, 27.3.98. Veröffentlicht in Drucksache 13/9516 vom 18.12.1997

[3] Sanders RS, Lee MT (1996) Implantable pacemakers. Proceedings of the IEEE 84(3):480-6.

[4] Levin PA, Love CJ (2001) Pacemaker diagnostics and evaluation of pacing system malfunction. In: Ellenbogen KA, Kay GN, Wilkoff BL, Editors. Clinical cardiac pacing and defibrillation. 2nd ed. Philadelphia: W.B. Saunders Company; 2001. p. 827-75.

[5] Nägele H, Rödiger W (1998) Langzeit-Arrhythmieüberwachung von Patienten mit eingeschränkter linksventrikulärer Funktion mit dem Mark 1A-Analyseprogramm. Herzschrittmacher 18:33-43.

[6] Irnich W, Müller R, Batz L (1999) Untersuchungen an 400 exstirpierten Herzschrittmachern. Herzschrittmacher 19:209-230.

[7] Dreifus LS, Fisch C, Griffin JC, et al (1991) Guidelines for implantation of cardiac pacemakers and antiarrhythmia devices: A report of the American College of Cardiology (ACC)/American Heart Association (AHA) task force on assessment of diagnostic and cardiovascular procedures. (Committee on Pacemaker Implantation). Circulation 84:455.

[8] Anonymous (1991) Recommendations for pacemaker prescription for symptomatic bradycardia: Report of a working party of the British Pacing and Electrophysiology Group. Br Heart J 66:185-91.

[9] Warren JA, Dreher RD, Jaworski RV, Putzke JJ, Russie RJ (1996) Implantable cardioverter defibrillators Proceedings of the IEEE 84(3):468-79.

[10] Maxim Integrated Products (2001) Evaluating the Accuracy of Maxim Real-Time Clocks. http://dbserv.maxim-ic.com/appnotes.cfm?appnote_number=632

[11] Junge M, Weckmüller J, Nägele H, Püschel K (2002) 'Natural Death' of a patient with a deactivated Implantable-Cardioverter-Defibrillator (ICD)? For Sci Int 125:1-6.