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## Negative results - Arrhythmia

# Fatal complications of pacemaker and implantable cardioverter-defibrillator implantation: medical malpractice?

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### Abstract

**Objective:** Pacemaker implantation has become a routine procedure in modern cardiology, and implantable cardioverter-defibrillators are implanted with rising frequency. Although fatal complications are relatively rare, they may give rise to malpractice lawsuits against medical personnel. The objective was to identify fatal complications after pacemaker and implantable cardioverter-defibrillators implantation and to evaluate the legal consequences in alleged malpractice cases. **Methods:** Retrospective analysis of all 27,730 autopsy cases performed at the Institute of Legal Medicine, Hamburg, Germany, between January 1983 and June 2007. Study cases were identified using the keywords 'cardiac death', 'malpractice', 'complications', 'pacemaker' and 'implantable cardioverter-defibrillator'. **Results:** Eleven pacemaker-related and four implantable cardioverter-defibrillator-related fatalities where lawsuits had been filed were identified. A causal connection between the procedure and fatal outcome was confirmed by autopsy in six cases. Malpractice or violation of the rules of good medical practice could be excluded in all cases. All inquiries were abandoned. **Conclusion:** Fatal complications after pacemaker and implantable cardioverter-defibrillator implantation attributable to medical malpractice are extremely rare. The study illustrates the importance of a medico-legal autopsy in alleged fatal malpractice cases.

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**Keywords:** Pacemaker; Implantable cardioverter-defibrillator; Malpractice; Medico-legal autopsy

### 1. Introduction

Pacemaker implantation is the main pillar of therapy for bradycardic arrhythmias. Germany has one of the highest pacemaker implantation rates worldwide, with increasing numbers each year. In 2004, 62,382 pacemakers were implanted nationwide [1]. Indications for pacemaker implantation are bradycardic arrhythmias [1, 2]. Transvenous access to the heart in local anaesthesia is the favoured technique, most commonly via the subclavian vein, the cephalic vein and, rarely, the femoral vein [1, 3].

Implantable cardioverter-defibrillators are designed to detect and terminate malignant ventricular arrhythmias. Studies have shown that implantable cardioverter-defibrillators are superior to antiarrhythmic drugs in the prevention of sudden death due to ventricular fibrillation [4, 5]. They are implanted after resuscitation from ventricular fibrillation, for haemodynamically poorly tolerated ventricular tachycardia, in patients with a history of unexplained syncope and poor ventricular function if ventricular arrhythmia can be induced in electrophysiological testing and after acute myocardial infarction with markedly

impaired ventricular function and/or spontaneous ventricular tachycardia [4, 6–10].

Complications of pacemaker/implantable cardioverter-defibrillator implantations can be divided into complications during and after surgery. Furthermore, technical defects of the devices must be considered [11–15].

The aim of the present study was to assess the number of alleged malpractice cases connected to pacemaker and implantable cardioverter-defibrillator implantation that occur in Hamburg each year, the respective autopsy results, and the legal outcome.

### 2. Materials and methods

All 27,730 autopsy protocols of the years 1983–2007 were searched for suspected fatal malpractice cases connected to pacemaker and implantable cardioverter-defibrillator implantation. As search key words, 'cardiac death', 'malpractice', 'complications', 'pacemaker' and 'implantable cardioverter-defibrillator' were used [16].

All cases identified were then reviewed with respect to demographic data, patient–doctor-factors, medical history, morphological features, complications of the interventions, their treatment and the legal consequences, using the autopsy protocols as well as all additionally performed tests, written expert opinions and prosecution files.

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### 3. Results

Of the 27,730 cases reviewed, 11 fatalities connected with pacemaker implantation and four fatalities connected with implantable cardioverter-defibrillator implantation were identified. They comprised 0.05% of all autopsies performed in the study period. The average age in patients with pacemaker implantation was 74.0 years (age range 65–87 years). Six patients were male (average age 71.7 years) and five female (average age 76.2 years). Average age in patients with implantable cardioverter-defibrillator implantation was 56 years (age range 49–64 years). Three patients were male, one was female (average age 56 years).

All pacemakers were implanted for bradycardic arrhythmias. Three implantable cardioverter-defibrillators were implanted for poor left ventricular function after myocardial infarction and one for dilated cardiomyopathy and resuscitation from ventricular fibrillation. All implantations were elective procedures.

Hypertension (nine patients), smoking (seven patients) and diabetes (three patients) were the most frequently reported risk factors. The average number of risk factors per patient was 1.2 in the pacemaker group and 1.8 in the implantable cardioverter-defibrillator group. Seven patients in the pacemaker group were overweight or obese.

#### 3.1. Clinical course

Ten pacemakers were implanted via the right subclavian vein and one via the right femoral vein. Five patients from the pacemaker group died in hospital from complications during the procedure. Three patients died suddenly and unexpectedly in hospital within four days after surgery. In one patient, wrong positioning of the pacemaker electrodes was suspected by the physician who signed the death certificate. Three patients died at home within two days to one year after surgery. In one case, the physician who signed the death certificate suspected pacemaker malfunction.

Three patients with implantable cardioverter-defibrillators died suddenly and unexpectedly within 12 h after implantation despite resuscitation. A causal connection between death and fatal outcome could not be excluded in view of the short time interval between surgery and death. One patient developed infection at the implantation site. Despite surgical intervention, he developed sepsis and died three weeks after the first surgery.

#### 3.2. Postmortem examination results

All pacemakers and implantable cardioverter-defibrillators were technically checked and the memories read. All devices functioned normally; no events were recorded. Implantable cardioverter-defibrillators had been explanted following special safety measures [16].

In all five patients who died in hospital from complications of the procedure, the causal connection between the complication and fatal outcome was confirmed at autopsy. Two patients had suffered a perforation of the subclavian artery during the procedure and died from haemorrhagic shock. In one patient, a stroke developed after injury of

the brachicephalic trunk and embolisation of thrombotic material from the brachiocephalic trunk injury into the right carotid artery. Two patients died from pericardial tamponade after perforation of the right appendage and the right ventricle, respectively.

In the three patients who died in hospital, the cause of death was myocardial infarction in two cases and pulmonary thromboembolism in one case. The suspected electrode displacement was not confirmed. A causal connection between the implantation and fatal outcome could not be established in any of the cases.

In the three patients who died at home, the cause of death was myocardial infarction, acute cardiac failure and stroke in one case each. The suspected pacemaker malfunction could be excluded by technical analysis of the device. A causal connection between the intervention and fatal outcome could not be confirmed in any of the cases.

In the three patients who died unexpectedly after implantable cardioverter-defibrillator implantation, the cause of death was myocardial infarction in two cases and acute cardiac failure in one case. A causal connection between the procedure and fatal outcome was excluded at autopsy. Sepsis as the cause of death was confirmed in the patient who developed infection at the implantation site. Postmortem procalcitonin was 15.8 ng/ml. A causal connection between the procedure and fatal outcome was thus confirmed.

#### 3.3. Legal implications

In the nine cases where a causal connection between death and the procedure could be ruled out by autopsy, autopsy results alone led to abandonment of the inquiries. In the remaining six cases, additional expert opinions were necessary. Two were given by forensic specialists and four by expert clinicians. In all cases, the experts found that the standards of good medical practice had not been violated. All inquiries were abandoned.

A summary of the cases is presented in Table 1.

### 4. Discussion

We identified 15 alleged malpractice cases related to pacemaker and implantable cardioverter-defibrillator implantations. All patients had a high degree of comorbidity and were thus at high risk for complications. An exact incidence of fatal complications cannot be determined, as the area covered by the Hamburg Institute of Legal Medicine is large, and exact implantation numbers from the different regions covered cannot be obtained. However, with the numbers obtained from the German pacemaker registry over the last years<sup>a</sup>, the incidence of fatal complications is in the range of 0.1%, which is in keeping with previous reports [5, 17, 18].

The overall perioperative complication rate of pacemaker and implantable cardioverter-defibrillator implantations is between 5.3% and 6.2% [1, 5, 6, 10, 19]. The risk of infection increases with the duration of the procedure [20]. Fatal infection after pacemaker implantation was found in

<sup>a</sup><http://www.pacemaker-register.de>.

Table 1  
Summary of study cases

Case	Reason for PM/ICD implantation	Clinical course	Cause of death	Legal outcome
PM1	Bradycardia	SCA perforation and haemothorax, death within 1 h post-procedure	Haemorrhagic shock	CC confirmed, MP excluded in additional opinion
PM2	Bradycardia	SCA perforation and haemothorax, death within 1 h post-procedure	Haemorrhagic shock	CC confirmed, MP excluded in additional opinion
PM3	Bradycardia	BCT perforation and stroke, death 1 day post-procedure	Stroke	CC confirmed, MP excluded in additional opinion
PM4	Bradycardia	RAp perforation, pericardial tamponade, death 2 h post-procedure	Pericardial tamponade	CC confirmed, MP excluded in additional opinion
PM5	Bradycardia	RV perforation, pericardial tamponade, death 2 h post-procedure	Pericardial tamponade	CC confirmed, MP excluded in additional opinion
PM6	Bradycardia	Sudden, unexpected death in hospital within 4 days post-procedure, suspected electrode displacement	MI	CC excluded at autopsy
PM7	Bradycardia	Sudden, unexpected death in hospital within 4 days post-procedure	MI	CC excluded at autopsy
PM8	Bradycardia	Sudden, unexpected death in hospital within 4 days post-procedure	Pulmonary thromboembolism	CC excluded at autopsy
PM9	Bradycardia	Sudden death at home within 1 year post-procedure, suspected pacemaker malfunction	MI	CC excluded at autopsy
PM10	Bradycardia	Sudden death at home within 1 year post-procedure	Stroke	CC excluded at autopsy
PM11	Bradycardia	Sudden death at home within 1 year post-procedure	Acute cardiac failure	CC excluded at autopsy
ICD1	Poor LV function after MI	Sudden death within 12 h post-procedure, causal connection possible	MI	CC excluded at autopsy
ICD2	Poor LV function after MI	Sudden death within 12 h post-procedure, causal connection possible	MI	CC excluded at autopsy
ICD3	Poor LV function after MI	Sudden death within 12 h post-procedure, causal connection possible	Acute cardiac failure	CC excluded at autopsy
ICD4	Dilated CMP, resuscitation from VF	Infection of implantation site, sepsis, death 3 days post-procedure	Sepsis	CC confirmed, MP excluded in additional opinion

Summary of the complications, clinical course and legal outcome in the study cases. BCT, brachiocephalic trunk; CC, causal connection; ICD, implantable cardioverter-defibrillator; LV, left ventricle; MI, myocardial infarction; MP, malpractice; PM, pacemaker; RAp, right appendage; RV, right ventricle; SCA, subclavian artery.

one case, in which the implantation had been complicated and took 140 min.

Haemothorax is a rare complication of pacemaker implantations and has been reported to occur in about 0.1% of all cases. Haemothorax is more common when the subclavian vein is used compared to the cephalic vein [1]. The exact incidence of fatalities is unknown, but these appear to be extremely rare based on a literature research. Cases of survived/treated haemothorax have been reported [21, 22], but fatal haemothoraces are, to the best of our knowledge, not reported in the recent literature. In keeping with this, two patients with haemothorax after perforation of the subclavian vein were identified in the present study. Although pericardial tamponade complicating implantation is rare [1, 14], two patients with pericardial tamponade after pacemaker implantation were identified. This indicates that if pericardial tamponade occurs, fatal outcome

is likely. In one case, lipomatosis of the right ventricle was identified at autopsy as a risk factor for perforation.

One complication identified in the present study was stroke after injury of the brachiocephalic trunk. Pre-existing atherosclerotic changes of the arterial wall were identified as a risk factor for the injury. Autopsy revealed a small defect in the arterial wall with thrombotic material which had embolised into the internal carotid artery. To our knowledge, this complication has not been described in the literature and appears to be rare.

Late complications and technical defects must always be considered and are more frequent in implantable cardioverter-defibrillator patients than in pacemaker patients, with reported annual rates of 2.4–12.7% [6, 23–25]. Fatal late complications or technical defects were not found in any of the cases. For technical analysis of the devices,

explantation employing special techniques must be carried out [16].

Data on the perioperative lethality in patients after pacemaker and implantable cardioverter-defibrillator implantations are rare. The German pacemaker registry reported a 1.2% lethality within seven days after implantation in 2005, but only 0.1% of all patients died as a direct sequel of the intervention, the underlying arrhythmia or device dysfunction [18]. Even fewer data exist on lethality in connection with implantable cardioverter-defibrillator implantation. One study reported a 30-day lethality of 2.4% [17], whereas in a second study, no fatal case occurred in a period of 30 days [5].

Regarding the legal consequences, the autopsy results alone led to abandonment of the inquiries in 9 out of 15 cases, as a causal connection between the complication and fatal outcome was not confirmed. This shows the overriding importance of a medico-legal autopsy as a ‘first gate’ in alleged malpractice cases, especially as malpractice claims in surgical disciplines are on the rise (Turk et al., unpublished results). Fatal malpractice can always be excluded as soon as the autopsy identifies an unrelated cause of death. In the remaining six cases, the autopsy confirmed a causal connection between the complication and death, thus making further investigation necessary. In all cases, the specialists excluded violations of the rules of good medical practice, which led to an abandonment of the inquiries. These findings show that malpractice leading to a patient’s death is a very rare event in pacemaker and implantable cardioverter-defibrillator implantations.

## 5. Conclusion

In general, the number of fatal complications of pacemaker and implantable cardioverter-defibrillator implantation identified in the present study is very small in relation to the high number of procedures performed every year. This reflects the very high standard of cardiac surgery and long-term follow-up today. Our study shows that a medico-legal autopsy is vital in establishing the presence of a fatal complication and the elucidation of whether malpractice can be confirmed in connection with a fatality after pacemaker and implantable cardioverter-defibrillator implantation, as well as for the identification of cardiovascular risk factors and other factors contributing to fatal outcome. Furthermore, the explantation of the device in toto during the autopsy allows the assessment of device function and correct placement of the electrodes.

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