Post-mortem evaluation of 415 pacemakers: in situ measurements and bench tests

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Abstract Aim The hypothesis was that there is more undetected dysfunction of implanted pacemaker systems than that detected and corrected. This prompted a research project (sponsored by the German Research Foundation) to detect pacemaker abnormalities and evaluate their complications for patients, thus, proving or disproving the hypothesis.

Methods and results Four hundred and fifteen pacemakers of deceased patients were analyzed assessing their functionality by in situ measurements and bench tests including five measurements and one telemetric interrogation. Results were divided into four categories and statistically evaluated. Life-threatening abnormalities were found in 3.8%, potentially life-threatening in 3.7%, probably symptomatic, divided into atrial and ventricular problems, 13.3% and 2.8%, respectively, and premature exhaustion in 1.2%. Three of 179 bipolar ventricular leads and 2 of 131 bipolar atrial leads had insulation defects corresponding to 1.7% and 1.5%, respectively. The bipolar complication rate was 2.8 times higher than unipolar.

Conclusion The pacemaker patients investigated, living 4 years with their pacemaker on average, had a post-mortem evaluated complication rate of the category "life-threatening" of 3.8%. This result corresponds to an annual complication rate of 0.94% compared with a rate of only 0.39% in an earlier investigation.

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Introduction

Due to implantable pacemaker systems, currently approximately 2500–3000 patients per million in the United States and Europe live a normal life. As a result of the growing number of older people in the population, particularly those aged over 75 years, an increasing number of pacemakers will be needed worldwide [1]. Possible pacemaker dysfunction in daily clinical practice has already been described. Lead malfunction, for example, is still the predominant cause of system dysfunction [2]. Surgery related complications during and after implantation are also well known [3], but little is known about technical defects and dysfunction of generators and electrodes during system life [4].

It was expected that there is more undetected dysfunction of implanted pacemaker systems than that detected and corrected [4]. This hypothesis challenged us to initiate a research project, sponsored by the German Research Foundation, to detect pacemaker abnormalities and evaluate their complication rate for patients, thus, proving or disproving the hypothesis.

Materials and methods

The population investigated consisted of pacemakers from deceased patients from different regions in Germany (Giessen, Friedberg, Hamburg). Between August 2001 and November 2002, 415 pacemakers together with 556 leads were removed and analyzed in bench tests. Four hundred and three of these units were also investigated in situ in the cadaver before cremation. Table 1 summarizes all populations in more detail. A measurement method was applied that is suitable to judge the functionality of a pacemaker system and guarantees clear results promptly after the patients’ death leaving little room for discussion as to the cause. The functionality of the pacemaker was assessed by in situ measurements and bench tests including five measurements and one telemetric interrogation, carried out at room temperature, in the following sequence [5]:

In situ measurements

1. Signals proportional to pacing pulses were derived with a differential amplifier connected to a digital storage oscilloscope read offline by a personal computer (Fig. 1). The amplifier connected to three cannula electrodes positioned linearly between apex and right clavicle to reduce noise (Fig. 2).

2. With a test pacemaker (5 V, 1 ms pulse with a rate of 85 min⁻¹) and two additional cannula electrodes, synchronization of the implanted pacemaker could be tested.

3. The lead impedance was measured with another test pacemaker that could be interrogated by a hand-held programmer.

Bench tests

4. The parameters: pulse period, pulse amplitude, pulse duration, sensing threshold, and magnet influence were measured in the laboratory. The connector pins were checked for notches, which are a prerequisite for good

Table 1 Investigated populations

<table>
<thead>
<tr>
<th>1</th>
<th>Generators</th>
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<tbody>
<tr>
<td>All</td>
<td>415</td>
</tr>
<tr>
<td>Single</td>
<td>271¹</td>
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<tr>
<td>Dual</td>
<td>144</td>
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<table>
<thead>
<tr>
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<th>Leads</th>
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<td>All</td>
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<tr>
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<td>310</td>
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<tr>
<td>Unipolar</td>
<td>246</td>
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<tr>
<td>Ventricular</td>
<td>411</td>
</tr>
<tr>
<td>Bipolar</td>
<td>179</td>
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<tr>
<td>Unipolar</td>
<td>232</td>
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<tr>
<td>Atrial</td>
<td>145</td>
</tr>
<tr>
<td>Bipolar</td>
<td>131</td>
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<td>Unipolar</td>
<td>14</td>
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<table>
<thead>
<tr>
<th>3</th>
<th>Patients</th>
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<td>Patients in situ</td>
<td>403</td>
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<table>
<thead>
<tr>
<th>4</th>
<th>Intermedics generators and leads</th>
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<tbody>
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<td>24</td>
</tr>
<tr>
<td>Single</td>
<td>12</td>
</tr>
<tr>
<td>Dual</td>
<td>12</td>
</tr>
<tr>
<td>All leads</td>
<td>36</td>
</tr>
<tr>
<td>Bipolar</td>
<td>24</td>
</tr>
<tr>
<td>Unipolar</td>
<td>12</td>
</tr>
<tr>
<td>Ventricular</td>
<td>23</td>
</tr>
<tr>
<td>Atrial</td>
<td>13</td>
</tr>
</tbody>
</table>

¹ One AAI.

Figure 1 Block diagram of in situ measurement in pacemaker patients.
contact between pin and screw(s). The bipolar lead insulation was checked with an ohmmeter.

5. Programmed pacemaker parameters and historical data were interrogated by telemetry (implantation date, date of the last follow-up, date of attainment of the electric replacement indicator (ERI) state).

6. If no pacing pulses were delivered by the device, the can was opened. The battery voltage was an indication of whether exhaustion and/or defect was present. In cases of battery exhaustion, the circuitry was connected to a 2.8 V power source to assess its function. Without a pacing pulse, the pacemaker was judged to be defective.

To evaluate the measurements of all 415 pacemakers the results were divided into different subgroups with respect to the severity of their impact (Tables 1–8).

Results

Three hundred and seventy six cases had dates of birth and death available allowing mean age at death to be calculated; 84.7 years (Table 2). In 117 deceased pacemaker patients the date of implantation could be interrogated. Mean age at implantation of the last pacemaker was 80.7 years, in the other 298 cases the implantation age was not available. Of the 411 ventricular leads (as four generators were received by us without leads), 387 leads were checked for notches while 24 pacemakers were from Intermedics, which do not possess screws (Tables 1,5). Figures 4–6 demonstrate that abnormal pulses usually show characteristic deviations from normal (Fig. 3), which have been described earlier [5–7]. A shunting resistor within the pacemaker circuitry parallel to the electrode decreases the output rapidly and below zero (Fig. 4). If the insulation of a bipolar lead degrades with fluid between the conductors, a shunting capacitance is created that rounds leading and trailing edges (Fig. 5). Breakage or bad contact produces sharp spikes followed by a low and flattened curve (Fig. 6).

The discovered abnormalities were divided into four categories: “life-threatening”, “potentially life-threatening”, “probably symptomatic” and “premature exhaustion” (Table 3). If the elective replacement indicator (ERI) was reached within warranty period (48 months), exhaustion was termed “premature” which was found in 1.2%.

Table 4 shows the results for the category “life-threatening”, from which a complication rate of 3.8% can be derived. The leading problem was battery exhaustion (1.7%), followed by failures of ventricular leads (1.0%). Pacemaker defects were
about 0.5% and lastly infection, 0.2%. Infection as cause of death was confirmed by autopsy.

The category "potentially life-threatening" included 3.7% (Table 5) which is restricted only to ventricular problems, consisted of complications "infection" (diagnosis without autopsy), "missing notch" and "indifferent screw not tightened", in which missing notches on ventricular lead pins were most frequent (2.8%). A notch is a prerequisite for a good contact. Missing notches are potentially dangerous because of corrosion between different metals, an effect which was confirmed in some cases by high output voltages (5 V or higher) and long duration (1 ms). In the category "probably symptomatic" (Table 6) the complication rate for atrial problems was 13.3% with deactivated atrial channels being the leading problem. Ventricular problems were found in 2.8% with insulation defects being most prominent (0.9%). There was a discrepancy in one case between the magnet test resulting in "ERI" while the programmer interrogation claimed battery to be "good". This uncertainty is surely of clinical relevance. "Magnet function unreliable" meant that several trials were necessary to open the reed switch. A lead that could be withdrawn by low extraction force was "not tightened".

Three of 179 bipolar ventricular leads and two of 131 bipolar atrial leads had an insulation defect corresponding to 1.7% and 1.5%, respectively (Table 7). Table 8 shows that the failure rate of ventricular bipolar leads is 8.9% versus 2.6% for unipolar yielding a defect ratio bipolar versus unipolar of 3.5%. If the defect ratio of all bipolar leads (6.8%) versus unipolar (2.4%) is calculated, the defect ratio drops to 2.8% (Table 8).

### Table 5

<table>
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<tr>
<th>Dysfunction</th>
<th>N</th>
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<th>%</th>
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<tr>
<td>Infection</td>
<td>403</td>
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<td>0.25</td>
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<tr>
<td>Missing notch (ventricular leads)</td>
<td>387</td>
<td>11</td>
<td>2.84</td>
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<tr>
<td>Indifferent screw not tightened</td>
<td>168</td>
<td>1</td>
<td>0.60</td>
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<td>Total</td>
<td>13</td>
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<td>3.69</td>
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N, population; n, number.

### Table 6

<table>
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<th>Feature</th>
<th>N</th>
<th>n</th>
<th>%</th>
</tr>
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<tbody>
<tr>
<td>Atrial lead not tightened</td>
<td>132</td>
<td>2</td>
<td>1.52</td>
</tr>
<tr>
<td>Atrial channel deactivated</td>
<td>144</td>
<td>12</td>
<td>8.33</td>
</tr>
<tr>
<td>Atrial lead defect</td>
<td>145</td>
<td>5</td>
<td>3.42</td>
</tr>
<tr>
<td>Total atrial problems</td>
<td>19</td>
<td>13</td>
<td>13.27</td>
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<tr>
<td>Connector problems</td>
<td>520</td>
<td>3</td>
<td>0.58</td>
</tr>
<tr>
<td>Unipolar, indifferent notch missing</td>
<td>286</td>
<td>1</td>
<td>0.35</td>
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<tr>
<td>Insulation defect</td>
<td>232</td>
<td>2</td>
<td>0.86</td>
</tr>
<tr>
<td>Magnet, ERI; program, good</td>
<td>415</td>
<td>1</td>
<td>0.24</td>
</tr>
<tr>
<td>Magnet function unreliable</td>
<td>415</td>
<td>3</td>
<td>0.72</td>
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<td>Total</td>
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N, population; n, number.

### Table 7

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<th>Feature</th>
<th>n</th>
<th>N</th>
<th>%</th>
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<td>Ventricle</td>
<td>3</td>
<td>179</td>
<td>1.68</td>
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<tr>
<td>Atrium</td>
<td>2</td>
<td>131</td>
<td>1.53</td>
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n, number; N, population.

### Table 8

<table>
<thead>
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<th>Lead</th>
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<th>N</th>
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<tr>
<td>Ventricular Bipolar</td>
<td>16</td>
<td>179</td>
<td>8.94</td>
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<td>Ventricular Unipolar</td>
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<tr>
<td>Atrial bipolar</td>
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<tr>
<td>Atrial unipolar</td>
<td>0</td>
<td>14</td>
<td>0</td>
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<tr>
<td>Bipolar</td>
<td>21</td>
<td>310</td>
<td>6.77</td>
</tr>
<tr>
<td>Unipolar</td>
<td>6</td>
<td>246</td>
<td>2.44</td>
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n, number; N, population.

### Discussion

We analyzed and evaluated the functionality of 415 implanted pacemaker systems post mortem to find out possible complications and to derive complication rates. The applied post mortem in situ measurement method seems to be unique worldwide. To our knowledge, no data comparable to our results are available. In the category "life-threatening" we found a complication rate of 3.8% of patients that lived on average 4 years with their pacemaker which means that those patients died with or because of a dysfunction of their pacemaker. Thus, 3.8% divided by 4 years yields an annual complication rate of 0.95% which can be compared with the 0.39% of an earlier investigation [4]. Thus, life-threatening dysfunction of implanted pacemaker systems are 2.4 times higher than anticipated. Moreover, the category "probably symptomatic" including atrial and ventricular problems reveals a surprisingly high percentage of 13% respectively, 3% of pacemakers which do not
work correctly or optimally with atrial problems being predominant. Lead defects are more frequent (ventricular 1%, atrial 3.4%) than generator defects (0.5%) (Tables 4 and 6) which support the statement that lead malfunction is still the predominant cause of system dysfunction [2]. The defect ratio of ventricular bipolar leads is 3.5 times higher compared with unipolar leads. Indeed, bipolar leads are advantageous with respect to electromagnetic interference, but this is counterbalanced by a higher defect rate.

The discrepancy in one case between magnet test resulting in "ERI" while the programmer interrogation claimed battery to be "good" raises concern because such an uncertainty provokes explantation which is surely of clinical relevance.

The age at last implant, which was 80.7 years in our study, is not representative of the German pacemaker population which is characterized by mean age at initial implantation for men of 73.3 years and for women 77.1 years (mean value 74.9 years) [8]. Thus, our population of deceased patients undergoing cremation is approximately 6 years older than the general population. It has been shown [9,10] that pacemaker treatment is less generous with respect to mode selection with increasing age. Whether this can also be extrapolated to post implant care of older patients cannot be derived from our data.

Conclusions

Our data reveal that there is much undetected pacemaker dysfunction and possibly more than that detected and corrected. A post mortem evaluation of 415 pacemakers 179
Perhaps follow-up intervals for pacemakers should be shortened. Incorrect handling during or after implantation produces an astonishingly high proportion of atrial (1.5%) and ventricular lead (3.1%) dysfunction that must be reduced. More data will reveal whether these results are also valid for other regions in Germany.

References