

An Analysis of 460 Pace Makers Explanted Post-Mortem During 2000/2001

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The functional state of pace makers (PM) and their possible involvement in the death of patients was examined in a cross-section analysis of all cases seen in the crematorium Hamburg-Ojendorf, Germany, during the years 2000/2001.

Materials and Methods:
 21382 bodies were examined in the years 2000/2001 as part of the mandatory second external examination before cremation in the crematorium Hamburg-Ojendorf, Germany.
 460 pace makers (PM), 9 implantable cardioverter/defibrillators (ICD) as well as 2 neuro stimulators were explanted in accordance with Federal law (Batterieverordnung BattV).
 All generators were examined as to the quality of the electrical output pulses. The generators were telemetrically interrogated in all cases where possible (443 of 460). In cases where this was not possible, the titanium case was sawn open, a new battery was connected, and the Hybrid[®] was subjected to the standard testing (electrical output measurement, telemetric interrogation). The statistical analysis was performed using SPSS Version 11.0 in conjunction with Mathematica 4.1. The coloration of the diagrams was done by using Lotus Freelance Graphics.

Results:
 • Mean duration of implantation: 4.0+/-3.3 years (Diag. 7)
 • Age of the patients at generator implantation: 80+/-9.5 years (Diag. 6)
 • Age of the patients when deceased: 84+/-8.6 years
 • Gender distribution (457 of 460):
 - 239 female (52.3%)
 - 218 male (47.7%)

• Functional state of the generators (of 460 testable PM) (Diag. 3):
 - 343 (74.6%) fully functional
 - 71 (15.4%) ERI (elective replacement indicator)
 - 35 (7.6%) EOL (end of life)
 - 8 (1.7%) output signal only after telemetric reset
 - 3 (0.3%) undetermined
 • Many distinct PM models: 172 different models out of a total of 460 generators (Diag. 1)
 • High non-compliance with regard to the follow-up PM/ICD checks (max. 2859 days without follow-up) (Diag. 4).
 • PM/ICD generators in residents of old people's homes are not better cared for as those implanted in patients living on their own (Diag. 5).
 • All newer generators with a short duration of implantation worked flawlessly, with one exception.
 • In some cases the data stored in the PM/ICD generators could be used to reconstruct the agonal phase and the time of death.

Conclusion:
 • The cause of death has to be examined very thoroughly in cases with a short duration of implantation.
 • The PM/ICD generators have to be telemetrically interrogated in order to clarify the role of the PM/ICD system with regard to the death of the patient. For this purpose the functional state of the electrode system has to be assessed as well.
 • The importance of cardiologic follow-up checks of the PM/ICD system (generator and electrodes) has to be communicated to the patients in a more effective manner.

The complete study can be downloaded from the Internet at:
<http://www.DrJunge.de>

Frequency Distribution of the Different PM Models

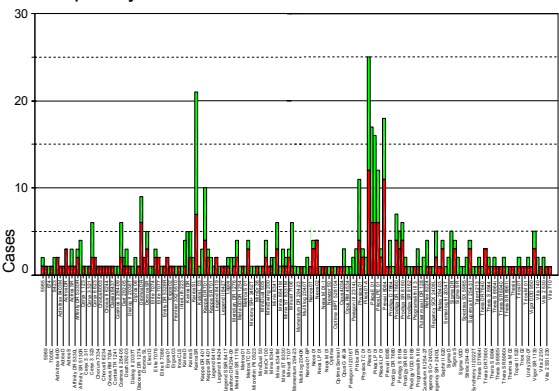


Diagram 1:
 Frequency distribution of the different pacemakers (PM) generators explanted during the years 2000/2001. Most generator models were found only once or twice, due to the large number of different models on the market. (Annotations next to Diag. 2)

Manufacturer Distribution

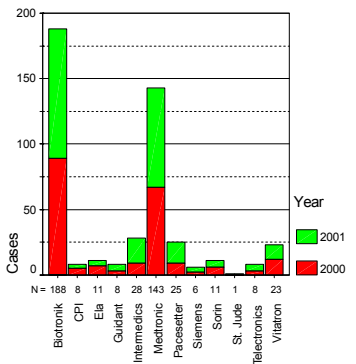


Diagram 2:
 Frequency distribution of the PM generator manufacturers of the generators explanted during the years 2000/2001 in the crematorium Hamburg-Ojendorf. Some consolidation has taken place on part of the manufacturers during the last couple of years, reducing their number considerably (Intermedics, Siemens, Teletronic, Vitatron).

Functional State of the Generators

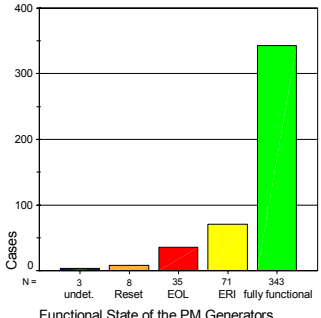


Diagram 3:
 Functional state of the 460 pace maker generators examined. 343 generators were functioning flawlessly, 71 were in ERI (Elective Replacement Indicator) state, and 35 were in EOL (End of Life) state.
 8 generators were in need of a telemetric reset in order to start outputting pacing signals. For three devices the functional state could not be assessed, even when using electrical measurements and telemetric information.

Time since last PM Follow-up

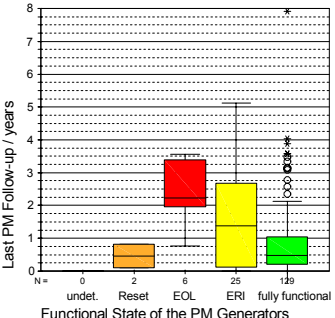


Diagram 4:
 Box-Plot diagram of the duration since the last telemetric interrogation of the pace maker generator. The high quality of the PM/ICD generators is documented by the outliers in the functional box: One PM generator functioned flawlessly for the whole duration of implantation—nearly 8 years—without any follow-up. The generator was still programmed with the factory set-up for implantation. Most of the patients (81%) had a follow-up check of their PM/ICD within one year. The check had a positive effect with regard to the functional state.

PM State vs. Place of Residence

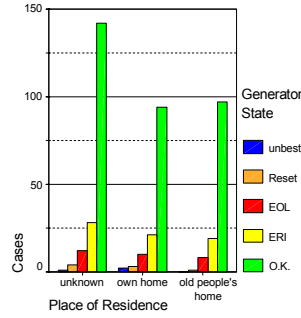


Diagram 5:
 PM/ICD-generator function according to place of residence. No statistically significant higher numbers of pace maker in ERI or EOL state could be found for deceased living in old peoples homes as compared to those living on their own.

Age Distribution

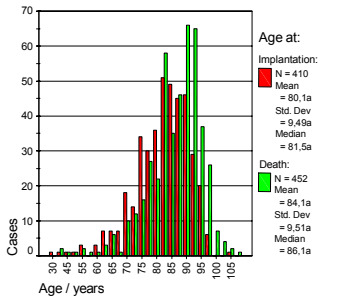


Diagram 6:
 Histogram of the ages of the patients at PM implantation (red) as well as the age at death (green). Both age distributions do not follow the normal distribution; there is a marked tailing with regard to low age groups.

Duration of Implantation

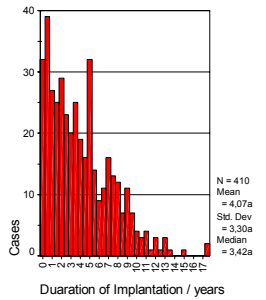


Diagram 7:
 Duration of pace maker implantation in years. A nearly linear decline in the number of patients is depicted with regard to the duration of implantation. The implantation dates could only be reconstructed for 410 of the 460 generators examined.

Life Expectancy vs. Duration of Implantation Frequency Distribution

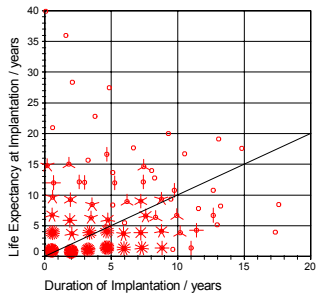


Diagram 8 und 9:
 Sunflower-Plot (Diagram 8) of the life expectancy of a statistically normal person of the same age and gender as the pace maker patient in the year of implantation, compared to the observed duration of implantation. The diagonal line marks the points in the diagram where the expected years at the age of implantations are equal to the observed years lived by the patient. All data points below the diagonal line mark cases where the duration of implantation was longer than the life expectancy of the normal population at the age of implantation. Meaning that the PM/ICD patients lived longer than the possibly healthy normal population. All data points above the diagonal line represent patients who lived shorter than the matched normal population. Scatter-Plot (Diagram 9) of the functional pacemaker generator state after explantation in relation to the duration of implantation and the life expectancy at the time of implantation.

Life Expectancy vs. Duration of Implantation Frequency Distribution/Functional State

