Efficiency of a pacemaker clinic to prevent sudden pacing failures

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Two hundred patients with implanted pacemakers were followed in a pacemaker clinic over a period of 3 years. The follow-up times ranged from 1 to 36 months, with a mean of 22 months. The material represents 366 patient-years of pacing and 361 pacemakers. One hundred and twenty replacements were done. Most of these were elective (93%) and based on gradual deterioration of the pacing detected by photoanalysis of the generator impulse. Of the single variables the duration of the impulse and the discharge rate were most revealing; recording changes in these two variables led to 96 per cent failure detection. There were 28 deaths within the follow-up time: 3 of them were related to pacing failure and 5 were possibly so. When these sudden fatal events were added to the sudden nonfatal failures not detected by the routine control system a 16 per cent failure rate of detection emerged. The total annual mortality was 7.7 per cent. The mortality caused by pacing failures was 2.2 per cent per annum.

After the primary descriptions of the significance of impulse analysis in detecting pacemaker failures (Davies and Sowton, 1964; Nickel, 1964; Knuckey, McDonald, and Sloman, 1965) organized special pacemaker clinics have gained wide acceptance. The primary goal is to prevent sudden pacing failures, with the associated mortality and morbidity, and to get the maximal life span out of each implanted unit (Siddons and Sowton, 1967; Thalen et al., 1969). While it is evident that the number of emergency replacements is greatly reduced, they still occur (e.g., Parsonnet et al., 1970; Furman, Escher, and Parker, 1971a), and a number of patients succumb outside hospital from pacing failure without detailed data on the mode of death.

A pacemaker clinic has been in operation in Helsinki University Central Hospital since 1968. This report is based on the analysis of its efficiency in preventing pacing failures during a period of three years.

Patients and pacemakers

During the time of analysis 207 patients were followed in the clinic. Seven of them were lost to follow-up (3 transferred to other hospitals, 2 moved abroad, 2 not traced), leaving 200 patients, 103 women and 97 men, for analysis. The age ranged from 28 to 88, with a mean of 61 years. The follow-up ranged from 1 to 36 months, with a mean of 22 months. All together this represents 366 patient-years. The pacemaker material consisted of 361 units, 207 of which were Elema-Schönander (Types 139, 152, 153), 106 Vitatron (Types 150, 400 R), and 48 Medtronic (Types 5841, 5842 d, 5843 d, 5860, 5862, 5868, 5870). Only two units functioning normally were replaced solely because they approached the maximal life span reported by the manufacturer. These have been excluded from the analysis. All the other units have been followed to the point when clear-cut indications for replacement became evident or sudden failure occurred.

Endocardial pacing was accomplished in 201 instances while 160 units were connected to epicardial electrodes inserted either earlier or simultaneously through a pericardiotomy. Of all insertions 241 were primary and 120 were replacements. This number does not include early replacements due to infections, faults reported by the manufacturers, or exit blocks with normal data in the impulse analysis.

Function of the clinic

The insertion of the endocardial electrode and the subcutaneous pacemaker has routinely been done in two stages. After positioning of the electrode, almost exclusively Elema 588, to the apex of the right ventricle, a 2 to 3 days' period with external pacing and the patient in left lateral position have preceded the insertion of the pacemaker. This practice has been helpful in the detection of early malpositions of the electrode as well as rises in the threshold. If epicardial wires were indicated they were inserted through a small pericardiotomy. The
hospital mortality resulting from this procedure has been one patient dying from rupture of the right ventricle.

The primary photoanalytic data were obtained when the patient was discharged from the hospital. The next check-up was one month later, followed by successive controls at intervals of 3 months. If slight changes were noted or the pacemaker was approaching its maximal duration the intervals were shortened. Each visit consisted, in addition to taking the patient’s history, of a chest x-ray, electrocardiogram, and a photograph of the oscilloscope display of the generator impulse. A Tektronix 502 A oscilloscope with a pacemaker-triggered horizontal sweep was used. The impulse was detected from the bipolar extremity leads with the highest voltage, and the same lead was always used in the following check-ups.

Indications for elective replacement were as follows: 1) A clear-cut history of syncopal attack(s), with or without observations of dysrhythmia; 2) electrocardiographic evidence of pacing failure (impulse without capture outside the refractory period); 3) a change in stimulation rate of ± 5 beats/min; 4) a change of ±25 per cent in the impulse duration; 5) a 20 per cent decrease in the peak amplitude as compared to the data one month after the implantation; and 6) a 20 per cent change in the slope (decay ratio).

**Results**

The mode of detection of the pacing failures leading to 120 replacements is presented in Table 1. All the sudden changes observed by the patients were alterations in rate. These were usually gross and in either direction. They constitute 11 per cent of all replacements. All the patients had obeyed the routine 3-month follow-up scheme. Ten of the sudden changes not observed by the patients but detected at the next clinical visit were changes in rate. In 3 instances a sudden change in the slope due to fractured wires and broken insulation was observed. All these replacements were elective. The data of the analysis on the time elapsed from the last accepted control to sudden changes observed by the patients and leading either to elective or emergency replacements are shown in Table 2. The shortest interval was 4 days, after which the patient returned having observed a rapid pulse (95/min).

**TABLE 2** Time elapsed from last valid control data to sudden failure observed by patients

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>Total duration of pacing (mth)</th>
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<tbody>
<tr>
<td></td>
<td>1-2 months</td>
</tr>
<tr>
<td>3</td>
<td>11, 12, 13</td>
</tr>
<tr>
<td>4</td>
<td>10, 13, 17, 21, 24</td>
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The age of the pacemakers had a wide range without evident trend to very old units.

The majority of replacements were done consequent to repeated controls finally showing data that fulfilled the present criteria for pacing failure. Of the various findings in the photoanalysis, the change in impulse duration was most revealing,

**TABLE 1** Mode of detection of pacing failures in 120 replacements

<table>
<thead>
<tr>
<th>Sudden changes observed by patients</th>
<th>Sudden intercontrol changes not observed by patients</th>
<th>Slow deterioration detected by successive controls</th>
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</thead>
<tbody>
<tr>
<td>Elective replacements</td>
<td>Emergency replacements</td>
<td>5</td>
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</table>
FIG. 2  Battery survival rate of pacemakers of three different manufacturers. Units replaced because of infections, exit blocks, and defects in the electrodes are not included.

either alone or in combination with other alterations (Fig. 1). The combination of changes in duration and stimulation rate detected 96 per cent of failures. In 3 patients with faults in wires, the slope changed together with impulse duration in 2, and together with peak voltage in 1.

The battery survival time was longest with Medtronic pacemakers (Fig. 2), the 50 per cent survival time being 22 months. It was 17 months for Elema and exactly a year for Vitatron.

There were 28 deaths within the follow-up time (Table 3). In 3 patients the deaths were due to sudden pacing failure. In the cases with runaway pacers the wires were cut but resuscitation was unsuccessful. One death was due to asystole caused by a broken wire. There were 5 sudden deaths outside the hospital possibly related to pacing. In 15 of 20 patients who died from causes not related to pacing, the pacemaker function was checked and found good at the time of death. In 7 patients necropsy was not done, but the cause of death was ascertained by valid clinical data. Four patients in this group were not adequately followed in the clinic since they were transferred to municipal hospitals where they later died. The overall necropsy rate was 64 per cent.

When the fatal sudden events which were surely or possibly related to pacing failure are added to the sudden nonfatal failures observed by the patients (Table 1), 21 events are encountered. This represents a 16 per cent failure rate in detection by the

<table>
<thead>
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<th>TABLE 3  Data on 28 patients who died within follow-up period</th>
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<tr>
<td><strong>Cause of death</strong></td>
</tr>
<tr>
<td>A) Related to pacemaker function (3 patients)</td>
</tr>
<tr>
<td>B) Possibly related to pacemaker function (5 patients)</td>
</tr>
<tr>
<td>C) Not related to pacemaker function (20 patients)</td>
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</tbody>
</table>
present system. The breakdown of the 128 pacing failures into different categories is presented in Fig. 3.

Taking into account the 366 patient-years of pacing the total annual mortality was 7.7 per cent. The mortality due to pacing failure was 2.2 per cent per annum and the mortality not related to pacing 5.5 per cent per annum.

Discussion

It is evident from several reports that sudden pacing failures cannot be completely eliminated by any follow-up system (Sowton, 1967, 1968; Edhag, 1969; Parsonnet et al., 1970; Edhag et al., 1971; Furman et al., 1971a; Smith, McDonald, and Sloman, 1971; Green et al., 1972; Robinson, Sutton, and Craigie, 1973). This is due to the fact that there is no method to predict sudden component failure or acute lesions in the electrodes. Recently a trans-telephonic system for follow-up was described which predicted 26 of 28 battery failures (Pennock et al., 1972). This is an expanded version of the first application (Furman, Parker, and Escher, 1971b). Both systems facilitate frequent contacts between the patients and the clinic, thus theoretically increasing the possibility of failure detection.

All the changes in pacemaker function observed by the patients in this series (Fig. 3) which resulted either in elective or emergency replacements were sudden alterations in rate, which could not be predicted by any system. The same applies to the two fatal cases of runaway pacers and the one fatal case of asystole due to broken wire. The follow-up system was efficient enough to detect 13 instances of sudden intercontrol changes (10%) leading to elective replacements. One system advocated in addition to organized follow-up is the replacement of the units electively when they approach their maximum life span even if functioning normally (Escher et al., 1970; Lown and Kosowsky, 1970). Analysis of the data of the present series with regard to the age of the pacers at the time of replacement (Fig. 4) shows that very little would have been accomplished by routine replacement of old units.

The annual mortality of paced patients is difficult to judge from the various published series since many lack relevant information on the follow-up times (Siddons and Sowton, 1967). Recently, a survey of the mortality of paced patients was published (Zion, Marchand, and Obel, 1973), showing that wide variations occur. The mortality in the present series is close to that reported by Sowton and Flores (1971) and less than the average. 71 per cent of the deaths were due to causes not related to pacing. Thus with the hypothetical fool-proof system to prevent pacing failures, the mortality could be reduced by some 30 per cent. A more realistic alternative would be the development of safer pacemakers.

References


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