Early Malfunction of Transvenous Pacemaker Electrodes
A Three-Center Study

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SUMMARY A 3-year study by three medical centers has revealed a 1-year electrode malfunction rate of 7.4%; most malfunctions occurred within the first 30 days. The incidence of unavoidable early malfunction (3.2%) fell within the 5% standards suggested by the committee report of the Inter-Society Committee on Heart Diseases.

Incidence of obscure cause (3.2%) may be difficult to identify prospectively and may be, to a certain extent, unavoidable. The majority of the malfunctions (4.2%) showed specific clues that indicated that they were preventable. Successful repositioning was achieved on the first attempt in 80.6% of the cases with malfunction, and only 0.7% required ultimate myocardial electrode implantation. The principal clues to potentially unsatisfactory positioning included the presence of a large right ventricle with or without tricuspid insufficiency, current thresholds greater than 0.5 mA and ST-segment deviations on the intracardiac electrogram of less than 2 mV.

Electrode malfunction may be more common with bipolar than with unipolar electrodes; but significant differences in the incidence of malfunction among different unipolar electrodes were observed. These data indicate that further developments in transvenous electrode design are warranted.

PERMANENT transvenous right ventricular apical pacemaker electrodes initially maintain their position by loose entrapment in the trabeculae, and by slight axial pressure exerted by the attached lead wire. Eventually, a fibrous sheath forms around the wire and the position of the electrode becomes secure. The freshly implanted electrode, however, may be displaced from an optimal position for several reasons.

The training and expertise of persons inserting pacemaker electrodes vary, whether the procedure is performed by a surgeon, cardiologist or both. Early electrode malfunction (within the first 30 days) may be rare; or it may occur in as many as 56% of cases. A 10% rate is typical. These figures are higher than the upper limit of 5% suggested by the Inter-Society Committee on Heart Diseases (ICH) Report of 1974. High failure rates have stimulated interest in direct myocardial pacing, especially since the development of sutureless screw-in electrodes.

Myocardial pacemaker implantation has a higher risk of mortality and morbidity than the transvenous approach, and the procedure is more uncomfortable for the patient. An understanding of the factors that contribute to early electrode malfunction should substantially reduce the reoperation rate; it might then be possible to use transvenous pacing in most patients who require permanent cardiac pacemakers. With this objective, malfunction data were collected jointly by centers at the Los Angeles County University of Southern California Medical Center (LAC/USC), Montefiore Hospital and Medical Center (MHMC) and Newark Beth Israel Medical Center (NBIMC).

Methods

Data Collection

Data were collected as part of a comprehensive cardiac pacemaker protocol; information at the time of implant was logged in a common format and included the following information:

1) Reason for pacing;
2) type of electrode;
3) initial implantation thresholds;
4) difficulties encountered during implantation;
5) amplitude of the R wave and extent of current of injury;
6) time of identification of malfunction;
7) cause of malfunction;
8) thresholds and QRS studies before and after repositioning;
9) procedure used for correction;
10) evidence of electrode stability;

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11) slew rate of R wave if intracardiac electrogram (MHMC only).

Malfunctioning electrodes of patients transferred from other hospitals, validation devices and unusual transvenous systems (bifocal or atrial units) were excluded. All transvenous electrode insertions from July 1, 1974 through June 30, 1977 were included.

Electrode Measurements

The method for electrode measurement (threshold and QRS-T waveform) varied slightly between centers. QRS waveform and ST-segment deviation were measured oscilloscopically at centers A and C and both oscilloscopically and on an Electronics for Medicine strip chart recorder at center B. Threshold determinations were made by decreasing the output of an external pulse generator until one or more impulses failed to capture the ventricles during the diastolic period; values were recorded in both current and voltage. At centers B and C either four-, five- or six-point strength duration curves were recorded on each patient. At center A, thresholds were measured at 1.5-msec pulse width. Strength duration curves evaluated independently at each center revealed threshold values of current and voltage at pulse durations of 1 and 1.5 msec to be similar. Precise comparison of specific parameters was accomplished by selecting a group of normal subjects from the same center. “Normals” were patients in whom there was no untoward operative event and no subsequent electrode malfunction. Normal cases were selected consecutively by a technician uninvolved in the study; these patients, however, were persons operated on during the study period.

Study Surgeons

Surgeons and surgical technique at centers A and B did not change substantially during the years of the study. At center C, however, procedures were performed by supervised cardiology fellows. The choice of pulse generator and electrode was made independently at each center.

Definitions of Types of Malfunctions

Malfunctions were classified by agreement among the investigators during retrospective analysis of each case, but before detailed analysis of the collective data. The following definitions were used:

Malposition. Improper initial positioning of the electrode as shown by threshold data and chest x-rays.

Dislocation. Displacement of an electrode from its original position in the ventricular apex into the pulmonary artery, pulmonary outflow tract, atrium or superior or inferior vena cava.

Perforation. Projection through the myocardium recognized radiographically or by resumption of pacing on retracting the electrode; alternatively, by associated failure to pace in the presence of normal sensing, accompanied by stimulation of the left diaphragm, the latter being absent at the time of implantation.

Obscure cause. Constant or intermittent early (usually within the first week) failure to capture or sense without evidence of catheter dislocation or diaphragmatic stimulation. These findings were not attributable to any other identifiable cause.

Statistical analysis was performed by the chi-square method.

Results

During 3 years of study there were 1117 primary pacemaker implantations. Of these, 978 were transvenous and constitute the study group. Of the 978 implantations, 72 (7.4%) required one or more interventions. Sixty-one (85%) of the 72 with malfunction had been implanted through the cephalic vein, 10 (14%) through the external jugular vein and one (1.4%) through the internal jugular vein. Sixty-two (86%) were on the right side. There were no postoperative deaths.

The indications for pacing in the patients with malfunction were: fixed or intermittent complete atroventricular block in 32 (44%), sick sinus syndrome in 25 (35%), incomplete atroventricular block in 14 (19%) and tachyarrhythmias in 1 (1.4%).

The incidence of malfunction as judged by the various defined causes is shown in table 1. More than half (56.9%) were in a group that could be judged to be related to technical factors, while the remainder (43.0%) were of obscure cause. Those failures of technical origin (malposition, dislocation and perforation) comprised 4.2% of the total cases; 3.2% of these complications occurred within 30 days of implantation. Center differences in malposition were statistically different between centers A and C and B and C (table 2). There was no statistical difference in malposition rate between centers A and B. The incidence of dislocation was statistically less frequent in center A compared with either centers B or C. There was no difference in the incidence of dislocation between centers B or C. The overall incidence of technical causes was not statistically different between centers A and B, but was higher in center C compared with centers A or B. Both centers A and B met the ICHD guidelines for incidence of early malfunction.

With the exception of high threshold, malfunctions occurred early, particularly within the first week (fig. 1). Twenty-six cases (36%) occurred after one month, one 223 days after implantation. Problems with increasing threshold began to appear after the second week (fig. 2). We noted a difference in the incidence of malfunctions by types of electrode (table 3). When the Cordis 2-mm electrode was taken as a standard (having the lowest percentage incidence of malfunction of the electrodes with substantial numbers of implants), statistically significant incidences of problems were noted with the Medtronic 6901 (bipolar) electrode (p = 0.001), the unipolar 6907 electrode (p = 0.01) and Biotronik unipolar electrode (p = 0.01).

The relationship between subsequent electrode malfunction and initial electrophysio logic measurements (stimulating thresholds in current, ST-segment
deviation, and R-wave amplitude) was evaluated. We compared malfunction between technical causes that were obvious (malposition and dislocation) and cases in which apparent satisfactory functional values and position has been achieved (those of obscure cause and perforations) (fig. 3). Current thresholds tended to be higher among complications that resulted in malposition and dislocation compared with perforation and obscure cause (0.69 mA vs 0.44 mA) and the degree of ST-segment deviation was smaller in instances of malposition and dislocation (2.1 mV vs 3.3 mV, respectively). Using data from center A only (to eliminate subtle differences in methods between centers) a comparison was made with a random normal group from the same center (fig. 4). The normal group had values of threshold and ST-segment deviation similar to those with perforation and obscure cause with lower current thresholds and greater degrees of ST-segment deviation than in cases involving malposition or dislocation. ST-segment deviation was always observed (usually > 2.5 mV) in both normal subjects and in those with malfunction due to perforation or obscure cause. In contrast, in the group that showed malposition and dislocation, there were four cases (14.8%) with no ST deviation and in half of the cases the ST deviation was < 2 mV.

Electrophysiologic data obtained at the time of implant were compared with those obtained once the final repositioning had been achieved, usually on the next attempt. The results showed a tendency to lower threshold (both voltage and current) and greater ST-segment deviation after the problem was corrected; these differences were not, however, statistically significant (fig. 5). There was no significant difference in R-wave amplitude or slew rate between initial and postcorrection determinations.

### Table 1. Incidence of Malfunction

<table>
<thead>
<tr>
<th>Causes</th>
<th>Center A</th>
<th>Center B</th>
<th>Center C</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malposition</td>
<td>5 1.5</td>
<td>3 0.5</td>
<td>5 5.3*</td>
<td>13 1.3</td>
</tr>
<tr>
<td>Dislocation</td>
<td>1 0.3†</td>
<td>11 2.0</td>
<td>2 2.1</td>
<td>14 1.4</td>
</tr>
<tr>
<td>Perforation</td>
<td>3 0.9</td>
<td>9 1.6</td>
<td>2 2.1</td>
<td>14 1.4</td>
</tr>
<tr>
<td>Subtotal</td>
<td>9 2.7</td>
<td>23 4.2</td>
<td>9 9.6‡</td>
<td>41 4.2</td>
</tr>
<tr>
<td>Obscure causes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unidentified</td>
<td>7 2.1</td>
<td>13 2.4</td>
<td>0 0</td>
<td>20 2.0</td>
</tr>
<tr>
<td>High threshold</td>
<td>2 0.6</td>
<td>7 1.3</td>
<td>2 2.1</td>
<td>11 1.1</td>
</tr>
<tr>
<td>Subtotal</td>
<td>9 2.7</td>
<td>20 3.6</td>
<td>2 2.1</td>
<td>31 3.2</td>
</tr>
<tr>
<td>Totals</td>
<td>18 5.4</td>
<td>43 7.8</td>
<td>11 11.7§</td>
<td>72 7.4</td>
</tr>
</tbody>
</table>

*Significant—A vs C (p = 0.05) and B vs C (p = 0.001).
†Significant—A vs B (p = 0.05).
‡Significant—A vs C and B vs C (p = 0.05).
§Significant—A vs C (p = 0.05).

### Table 2. Center Differences

<table>
<thead>
<tr>
<th>Surgery done by</th>
<th>Center A</th>
<th>Center B</th>
<th>Center C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attending—Fellow or Resident, passive</td>
<td>×</td>
<td>×</td>
<td></td>
</tr>
<tr>
<td>Fellow—Attending, often passive</td>
<td></td>
<td></td>
<td>×</td>
</tr>
<tr>
<td>Case load</td>
<td>335</td>
<td>549</td>
<td>94</td>
</tr>
<tr>
<td>Incidence of malfunction (%)</td>
<td>5.4</td>
<td>7.8</td>
<td>11.7</td>
</tr>
<tr>
<td>Technical cause</td>
<td>2.7</td>
<td>4.2</td>
<td>9.6</td>
</tr>
<tr>
<td>Obscure cause</td>
<td>2.7</td>
<td>3.6</td>
<td>2.1</td>
</tr>
<tr>
<td>Average current threshold at implant (mA)</td>
<td>0.30</td>
<td>0.50</td>
<td>0.57</td>
</tr>
<tr>
<td>Average voltage threshold at implant (V)</td>
<td>0.46</td>
<td>0.65</td>
<td>0.66</td>
</tr>
<tr>
<td>ST elevation or depression at implant</td>
<td>2.9</td>
<td>3.1</td>
<td>2.5</td>
</tr>
<tr>
<td>Ultimate management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abandoned</td>
<td>0</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Stiffening Wire</td>
<td>0</td>
<td>4</td>
<td>0</td>
</tr>
</tbody>
</table>

*Includes recurrences

### Figure 1. Time of occurrence of electrode malfunctions.
Patient Management

The initial step in management was an attempt to reposition or replace the malfunctioning electrode; this was accomplished on the first attempt in 58 cases (8.5%), 45 by repositioning the same electrode, and 13 by replacing it with a different type of transvenous lead (fig. 6). None of the 13 replaced electrodes showed subsequent malfunction. However, 12 of the repositioned electrodes malfunctioned again, in general for the same reason that produced the original malfunction (table 4). Two of the original group were simply abandoned for a myocardial implant, as were five more that were abandoned after additional attempts to reposition them transvenously.

Table 3. Incidence of Malfunction of Various Electrodes Used

<table>
<thead>
<tr>
<th>Electrode type</th>
<th>Number</th>
<th>Malfunction (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Pacemakers Inc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bipolar</td>
<td>9</td>
<td>1 (11.1)</td>
</tr>
<tr>
<td>Biotronik IE00K10</td>
<td>42</td>
<td>6 (14.3)†</td>
</tr>
<tr>
<td>Cordis/continuous coil or ball tip</td>
<td>202</td>
<td>15 (7.4)</td>
</tr>
<tr>
<td>2 mm</td>
<td>199</td>
<td>8 (4.0)</td>
</tr>
<tr>
<td>Medtronic/6901 (bipolar)</td>
<td>35</td>
<td>7 (20.0)*</td>
</tr>
<tr>
<td>6907 (unipolar)</td>
<td>295</td>
<td>29 (9.8)†</td>
</tr>
<tr>
<td>Starr-Edwards</td>
<td>20</td>
<td>2 (10.0)</td>
</tr>
<tr>
<td>Vitatron/M 086</td>
<td>5</td>
<td>1 (20.0)</td>
</tr>
<tr>
<td>MIP 2000</td>
<td>17</td>
<td>2 (11.8)</td>
</tr>
<tr>
<td>147 LOE</td>
<td>13</td>
<td>1 (7.7)</td>
</tr>
<tr>
<td>Miscellaneous or not specified</td>
<td>141</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>978</td>
<td>72 (7.4%)</td>
</tr>
</tbody>
</table>

*Significant difference from Cordis 2 mm (p = 0.001).†Significant difference from Cordis 2 mm (p = 0.01).

Stable pacing was ultimately attained in all 72 cases, with final transvenous stimulation in 65 (eight with grasping electrodes of some sort) and with myocardial leads in seven. Four times we attempted to retain an initially unstable transvenous position by leaving the stiffening wire in place; this failed in one case.

Figure 2. Time of occurrence of malfunction by cause.

Figure 3. Proper functional position. Electrophysiologic measurements taken at implantation indicate differences in threshold (in current) and ST-segment deviation (in mV) between malfunctions caused by malposition or dislocation and those caused by perforation or obscure causes.
and in another both the stiffening wire and the lead fractured.

Extenuating factors that might have contributed to malfunction were identified in 12 patients. Eight patients had an enlarged right ventricle, congestive heart failure and tricuspid insufficiency. In one case, a satisfactory position was never achieved, and a compromised position was accepted.

Three cases were unique. In one instance, the surgeon accidentally dislodged an electrode while inserting the transvenous atrial electrode of a bifocal system; one electrode was dislodged in a fall on the first postoperative day; and one dislodgement occurred in a hyperactive child.

Discussion

The malfunction rate in our series was higher than expected. If those instances with clearly technical origin are excluded, the overall incidence of malfunction was 3.2%, a value well within the recommended ICHD guidelines of 5% or less. Indeed, if the cases of obscure cause were combined with those in which there was perforation, the value continued to be within these guidelines (4.6%).

In the eight patients who had right ventricular dilatation and tricuspid insufficiency, dislocation might have been anticipated. Solutions to this problem include the use of a myocardial electrode or, now that they are available, grasping or entrapping right ventricular electrodes. A study is in progress at both the NBIMC and the MHMC to evaluate the ease of insertion and effectiveness of these specialized electrodes. However, two of 17 (11%) Vitatron MIP 2000 electrodes malfunctioned. This electrode has nylon bristles designed to aid in entrapment of the electrode against the endocardial surface. Our experience shows that stimulation thresholds may continue to rise to un-

![Figure 4](http://circ.ahajournals.org/)

**Figure 4.** Functional position compared to "normal." Note the similarity between those judged to be normal and the group that had perforation and obscure cause. As in figure 3, the R-wave amplitude is similar between the two groups with complications (see text for details).

![Figure 5](http://circ.ahajournals.org/)

**Figure 5.** Electrophysiologic data at implantation and repositioning. The data indicate that after correcting the position of the electrode there is improvement in threshold (current and voltage), less obvious improvement in ST-segment deviation and no difference in R-wave amplitude.
acceptable levels with this electrode, presumably because of lack of continued contact between the electrode and endocardial surface. In the combined series there were seven instances in which the myocardial electrode was ultimately used; center A, however, never found this necessary.

Technical factors accounting for malfunction are not easy to identify. Fifty-eight of 72 malfunctions (80.6%) required one transvenous reoperation for final stability. Furthermore, in 65 of the 72 instances in which malfunction occurred, final, stable, intracardiac electrode positioning and pacing was realized. These factors indicate that a combination of proper electrode selection and careful attention to technical detail might result in a transvenous complication rate below 1.0%.

Electrophysiologic data indicate differences with various types of malfunction. Stimulation thresholds were slightly higher with malposition or dislocation compared with a normal subset of patients and those with perforation and failures of obscure cause, suggesting that a tight apposition of the electrode and endocardium was not achieved. This tends to be confirmed by noting that the amplitude of the current of injury (ST-segment deviation) was greater in those without malposition or dislocation and those with complications of obscure cause or perforation. If during transvenous electrode insertion current thresholds are higher than normal (normal values should be established by each operating team, since they depend upon electrode size and shape and methods of measurement) and ST-segment deviation is less than 2 mV, it must be assumed that the functional electrode position is unsatisfactory. The amplitude of the R-wave was the same in all instances, indicating that this measurement provides no clue as to the adequacy of electrode position for long-term stimulation. This is not surprising, since the electrode merely provides one recording point for an intracardiac electrogram between two widely spaced electrodes; a small variance in electrode-endocardial distance should not significantly affect this measurement.

<table>
<thead>
<tr>
<th>Table 4. Causes of Malfunction in Cases with Recurrent Malfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Original cause</strong></td>
</tr>
</tbody>
</table>
| Malposition, dislodgement or perforation | 8 | 6 - same cause  
1 - minor perforation  
1 - high threshold |
| Obscure cause or high threshold | 5 | Same |
| Total | 13 | |
Failures of obscure cause are difficult to explain. Soon after electrode implantation, failure to capture, failure to sense, or both occur; at the same time, there is no evidence of malposition by x-ray. This might be explained by slight movement of the electrode, or thrombus or excessive tissue reaction between the electrode and the endocardium. The latter is difficult to support, because one would expect these changes to occur a week or more after implantation, not in the first few days (fig. 2). Thrombus, or more particularly excessive tissue reaction, would be more likely to apply to increases in threshold beginning at 2 weeks or more. On the other hand, bipolar electrodes tend to be stiffer and might be expected to produce greater degrees of traumatic tissue reaction. The fact that the bipolar electrodes in our series had the highest incidence of complications is, therefore, somewhat intriguing. An alternative explanation for early failure might be partial penetration of the electrode through the myocardium with the electrode tip lying beneath the epicardium, without overt advancement into the pericardial cavity.

Results between centers differed; some of the reasons for this are unclear. However, at two of the centers, implantations were performed by the same surgical groups with long-term experience in cardiac pacing; residents and fellows served a more passive role. At center C, the reverse was true. This indicates, as might be expected, that the level of expertise of the operator is clearly a factor in transvenous cardiac pacemaker implantation. The common practice of relegating permanent transvenous (and probably myocardial) permanent pacemaker implantation to junior members of operating teams is therefore not advisable. These findings have resulted in modifications in technique, devices, and personnel at each center; subsequent studies should determine whether these modifications decrease the incidence of reoperation.

The 26 cases of late malfunction in our series cannot be entirely explained by the available data. A gradual increase in fibroplasia depends on host response, and probably explains the high thresholds. Other late malfunctions may be explained by the fact that some patients do not depend on their pacemaker systems for life support; electrode malfunction may have existed for some time before it was accidentally discovered, either by recurrence of symptoms or during incidental routine examination. The data indicate, however, that cases of electrode malfunction do occur late, though with low frequency.

This study, combined with our prior judgements on proper technique, allow us to identify four elements that are required to achieve adequate and stable transvenous cardiac pacing:

1) accurate placement of the electrode in the apex of the right ventricle under fluoroscopic control;
2) good apposition of the electrode to the endocardium as evidenced by low stimulation threshold;
3) documentation of a distinct current of injury;
4) demonstration of an R-wave of adequate amplitude. This study indicates that the R-wave amplitude alone cannot be used to judge adequacy of placement for the purpose of pacing. However, if the R-wave is not large enough (or the slew rate is too slow), the electrode location must be changed or a pulse generator more sensitive to small signals should be used.9

Implications

Our study indicates that proper transvenous placement of permanent cardiac electrodes requires trained personnel, careful electrophysiologic measurement (R-wave amplitude and slew rate, ST-segment measurement, and voltage and current threshold determinations) to hold the need for reoperation to a minimum. In addition, special grasping transvenous electrodes must be selected when certain situations that lead to electrode instability occur, particularly the large right ventricle with tricuspid insufficiency.

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