

GENERAL  ELECTRIC  
COMPANY

X-RAY DEPARTMENT

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Adrian Kantrowitz, M.D.  
Director of Surgical Services  
Maimonides Hospital of Brooklyn  
4802 Tenth Avenue  
Brooklyn, New York 10019

Dear Dr. Kantrowitz:

The past few weeks we have been analyzing the implant and failure data we have received back on our present model pacemaker (with connector) as to cause of failure and treatment to correct especially in regard to exit block or threshold problems.

Our findings on this data show that through December 31, 1965 twenty-one (21) connector pacemakers were returned after use for the following reasons.

- 6 - deaths
- 11 - exit blocks
- 1 - connector failure
- 1 - short in connector adapter
- 2 - unknown

Of the eleven (11) exit blocks, seven (7) are being controlled by use of our high energy pacemaker, two (2) by Medtronic catheter and two (2) by relocated electrodes (your patients). There are several other exit block patients who are being controlled by drug therapy.

It is also interesting that four (4) of the exit blocks occurred on the patient's first implant (out of 126 known new implants) and seven (7) on reimplants (out of 56 known reimplants). This indicates that for initial implants approximately 97% are being successfully stimulated by our regular unit confirming that the output is satisfactory. However, it also shows that a fairly high percentage of patients are running into trouble when new electrodes are put in. It also shows that the High Energy unit is doing the job nicely for most of the high threshold people.

There are three choices to consider when the batteries on an old style (non-connector) pacemaker give out and the unit must be replaced. They are listed below with the advantages and disadvantages of each as I see them.

1. Use connector adapter and splice to old electrodes.  
(Splicing instructions are enclosed for your pursual.)

A special rate pacemaker is required since stainless steel electrodes have a different impedance than our HELICABLE electrodes. (Unit set to run at 70 ppm with HELICABLE leads will run approximately 12-13 ppm higher on stainless-steel electrodes.)

Advantages:

- A. Eliminates danger of exit block which can occur with reimplanted unit.
- B. Avoids thoracotomy for very old or ill patient.
- C. Shorter hospital stay for patient and minor operation helps to offset higher cost of special unit.

Disadvantages:

- A. Patient file must be clued to make sure special rate replacement generator is ordered when replacement is necessary.
- B. Cost of a special rate replacement generator is presently \$100 more than regular rate unit.
- C. Spliced leads are more subject to bad breakage; especially if the unit is in the abdomen.
- D. May take three-four days to deliver after order.

Identification of the patient and/or the old P/M serial number will assist G.E. in providing the correct splicing material and instructions.

2. Implant new HELICABLE electrodes and use regular five cell battery pacemaker generator.

Feel this should be tried only on patients with demonstrated low threshold and if willing to follow closely for three months post-implant with the threshold analyzer.

Advantages:

- A. Gives the patient good electrode all the way to the heart virtually eliminating the possibility of electrode breakage.
- B. Replacement generators are standard; thus, replacement cost is reduced.
- C. Generator in stock can be used eliminating the possible three to four day delivery delay.
- D. If exit block occurs, high energy unit can be quickly substituted.

Disadvantages:

- A. High probability of exit block occurring (our present estimate is one chance in four or five).
- B. Higher hospital and operation costs for the patient.
- C. Longer recovery period.
- D. Close following with threshold analyzer for first three months will be required.
- E. High probability of continued drug therapy to hold threshold at desired low level.
- F. Maintenance of the patient in the hospital while awaiting high energy replacement generator when required.

3. Implant new HELICABLE electrodes and use high energy pulse generator.

Advantages:

- A. Gives the patient good electrodes to the heart virtually eliminating possibility of electrode breakage.
- B. High energy pacemaker generators available at the same price as the regular units.
- C. Greatly reduces possibility of exit block problems. (All seven of last seven high energy units used on exit block patients are pacing successfully (two oldest--eight months since installation).
- D. Reduces necessity of drug therapy.

Disadvantages:

- A. Shorter life expectancy of the batteries (estimated 15 to 18 months).
- B. Thoracotomy required resulting in higher hospital and surgical costs and a greater risk to the patient.

The surgeon and cardiologist must weigh the advantages and disadvantages of each method against the known condition of the patient and select the most appropriate method.

If a patient who has a competitive make pacemaker with myocardial implant is to receive a G.E. myocardial implant pacemaker only choices (2) and (3) are available. Limited data available indicates (3) will result in the most trouble free operation.

When our implantable intracardiac (catheter) electrode becomes available, you will then have a fourth choice. One which may prove superior to (1) and (2).

If you have any questions or comments, please let me know.

Cordially,

  
W.H. Duehren  
Pacemaker Specialist