

Long-term evaluation of the General Electric cardiac pacemaker

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A review of General Electric (G.E.) electronic cardiac pacemakers for symptomatic complete A-V heart block in two sequential three-year periods at the University of Michigan Medical Center indicates that there has been no increase in the useful life of these units. With G.E. epicardial pacemakers failure occurred after an average of 12 months. In the early years the major cause of failure was wire breakage, and the later major cause was battery exhaustion or component failure. Exit block was a major complication. There was no improvement when G.E. catheter pacemakers were used instead of the epicardial type. The Medtronic catheter pacemakers lasted longer, with fewer battery and component failures and no instances of exit block. Although infection was more common with Medtronic pacemakers, secondary to erosion of the power unit or the catheter through the skin, it may be that this complication could be eliminated by locating the battery box beneath the latissimus dorsi muscle in the axilla and by careful catheter placement to avoid pressure necrosis and subsequent cutaneous perforation.

The treatment of complete atrioventricular heart block by the operative implantation of electronic cardiac pacemakers has prolonged the life of many patients who would otherwise have died. Published reports repeatedly confirm this increased survival and also document the improvement of the quality of the life of these patients accomplished through the alleviation of Adams-Stokes attacks and the relief of symptoms of congestive failure (Chardack, Gage, Federico, Schimert, and Greatbatch, 1965; Friedberg, Donoso, and Stein, 1964; Johansson, 1966; Vookles and Milnor, 1965). Despite these clinical benefits, many problems have resulted from the use of cardiac pacemakers, and the high rate of pacemaker failure has meant that many patients have had to have two or three permanent pacemakers implanted in only a few years.

This report covers a six-year period at the University of Michigan Medical Center during which 262 pacemakers were used in the treatment of 140 patients with complete heart block. Practically all (236) were General Electric (G.E.) pacemakers. In reviewing this experience, we were chiefly interested in determining whether the G.E.

pacemaker has been improved in design and construction enough to improve its function in the clinical setting. We also compared the results with epicardial and catheter type G.E. pacemakers. Even though only 26 Medtronic catheter pacemakers were used, we included these results to note any gross differences in results between the G.E. and Medtronic pacemakers.

CLINICAL FEATURES

For purposes of comparison, the period from 1 January 1962 to 31 December 1967 was divided into two three-year periods. In the first period, 88 pacemakers were implanted, and all were the G.E. epicardial type. In the second period, 103 G.E. epicardial pacemakers, 45 G.E. permanent epicardial pacemakers, and 26 Medtronic permanent catheter pacemakers were implanted. Most of the implantations were carried out for complete heart block associated with Adams-Stokes attacks or congestive heart failure. Over the past two years, not included in this study, more permanent catheter pacemakers have been implanted than the epicardial type.

For epicardial implantation, an anterolateral submammary incision was made and the chest was entered through the fourth or fifth intercostal

space. The electrode wires were placed in an avascular area of the left ventricle, and the wires led in a smooth curve through the intercostal space to the power unit, which in the early cases was buried subcutaneously in the left upper quadrant and in the lateral aspect of the left axillary wound in the later cases.

Catheter pacemakers were installed under local anaesthesia. An endocardial electrode was placed in the right ventricle through the right or left external jugular vein or cephalic vein, and then connected to a pulse generator implanted in the soft tissues below the pectoralis major muscle or in the right axilla.

Ninety-seven of the 140 patients survive and have pacemakers which function satisfactorily, although many patients have required two or three different pacemakers to maintain continuous electrical control of the ventricular rate. Of the 43 deaths in this series, three occurred during or soon after pacemaker implantation—one from haemorrhage, one from cerebrovascular accident, and one from pacemaker failure. The three hospital deaths occurred after implantation of an epicardial pacemaker. There have been no hospital deaths after permanent catheter placement. Of the 40 deaths that occurred after discharge from hospital, 17 (12%) were definitely not related to pacemaker malfunction, 14 (10%) may have been related to pacemaker malfunction, and 9 (6%) were definitely related to pacemaker malfunction (see Figure).

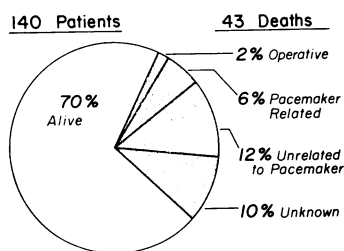


FIGURE. Cardiac pacemakers, 1962-67.

PACEMAKER FUNCTION

GENERAL ELECTRICAL EPICARDIAL None of the original 88 G.E. epicardial pacemakers used during the first three-year period is still functioning. In patients who are still alive, 71 pacemakers were used during this period and functioned for an average of 12 months before failure. In patients who have died, the average duration of pacemaker

function was nine months. Pacemaker failure was due to battery exhaustion or component failure in 38%, wire breakage in 39%, exit block in 10%, infection in 5%, and to an unknown cause in 8% (Table I).

TABLE I
CAUSES OF FAILURE IN G.E. EPICARDIAL PACEMAKERS, 1962-64

Battery or component failure ..	38%
Wire breakage ..	39%
Exit block ..	10%
Infection ..	5%
Unknown ..	8%

In the second three-year period, 103 G.E. epicardial pacemakers were used. After an average of 12 months, 25 are still functioning and 69 have failed. In patients who died, the average duration of pacemaker function was seven months. Pacemaker failure was due to battery exhaustion or component failure in 80%, wire breakage in 11%, exit block in 6%, infection in 1%, and to an unknown cause in 2% (Table II).

TABLE II
CAUSES OF FAILURE IN G.E. EPICARDIAL PACEMAKERS, 1965-67

Battery or component failure ..	80%
Wire breakage ..	11%
Exit block ..	6%
Infection ..	1%
Unknown ..	2%

GENERAL ELECTRIC CATHETER TYPE During the second three-year period, 45 G.E. catheter type pacemakers were installed. After an average of 13 months, 21 are still functioning. Fifteen, however, have failed after functioning for an average of 10 months. The other nine functioned for six months. Failure was associated with battery exhaustion or component failure in 66%, wire breakage in 13%, exit block in 13%, and perforation of the ventricle in 8%.

MEDTRONIC CATHETER TYPE The Medtronic pacemakers were all of the catheter type used in the second period. After implantation five are still functioning with an average life of 23 months, and 16 were removed after functioning for an average of 15 months. Five patients died an average of seven months after pacemaker implantation. Power unit replacement was necessary in 56% because of battery exhaustion or component failure, in 31% because of infection from erosion, and in 13% because of wire breakage.

COMPLICATIONS Aside from mechanical failure, the most common complications were exit block and infection. Exit block is said to be present when a pacemaker functions normally but the myocardium ceases to respond because of a critical rise in the electrical threshold for stimulation. Exit block was not observed in this series in any patient in whom a Medtronic catheter pacemaker was used. With both types of G.E. pacemakers, however, the prevalence of exit block was about 13%. During the first three-year period, less than half of the patients with exit block responded to treatment with steroids and potassium. Results were better in the second period, particularly among those patients with G.E. catheter pacemakers (Table III).

TABLE III

RESPONSE TO THERAPY WITH CARDIAC PACEMAKERS

No. of Pacemakers	Type of Pacemaker	Exit Block	Response
88	G.E. epicardial (1962-64)	12%	37%
103	G.E. epicardial (1965-67)	14%	43%
45	G.E. catheter (1965-67)	13%	66%
26	Medtronic catheter (1965-67)	0	

Of the 262 pacemakers in this series, 12 developed infections at the site of implantation. Seven patients had infection secondary to erosion of the pacemaker through the skin 2 to 15 months after the initial operation; four infections occurred after pulse generator replacement in the operating room; and one occurred immediately after the initial implantation of a catheter pacemaker in the cardiac catheterization laboratory. Management included removal of all foreign material, including the pacemaker and electrodes, with temporary pacing at a different site while the infection was under treatment. After all infection had been eliminated, a new pacemaker was implanted at a new, clean site (Firor, Lopez, Nanson, and Mori, 1968).

DISCUSSION

The 70% patient survival in this series is consistent with rates reported elsewhere (Chardack, Gage, Federico, Schimert, and Greatbatch, 1966; Bigelow, Herr, Wood, and Starr, 1968) and confirms the value of pacemaker implantation despite the problems that complicate this type of therapy.

It now appears that a 'demand' pacemaker may eliminate some of the pacemaker related deaths that are secondary to competitive firing and fatal arrhythmias.

With respect to the main purpose of this review—evaluation of instrumentation—it would seem at first glance that the reduction in wire breakage which plagued the early pacemakers constitutes improvement. It must be noted, however, that the problems merely shifted from wire breakage in the first period to battery and component failure in the second period. The duration of satisfactory G.E. pacemaker function was about the same from one period to the next whether the epicardial or catheter type was implanted.

Although the number of Medtronic catheter pacemakers used was small, this instrument seems more durable in view of the longer interval between implantation and failure. On the other hand, possibly because of the protrusions on the case of the instrument, erosion and subsequent infection were much more common than with the G.E. power unit. Perhaps this complication could be avoided by placing the pacemaker beneath the latissimus dorsi muscle in the axilla.

Exit block was a major problem with G.E. pacemakers but did not occur with Medtronic units. The apparent decrease in pacemaker failure from exit block through the years simply reflects the growing recognition that this condition will respond to treatment with steroid hormones and potassium salts. The prevalence of this complication with G.E. pacemakers did not decrease the second time period; it remained the same when G.E. endocardial pacemakers were used instead of the epicardial type.

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