Four years experience of cardiac pacemaking with the Devices asynchronous generator

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The results of fixed-rate cardiac pacing during a 4-year period are reported. In 90 patients, 107 Devices TF (type 2970) asynchronous generators were implanted. An actuarial estimate of generator lifetime showed that 84 per cent of generators were functioning at 2 years and 65 per cent at 3 years after implantation. Ten generators failed from battery depletion after more than 30 months' use, while generator malfunction was demonstrated in 9 of 10 units failing before 30 months. At 2 years, 59 per cent of pacing systems were satisfactory and 34 per cent continued in use for more than 3 years. Extrusion of the generator, exit-block, and fractured electrodes accounted for more than half the premature pacing system failures. Nine patients died during the period of study, none due to pacemaker failure. While pacemaker follow-up was minimal, only 16.6 per cent of generators were removed because of unpredicted failure. These results indicate that, with a reliable generator, pacemaker follow-up can be simplified and this may encourage wider use of long-term pacing for the management of heart block outside specialist centres.

Patients with heart block have a mortality of 50 per cent within one year of the development of symptoms (Penton, Miller, and Levine, 1956; Friedberg, Donoso, and Stein, 1964; Johansson, 1966). The introduction of long-term artificial cardiac pacing reduced this mortality to between 10 and 20 per cent (Chardack *et al.*, 1965; Harris *et al.*, 1965; Lagergren *et al.*, 1966), but early experience of totally implanted pacemakers was marred by a considerable morbidity associated with premature pulse-generator failure. A survey of British experience (Sowton, 1968a) emphasized that more than 40 per cent of failures were due to other faults such as electrode failure, infection, and exit block. More recently technical advances in electrode and circuit design, associated with better encapsulation techniques, have improved the reliability of pacemaker implants (Green *et al.*, 1972; Furman, Escher, and Parker, 1972). There is a need, however, for studies which assess generator lifetime.

Between February 1969 and February 1973, 173 pacemaker generators were implanted in 111 patients. This report concerns the results of implantation of 107 asynchronous pacemakers of uniform type (Devices TF type 2970) in 90 patients using a transvenous endocardial electrode. Twenty-four fixed-rate generators implanted during the last

6 months up to February 1973 have not been included in the analysis.

Patients and methods

There were 63 men and 27 women. The average age was 69 years (range 47-89 years) (Fig. 1). The indication for long-term cardiac pacing was the finding of complete or second-degree atrioventricular block causing Adams-Stokes attacks or near syncopal episodes in 87 patients. In 3 patients with complete heart block the sole indication was heart failure. Twenty-nine patients had been paced for varied periods of time before the insertion of a Devices TF generator and 61 patients were being paced for the first time (Fig. 2).

Pacemaker implant

The Devices TF type 2970 generator provides stimulation at a fixed rate using a unipolar electrode system, the indifferent electrode being provided by a metal plate moulded into one side of the unit. The electronic circuit is protected within a hermetically sealed metal box with glass insulated connexions to four Mallory mercury batteries and the unit is encapsulated in epoxy resin. With battery exhaustion a reduction of rate is observed with an increase in the stimulation pulse width. The anticipated battery life is 3 years. Unipolar transvenous electrodes (Devices type L90SR) were used, but in 2 patients at the time of initial implantation of a type 2970 generator a USCI electrode (type C50) was in use though later replaced.

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FIG. 1 Age distribution of 90 patients.

Technique of implantation

The unipolar endocardial lead was inserted, in preference, into a cephalic vein in the deltopectoral groove or the external jugular vein. In 2 patients the internal jugular vein was used. The tip of the lead was positioned under fluoroscopic control in the right ventricular apex. The final position was chosen to give a stimulation threshold of less than one volt with a pulse width of 2 msec. The generator was implanted in a subcutaneous pocket in the axilla though occasionally in thin patients or when extrusion had previously occurred the unit was placed anterior to the pectoral muscles.

FIG. 2 Duration of permanent pacing in 90 patients.

Patient follow-up

Patients were reviewed at 6-monthly intervals during the first year, and at 3-monthly intervals up to 2½ years after implantation and thereafter at 2-monthly intervals. Technical evaluation was minimal, consisting of a routine electrocardiogram including a long rhythm strip and counting the pulse rate. An alteration in the generator pulse rate of 4 per minute was used as an indication of imminent battery exhaustion and indicated immediate replacement of the unit. Competitive rhythms due to the return of atrioventricular conduction were treated with small doses of beta-adrenergic blocking drugs, and frequent ventricular ectopics with procainamide 250-500 mg four times a day.

Results

The results are summarized in Table 1 and Fig. 3. An assessment of generator lifetime has been made. All generators which were removed for technical failure have been considered, excluding those removed electively while pacing function was satisfactory, and those removed because of infection, extrusion, exit block, or electrode failure. An actuarial estimate of generator lifetime (Pike and Roe, 1963) (Table 1 and Fig. 3) with the standard error of the estimate allows a more precise quantification to be made correcting the data for the generators removed for nontechnical failure. It can be seen that only two generators failed during the first year and that 84 per cent were functioning normally at 2 years and 65 per cent at 3 years after implantation.

Pacing system lifetime has been assessed where all reasons for removing the generator have been considered, excluding only those deaths not associ-

FIG. 3 Actuarial analysis of (a) generator lifetime ●—●; (b) pacing system lifetime ●---●; (c) battery lifetime ●----●.

TABLE 1 Results

Interval (mth)	6	12	18	24	30	36	42
No. of pacemakers implanted	107	91	76	63	52	37	22
No. of deaths	3	4	4	4	4	4	4
<i>Generator lifetime</i>							
No. of failed generators	1	2	5	9	11	11	11
Per cent of generators functioning (actuarial estimate)	99	97.7	93	83.8	75.3	64.5	40.5
Standard error of estimate (%)	0.9	1.7	3.2	5.2	6.0	6.3	4.9
<i>Pacing system lifetime</i>							
No. of failed systems not due to generator failure	2	6	6	11	11	8	3
Per cent of systems functioning (actuarial estimate)	94.3	86.5	80	59.3	48	34.3	—
Standard error of estimate (%)	2.1	3.8	4.8	5.1	3.8	2.2	—
<i>Battery lifetime</i>							
No. of generators removed for battery depletion	0	0	0	0	0	4	10
Per cent of generators without battery depletion	100	100	100	100	100	85.5	44.5

ated with pacing failure (Table 1 and Fig. 3). This shows that the most common causes of failure within two years are not related to the function of the generator. On an actuarial basis 87 per cent of the implanted systems were functioning at 1 year but this had fallen to 59 per cent at 2 years and 34 per cent at 3 years.

Generator failure

Fig. 4 shows the time of failure after implantation of 20 generators and Table 2 summarizes the causes of failure. In 11 instances generator failure was predicted by a slowing of the pacing rate, and in 6 cases the generator had been in use for more than 3 years. All the unpredicted failures occurred before 2 years.

FIG. 4 Time after implantation when 20 generators failed.

Three patients with unexpected failure experienced syncopal episodes but there was no mortality associated with generator failure. Ten of the failures were due to battery exhaustion and occurred after 2½ years. Including the 2 units which failed under 1 year, there were 6 units implanted in a 6-month period between November 1969 and April 1970, which were shown to have a failure of encapsulation resulting in a leakage of electrolyte from the battery to the positive terminal of the sealed metal box leading to loss of pacing. A specific component fault was identified in 3 of the other 4 unpredicted failures; a transistor failure in 1; a short-circuit of the generator output due to metallic deposition in 1; and fracture of an internal connexion in 1. The remaining unit was not examined after removal.

Elective removal

Ten generators were removed electively while generator function was still satisfactory. One unit was replaced by a demand pacemaker under 1 year because of competition. One patient intended leaving the U.K. for a prolonged period and the generator was changed at 2½ years. Initial analysis of

TABLE 2 Causes of generator failure

	Unpredicted	Predicted	Total
Battery exhaustion	0	10	10
Leakage of electrolyte	5	1	6
Other component failure	3	0	3
Not known	1	0	1
Total	9	11	20

experience with the 2970 generator indicated (Table 1, Fig. 3) that battery exhaustion was unlikely to occur before 2½ years but might occur in about 15 per cent between 30 and 36 months, and 40 per cent between 36 and 42 months after implantation. On this basis a decision was made to remove all units electively at a convenient time after 3 years' use and this has been done in 8 cases.

Failure of the pacing system apart from generator failure has occurred for 3 reasons; infection or extrusion of the pacemaker on 9 occasions in 8 patients; exit-block due to a rise in the endocardial threshold of stimulation in 4 instances; and fracture of the endocardial electrode in 2.

Infection or extrusion

Of the 9 occasions, 3 occurred within 6 months, 2 between 6 months and 1 year, 3 between 1 year and 18 months, and 1 between 18 months and 2 years. While infection was thought to be the primary cause in the 3 occurring within 6 months, in the remaining 6 cases an aseptic erosion through the skin was the likeliest explanation. In 2 of the 9 instances extrusion occurred after generator replacement.

Exit-block

A rising threshold of stimulation led to loss of ventricular capture in 4 patients. Three occurred within 6 months of implantation. In 1 case exit-block occurred after the electrode had been in use for 4 years.

Fracture of endocardial lead

In both cases the electrode was a unipolar USCI (type C50) electrode. This electrode was not designed for long-term use but had been used in these patients for 9 and 6 years, respectively, before fracture.

Deaths

During the 4-year period of the study 9 patients died. None died of pacemaker failure; indeed, in all

generator function is known to have been normal before or after death. In 44 patients who could have completed their first year of pacing in this study, 3 died giving a 1-year mortality of 6.8 per cent. The causes of death, based on clinical and necropsy evidence in all patients is shown in Table 2. The average age at death was 76 years (range 62–87).

Discussion

Permanent pacing is an effective treatment of symptoms of heart block, reducing mortality, preventing syncope, and alleviating heart failure. It has been emphasized (Green *et al.*, 1970) that there is a continuing need for detailed results of patients treated by a uniform method with a long enough period of follow-up in order to assess generator life. There has been only one previous report of the Devices asynchronous TF pacemaker (type 2970) (Siddons and Davies, 1973), but a policy of early elective removal prevented analysis of generator and battery lifetime. The present study shows that the Devices unit is reliable, with an estimated failure rate of 7 per cent at 18 months and 35 per cent of the generators fail before 3 years. Of the 10 generators which failed before 30 months, 9 were due to generator malfunction and not battery exhaustion.

Between 40 and 50 per cent of pacing system failures are caused by factors other than generator failure (Sowton, 1968a; Green *et al.*, 1972; Siddons and Davies, 1973). In this series there were 14 generator failures before 3 years and 17 pacing system failures due to extrusion of the unit, exit-block, fractured leads, and elective removal. The commonest cause of non-generator failure in this series was infection or extrusion of the unit, occurring on 9 occasions. With greater care at the time of insertion and prompt repositioning at the earliest signs of extrusion, most of these should be avoidable. Lead fracture occurred only in electrodes that were not designed for long-term use, and should be a very rare occurrence with the present lead employed.

In a study of patients with asynchronous units (Sowton, 1965) it was noted that 25 per cent returned at times to sinus rhythm. An increased incidence of ventricular fibrillation has been observed in those patients who had a competitive rhythm (Sowton, 1965; Bilitch, 1969). For this reason noncompetitive pacemakers of the ventricular-triggered or ventricular-inhibited type have been advised. In general, however, later experience has shown no increased mortality associated with asynchronous pacing (Chardack *et al.*, 1969; Furman, Escher, and Parker, 1971; Green *et al.*, 1972) as is the case in the present series. There would, therefore, not be any advantage for the majority of patients to have a non-competitive system. Demand units have been

TABLE 3 Causes of death

	No. of patients
Heart failure	3
Cerebrovascular accident	1
Cardiac infarction	1
Ruptured aortic aneurysm	1
Pneumonia	1
Diabetes ketosis	1
Aortic valve replacement	1
Total	9

employed, by us, when competition has caused symptoms or when sinus rhythm has been the dominant rhythm.

Actuarial analysis of generator and battery life indicates that very few units will fail from battery depletion before 30 months but about 58 per cent of those still functioning will fail between 30 and 42 months. A policy of elective removal after 3 years of use therefore seems a reasonable compromise between maximizing generator usage and minimizing the number of emergency replacements (Furman *et al.*, 1972). The slight economic loss of replacing units early is considered to be offset by the reduced duration of stay in hospital for a planned generator replacement when the surgical time can be scheduled in advance.

The technical follow-up of our patients has been minimal, though the need for more sophisticated methods of analysing the function of implanted pacemakers by analysis of the pacemaker stimulus has been advocated (Knuckey, McDonald, and Sloman, 1965; Davies and Siddons, 1969; Green *et al.*, 1969; Ryden and Thornander, 1970; Edhag *et al.*, 1971; Escher and Furman, 1971; Sowton and Gray, 1971). However, it is difficult to establish how effective such techniques are in predicting failure though they are undoubtedly effective in analysing the nature of malfunction once it occurs. Reporting the large experience of pacing at St. George's Hospital, Davies and Siddons (1969) indicated that they had predicted 17 of their last 19 failing pacemakers. Of 42 defective pacemakers (Edhag *et al.*, 1971), only 16 were detected before symptoms and electrocardiographic signs of failure occurred. On the other hand, others have reported (Ryden and Thornander, 1970) that only 4 of 56 failed generators would have been found by an analysis of the rate and the electrocardiogram. However, the value of these techniques is greatest when premature generator failure is frequent, and in the latter series (Ryden and Thornander, 1970) most units failed before 18 months. With the increased reliability of generators, battery depletion is now the principal reason for generator failure and it is invariably predicted by a rate change in those generators designed to give this simple warning of depletion (Furman *et al.*, 1972). Using more detailed technical follow-up (Siddons and Davies, 1973) of the same type of generator, unpredicted failure accounted for 12 per cent of the removed generators as compared to 16.6 per cent in this series. Simpler methods of follow-up, therefore, seem to be acceptable at least for asynchronous units.

Estimates of the prevalence of heart block (Sowton, 1968b); Eraut, Evans, and Shaw, 1973) suggest that there are between 12,000 and 20,000

patients in the United Kingdom. Only a minority of patients who would benefit from permanent pacing are treated in this way, mainly in specialist cardiac centres with considerable technical facilities. However, if the majority of patients with heart block are to be treated facilities must be made more widely available. Many district general hospitals now provide temporary pacing facilities and little further expertise would be necessary to extend this work to permanent systems provided that the follow-up remained clinical rather than electronic. Experience in this series indicates that this is feasible.

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