Long-term follow up of cardiac pacing threshold using a noninvasive method of measurement

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SUMMARY Seventeen patients were followed up for a period ranging from 12 to 40 months after implantation of an Elema Vario pacemaker with an endocardial electrode. Two patients had a greater stimulation threshold beyond 6 months after implantation than the maximum threshold recorded before 6 months. One of these patients required replacement of the pacing system because of exit block. The 16 patients who retained their pacing systems showed, as a group, a statistically significant fall in stimulation threshold at 12 months after implantation despite continued pacing. These findings are important in relation to the occurrence and prediction of late exit block when long-life impulse generators are used.

The initial rapid rise in stimulation threshold after implantation of an endocardial pacing electrode has been well documented, and may continue over a period ranging from 12 days to 3 months or more (Grendahl and Schaaning, 1970; Preston, 1971; Contini *et al.*, 1973). After this time the mean pacing thresholds of groups of patients have been found to increase (Marchand *et al.*, 1969), to decrease (Gadaleta *et al.*, 1971), or to remain constant (Contini *et al.*, 1973). This inconsistency is explained by the reduction in numbers and the changing composition of the groups being studied as length of follow-up increases. Studying individual patients, Martinis (1972) failed to find a progressive increase in threshold between successive pacemaker box changes, but in dogs Albert *et al.* (1964) found a progressive increase in threshold up to 30 months after implantation.

The initial rise in threshold has been shown to occur whether the electrode is used for pacing or not, and is thus the result of a local foreign body reaction (Westerholm, 1971; Contini *et al.*, 1973). To explain the continued slow rise in threshold over a more prolonged period in some patients, it has been suggested that local tissue damage continues as a result of the pacing current, and that the intensity of damage is directly related to the local current density (Marchand *et al.*, 1969).

The present investigation was undertaken to establish whether or not a long-term threshold rise took place, using a pacing system where threshold determinations could be carried out at intervals

during follow-up, noninvasively, using the implanted system itself. If continued threshold rise did occur, it was hoped to be able to record this and thus forestall a rise in threshold in excess of the output voltage of the pacemaker, leading to failure of pacing. Such a failure of pacing caused by excessive threshold rise is termed 'exit block'.

Patients and methods

Eighteen patients received an Elema-Schonander EM 169/70 Vario pacemaker and were followed for a period ranging from 12 to 40 months. The pacemaker was implanted in the pectoral region and connected to a unipolar transvenous electrode. The use of this unit and the method of implantation are described by Roy and Sowton (1974). Threshold measurement was carried out at the time of implantation and at the time of replacement of the impulse generator, using a Devices Type E 4161 external demand pacemaker with impulse duration of 2.0 ± 0.15 ms and voltage settings at 0.1 volt intervals. The threshold was taken as the highest voltage at which an impulse failed to depolarise the ventricles.

It might be expected that the longer impulse duration of the Devices E 4161 pacemaker would result in a lower stimulation threshold than the shorter impulse duration (1.0 ms) of the Elema Vario unit. However, Davies and Sowton (1966) showed that the curve of threshold voltage against impulse duration was exponential in form, and that for an increase in impulse duration from 1.0 to 2.0 ms the drop in threshold voltage was very small.

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Threshold values obtained using the Devices and Elema units were, therefore, taken to be equivalent. All measurements obtained with the Devices E 4161 were expressed to the next highest multiple of 0.35 volt in order to correct for any apparent difference in threshold caused by the greater accuracy of measurement possible with this unit.

Shortly after implantation and once during the follow-up period, standard posteroanterior and left lateral chest x-rays were taken. After implantation and at each follow-up visit the impulse waveforms of the pacemaker were subjected to analysis of rate, voltage, and duration in electrocardiographic leads I, II, and III, using a Nukab pacemaker impulse analyser HIA 1 (Rydén *et al.*, 1970).

Cases were excluded if movement of the tip of the electrode in any direction between initial and subsequent chest x-rays was greater than 2 standard deviations for the group as a whole. Cases were also excluded if the change in frontal plane vector of the leading edge of the pacemaker artefact was greater than 2 standard deviations for the group (Green, 1971).

The thresholds in the individual patients at intervals after implantation were compared with the maximum threshold recorded in the first 6 months after implantation by means of Student's *t* test for paired comparisons. (In one case no threshold measurements were made between 5 weeks and 7 months, and the 7-month value was used for the comparison.)

Results

Of the 18 patients studied, 1 was excluded because of excessive movement of the electrode tip on chest x-ray. Of the remaining 17, all were followed for 12 months, 13 for 18 months, 10 for 2 years, and 7 for 2½ years.

The 17 individual plots of pacing threshold against time are shown in Fig. 1 to 4. The general trend of the cases in Fig. 1, 2, and 3 can be seen to be one of a slow fall in threshold or no change after 6 months of follow-up. The 3 patients with late rises in threshold are shown together in Fig. 4. Of these 3 patients, 2 had a higher threshold 6 months or more after implantation than the highest recorded before that time. One of these 2 had shown an excessive rise in threshold with previous pacing systems, and the rise on the present occasion was to 6.0 volts, necessitating replacement of the system (dotted line, Fig. 4).

When the thresholds for all the patients at 6-monthly intervals after implantation are compared with the same patients' maximum recorded values during the first 6 months, a fall in threshold is

Fig. 1 Endocardial pacing threshold against time after implantation: cases 1 to 5. After 6 months, threshold is steady or shows a downward trend.

Fig. 2 Endocardial pacing threshold against time after implantation: cases 6 to 10. After 6 months, threshold is steady or shows a downward trend.

Fig. 3 Endocardial pacing threshold against time after implantation: cases 11 to 14. Two patients show a transient, small, late rise in threshold.

Fig. 4 Endocardial pacing threshold against time after implantation. Case 15: patient with distinct late rise in threshold on one reading only. Case 16: patient with progressive rise in threshold, greater than previous maximum threshold at 7 months. Case 17: patient with progressive rise in threshold, leading to exit block at 28 months.

Table Statistical significance of fall in pacing threshold at stated intervals after implantation

Interval after implantation (mth)	No. of cases	t	P
12	16	-3.35	<0.005
18	12	-2.74	<0.02
24	10	-2.58	<0.05
30	7	-2.40	<0.05

apparent for the group as a whole. This fall is only statistically significant at 12 months after implantation ($t = -2.83$, $P < 0.02$). If the single case requiring system replacement because of threshold rise is excluded, the threshold fall for the remainder is statistically significant at all times up to 30 months after implantation (Table).

Discussion

Only one patient (6%) in the present series required replacement of the electrode because of excessive threshold rise, a similar incidence to that found elsewhere. Brenner *et al.* (1974) found that 3 out of 28 patients with endocardial electrodes (11%) developed exit block, in all cases within six months of implantation. Berning and Larsen (1976) found that 11 (9%) of 125 patients developed exit block, 5 in less than and 6 in more than 6 months after implantation; follow-up was for at least 18 months in three-quarters of the cases.

To exclude the possibility that late rises in thresh-

old had been prevented in the present series by a return of normal conduction and cessation of pacing, the electrocardiograms of 12 patients with falling thresholds were examined; in 11 of the 12 pacing was continuing. The results thus indicate that, in general, a progressive rise in endocardial stimulation threshold does not occur after the first 6 months following implantation, and that there is a tendency to a reduction in threshold despite continued pacing.

With increasing longevity of pacemaker impulse generators, it is of practical importance to be able to detect those cases where a progressive threshold rise is occurring. The Elema Vario system used in the present study has the advantage that threshold estimation may be carried out noninvasively. The results presented suggest that late exit block may be preceded by a rise in stimulation threshold continuing beyond the first six months after implantation, so that the threshold then exceeds the maximum recorded before that time. If this suggestion is correct, the use of a Vario type system in lithium iodide and plutonium powered units would make it possible to forestall sudden pacing failure caused by late exit block.

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