Displacement of pacemaker leads—a 10-year survey

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SUMMARY Displacement of endocardial pacemaker leads from the initial site at the time of implantation is a major cause of unpredictable pacemaker failure. In this survey, we have made a retrospective study of the effectiveness of the attempts made by two manufacturers to design leads to reduce the frequency of this occurrence. The cumulative displacement records of 5 types of leads (Medtronic types 5818, 6904, 6901, and 6950, and Cardiac Pacemakers Inc. type 4210) have been studied, and show that Medtronic 5818 and 6950, and CPI 4210 leads are superior in this respect.

During the past decade the major problem in permanent pacing of the heart has been premature battery exhaustion. Intensive research on suitable long-lived power sources produced the various kinds of lithium cell, which are predicted to lose power gradually in contrast to the often catastrophic failure of the mercury cell. The subsequent increase in the use of these pacemaker generators employing power sources which promise a longer generator lifetime places greater emphasis on the need to implant leads whose design will permit a problem-free lifetime of the same order as that of the generator. The major problems occurring in the use of endocardial pacemaker leads are displacement of the tip of the lead, fracture of a conductor, high threshold, extrusion, and insulation failure.

There will clearly be a broad range of displacements from the extreme case of movement of the tip into the vena cava to the microdisplacement which may well be attributed to 'high threshold'. In this work we consider only those displacements which have been shown either by *x*-ray examination or by a significant change in the direction of the frontal plane vector of the pacemaker stimulus (Green, 1971). The displacement records of 5 types of leads have been analysed retrospectively over a 10-year period to determine whether some types suffer fewer displacements than others.

Material and methods

Details of the construction of each type of lead used are shown in Table 1 (see also Fig. 1). The Medtronic leads 5818 and 6904 are cylindrical between the electrodes, the main difference between

the two types being a reduction in the area of the distal electrode of the 6904 to achieve lower pacing thresholds. The Medtronic 6901 and Cardiac Pacemakers Inc. 4210 leads were specifically designed to reduce the incidence of displacements, the flange behind the distal electrode trapping the tip in the trabeculae until endothelial growth secures a stable position. The design of these two leads is similar but the 4210 has triple-wound helical coil conductors to provide fail-safe protection against fracture of one conductor. In a further attempt to achieve stable fixation of the distal electrode, Medtronic introduced the 6950 lead which has 4 flexible silicone rubber tines as an integral part of the body. These tines are designed to be entrapped firmly in the trabeculae.

The usual procedure in Glasgow (Forbes *et al.*, 1968) for placement of the lead tip has remained unchanged during the 10-year period of the survey. The data reported in this survey were extracted from the computer data bank used in Glasgow for storage of information on all pacemaker operations (Green and Reekie, 1975).

Displacements were often detected within 7 days of initial implantation, before the patient was discharged from hospital, when failure of the

Table 1 Construction of leads analysed in survey

Model	Conductor	Distal electrode diameter (mm)	Area (mm ²)	Tip
Medtronic 5818	Single helix	3.2	53	Plain
Medtronic 6904	Single helix	3.2	15	Plain
Medtronic 6901	Single helix	2.2	11	Flange
CPI 4210	Triple helix	2.3	12	Flange
Medtronic 6950	Single helix	2.2	11	Tines

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Table 2 Analysis of pacemaker lead failures

Model	No. used	Lead extrusions*	Failed conductors	Failed insulation	Increased threshold	Clinical complications†	Total displacements	Displaced within 12 months	Total lead failures
Medtronic 5818	417	19	21	9	18	20	48	30	135
Medtronic 6904	225	4	10	—	16	14	36	31	80
Medtronic 6901	57	2	1	—	4	—	11	11	18
CPI 4210	145	1	—	—	2	2	6	6	11
Medtronic 6950	95	—	—	—	2	—	6	6	7

* Extrusion of lead at or near wound site.

† Including infection of generator site and/or extrusion of the generator.

pacemaker to capture the ventricle was shown on the monitor or during routine electrocardiographic recording. Lateral and anteroposterior x-ray films were sometimes sufficient to confirm displacement of the tip of the lead, especially if films obtained immediately after implantation were available for comparison. In patients with little pacemaker dependence, even major displacements sometimes remained undetected until, at a pacemaker clinic visit, a change in the direction of the frontal plane vector of the pacemaker stimulus artefact was observed (Green, 1971), indicating a displacement which was subsequently confirmed by x-ray examination. However, occasionally small displacements producing loss of capture were not demonstrable on either x-ray film or vector evidence, but were confirmed by fluoroscopy when the tip was seen to be mobile within the ventricle.

The records of displacements observed during the use of these leads were analysed using the 'actuarial method' or 'cumulative survival method' introduced to pacemaker analysis by Schaudig *et al.* (1975) and Greatbatch (1975). This method allows the evaluation of the cumulative survival time of the leads without displacement, when the periods of observation differ for each patient. Leads which have been implanted for a certain time without

being displaced are included in the survival curve up to that time. In this survey, extending from 1 April 1968 to 31 March 1978, 939 endocardial leads were implanted in 792 patients.

Results

Lead displacement accounted for 42.6 per cent of all lead-related pacemaker failure (Table 2). The risk of displacement is greatest in the period after initial implantation of the lead before the tip is anchored in contact with the endocardium by the growth of fibrous tissue. Displacements within the first 12 months after the initial implant comprised 78.5 per cent of all displacements (Table 2) and this period has been considered in greater detail.

An example of the analyses performed is shown (Table 3) for the Cardiac Pacemakers Inc. (CPI) type 4210 lead after initial implantation. Column A ('incomplete lifetime') shows the number of leads which have not yet reached the end of that 1-month period. Column B ('curtailed lifetime') shows the number of leads ceasing to function for any reason in that 1-month period and includes those displaced leads which were then abandoned rather than re-manipulated; it also includes leads lost to follow-up. Only demonstrable displacements within the

Table 3 Cumulative stability for CPI 4210 lead after initial implant

Age (mth)	(N) Number of leads	(A) Incomplete lifetime	(B) Curtailed lifetime	(D) Number displaced	(T) Total (A+B)	(X) Number at risk $\left(N - \frac{T}{2}\right)$	Fraction displaced $\left(F = \frac{D}{X}\right)$	Fraction stable (S=1-F)	Cumulative stability $\left(GS = 1 - \frac{\Sigma D}{X}\right)$
1	145	5	10	4	15	137.5	0.029	0.971	0.971
2	130	7	3	1	10	125.0	0.008	0.992	0.963
3	120	4	2	—	6	117.0	0	1.000	0.963
4	114	4	1	—	5	111.5	0	1.000	0.963
5	109	8	1	—	9	104.5	0	1.000	0.963
6	100	3	1	—	4	98.0	0	1.000	0.963
7	96	4	3	1	7	92.5	0.011	0.989	0.953
8	89	11	—	—	11	83.5	0	1.000	0.953
9	79	7	—	—	7	74.5	0	1.000	0.953
10	71	12	—	—	12	65.0	0	1.000	0.953
11	59	7	—	—	7	55.5	0	1.000	0.953
12	52	12	—	—	12	46.0	0	1.000	0.953

Fig. 1 Construction of tip of endocardial lead (a) Medtronic 5818, (b) Medtronic 6904, (c) Medtronic 6901, (d) Cardiac Pacemakers Inc. 4210, (e) Medtronic 6950.

right ventricle, into the right atrium, or into the vena cava, have been shown in column D.

The cumulative stability of each type of lead after initial implantation is shown in Fig. 2. For each type there is a relatively high displacement rate in the first 2 months before a more gradual rate of displacement is established over the remainder of the 12 months. The 3 lead types 4210, 6950, and 5818 show a considerably lower displacement rate than the 6904 or 6901 over the first 2 months.

Discussion

The overall rate of demonstrated displacement of endocardial leads in Glasgow is 11.3 per cent which is similar to the average value found from other reports (Table 4). It is essential to have a clear definition of lead displacement since, though many displacements are apparent on the x-ray film, a number can be shown only by careful fluoroscopic

Fig. 2 Cumulative stability after initial implant.

examination. Minute displacements of the catheter tip are impossible to differentiate from tissue reaction at the tip, since with both an increased stimulation threshold is found at reoperation. Many of the reports summarised in Table 4 fail to specify the criteria used to determine displacement of the lead. The position of the tip of the lead was

Table 4 Published displacement rates

Authors	Number of leads	Displacement rate per cent
Berning and Larsen (1977)	130	20.8
Bette <i>et al.</i> (1975)	1085	11.4
Bilitch (1975)	569	18.0
Buffle (1976)	98	15.0
Charles <i>et al.</i> (1977)	164	15.9
Edhag (1969)	260	17.3
Grendahl and Sivertssen (1977)	232	11.2
Griesenbeck and Pesendorfer (1975)	323	12.7
Grögler <i>et al.</i> (1975)	770	10.1
Haghfelt <i>et al.</i> (1974)	176	15.9
Havia <i>et al.</i> (1977)	98	11.2
Johansen <i>et al.</i> (1977)	159	23.9
Kalmar <i>et al.</i> (1975)	672	15.8
Kostiainen (1977)	151	20.5
McGuire <i>et al.</i> (1977)	?	11.4
Ohm <i>et al.</i> (1977)	213	5.6
Renyi-Vamos <i>et al.</i> (1977)	826	17.4
Säuberli <i>et al.</i> (1972)	199	17.1
Schaudig <i>et al.</i> (1975)	396	18.9
Stertz <i>et al.</i> (1976)	186	3.0
Venere <i>et al.</i> (1975)	148	6.3
		Average 14.3
Glasgow	944	11.3

noted by Johansen *et al.* (1977), Kostiainen (1977), and Ohm *et al.* (1977), and Bette *et al.* (1975) and Grendahl and Sivertssen (1977) indicate that displacement was determined by x-ray. Only Berning and Larsen (1977) state that they use x-ray film and fluoroscopy and would therefore be in a position to identify small displacements not apparent on x-ray films alone.

Attempts to design leads which will overcome the problem of displacement appear to have achieved some success. The CPI 4210 lead, introduced in October 1976 and with similar configuration to the Medtronic 6901, has shown a much lower displacement rate, possibly because the triple-wound conductors impart a slightly greater rigidity to the electrode loop in the atrium which helps to maintain contact with the endocardium until fixation occurs. The shorter flange of the CPI 4210 lead will also be trapped within the trabeculae closer to the myocardium. The Medtronic 5818 lead also has a greater rigidity than the Medtronic 6901 and 6904 leads and shows a displacement rate similar to the CPI 4210 and Medtronic 6950 leads. The Medtronic 6950 lead, first used in November 1976, is proving equally successful in preventing lead displacement, especially after fixation by fibrous growth is established, because there is a greater surface area available over which endothelial tissue can grow.

Conclusions

It is increasingly important to make careful measurements at the time of implantation, of stimulation threshold, tissue impedance, and R-wave amplitude as the use of leads of improved design will result in a greater proportion of minute displacements which will be recognised only by the appearance of exit block or by a rapid increase in threshold. Lead displacement has been shown to occur most frequently in the 2-month period immediately after implantation with all 5 types of leads. The new designs of leads are proving effective in reducing the frequency of lead displacement. Follow-up of patients during the weeks after operation is concerned mainly with the possibility of lead failure, but thereafter with the possible occurrence of generator malfunction or clinical complications.

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