

Potential candidates for pacemakers

Survey of heart block and sinoatrial disorder (sick sinus syndrome)

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SUMMARY Future pacemaker requirements in Britain are related to the incidence of heart block and sinoatrial disorder (sick sinus syndrome) in the community. This paper reports an 8-year survey of these conditions by direct approach to the general practitioners looking after approximately 600 000 people. The patients were divided into 4 non-exclusive groups (numbers of patients are in parentheses); chronic complete heart block (436), sinus bradycardia (potential and established sinoatrial disorder) (305), established sinoatrial disorder (131), and paced patients (209). Patients with sinoatrial disorder and sinus bradycardia were some 10 years younger than those with heart block and their prevalence tended to decline in the very old, whereas the prevalence of heart block continued to increase almost exponentially, exceeding 5 per 1000 in men aged 80 and above.

Only a minority of patients gave a past history of cardiac infarction or diphtheria, but both conditions were commoner in sinoatrial disorder (16% and 14%, respectively) than in complete heart block (9% and 8%, respectively). A surprising finding was that men predominated in all groups, particularly in those with sinus bradycardia where the male:female ratio was 2.5:1.

The annual number of new paced patients rose during the course of the survey, reaching 73 per million (per year) by the seventh and eighth years, but the annual incidence of conditions producing bradycardia and potentially requiring pacemaker therapy was still much greater at 159 to 174 per million of the population.

In Britain the number of initial implantations of cardiac pacemakers has almost trebled since 1972 and it is predicted that there will be a further three-fold increase in the next 5 years (Sowton, 1976). In view of this dramatic rise in the use of such expensive and sophisticated equipment it might be expected that the incidence and aetiology of the main conditions requiring pacemaking, namely heart block and sinoatrial disorder, would be well known, but in fact the lack of epidemiological data on heart block has been bewailed by Campbell as recently as 1977. Data on sinoatrial disorder are even more scarce (*British Medical Journal*, 1977), while the problem is compounded by the absence of a clear-cut definition of the condition. In the past coronary artery disease was blamed for both chronic heart block and sinoatrial disorder, and if this were correct the current 'epidemic' of ischaemic heart disease should be followed by an increase in their

incidence. There is now general agreement that cardiac ischaemia is not the usual cause of heart block, but its place in the aetiology of chronic sinoatrial disorder is still in dispute (Scarpa, 1976; Shaw, 1976). The study reported here was started in 1968 in the endeavour to discover the annual incidence of patients reporting to their doctors with complete heart block or sinoatrial disorder. In addition it was hoped to gain some information concerning the aetiology of sinoatrial disorder by comparing the frequency in the past history of possible causative factors in the two conditions.

Plan of study

The survey was started in the autumn of 1968. The doctors in the Devon Clinical Area were written to annually and asked to report any of their patients suspected of having heart block or found to have persistent bradycardia (resting pulse rate below 56 per minute on 2 occasions), even if asympto-

Table 1 1971 census population figures for England and Wales and for the survey area of Devon

Age	0-9	10-19	20-29	30-39	40-49	50-59	60-69	70+
England and Wales								
Male	8.6	7.3	7.1	5.9	6.2	5.8	4.8	2.8
Female	8.2	6.9	7.0	5.7	6.3	6.2	5.8	5.3
Survey Area								
Male	6.9	6.5	6.0	4.8	5.4	5.8	6.6	4.9
Female	6.6	6.3	5.9	5.0	5.9	6.9	8.4	8.4

Figures expressed as percentage of total populations.

matic. If no reply was received to the first inquiry, further letters were sent up to a total of 3. During the past 3 years the letters have been supplemented by visits to the doctors' surgeries by a member of the Cardiac Department. No lower age limit was given, but owing to the pattern of referral of children in Devon it was expected that few patients in the paediatric age group would be notified. During the period of the study, the population of the area has risen. The 1966 sample census gave a figure of 578 000, whilst the Executive Council lists for practitioners gave a figure of 581 000. The full census in 1971 gave a population of 611 640 (Table 1 gives details of age and sex), against a family practitioner service population of 611 293. In 1976 the family practitioner service population was 646 958.

All notified cases were investigated, provided that both the family doctor and patient agreed to the examination. Patients were usually seen in the Cardiac Department, but if they were unable to make the journey into Exeter they were visited at home. After a general history had been taken, specific questions were asked concerning drug therapy and past history of cardiac infarction, rheumatic fever, diphtheria, arthritis (including osteoarthritis, rheumatoid arthritis, Reiters syndrome, and ankylosing spondylitis) and cerebrovascular accident. The particular symptoms sought were syncope, dizzy attacks, angina of effort, and breathlessness on exertion. A routine physical examination was carried out and a count taken of the heart rate at rest and after mild exertion. A 12-lead electrocardiogram was recorded, including a 3-foot continuous strip of lead II in all cases. If there were any uncertainty concerning rhythm or conduction, further records were taken on a multichannel Mingograph recorder and if doubt remained the cardiogram was monitored for 24 hours on electro-magnetic tape. In patients undergoing assessment with a view to permanent pacing, intracardiac conduction was studied by His bundle electrocardiography and sinoatrial function was measured by the overdrive suppression test (Mandel *et al.*, 1971).

Classification and criteria for admission

This paper is concerned with 4 groups of patients: group 1: complete heart block; group 2: sinus bradycardia (sinoatrial disorder and potential sinoatrial disorder); group 3: sinoatrial disorder; group 4: paced patients.

Patients were admitted to the heart block group (group 1) if they had at any time had electrocardiographic evidence of third degree atrioventricular block in the absence of recent treatment with digitalis-like drugs, verapamil, or beta-blocking agents. Those in the acute phase of rheumatic fever, pericarditis, or myocardial infarction (infarction within the preceding month) were excluded. Patients with atrial fibrillation, flutter, or tachycardia were excluded unless the ventricular rate was under 56 a minute (in the absence of digoxin or similar drugs) and the RR interval was constant.

Group 2 (sinus bradycardia) consisted of patients with a pulse rate below 56, in the absence of myxoedema, raised intracranial tension, jaundice, or myocardial infarction within the preceding month, or the recent use of hypotensive drugs, beta-blocking agents, or any other drug known to affect heart rate. Athletes currently in training would have been excluded had they been reported.

Patients were considered to have established sinoatrial disorder (group 3) if in addition to sinus bradycardia as defined for group 2, the electrocardiogram showed one or more of the following: (i) periods of sinus arrest or sinoatrial block in which cessation of atrial activity persisted for 2 seconds or more, (ii) profound atrial slowing (below 40 per minute with or without junctional rhythm), (iii) tachyarrhythmias, namely atrial fibrillation, atrial flutter, or paroxysmal atrial or ventricular tachycardia.

The pacemaker group (group 4) included all patients fitted with a permanent pacemaker for more than 28 days, who survived to be discharged from hospital and who lived within the survey area. Patients referred for pacemaker implantation from Cornwall, Plymouth, and East of the Devon and Somerset Border were excluded, as were those fitted with pacemakers while on holiday in Devon.

Table 2 Number of doctors in area and number replying each year

Year	1968	1969	1970	1971	1972	1973	1974	1975
Survey year	1	2	3	4	5	6	7	8
Doctors in area	290	278	285	292	303	308	305	316
Doctors replying	282	273	253	272	293	296	303	307
Cases reported	181	121	136	154	182	129	128	169

Once in the survey, patients were seen at least annually and their classification changed if necessary. From 1970 onwards the death registration forms for the area have been scanned and the cases registered as dying with heart block have been checked against the known cases in the survey to try and assess the degree of under reporting.

Results

The family doctors in the area were co-operative, replies being obtained from over 96 per cent in 6 of the 8 survey years (Table 2). There were 742 patients who fulfilled the criteria of 1 or more of the 4 groups and a further 6 potential cases declined to be seen or died before an electrocardiogram was recorded. Nineteen patients were common to both groups 1 and 2, and 11 were in groups 1 and 3. Lesser abnormalities of conduction were present in 14 patients in group 2 and 6 patients in group 3. By definition all those in group 3 were also in group 2, 130 of the 131 cases had sinus rates below 50 per minute, 65 had sinus arrest, 69 had gross bradycardia (usually junctional rhythm), and 59 had 1 or more forms of tachyarrhythmia. Group 4 (those with pacemakers) included 18 cases of partial heart block and 2 cases of sinoatrial block, in addition to the 189 patients from groups 1 to 3 (shown in parentheses in Table 3).

Patients with bradycardia and sinoatrial disorder tended to be younger than those with complete heart block and the difference between the mean values was significant ($P < 0.001$ by the Kolmogorov-Smirnov 2 sample test, used because of the skew distribution). The mean age at presentation was 60 for group 2, 62 for group 3 and 73 for group 1

Table 3

Condition	Group No.	Total patients	Sex ratio M-F	Age Mean and SD
Complete block	1	436 (149)	1.3:1	73 ± 14
Bradycardia	2	305 (46*)	2.5:1	60 ± 17
Sinoatrial disorder	3	131 (33†)	2.1:1	62 ± 16
Pacemaker	4	209 (209)	1.5:1	68 ± 11

Figures in parentheses refer to the number of paced patients in each group.

*6 paced patients also in group 1.

†4 paced patients also in group 1.

(Table 3). There were more men than women in all groups, the highest sex ratio being 2.5:1 in group 2. The male dominance was present throughout the age range (Fig. 1).

In the period 1970 to 1976 heart block was mentioned either as a primary or subsidiary cause of death on the death certificate in 155 cases. In 100 cases the type of block fulfilled the criteria for group 1 and 97 of these had already been reported to the survey. Fourteen were associated with acute myocardial infarction or were ineligible on other grounds. In 41 cases data of the type and degree of heart block were unobtainable.

The numbers of new patients reported each year in the 4 groups are given in Table 4. Inevitably the figures from the first survey year (column 1, Table 4) include both new and established cases, so that they cannot be used in estimating the incidence of the conditions under study. In succeeding years the new cases of complete block (group 1) have varied from 41 to 54 up to the eighth year in which there were 68. In view of this apparent increase, the incidence was examined for a further year and 58

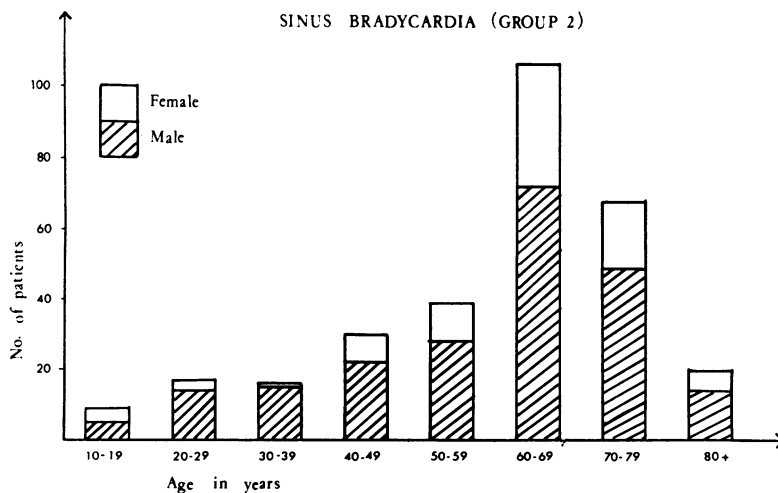


Fig. 1 The numbers of patients in group 2 are plotted according to their age on entering the survey in 10-year cohorts from the age of 10. Women and men are represented by open, and cross-hatched sections of the columns, respectively.

Table 4 Annual rate of new cases in the 4 groups

Group	Survey year							
	1	2	3	4	5	6	7	8
1	(93*)	42	47	46	54	45	41	68
2	(34)	21	35	27	50	48	40	50
3	(24)	6	16	10	19	20	15	21
4	(13)	9	13	23	33	23	48	47

*Not necessarily new cases—see text.

cases were found. Including the extra year a mean of 50 new cases were found per year, implying an incidence of 82 per million (assuming the 1971 census population), but if only the last 2 years are considered, the annual incidence becomes approximately 97 per million for the 1976 family practitioner population of the area. In groups 2 and 3 the number of new cases tended to increase over the first few years, becoming fairly stable from the fifth survey year onwards, with a mean of 47 for group 2 and 19 for group 3 (incidence for 1971 census population 77, and 31, per million, respectively). The figures for group 4 tended to rise throughout the survey. Taking the mean of the last 2 survey years and assuming that the 1976 population for the area was approximately 647 000, the annual pacemaker implantation rate was 73 per million.

The prevalence of complete heart block rises sharply with age. Fig. 2 gives the age distribution of the 235 patients with complete heart block in the survey and alive on 1 January 1976 expressed as the prevalence per 100 000 patients at risk in the population (overall prevalence 36 per 100 000). The age bracket 0 to 9 has been omitted since, by the nature of the conditions of the survey, cases in the paediatric age group are particularly likely to have been missed. However, even in the age brackets 10 to 40 the prevalence is less than 5 per 100 000, whereas above the age of 75 the prevalence is well above 2 per 1000, and exceeds 5 per 1000 in men aged 80 and above.

None of the potential aetiological factors sought in the past history proved to be common (Table 5). Indeed, approximately half of the patients in every group were free from significant disease. Arthritis was recorded in 19 to 26 per cent of patients in all groups. Though only a minority of patients gave a past history of cardiac infarction it was significantly commoner in groups 2 and 3 than in group 1 ($P < 0.01$ χ^2 test). Approximately 10 per cent of patients had had rheumatic fever and there was no significant difference between the groups ($P > 0.5$ χ^2 test). A past history of diphtheria was obtained in rather more patients in groups 3 and 4 (15%), than in groups 1 and 2 (8% and 9%, respectively), and the difference between groups 1 and 3 was

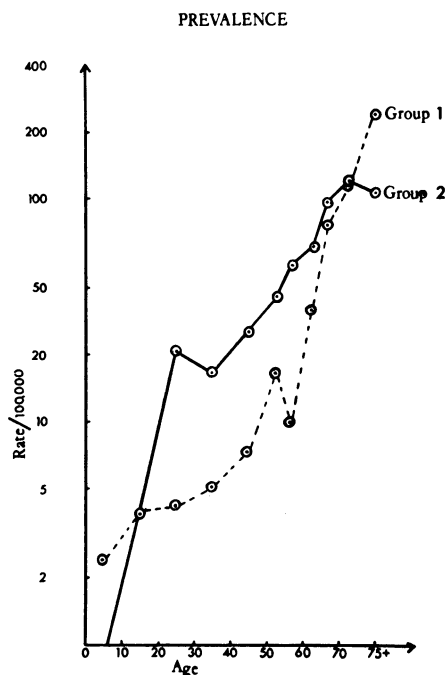


Fig. 2 The prevalences of heart block and sinus bradycardia are plotted on a semilogarithmic scale for different age groups. The mean of cohorts of 10 years are given up to the age of 50 years, after this points are plotted at 5-year intervals up to the age of 75.

significant to the 5 per cent level. Other potential aetiological factors in the present or past history such as diabetes, thyroid disease, congenital heart disease and cardiomyopathy, were present in less than 5 per cent of patients.

Discussion

Previous attempts to estimate the incidence of complete heart block from highly selected hospital statistics have been criticised by Siddons and Sowton (1967), while Thalen *et al.* (1969) comment 'accurate details on the occurrence of complete A-V block do not exist'. Averill and Lamb (1960)

Table 5 Comparison of probable aetiological factors (not mutually exclusive) in past history of patients in groups 1 to 4

Past history	1	2	3	4
Cardiac infarction	37 (8%)	48 (16%)	21 (16%)	28 (13%)
Rheumatic fever	38 (9%)	32 (10%)	14 (11%)	20 (10%)
Diphtheria	35 (8%)	27 (9%)	19 (15%)	31 (15%)
Arthritis	95 (22%)	78 (26%)	26 (20%)	40 (19%)
None of these	244 (56%)	145 (48%)	61 (47%)	121 (58%)

surveyed the electrocardiograms from 67 375 normal service personnel and recorded only a single case of complete heart block, but the subjects were predominantly young men, so that the findings cannot be applied to the general population. The closest approximation to the study reported here is that of a population of approximately 250 000 living around Malmö in Sweden served by a single cardiac department (Johansson, 1966). Analysis of all electrocardiograms recorded over a period of 14 years gave an incidence for heart block of 63 patients per million inhabitants per year, including cases caused by acute myocardial infarction and digitalis intoxication. Excluding these 2 groups the incidence of chronic complete block was 39 per million (B. W. Johansson, 1977, personal communication). It is not surprising that the figure for comparable cases in Devon is over double (82 to 97 per million) both because the current increased use of pacemakers has alerted doctors to the condition of heart block, and because a direct approach was made to the general practitioners in the area rather than relying on cases referred to a hospital department. Indeed, in the pilot study of the Devon survey (Shaw and Eraut, 1970), 29 out of 100 patients with heart block had never attended hospital either as inpatients or outpatients and so could not have been traced by a hospital-based system of search. Any survey of the incidence of a condition must give an underestimate since many cases will escape diagnosis and a proportion of those discovered may not be reported. Nevertheless, if the objective is to discover potential candidates for pacemakers, the relevant figure is the number of such subjects known to the general practitioner, since only these can be referred for treatment. Some indication of the margin of error in the reporting of patients with heart block to the present survey can be obtained from the Death Registration Forms. In cases with adequate data the proportion already known to the survey was high (97 out of 100). Unfortunately in about a third of the deaths the information was insufficient to assess whether the criteria for admission to the survey were met. In practice this very lack of data implies that at least in the majority of these cases the patient was not known to the general practitioner as a case of chronic complete heart block. It seems likely, therefore, that the majority of known cases have been reported and that for diagnosed cases the mean incidence for 1975 and 1976 of 97 per million is of the correct order.

Estimation of the incidence of sinoatrial disorder is much harder than that for complete heart block, both because of the lack of a clearcut definition and because the faster pulse rate and less dramatic symptoms make the condition harder to diagnose.

Several of the 'pathological rhythms' associated with the condition have been found in athletes and in normal subjects studied by 24-hour electrocardiogram tape monitoring (Clarke *et al.*, 1976). However, it is unlikely that the arrhythmias recorded at routine electrocardiography in the present study could be physiological and the major error is likely to be that of omission of cases. Indeed, known instances of sinoatrial disorder were excluded from groups 2 and 3 because of the difficulty of establishing criteria which could easily be applied in a general survey of this kind; 5 patients with sinoatrial block, including 2 with periods of cardiac arrest necessitating permanent pacing, were discovered, but were not eligible for group 2 since random atrial rates of below 56 had not been recorded. In addition it is likely that a number of patients with sinus bradycardia (group 2) but lacking all the criteria for group 3 had sinoatrial disorder, since evidence of abnormality of other parts of the specialised cardiac tissue was present in 33 cases, and 13 were fitted with pacemakers. Thus the incidence of patients in group 2 is probably a truer reflection of the potential number of cases of sinoatrial disorder than that for group 3. Unfortunately sinus bradycardia and sinoatrial disorder very rarely appeared in death registration forms, so that this method of checking the adequacy of notification was useless and an alternative approach must be found for future studies.

In the past the incidence of sinoatrial disorder has been expressed in relation to heart block, the figure being derived from groups of patients being assessed for pacing. This is clearly unsatisfactory since the proportion of patients with the condition who are fitted with pacemakers is unknown. Furthermore, the percentage of patients with sinoatrial disorder in different series of paced patients differs widely. For example, recent reports give figures of 9 per cent (Hosoda *et al.*, 1974), 11.5 per cent (Radford and Julian, 1974), 13 per cent (Mond and Slowman, 1976), 15 per cent (Sauerwein *et al.*, 1976), 23 per cent (Härtel and Talvensaari, 1975), 24 per cent (Rokseth and Hatle, 1974), and 36.5 per cent (Furman, 1977), while in Exeter for 1975 and 1976 the percentage of all the pacemakers implanted (including cases from outside the survey area) was 27. Rokseth and Hatle (1974) reported that irrespective of whether a pacemaker was fitted the relative incidence of sinoatrial disorder to 'A-V block' was 34 per cent, though the degree of block was not defined. In Devon the relative incidence of patients with potential sinoatrial disorder was approximately equal to that of complete heart block at 48 per cent.

In the present study patients with sinus bradycardia both in groups 2 and 3 were on average over

10 years younger than those with heart block, and as with the group described by Rokseth and Hatle (1974) there was no evidence of a bimodal age distribution. Men outnumbered women by more than 2 to 1 in the patients with sinoatrial disorder. In the past some authors found a predominance of women patients (Rasmussen, 1971; Rubenstein *et al.*, 1972; Härtel and Talvensaaari, 1975), and others have reported no sex bias (Slama *et al.*, 1969). It seems unlikely that the male trend in the present study reflects any difference in criteria for sinoatrial disorder, since the male dominance is even greater in the larger pool of patients with sinus bradycardia. Again, the trend does not seem peculiar to any age group but rather occurs consistently throughout the full range (Fig. 1). Furthermore, from age 60 onwards women increasingly outnumber men in the population so that a male to female sex ratio of 0.8:1 might be expected if the individual chance was equal between the 2 sexes.

The male preponderance in sinoatrial disorder would be expected if it were usually the result of coronary artery disease as concluded in a recent review (Scarpa, 1976). However, though the incidence of ischaemic heart disease in sinoatrial disorder has been put as high as 71 per cent (Conde *et al.*, 1973) and 61 per cent (Härtel and Talvensaaari, 1975), it has also been reported as low as 14 per cent (Rokseth and Hatle, 1974), and 15 per cent (Fairfax *et al.*, 1976). The results in the present survey appear to be in close agreement with the latter 2 studies in that a past history of myocardial infarction was found in just under 16 per cent of instances of established and potential sinoatrial disorder. However, this was almost double the incidence of infarction in patients with complete block, so that it seems likely that coronary artery disease is relevant in a minority of cases. At least some of the discrepancies between past reports could be attributed to differences in definition. Thus in 1 series, 61 per cent of patients were considered to have coronary artery disease, yet a past history of myocardial infarction was present in only 20 per cent (Härtel and Talvensaaari, 1975). Presumably most of the rest were diagnosed on the basis of angina of effort, but some believe that this may itself be a manifestation of the bradycardia (Fowler *et al.*, 1969). Postmortem coronary angiography and histological examination of the sinoatrial node should be the final arbiters. So far very few necropsy studies have been reported in sinoatrial disorder, but the blood supply to the sinoatrial node was essentially normal in all the 8 patients examined after dying in the present survey (Evans and Shaw, 1977).

In addition to coronary artery disease, both diphtheria (Rasmussen, 1971) and rheumatic fever

(Rokseth and Hatle, 1974) have been suggested as possible causes for sinoatrial disorder, while Ferrer (1973) emphasises the multifactorial nature of the aetiology of the condition. It is not surprising that the incidence of potential aetiological agents should differ between different reports, since in general the number of patients with sinoatrial disorder in each series is small, and most come from major cardiothoracic surgical centres where the degree of selection must be considerable. The only selection in the present study is that the family doctor was aware of the bradycardia and reported the patient to the survey. It seems, therefore, that the findings here are likely to be more representative of the population as a whole than are previous series. The data do not indicate any dominant risk factor, but the considerable male bias in the sex ratio, particularly in the younger patients, is a new observation and may be of significance.

Predictions of future pacemaker requirements in Britain tend to be made by comparison with other Western countries, though even among these the current implantation rate varies from 110 per million for Canada to 270 per million for the USA (Sowton, 1976; Parsonnet and Manhardt, 1977). As Campbell (1977) points out, it seems better to base the forecast of pacemaker needs upon epidemiological data of the incidence of conditions requiring treatment. Certainly it seems likely that in some developed countries virtually all known cases of complete block are fitted with pacemakers, though the precise proportion who need them has not yet been established. Probably the majority in their 60's and 70's benefit from treatment, both in respect of mortality and quality of life. Data are lacking in the very old, but again a considerable proportion will require pacemakers. Now that the vogue for pacing cases of asymptomatic bifascicular block is waning, patients with incomplete block might be expected to form only a small proportion of new cases undergoing implantation. In sinoatrial disorder the future is uncertain, but the data from the present study can be used to set limits on the number of patients likely to be referred for treatment in this country. The combined annual incidence of patients with chronic complete heart block and potential sinoatrial disorder known to their general practitioners in Devon was 174 per million, which is remarkably close to the projected pacemaker implantation rate suggested by Sowton (1976).

We thank the clinicians of Devon for their consistent co-operation in the survey (Table 2 gives proof of their help), and Mr J. Gowers and Dr D. Morgan of the Institute of Biometry and Community

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