Pacemaker assessment in the ambulant patient

ALAN MURRAY, RICHARD S JORDAN, RONALD G GOLD

From the Regional Medical Physics Department and Cardiology Department, Freeman Hospital, Newcastle upon Tyne

SUMMARY A new technique for assessing implanted cardiac pacemaker function in the ambulant patient has been introduced and assessed. A modified portable electrocardiograph recorder is used to store 24 hours of electrocardiograms along with marker pulses indicating the timing of pacemaker impulses. The recorder detects this narrow impulse and records a wider marker pulse on a second channel.

The false positive detection rate was estimated from recordings, each of 24 hours, taken from 10 patients. All of these patients were ambulant and none had a cardiac pacemaker. There was on average less than one false positive per 24 hours. When similar recordings were taken from a group of 15 patients with pacemakers, the average false positive rate in 13 of these patients was also less than one per 24 hours. In the two other recordings artefacts resulted in false positive rates of 28 and 960 per 24 hours. Failure to detect pacemaker pulses was confirmed in only one patient.

In addition to determining the accuracy of pacemaker pulse detection, the clinical usefulness of this technique was assessed. Two patients had fixed-rate pacemakers and 13 had demand pacemakers. Of the latter, two patients had a total of three episodes of failure to sense, one patient frequently failed to capture, and six patients had episodes of inappropriate inhibition of the pacemaker, the number of episodes ranging from one to 21 in 24 hours.

Paced complexes were easily identified even when they occurred as fusion complexes. The frequency of paced complexes was quantified in each patient and varied from 21 to over 100 000 impulses in the 24 hour period.

The number of pacemaker implants continues to increase each year. In the United Kingdom over 4000 pacemakers were implanted during 1978, and in the USA this figure was 66 000.¹ In spite of the large number of devices which are now in use, there is no easy means of assessing the functioning of these pacemakers except when a patient visits, for example, a hospital out-patient department or uses highly specialised telephone transmission equipment. These measures are, of necessity, confined to assessment over very short periods. Many pacemaker problems, such as battery depletion, can be detected when the patient attends a pacemaker clinic but those of a transient nature are not so easy to detect. To evaluate the performance of a pacemaker while the patient is carrying out his normal daily activity poses problems, but is essential in a patient with an apparently normally functioning pacemaker who continues to complain of symptoms possibly related to pacemaker malfunction.

Received for publication 2 June 1981

Some centres have used ambulatory electrocardiographic recording techniques to help identify such transient failures. The more traditional use of such techniques, however, has been in helping to select patients who require pacing^{2,3} by, for example, detecting periods of sinus arrest.⁴⁻⁶

Boal⁷ described a number of patients in whom pacemaker malfunction was discovered. Some problems were easily identified, but in one patient even an eight hour electrocardiographic tape recording failed to discover any malfunction. This patient was finally admitted to the coronary care unit, and not until the second day were his symptoms related to a pacemaker problem.

Morganroth and Michelson⁸ described one case of intermittent failure to sense discovered by the use of an ambulatory tape recorder.

Bleifer *et al.*⁴ made 10 hour electrocardiographic recordings in 48 patients with suspected intermittent pacemaker malfunction, and discovered actual malfunction in nine.

Ward *et al.*⁹ recorded the electrocardiograms of 20 pacemaker patients for up to five days and observed one patient with inappropriate pacing and eight patients with evidence of failure to capture.

In using traditional electrocardiographic tape-recording techniques, care has to be taken to ensure that electrode sites are selected to give an electrocardiogram which is suitable for recording by producing a pacing pulse artefact which is visible on the electrocardiograph write-out. Because of its brief duration and fast rise-time the pacing pulse is not normally reproducible and requires a recorder with a high frequency response well above that normally available on electrocardiographic tape recorders.

Pulses which are frequently visible on direct paper records of electrocardiograms are reproduced because of the frequency response of the write-out used. Many electrocardiographs will record frequencies up to 400 Hz. Even in such cases the characteristics of the narrow pacing pulse will be greatly altered. Ambulatory electrocardiograph recorders will, at best, record up to 100 Hz, however, and more commonly only to 50 Hz. In addition to the recording problem the analysers used to detect and write out transient events often reduce the frequency content even further; an upper frequency response limit of approximately 30 Hz is not uncommon. The more important features of the surface electrocardiogram are still reproduced with this lower frequency range, but the original pacing pulses, if present, will have been lost.

The technique of recording pacemaker impulses using traditional electrocardiograph recorders works because the pacing pulse is so large that it results in a pacing pulse artefact that is much wider than the original pacing pulse. Unfortunately, this artefact is not always easily visible on the electrocardiographic recording, especially during periods of artefactual noise, such as from muscle, when it is especially important to know whether the pacemaker is subject to inappropriate inhibition. In addition, such a technique relies on a visual inspection of the electrocardiographic write-out after the important electrocardiographic events have been detected. Hence automatic analysis using the pacemaker pulse information is not possible.

Some developments have been made in attempting to record clear pacemaker pulses¹⁰⁻¹² and though they have shown that it is possible, the accuracy and usefulness of the technique have not yet been assessed. One disadvantage of the two systems described is that both require an additional unit which has to be connected between the patient and the recorder. The new system assessed below is self-contained.

Patients and methods

Ten ambulant patients who did not have an implanted cardiac pacemaker were used to assess the false positive pacemaker detection rate. Two patients with fixed-rate pacemakers were used to assess the false negative rate. A further 13 patients with demand pacemakers, who were also ambulant, were used for both the assessment of technical performance of the pacemaker detector and assessment of the clinical performance of the pacemakers.

PACEMAKERS

A variety of ventricular-inhibited demand pulse generators were used in this study. They included CPI 0501, Medtronic 5985, Medtronic 5929, Siemens Elema 627, Sorin LIT 222, Teletronics 161, Vitatron S3121 and Vitatron MIP 42RTa. The two fixed-rate pulse generators used were Sorin LIT 111 and Vitatron MIP 501T.

All pacemakers were of unipolar type and all electrodes were positioned endocardially at the apex of the right ventricle. Five pulse generators were positioned in the right prepectoral or axillary region, and 10 in the left.

RECORDING

Fig. 1 illustrates in block diagrammatic form the system in its fully developed form. The electronic pacemaker detector, which was inserted in a Medilog recorder, was developed by Reynolds Medical in conjunction with continuous assessment of several prototypes at Freeman Hospital. Though the development work is not discussed in this paper, reasons are given for the final selection made. Four channels of information are recorded:

Channel 1: Electrocardiogram used for rhythm analysis;

Channel 2: Marker pulse derived from pacing pulse;

Channel 3: Electrocardiogram from which pacing pulse is detected;

Channel 4: Elapsed time.

The electrocardiograph amplifier (ch1) and elapsed time generator (ch4) are standard Medilog modules. The electrocardiograph amplifier used for pacing pulse detection (ch3) is also standard except that an electrocardiographic signal of suitable gain has been brought out for routing through the Medilog recorder wiring to the pacing pulse module (ch2). This module is a completely new development.

The electrocardiogram recorded for rhythm analysis was obtained using our standard techniques. The chest was searched for electrode positions which resulted in an electrocardiogram with a QRS which was large, stable, and preferably monophasic and with

Fig. 1 Block diagram of electrocardiogram and pacemaker pulse recording system.

a small T wave. Any large muscle masses were avoided when applying the electrodes.

The second channel of the electrocardiograph, which was subsequently fed to the pacing pulse detector, was obtained by placing one electrode as close to the pacemaker as possible and the other electrode close to the apex of the heart. It was not necessary to avoid any muscle masses with these electrodes as the presence of muscle artefact did not result in any false positive detection.

As well as two electrodes for each electrocardiograph channel a further electrode was used (commonly referred to as the "right leg" or RL electrode). This was necessary to reduce the effect of sudden transient electrical interference or static pick-up on the patient which could then be relayed to the pacemaker pulse detector. Without this electrode the false positive detection rate on the preliminary assessment was considerably higher.

In order to reduce artefact pick-up all electrodes were applied with care. The skin area to which the electrode had to stick was cleaned with isopropyl alcohol and allowed to dry. The small electrode contact area was further cleaned with gauze to remove dead surface skin. Using such techniques a high quality electrocardiograph signal was obtained with little baseline instability or artefact. Low interference reduced the possibility of false positive pacemaker detection. Two of the 26 recordings made had serious baseline instability problems (see below).

The marker pulse derived from the pacing pulse on this electrocardiograph was approximately 60 ms long with the leading edge synchronous with the leading edge of the narrow pacing pulse. The majority of currently used pacemakers produce pacing pulses 0.25 to 0.8 ms long. The elapsed time indication was obtained by recording 60 pulses per second on the fourth channel.

The tape recorder was fitted with a locking device¹³ on the patient lead plug to prevent artefactual asystolic pauses¹⁴ which can be produced with movement of the plug.¹⁵

ANALYSIS

During analysis it was necessary to identify and separately scrutinise problems arising from the pacemaker detector as well as from the pacemaker itself. A simplified representation of more common problems is illustrated in Fig. 2. At the heart of the analysis system is a computer for fast storage of relevant electrocardiographic events detected during high speed replay of the tape recording.¹⁶ The selected electrocardiograms are held on computer disc until they have been edited by the operator. Electrocardiograms are automatically plotted when a hard copy is required. The system was originally designed to store 10 s electrocardiograph samples containing each detected arrhythmia. This same system was triggered by the pacemaker marker pulse to enable all paced beats to be examined.

As the majority of patients recorded, however, had many thousands of paced complexes, an accessory analysis unit was developed to enable unexpected pacing conditions to be detected and hence stored and plotted for subsequent examination. This unit could detect the following conditions in which the expected period approximated to the pacing period:

- A pacing pulse earlier than expected in relation to the previous QRS.
- Pacing pulse later than expected in relation to the previous QRS.
- QRS later than expected in relation to the previous QRS.

The unit takes account of the average delay between the pacing pulse and the QRS trigger point. In addition, an area of uncertainty 100 ms on either side of the expected time of a pacing pulse (a 200 ms blocking period) was built into the unit so that variable time differences between the pacing pulse and the trigger signal derived from the QRS of the surface electrocardiogram would not cause an excessive number of irrelevant electrocardiograms to be stored. Increasing the 200 ms blocking time would have reduced the number of electrocardiograms requiring editing but would also have increased the possibility of missing a

Fig. 2 Diagram of various pacing conditions and problems encountered.

pacemaker condition which should have been detected. As this paper is concerned with the validation of a technique as well as the presentation of the clinical analysis technique, no additional attempt was made to reduce the editing.

The counting of all pacemaker pulses was achieved by routing the pacemaker pulses to the computer, which typed the frequency of pacemaker pulses during each hour of the recording.

When pacing pulses were neither almost continuous nor infrequent it was difficult to assess the false negative detector rate. In six such recordings the rate was estimated by examining one-tenth of the recordings (six minutes each hour) by eye, using the editing feature of the computer analysis system.

In two other cases estimates of other values were made using the same technique: in case 3 with frequent false negatives and case 11 with frequent failure to capture. Both cases are discussed later.

Results

FALSE DETECTION OF PACEMAKER PULSES

The false detection of pacemaker pulses (the false positive rate) was first assessed using the recording equipment on 10 ambulant patients who did not have a cardiac pacemaker. These results are shown in Table 1. Seven of these patients had no false positives, two had one, and one had three over a 24 hour period. This averaged fewer than 0.5 false detections each 24 hours. The false detection rate from 15 patients with implanted pacemakers is shown in Table 2. Eleven patients had no false detections. In two, however, the rate was high: In case 6 this resulted from a period of a few hours overnight when very large electrocardiographic baseline swings were encountered causing the electrocardiograph amplifier of channel 3 to saturate and so produce fast transient edges which the detector classified as pacemaker pulses. In case 11 baseline swing was frequent throughout the recording. In spite of these two recordings the median false positive rate was less than 1 per 24 hours.

Table 1 Number of false pacemaker detections (false positives) in 10 subjects with no cardiac pacemaker

No. of patients	False detections per 24 hours
7	0
2	1
1	3

Table 2 Accuracy of ambulatory pacemaker pulse detector assessed on two fixed rate (F1, F2) and 13 demand pacemakers. Estimates (*) were made in some cases (see text)

Case No.	Pace detections	False detections	Missed detections
F1	101 243	0	0
F2	132 263	0	0
1	21	2	0
2	102 142	0	0
3	68 384	0	30 500*
4	101 795	0	0
5	91 751	0	0
6	17 308	28	0*
7	101 515	0	0
8	56 090	0	0*
9	102 277	0	0
10	97 493	1	0
11	85 756	960*	0*
12a	66 642	0	0*
12b	66 024	0	0*
13	98 564	0	0

Table 3 Pacemaker assessment

Case No.	Failure to sense	Failure to capture	Inappropriate inhibition	Total pace
F1	—	0	—	101 243
F2	—	0	—	132 263
1	0	0	0	21
2	0	0	0	102 142
3	0	0	3	99 000*
4	1	0	20	101 795
5	2	0	0	91 751
6	0	0	0	17 308
7	0	0	0	101 515
8	0	0	0	56 090
9	0	0	4	102 277
10	0	0	1	97 493
11	R	C	0*	85 756
12a	0	0	13	66 642
12b	0	0	1	66 024
13	0	0	21	98 564

R, only in pacemaker refractory period; C, almost continuous; *, estimate. For discussion see text.

MISSED DETECTION OF PACEMAKER PULSES

The false negative rate was first assessed in two patients with fixed-rate pacemakers. No false negatives occurred. In only one of 13 patients with demand pacemakers was missed detection (false negatives) encountered (Table 2). This resulted because the pacing pulse amplitude varied and sometimes fell below that required for detection. The low amplitude pacing pulse resulted because the electrode over the apex of the right ventricle was incorrectly attached to channel 1 (monitoring electrocardiogram) and an electrode at V6 used for the pacemaker pulse detector channel.

FAILURE TO SENSE

Only two patients showed any evidence of failure of the pacemaker to sense the cardiac rhythm (Table 3). One patient had a single episode of failure to sense which was during a period of fast ventricular tachycardia. The other patient had two episodes, one during ventricular tachycardia (Fig. 3a) and the other when an early ventricular ectopic complex, interpolated between two paced complexes (Fig. 3b) was not sensed. Case 11, whose pacemaker frequently failed to capture, was as a result unable to sense complexes falling within the pacemaker's refractory period.

FAILURE TO CAPTURE

Only one patient was shown at any time to show failure to capture (Fig. 4). This patient was suspected of having such periods before the recording was made. The analysis showed that this was a common

Fig. 3 (a) Failure to sense during ventricular tachycardia. (b) Failure to sense early ventricular ectopic complex.

Fig. 4 Failure to capture. The pacemaker still senses ventricular complexes.

occurrence in this patient. Of the pacemaker problems that Ward *et al.*⁹ investigated, the most frequent was failure to capture.

INAPPROPRIATE INHIBITION

Six of the patients had periods during which the pacemaker was inhibited as a result of artefact (Fig. 5). This was mostly as a result of muscle activity. The frequency with which inappropriate inhibition occurred varied from one to a maximum of 21 in a 24 hour period. There was a total of 63 periods of inappropriate inhibition in six patients. The longest period of continuous inhibition was 2.5 s. This interval contained one spontaneous complex, but both intervals making up the 2.5 s were longer than the pacing period. The greatest asystolic pause during a period of inhibition was 2.0 s. Inappropriate inhibition has already been described^{10 17} but has not been thought to occur so frequently.

IDENTIFICATION OF INFREQUENT PACED COMPLEXES

Some patients make use of their demand pacemaker infrequently. For example, one patient in our series paced only 21 times in 24 hours. Two paced complexes from this patient are shown in Fig. 6.

Fig. 5 Inappropriate inhibition.

Fig. 6 Paced complexes. This patient had only 21 paced complexes in 24 hours. The clear artificial pacing artefact allows them to be identified automatically.

These periods can be detected automatically and identified clearly using the pacemaker marker pulses.

ASSESSMENT OF PACEMAKER USE

All demand pacemakers were assessed for their frequency of use. This varied considerably. There were three typical patterns of use: infrequent, random, and almost continuous. Table 4 lists the minimum, average, and maximum number of pacing pulses delivered per hour for each pacemaker.

IDENTIFICATION OF PACED FUSION COMPLEXES

As the patients' normal heart rates slow below their pacemaker rates, the pacemakers will begin to capture the ventricles. During the time both rates are approximately equal, fusion complexes will occur. A typical example is shown in Fig. 7. If pacing coincides with the P wave inappropriate pacing occurs. It is not easy in such circumstances, if the pacing pulse is not

Table 4 Patients' use of their pacemakers

Case No.	Minimum pace/hour	Average pace/hour	Maximum pace/hour
1	0	1	10
2	4212	4251	4292
3	—	—	—
4	4248	4289	4311
5	4156	4244	4287
6	9	721	4170
7	4140	4177	4197
8	473	2357	3633
9	4241	4279	4312
10	4122	4160	4197
11	3413	3704	4013
12a	2121	2820	3992
12b	1790	2836	3847
13	4133	4182	4198

Fig. 7 Paced fusion complexes.

visible, to determine if the pacemaker has fired. If the patient has the sick sinus syndrome inappropriate pacing can result in a large fall in blood pressure.¹⁸

SPONTANEOUS COMPLEXES OCCURRING WITH FIXED RATE PACEMAKER

Spontaneous complexes can occur during fixed rate pacing. One of the two fixed rate pacemakers studied paced on the T wave of spontaneous depolarisations (Fig. 8). It can be noted that in this case a distorted pacing pulse artefact can be seen on the electrocardiogram recorded over the pacemaker – the lower of the two electrocardiographic traces. The pacing pulse detector allows such spontaneous complexes to be clearly differentiated from paced complexes.

Discussion

The accuracy of pacemaker pulse detection has been shown to be excellent. False positives have been infrequent, and low enough to cause no concern during analysis in the great majority of recordings. The false positives mainly resulted from electrocardiographic baseline instability saturating the recording amplifier and occasionally producing very

Fig. 8 Fixed rate pacemaker pacing on T wave of spontaneous ventricular complex.

fast edges which were interpreted as pacing pulses. Only one recording showed any false negatives, and this was the result of the wrong electrode site being used.

Although the pacemaker pulse recorder has been designed for use with pacemakers with unipolar electrodes this is hardly a disadvantage since the greatest proportion of pacemakers implanted are of the unipolar type. In the 1979 world survey on cardiac pacing¹ the United Kingdom was listed as using unipolar leads with 98% of pacemakers implanted.

The recorder and analysis system has been shown to be clinically useful in a number of ways: isolated and infrequent paced complexes can be identified easily, the frequency of pacemaker use can be quantified, periods of transient pacemaker malfunction can be detected, and the associated electrocardiographic rhythm strip, with its clearly indicated pacemaker pulses, can be studied.

Of the 13 patients with demand pacemakers studied only one was suspected of having possible pacemaker problems. It was confirmed that this patient's pacemaker was frequently failing to capture. The other 12 were selected at random to enable the equipment to be assessed. None of these patients showed failure to capture. In spite of the lack of selection six out of 13 patients and seven out of 14 recordings had one or more periods of inappropriate inhibition. These six patients had a total of 63 periods of inappropriate inhibition. Though no resulting asystole was greater than 2.0 s, and hence not of clinical significance, it indicates that inappropriate inhibition is perhaps more frequent than previously shown. In addition two patients had a total of three periods of failure to sense.

Even in this relatively small number of patients pacemaker assessment in the ambulant patient has been shown to be technically feasible and clinically useful.

References

- 1 Goldman BS, Parsonnet V. World survey on cardiac pacing. *Pace* 1979; 2(5): W1-17.
- 2 Levander-Lindgren M. ECG-tape recording for analysis of syncopal attacks before and during cardiac pacing. *Scand J Thorac Cardiovasc Surg* 1978; 22, suppl: 13-5.
- 3 Tzivoni D, Stern S. Pacemaker implantation based on ambulatory ECG monitoring in patients with cerebral symptoms. *Chest* 1975; 67: 274-8.
- 4 Bleifer SB, Bleifer DJ, Hansmann DR, Sheppard JJ, Karpman HL. Diagnosis of occult arrhythmias by Holter electrocardiography. *Prog Cardiovasc Dis* 1974; 16: 569-99.

- 5 Goldberg AD, Raftery EB, Cashman PMM. Ambulatory electrocardiographic records in patients with transient cerebral attacks or palpitation. *Br Med J* 1975; 4: 569-71.
- 6 Reiffel JA, Bigger JT, Cramer M, Reid DS. Ability of Holter electrocardiographic recording and atrial stimulation to detect sinus nodal dysfunction in symptomatic and asymptomatic patients with sinus bradycardia. *Am J Cardiol* 1977; 40: 189-94.
- 7 Boal BH. The function of a pacemaker follow-up clinic. In: Norman J, Rickards A, eds. *Proceedings of the pacemaker colloquium, 1975 Arnhem*. Dieren Vitatron, 1976: 141-8.
- 8 Morganroth J, Michelson E. The contributions of ambulatory ECG. *Geriatrics* 1979 Dec.; 34: 60-8.
- 9 Ward DE, Camm AJ, Spurrell RAJ. Ambulatory monitoring of the electrocardiogram in the pacemaker surveillance clinic in patients with presyncope. In: Stott FD, Raftery EB, Sleight P, Goulding L, eds. *Isam 1977*. London: Academic Press, 1978: 33-5.
- 10 Kelen G, Bloomfield D, Hardage M. Holter monitoring the patient with an artificial pacemaker - a new approach. *Ambulatory Electrocardiology* 1978; 1: 1-4.
- 11 Kelen G, Bloomfield DA. Detection of intermittent pacemaker malfunction by ambulatory monitoring (abstract). *Bull NY Acad Med* 1979; 55: 415.
- 12 Walsh T, Goldberg AD, Mehta S. A method for continuous monitoring of pacemaker function. In: Stott FD, Raftery EB, Goulding L, eds. *Isam 1979*. London: Academic Press, 1980: 493-6.
- 13 Murray A, Jamieson D. A simple locking device for securing patient lead plugs on ambulatory recorders. In: Stott FD, Raftery EB, Goulding L, eds. *Isam 1979*. London: Academic Press, 1980: 493-5.
- 14 Krasnow AZ, Bloomfield DK. Artifacts in portable electrocardiographic monitoring. *Am Heart J* 1976; 91: 349-57.
- 15 Tynan M, Murray A, Reid D, Hunter S, Goodwin A. Twenty-four hour tape monitoring of the electrocardiogram in infancy and childhood. In: Anderson RH, Shinebourne EA, eds. *Paediatric cardiology*. Edinburgh: Churchill Livingstone, 1978: 86-94.
- 16 Murray A, Campbell RWF, Julian DG. Operator-controlled computer system for analysis of 24 hour electrocardiographic recordings. In: Ripley KL, Ostrow HG, eds. *Computers in cardiology*. Long Beach, California: IEEE Computer Society, 1979: 197-9.
- 17 Mond HG, Sutton L, Sloman JG. Detection of pacemaker malfunction. In: Thalen HJ, Meere CC, eds. *Fundamentals of cardiac pacing*. The Hague: Martinus Nijhoff, 1979: 211-35.
- 18 Thalen HJ. Cardiac pacing in sick sinus syndrome. In: Thalen HJ, Harthorne JW, eds. *To pace or not to pace*. The Hague: Martinus Nijhoff, 1978: 61-72.

Requests for reprints to Dr Alan Murray, Regional Medical Physics Department, Freeman Hospital, Newcastle upon Tyne NE7 7DN.