External measurements of implanted pacemaker characteristics

A clinical appraisal

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A technique for determining the characteristics of impulses from implanted cardiac pacemakers with external methods is reviewed, and its value in detecting pacemaker failures is discussed. The results from a 2-year application with 611 controls in clinical routine are presented. Sixteen out of 42 defective pacemakers could be detected before symptoms or electrocardiographic signs of pacing failure developed. The reliability and specificity of the procedure justify its application in clinical routine.

Patients with cardiac pacemakers need regular check-ups for the control of the pacemaker unit. Clinical tools of importance are a careful history, electrocardiograms, and equipment for the external measurement of characteristics of the pacing impulse. The impulse from an implanted pacemaker generator can be visualized in a voltage-time plot and photographed with a polaroid camera, yielding an impulsogram. From this, the amplitude, i.e. voltage, time duration, and slope of the curve can readily be evaluated.

For accurately working pacemaker generators it is important to assess the expected lifetime of the mercury cells as safely as possible at each control. Accurate assessment would minimize the risk for the patient from a failing pacemaker function, and reduce the number of operations and thus patient discomfort. Furthermore, costs for pacing equipment and nursing will be reduced.

For failing pacemakers it is often possible to localize the fault through external measurements - whether it is due to electronic failure, battery exhaustion, or a disconnected or damaged electrode.

These techniques have been used routinely since the spring of 1967 on all patients with subcutaneous pacemakers at our hospitals.

The experiences over a two-year period are reported, with emphasis on the relative value of impulse analysis, electrocardiogram, and

history in detecting imminent pacemaker failures.

Impulse recording for determination of pacemaker characteristics was described in 1964 by Davies and Sowton, and its use for routine controls has been reported by Knuckey, McDonald, and Sloman (1965), Nickel (1964), Preston *et al.* (1966), Rydén (1969), and Thalen *et al.* (1969).

Methods and stimulating principles

The pacemaker system consists of an impulse generator, an endocardial electrode (Elema EMT 588), and an indifferent electrode (Elema EMT 564) subcutaneously implanted below the left costal margin. The generators (fixed rate generators, Elema EM 139 and 142; atrial synchronized, Elema EM 141; and QRS synchronized, Elema EM 143) are implanted subcutaneously in the abdomen. At the control performed every third to fourth month, and otherwise when symptoms indicate, the history and electrocardiogram are taken, a physical examination is performed, and an impulse recording undertaken.

The impulse frequency was calculated from the electrocardiogram (Elema-Schönannder Mingo-graf 42). The generator impulses detected from electrodes on the left arm and leg (lead III) were displayed on an oscilloscope (Tektronix 502 A). The horizontal sweep was triggered by the pacemaker impulses. The amplification was usually 50 millivolts per centimetre on the vertical axis, and the speed of the sweep 0.5 msec./cm. A photograph of the oscilloscope display has been taken at every check-up, and the peak amplitude and duration of the impulse have been measured.

The photographs and electrocardiograms from earlier controls of the same patient with the same impulse generator have been available for comparison at check-ups.

A pacemaker manufactured by Elema-Schönander delivers impulses by discharging a capacitor. With no load on the pacemaker circuit, i.e. when the resistance between the output electrodes is infinitely high, the impulse is a square wave on the voltage time plot. When the impulse generator is connected to a patient, the resistance between the output electrodes is decreased and the shape of the impulse is changed. Fig. 1 shows a typical impulse recording from a patient (lead III) with an adequate functioning generator, and Fig. 2 shows a recording from a patient with a generator with reduced voltage of the batteries.

Amplitude, duration, and shape of the impulse are constant parameters in a patient as long as he has the same pacemaker with an adequate voltage of the batteries and a functioning electrode system. This is true if the pacemaker is of a fixed rate type. Synchronized generators will decrease the amplitude and shorten the duration of the impulse with increasing frequency (Fig. 3). Synchronous pacemaker generators are therefore checked at about the same impulse rate from time to time in order to get comparable data.

The amplitude varies with respiration and especially during deep breaths; the difference may be considerable (Fig. 4). In normal breathing differences are small and can usually be neglected. These variations are estimated at every control since the oscilloscope display is observed during several respiratory cycles.

Indications for generator exchange

Indications for exchange of the generator have been a history of possible pacemaker failure, an alteration in the electrocardiogram or the impulse characteristics, and are listed below.

(1) A case history indicating pacemaker failure includes either syncopal (Adams-Stokes) attacks, or careful description of undue arrhythmia, or accurate observations of palpated arterial pulse rate changes not otherwise explained (as for example by competition).

(2) Electrocardiographic verification of pacing impulses failing to stimulate the heart when occurring in a non-refractory phase.

(3) Failing trigger mechanisms in synchronized generators (pacing).

(4) A decrease of the peak amplitude of more than 30 per cent from the initial value. (At the same stimulation rate when dealing with triggered pacing.)

(5) An increase of the impulse duration of more than 0.2 msec. from the initial value. (At the same stimulation rate when dealing with triggered pacing.)

(6) A change of stimulation rate exceeding 2 impulses a minute from the initial rate (only fixed-rate generators).

Subjects

The electrodes and pacemaker generators were

FIG. 1 Impulse from a pacemaker derived from lead III, in a voltage time plot. Amplitude voltage, impulse duration, and curve shape are the important features of such impulsograms. Horizontal axis, 0.5 msec./div.; vertical, 50 mV/div.

FIG. 2 Pathological changes of an impulsogram, with decrease in voltage, increase in duration but unchanged relative speed of voltage decrease. This is consistent with reduced voltage sum of the batteries and unchanged resistance of intracorporeal circuits. The initial findings were identical with those in Fig. 1. Horizontal axis, 0.5 msec./div.; vertical, 50 mV/div.

implanted at the department of Thoracic Surgery, Karolinska Sjukhuset. At the department of Clinical Physiology, Thoracic Clinics, initial post-operative oscilloscope photographs were taken. The routine controls were performed at the Department of Medicine, Serafimerlasarettet. The material consists of 137 patients, ages 21 to 88 (mean 68) years, followed from 2 to 23 months (mean 13 months) with regular routine controls every 3 to 4 months, and extra controls whenever indicated by symptoms. At 611 check-ups indications for premature explantations within the calculated lifetime of the subcutaneously implanted impulse generators were found in 43 cases. Routinely the generators EM 139 and 142 have been in use for 18 months, and EM 141 and 143 for 15 months before exchange.

Results

The indications for premature explantation of the pacemaker generators in the 43 patients are shown in the Table. Twenty-two patients (51%) had a definite history of arrhythmic syncope or had noticed a change in heart rate and they also had electrocardiographic findings indicating failing pacemakers. Four of the 43 patients had electrocardiographic changes suggesting generator failure without any symptoms. One of these had sinus rhythm and no signs of pacemaker activity and the other 3 had changes in heart rate exceeding 2 beats a minute. All 26 patients also showed an alteration in the impulse characteristics.

Seventeen patients had oscilloscope-verified impulse changes indicative of generator defects without a positive history or any abnormal electrocardiographic signs. Five of these had a decrease in the peak amplitude of more than 30 per cent, one had an increase of the duration exceeding 0.2 msec., and 10 patients had both a decrease of peak amplitude and an increase of impulse duration indicating a pacemaker defect. At later controls the generators which had been removed proved to be defective in different ways in all

TABLE Mode of detection of generator failure leading to exchange of implanted generators before 18 months' use

Reason for exchange	No. of exchanges
History of failure including change of stimulation rate	22
Electrocardiogram-verified failure with a normal history	4
Solely impulse analysis	17
Total	43*

* In all 43 exchanges the impulse photographs were abnormal.

FIG. 3 Changes in impulse in a patient with a QRS-synchronized generator due to extrasystoles. Horizontal axis, 0.5 msec./div.; vertical axis, 50 mV/div.

FIG. 4 Changes in pacemaker impulse amplitude between maximal inspiration and expiration. Horizontal axis, 0.5 msec./div.; vertical axis, 50 mV/div.

FIG. 5 Observations of relative impulse amplitude changes with time after implantation, for pacers EM 142¹. First postoperative measurements are set at 100 per cent and repeated measurements from the same pacemaker in the same patient are connected with a line.

¹ Elema-Schönander Company, Sweden.

cases but one. The oscilloscope measurements from this patient were incorrectly interpreted as indicative of a deficient pacemaker, due to erroneous amplification in the voltage-time plot.

Fig. 5 shows the change with time of pacing impulse amplitudes for generators of type EM 142. Fig. 6 shows the change with time in the impulse duration for generators of type EM 139, EM 141, EM 142, and EM 143. The initially measured value has been set to 100 per cent. Only values for defective pacemakers are included, but both from patients with and without a positive history and/or electrocardiographic signs.

If the anode and cathode electrodes are inverted at the exchange of a generator this will be observed on the oscilloscope as an inversion of the impulse. The impulse in Fig. 7 shows signs of an extremely low resistance between the 2 electrodes. The cause of this was a short circuit between the stimulating and indifferent electrode caused by an insulation defect on the wire of the stimulating electrode,

where it passed close to the indifferent electrode plate.

Discussion

A patient with atrioventricular conduction disturbances treated with an artificial cardiac pacemaker is depending on perfect function in the pacemaker system, not only in order to maintain an adequate cardiac output but also for his mental well-being. He will never have confidence in a pacemaker system if he suffers alarming symptoms before the exchange of the old pacemaker generator. To avoid this, a routine needs to be established for the control of these patients giving as exact data as possible concerning actual and 2- to 3-month future functioning of the generators (Gerst *et al.*, 1967). The present investigation indicates that an analysis of the pacing impulse gives such good information about the condition of the pacing system that it justifies its use as a control routine. The value of impulse recording is based on the

FIG. 6 Observations of relative impulse with changes with time after implantation for pacers¹ EM 139, 141, 142, and 143.

¹ Elema-Schönander Company, Sweden.

fact that the impulse data (amplitude, duration, and shape) are constant in a patient as long as he has the same adequately functioning generator and electrode system. The analysis of the pacing impulse is important not only for detection of premature battery exhaustion but also for giving information about other defects in the pacing system.

The predictive power of the impulse analysis is good. In all the 43 patients where the pacemaker generators were prematurely exchanged during the observation period, a change in the impulse indicative of premature battery exhaustion or generator failure was recorded. Twenty-six of these failures would have been detected from a case history and a conventional electrocardiogram, whereas 17 pacemaker generators were exchanged only because of an abnormal impulse.

Usually both duration and amplitude of the generator impulse were indicative of immi-

nent failure. Changes were, however, more common regarding the amplitude than the duration in those where only one of these characteristics was abnormal. The risk that the impulse analysis gives a false indication of malfunction seems to be small with good recording technique.

The pacemaker from one of the 17 patients in whom there was an exchange only because of alteration in the impulse characteristics, turned out to function normally at a later control. The cause of the abnormal impulse was faulty amplification on the oscilloscope. This indicates that a good recording technique is of major importance. Other factors to be taken into consideration are, for example, the changes in impulse amplitude with respiration and the decrease in amplitude and duration with increasing impulse rate. The vector of the pacemaker impulse can be more carefully estimated when using more than one

electrocardiographic standard lead. This technique can be helpful in the detection of defects in the insulation of the pacemaker electrodes, as shown by Green *et al.* (1969). To keep the procedure as simple as possible we have not used this technique of registration routinely.

The method described for the control of implanted pacemaker generators justifies a longer use of them than is routine today. In Stockholm, pacemakers have hitherto been exchanged routinely after one and a half years. This is much less than the theoretical life span of the generators, calculated to be 4.5 years (Lagergren, 1966). The controls should be more frequent during the last period of the estimated lifetime of the mercury cells.

The prolonged use of the generators not only decreases the cost for the impulse generators, but also reduces the need for hospital care of the patients. Above all, the oscilloscope tests make the patients more confident in their pacemaker equipment and spare them unnecessary operations.

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FIG. 7 Pathological shape of the impulso-gram, consistent with decrease in resistance, as from defective electrode insulation. Horizontal axis, 0.5 msec./div.; vertical axis, 50 mV/div.