Implantable Demand Pacemaker

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Adams-Stokes seizures can occur in patients with intermittent complete A-V block. The history of a single Adams-Stokes syncopal attack is an indication for intracardiac pacing. Fixed rate pacemakers employed in the presence of intermittent varying degrees of A-V block and sinus rhythm result in recurrent co-acting rhythms of artificial and natural beats (Linenthal and Zoll, 1962). This arrhythmia is usually considered to be innocuous. However, instances of repetitive firing have been reported when pacemaker stimuli fell in the vulnerable phase of the previous beat (Dittmar, Friese, and Holder, 1962; Elmqvist *et al.*, 1963; Tavel and Fisch, 1964; Castellanos *et al.*, 1964; Lemberg, Castellanos, and Berkovits, 1965; Bonnabeau *et al.*, 1963; Robinson *et al.*, 1965; Dressler, Jonas, and Rubin, 1965; Katz, 1965; Langendorf and Pick, 1965; Castellanos, Lemberg, and Gosselin, 1965a; Castellanos *et al.*, 1966b). The potential hazards of an increase in cardiac rates due to summation of both rhythms are also to be considered (Lemberg *et al.*, 1965; Núñez-Dey, Zalter, and Eisenberg, 1962). Occurrence of these complications justifies the use of modified pacemakers which can prevent these untoward reactions.

A pacemaker system that meets these requirements is the demand pacemaker which was developed in 1964 for temporary transvenous use (Castellanos *et al.*, 1964). Stimulation occurs when a preset interval following cardiac contraction has been exceeded. It will shut itself off when the natural rate exceeds that of the pacemaker. Sensing is immediate. This portable pacemaker has been useful in the treatment of various types of intermittent A-V block. The successful application of the demand pacemaker as a bedside unit stimulated the development of a synchronized implantable model.

Several preliminary steps were necessary before a permanent implantable unit could be considered ready for clinical use. There was needed assurance that the pacemaker would fire after a variable period of suppression by a more rapid sino-atrial rhythm. In addition a higher than optimal sensitivity would prevent discharges of the pacemaker by P on T waves. The present report deals with the steps taken to assure that an implanted unit would be clinically operative without iatrogenically induced arrhythmia.

SUBJECTS AND METHODS

Ten patients with intermittent complete A-V block were studied. Their ages ranged from 53 to 71 years. Eight had arteriosclerotic heart disease. Primary myocardial disease was the aetiological cause in the other two. Transvenous pacing was performed by means of an NBIH bipolar pacemaker electrode*, with the tip in contact with the right ventricular endocardium. Bipolar stimulation was used in all patients. The catheters were introduced via the external jugular or subclavian veins and connected to a small transistorized demand pacemaker. The battery powered demand pacemaker functions only after a preset programmed interval. The electrodes delivering the artificial stimuli also sense the QRS of the electrocardiogram. Two types of transistorized models† were tested. One unit had an adjustable rate and intensity, as well as a two-position switch for selection of either demand or continuous mode of operation. The other unit for permanent implantation was hermetically sealed with fixed rate and intensity. This model has a built-in magnetic device which can be switched by an extracorporeal magnet to select demand or continuous mode of operation as needed. Both units are powered by mercury batteries. The amount of consumed power is negli-

* U.S. Catheter and Instrument Corp. Glen Falls, New York, U.S.A.

† American Optical Company, Chelsea, Massachusetts, U.S.A.

FIG. 1.—Value of isoprenaline in assessing the function of pacemaking on demand. The upper strip was taken from a patient with intermittent complete A-V block. Atrial flutter appeared when a catheter electrode was introduced into the right ventricular cavity. The demand pacemaker repeatedly stimulated the ventricles at a rate of 58 a minute. An intravenous drip of isoprenaline induced a rapid A-V nodal rhythm (second strip). The pacemaker was discharged when the natural rate exceeded the preset artificial rate. It started to function again when the natural rate dropped below the preset artificial rate. Atrial fibrillation was now present (lower strip).

gible; therefore the shelf-life of these batteries will be the determining factor for replacement. The two models were used in all patients.

Transitory pacemaking on demand was performed for a period ranging between two days and one week. During the testing period 7 patients had various types of A-V block (first, second, or complete) or recurrent sinus rhythm with a normal P-R interval. In the latter group the natural rate was higher than the demand rate. The demand pacemaker was thus controlled by the patient's rate and stimulated the heart intermittently. Three patients had complete A-V block with a slow idioventricular rate during the period of testing. In these patients the demand pacemaker functioned continuously and controlled the ventricles.

METHODS OF TESTING

In the three patients with complete A-V block artificial pacing occurred early after enhancement of ventricular automaticity. An increase in the ventricular rate resulted with an infusion of isoprenaline (2 mg. in

400 ml.) (Fig. 1). When this occurred the drug was discontinued and pacemaker behaviour studied. The infusion was repeated several times on different days. When drug effects wore off and the ventricular rate fell to control level, artificial pacemaker stimulus again controlled the heart, as expected. Ventricular extrasystoles, when present, were adequately sensed by the units.

Carotid sinus massage or the Valsalva manoeuvre was employed in patients with sinus rhythm or first-degree A-V block and with natural rate above those of the pacemaker (Fig. 2). In 6 patients the slowing of the rate was insufficient to induce iatrogenic beating. In these cases the variable rate unit was employed repeatedly. Results of switching from demand to continuous pacemaking were noted in each patient.

Since the demand pacemaker can operate intermittently depending on the ventricular rate and degree of A-V block, testing of pacemaker by continuous monitoring was considered essential. This was performed by means of a portable tape recorder worn by the subject. The instrument used was the AVSEP Electrocardio-

FIG. 2.—Effects of carotid sinus pressure during periods of demand suppression by a faster sino-atrial rhythm. The electrocardiogram was obtained from a patient with syncopal attacks due to intermittent complete A-V block.

corder.* The functions of this unit have been described previously (Gilson, 1966). A symmetrical bipolar chest electrode from the apex to the base of the sternum was employed. This electrode connexion resembles lead II, and for monitoring arrhythmias was considered superior to the V5-V5R position which is commonly employed for the analysis of QRS patterns.

Each of the subjects tested wore the recorder from 12 noon until 8 a.m. The tape was changed at approximately 10 p.m. During this period they were allowed to perform the usual activities conditioned by their general status. During the playback the periods of pacemaker activity were monitored on the two display screens of the instrument. The oscilloscope screen displaying the superimposed sequential electrocardiographic signals revealed the change in morphology characteristic of the pacemaker beats, when they occurred with the sinus complexes. The former were always preceded by stimulus artefacts (Fig. 3, upper right). The natural complexes that were following each type of QRS complex frequently showed different polarity. The second screen displayed the predicted rate variations that occurred during periods of pacemaker activity (Fig. 3, lower right). These were characterized by a change from the sinus to the preset artificial rate. The general sequence of events could be identified correctly by the methods outlined above. Electrocardiograms were also recorded from the tape at selected or periodic intervals to allow detailed study of the rhythm and to determine the adequacy of sensing. Three patients with syncopal attacks had been monitored before intracardiac pacing. In these cases a change in the degree of A-V block could be properly detected during this period. Adams-Stokes seizures did not occur after initiation of pacing.

DISCUSSION

Demand or standby pacemaking has proved to be useful in the treatment of intermittent A-V conduction disturbances (Castellanos *et al.*, 1964; Lemberg *et al.*, 1965; Castellanos *et al.*, 1965b; Castellanos, Lemberg, and Berkovits, 1966a; Parsonett *et al.*, 1966; Dalle, 1966). The major advantages of this modified form of pacing are the prevention of interfering rhythms which otherwise result if an iatrogenic parasystole co-acts with a natural centre.

* Avionics Research Product, Los Angeles, California, U.S.A.

Repetitive firing due to artificial stimuli falling in the vulnerable phase of the ventricles during sinus rhythm, though rare, does occur and has been described (Castellanos *et al.*, 1964; Tavel and Fisch, 1964). More frequent is the possibility of inducing multiple responses with pacemaker impulses falling in the vulnerable phase of idioventricular beats or extrasystoles.

The deleterious effects of high ventricular rates resulting from summation of natural and artificial beats are also prevented with the use of the demand pacemaker. The experience gathered with this instrument in selected cases of intermittent A-V block confirmed its clinical usefulness. The con-

FIG. 3.—Evaluation of the function of a demand pacemaker by continuous (20-hour) monitoring. The photographs, which are slightly retouched, were obtained from the oscilloscope screens of the AVSEP units. Co-action of sinus and artificial pacemaker (lower left) is accompanied by very slight changes in rate (lower right). The natural rate was only slightly faster than the preset demand rate.

struction of an implantable unit thus appeared justified. Neville *et al.* (1966) introduced a modified implantable pacemaker with special characteristics. Although the pacemaker can escape when a long pause without natural beating ensues, this ventriculo-synchronized unit is really a variant of the continuous pacing in the atrio-ventricular synchronized pacemaker (Nathan *et al.*, 1963). We believe that the term 'demand' should be limited to those types of unit which stimulate electrically only on intermittent bases related to the rate.

General procedures can be employed in order to establish the continual reliability of pacing potential in an implantable demand pacemaker which has been suppressed by a heart rate exceeding the artificial rate. Magnetic switching of demand to continuous pacing under electrocardiographic control allowed periodic testing of function. Neurogenic slowing of the sino-atrial node proved to be a useful method in assessing pacemaker function during sinus rhythm. Acceleration of the rate by isoprenaline was useful in determining pacemaker suppression by a faster natural rhythm.

The first step in the construction of the implantable unit consists in extensive testing in dogs. This phase of the evaluation is currently in progress in our department. Another important step consists of testing the models to be used permanently in patients when pacing is performed by transvenous catheters. The second phase involves short-term evaluation of the units in patients with transvenous electro-catheters. The present study reports on its temporary use in patients up to a period of 10 days. Monitoring of the pacemaker during spontaneous periods of transient activity was simplified by the use of the AVSEP recorder. This instrument can be used in ambulatory patients as well as in those in hospital. By observing both the morphology of the QRS complexes, as well as rate changes, an estimate of the periods of transient pacemaker activity could be made. Permanent recording could be obtained at any time. In the majority of cases visual observations were sufficient. This instrument is particularly helpful in those patients in whom one type of rhythm persisted for a prolonged time and was then replaced by another rhythm. Beat-to-beat variation between natural and ectopic pacemaker was more difficult to analyse from the screen displaying only QRS morphology, but could be assessed with certainty by observing the occurrence of rate changes in the corresponding screen. In these cases selected electrocardiographic strips from the portion of the tape showing this type of abnormality were required.

The methods presented for evaluating transient, transvenous, demand pacemaking of the types to

be used for permanent implantation are useful, and the experience gained will be subsequently applied for chronic pacing in man. However, it is important that the reliability and long-term performance of any artificial pacemaker should be carefully studied in animals over long periods before application to man.

SUMMARY

Two miniature models of the demand pacemaker were tested in 10 patients with intermittent complete A-V block. Right ventricular endocardial pacing was performed for periods of 2 to 10 days. Assessment of pacemaker function was made in several ways. An isoprenaline infusion was employed in those cases in which complete heart block existed during the period of testing. Artificial pacemaker stimulus stopped when the natural rate exceeded the preset one. Pacing renewed when the natural rate became slower than that of the artificial unit. In the presence of sinus rhythm, pacemaker activity was exposed by neurogenic slowing of the sino-atrial node. Twenty-hour monitoring with rapid scanning proved to be a useful method for testing the intermittent features of the pacemaker. The experience gained through the analysis of temporary pacing with these units will be applied in the evaluation of the implantable demand pacemaker.

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