An Implantable, Synchronous Pacemaker for the Long-Term Correction of Complete Heart Block

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For the past two years, our research team has been engaged in the performance of 50 dog experiments. We have studied many parameters necessary to developing a pacing device capable of synchronizing the electromechanical events of the atrium with the ventricle for the correction of complete heart block. As a result of these studies, the unit, now completely self contained and totally implantable, has been observed for performance at rest and after exercise, during normal and rapid atrial rates. The results will be briefly detailed in this paper. Studies have indicated the importance of the atrial transport contribution to cardiac output, and attest to the importance of a pacer capable of restoring the atria and ventricles to the preblock state. Our experimental methods have been detailed elsewhere.

The Implantable Synchronous Pacemaker

The pacemaker (fig. 1) measures 5.5 cm in diameter, 1.8 cm in thickness, and weighs 5 ounces. It contains five hermetically sealed mercury cell batteries, each with an unloaded battery voltage of 1.3 volts. The pacer has a life of approximately three to five years, based upon the utilization of 35 μA average drain. The capacitor delivers a 1.7-msec pulse of 6.5 volts. There are 10 transistors and the sensitivity of the pacer is set at 2 mv. The unit is covered with an epoxy resin known to be well tolerated by human tissues. The electrodes are of continuous coiled platinum iridium.

The atrial pickup electrode is an expanded coil 2-cm long, curved in one plane, half embedded in the rubber and half exposed. The two stimulating electrodes consist of a coil extended about 0.5 cm from a flat pad. These electrodes are a modification of the Chardack leads. Both atrial and ventricular pads are reinforced with coarse plastic cloth to permit suturing without the danger of tearing the relatively low-tensile-strength rubber. All parts are encased in silicone rubber. Metals used in the electrodes are platinum with 10 per cent iridium. Satisfactory thresholds were obtained with this alloy similar to results of Chardack and Zoll. In anticipation of pacer replacements and a need for repeated measurements in the course of the current investigation, a special disconnect plug was devised. A simple silastic rubber boot was made to protect the connection between the plug and the pacer. This detachable connection permits easy substitution of either the pacer or leads. The circuit is so designed that a spare ventricular lead can be switched on by rotating the plug 180 degrees with respect to the socket.

In its simplest form, the synchronous pacer picks up the negative portion of the P wave at the atrial pickup electrode which is sutured to the atrial epicardial surface. After receipt of the P wave and its amplification, a time delay is introduced approximately equal to that of the normal P-R interval, 0.10 second. Ventricular depolarization is then initiated by conducting the output pulse to a lead which has been sutured to the ventricular surface. Naturally induced speeding or slowing guided from the sinoatrial node will cause the ventricles to follow and the heart to respond to body demands. The pacer is provided with a fixed total refractory delay of 0.4 second.

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which prevents its own output impulse from retriggering it. In the event of failure of pickup from the atrial electrode, or due to mechanical failure of the P-wave amplifier, atrioventricular delay, or a single battery, a standby self-pacer oscillator at a rate of 60 has been provided. In marked sinus bradycardia, or when two or more consecutive atrial beats occur at a rate slower than the designed automatic rate, the self-pacer oscillator will stimulate the ventricle.

**Atrial Potentials**

Atrial potentials were measured in 38 dogs for periods up to 12 months. Measurements of atrial potentials initially as high as 8 mv. leveled off in four to six weeks to approximately 3 mv. In three dogs, measurements of 3 mv. were obtained 14½ months after implantation (fig. 2). Atrial arrhythmias have not been a complication in these experimental animals.

**Atrioventricular Synchronization**

Twenty-six dogs have had pacemakers implanted with ensuing atrioventricular synchronization. Nine of the 26 dogs were used at a later date for atrial flutter and fibrillation experiments induced by aconitine. All nine dogs died of ventricular fibrillation. Seven dogs were sacrificed at intervals of 2 to 12 weeks for studies of atrial and ventricular fibrosis. Results again were similar to those of Chardack and Zoll. Three dogs died in the first month of infection (pneumonia, atelectasis, empyema). Three dogs were sacrificed in the first two months after thresholds for stimulation rose above the 5.0 ma. elicited by the pacemaker. The electrical stimulation did not affect the rise in threshold, as similar increases were obtained with both ventricular leads. Four dogs are alive and well with perfect synchronization for periods of two to eight months (fig. 3).

**Sinus Rhythm**

In considering the clinical event of complete heart block alternating with periods of normal sinus rhythm, studies were carried out with fixed-frequency pacers as well as with the synchronous pacer. In the former, with a constant slow pacer rate between 60 and 70, no conflict occurred as long as complete heart block was present. However, with return to normal sinus rhythm, an out-of-phase irregularity resulted of the nature of an artificially induced parasystole. Such occurrences were avoided when the synchronous pacemaker was used. Six normal dogs had synchronous pacers implanted. Normal sinus rhythm was not interfered with in any of the dogs over a period of one to two months’ observation (fig. 4). Stimulus was elicited at a time when the ventricle was in absolute refractoriness.

**Supraventricular Rapid Rhythms**

Supraventricular abnormal rhythms, such as atrial tachycardia, atrial flutter, or atrial fibrillation, are not infrequently present in complete heart block. Correction of complete heart block with a rapid atrial rate results in a rapid ventricular rate when it is corrected with a synchronous pacing mechanism. To obviate such an occurrence, the synchronous pacemaker includes a refractory delay, which reduces by a factor of one to six the number of pulses passed. In dog implantations, the maximal synchronous rate is 150. When the aconitine-induced atrial rate exceeds that value, the rate transmitted to the ventricle is automatically reduced by a factor of two. This factor applies until the atrial rate reaches...
300, when a blocking factor of three is introduced. Therefore, when the rate is below 150, the ventricle is paced at a 1:1 rate. At rates of 151 to 300, the ventricle is paced at a 2:1 rate. If the atrial rate reaches 300, a 3:1 block takes over and the ventricular pacing rate is downgraded to 100. In no case can ventricular contractions advance above 150. To obviate repeated rate shifts or "hunting" when borderline frequencies are involved, the cut-in and out rates are set apart by about 20 beats per minute. If the atrial rate is at 160, the pacemaker blocks 2:1 to give 80 ventricular beats per minute. The atrial rate must drop to 130 before the pacemaker will follow again with a 1:1 rhythm. Thereafter, it will not block again until a rate of 150 is reached.

To compensate for the possibility of failure to pick up an adequate initiating P wave because of a weak signal (less than 2 mv.), the circuit is provided with a standby, fixed-rate pacing system set at 60 pulses per minute. This circuit immediately takes over and will operate continuously in the absence of a suitable atrial signal, as frequently occurs in atrial flutter and fibrillation (fig. 5).

**Summary**

An implantable, synchronous cardiac pacemaker for long-term correction of complete heart block has been developed. It has been successfully used in dogs for periods up to eight months. The performance of the pacemaker during normal sinus rhythm and atrial arrhythmias is illustrated with electrocardiograms. After implantation of the pacemaker, the dogs have returned to completely normal activity and have tolerated all physical exercises well.
Acknowledgment

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Addendum

Recent experience with two successfully synchronized implantations in man has resulted in a revision of the sensitive atrial amplifier to respond to positive as well as negative P potentials. In one patient, the left atrial potentials were only positive. In five other human left atrial electrograms, positive and negative P waves were similar to those recorded in 30 dog left atria. A more detailed report will appear in the future.

References

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