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TRANSISTOR PACEMAKER FOR TREATMENT OF COMPLETE ATRIOVENTRICULAR DISSOCIATION

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The pacemaker here described has been used in 66 patients to correct complete heart block. In most cases the block followed surgical procedures, but it also occurred in some nonsurgical patients. The pacemaker consists of three parts: a 9.4-volt mercury cell battery as the source of power, a transistorized oscillator transformer to generate the pulses needed to stimulate the heart, and a unipolar or bipolar electrode in the form of a wire anchored by stitches to the myocardium. The myocardium of the right ventricle has usually been chosen as the most convenient site. Nonsurgical patients incapacitated by complete heart block with low cardiac output have had their conditions maintained on continuous stimulation for up to 15 months by means of this equipment.

A transistor pacemaker (fig. 1) and bipolar electrode has been developed for use in patients with complete atrioventricular dissociation and an inadequate cardiac output. This pacemaker is designed for either short-term or long-term ventricular stimulation by means of an internally implanted myocardial electrode.[1]

Complete atrioventricular dissociation is likely to occur in about 10% of patients who have undergone surgical repair of septal defects located in the vicinity of the atrioventricular node and the common bundle of His, and this method of internal stimulation was developed originally to meet this need.

Temporary or permanent complete heart block is not, however, a rare complication of many diverse types of myocardiopathy, sometimes idiopathic or induced by arteriosclerosis, infection, or drug administration, therefore this method of internal stimulation has found a place also in the treatment of selected patients with complete block from these causes.

At first the significance of surgically induced complete heart block rested in its high mortality. Of the first seven patients with septal defects in whom this complication of open-heart surgery developed in 1954-55, all died in the immediate postoperative interval, despite the use of epinephrine, ephedrine, atropine, sodium lactate, and the external electric pacemaker, death was clearly a result of an insufficient cardiac output owing to the acutely slowed ventricular rate. The condition was further aggravated by the increased metabolic needs in the immediate postoperative interval, so that cardiac rates below 70 per minute were usually incompatible with life. Moreover, as we have previously pointed out[1a] the widespread adoption by many surgeons of the practice of arresting the heart with potassium citrate and prolonged anoxia during surgical repair of septal defects significantly increases the incidence of complete heart block.

Attention then turned to the use of isoproterenol hydrochloride,[2] and this drug was effective in reducing the mortality to about 40% by increasing cardiac rhythmicity and rate.[3]

Treatment was not satisfactory, however, until the combined use of an electric pacemaker and a fine electrode implanted into the heart muscle was developed.[4] The ventricles in block are very responsive to repetitive electric stimuli, and only low currents, which are imperceptible to the patients, are needed. With this treatment the mortality of heart block occurring as a complication of cardiac surgery has fallen greatly, and this, together with other developments, has been one of the important factors reducing the over-all risk of operation for septal defect to low levels.[5]

In addition, a simple technique has recently been developed for percutaneous insertion of a myocardial electrode[1a] which should prove equally lifesaving for certain nonsurgical patients with this problem and in whom emergency treatment may be required.

Advantages of Internally Implanted Transistor Pacemaker

The pacemaker is compact, being only slightly larger than a package of cigarettes. Its small size, light weight, and self-contained power source allow for complete patient mobility. A light, washable shoulder "holster-type" sling, made of cotton with snap fasteners, has been developed to allow ambulant patients who require continuous stimulation to wear their pacemaker conveniently while leading an active life. Because it is battery-operated, patient safety and efficiency of patient care are greatly improved. The patient is not in danger of electrocu-

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tion should a short circuit develop, as he is with equipment operated by alternating current, nor is he at the mercy of a power line failure or an accidentally pulled power cord

Several recent developments in electronics make this practical and reliable pacemaker possible, namely, the transistor, improved mercury cell batteries, and miniature components, together with advances in plastics and insulating materials The transistor offers several advantages over the vacuum tube in pacemaker application These advantages have resulted in high reliability and long life expectancy, greater battery efficiency, elimination of need for warm-up time, and much smaller size Also, the transistor adapts well to the low-voltage, low-resistance, high-current circuits necessary for artificial cardiac stimulation

Method of Operation —The battery used in this pacemaker is a 9 4-volt mercury battery This battery has a high capacity-to-size ratio and flat voltage-discharge curve, so that for a given setting of the pacemaker stimulation is relatively constant throughout the useful life of the battery The pacemaker output chosen was a 2-msec square wave-current pulse, variable in amplitude from 1 to 20 ma into a 1,000-ohm load A 2-msec pulse length was used, since this is far enough out on the strength-versus-duration stimulation curve to evoke a systole with a reasonably small current and yet far short of that capable of triggering ventricular fibrillation A special blocking oscillator transformer was developed to secure the proper pulse width at the voltage used and yet have a low core loss Because experience has shown that heart circuit resistances seldom run below 350 ohms, the pacemaker is calibrated in milliamperes for this load

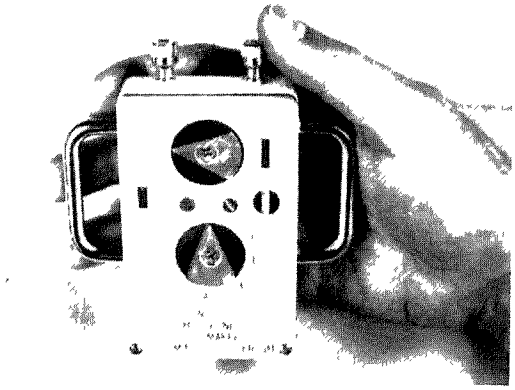

Fig 1 —Transistor pacemaker with self-contained battery for use in treatment of complete atrioventricular dissociation

plus a liberal margin, since it is current density at the cathodal lead that initiates a self-propagating excitation wave in the myocardium The blocking oscillator repetition rate is variable from 60 to 180 pulses per minute. A neon flasher is incorporated on the face of the pacemaker to indicate the stimulating pulse frequency

Location of Electrodes —The pacemaker stimulus is delivered directly to the heart by means of an electrode implanted in the ventricular myocardium This myocardial electrode is a braided tantalum (or stainless steel) wire (copper wires being less satisfactory because of fatigability and increased reaction about the electrode) insulated with poly-

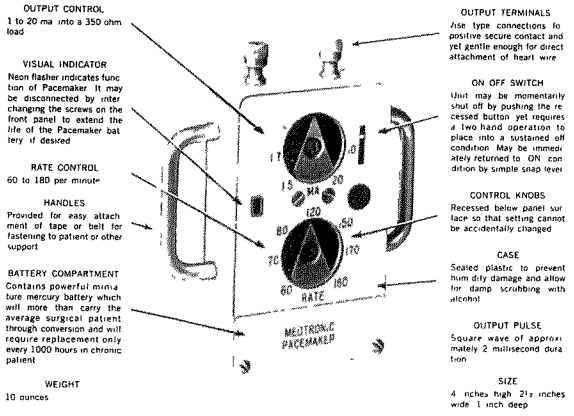

Fig 2 —Diagram describing details of pacemaker design, construction, and operation

tetrafluoroethylene (Teflon) A semicircular needle, swedged onto the end of the wire, facilitates rapid and easy insertion The electrode is anchored in the myocardium with several silk sutures, the wire is brought out through a tiny stab incision in the chest wall and connected to the negative pole of the pacemaker A flat metallic electrode is inserted into the subcutaneous tissue of the chest wall and connected to the indifferent pole of the pacemaker (fig 3, *top*) An alternative method, frequently used, has been bipolar stimulation by means of two myocardial electrodes, in which case the indifferent electrode is unnecessary (fig 3, *center*) More recently a bipolar electrode, as a single unit, with the two terminals 5 mm apart, has been developed (fig 3, *bottom*) This is advantageous when long-term stimulation is contemplated, since only a single small wire needs to emerge through the chest wall We also use this single bipolar electrode routinely now in our surgical patients

In our experimental work there have been no appreciable differences in demand for current or cardiac function with regard to whether unipolar or bipolar ventricular stimulation has been used It appears that in patients the ventricles are slightly more responsive to bipolar as compared to unipolar stimulation and slightly more responsive to endocardial as contrasted with myocardial stimulation While it should be obvious that in the presence of complete heart block the electrode must be placed within the ventricular myocardium, it makes no difference [6] where in the ventricles the electrode(s) is implanted. Thus, the right ventricle is usually chosen as the most convenient site, and in surgical

patients the diaphragmatic surface of the right ventricle away from the cardiotomy incision is recommended

In medical patients or in other emergency situations, pacemaker stimulation can be instituted by

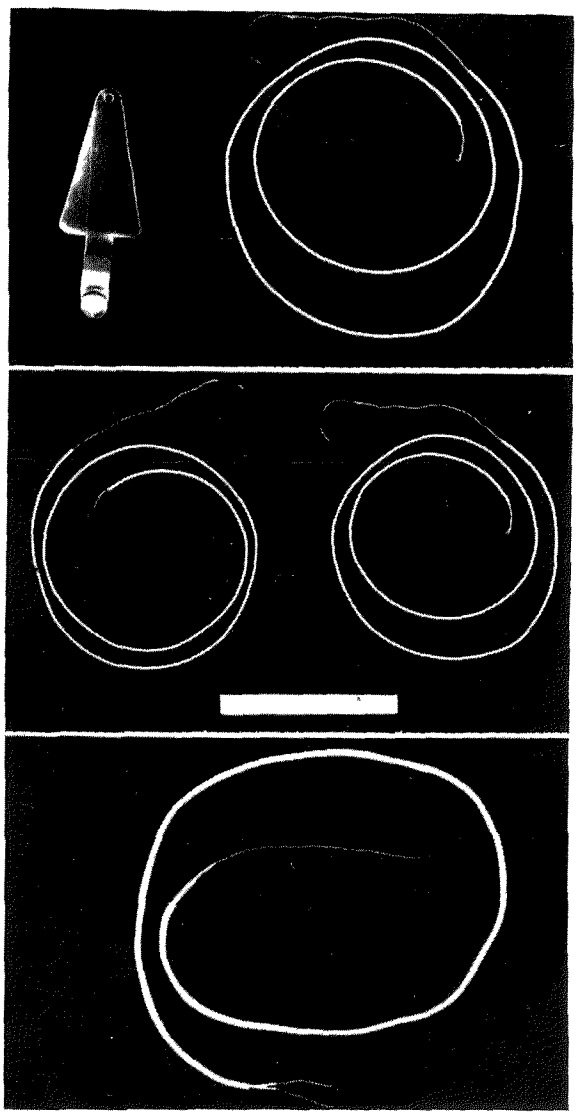

Fig. 3.—Myocardial electrodes used with pacemaker for direct cardiac stimulation. *Top,* braided tantalum electrode with Teflon insulation. Swedged-on needle facilitates implantation into myocardium, after which needle is cut off and electrode wire secured in place with several silk stitches. Triangular indifferent electrode is placed subcutaneously in thorax over left apex beat as indifferent electrode. *Center,* alternative method of bipolar stimulation, with use of two electrodes implanted directly into myocardium. *Bottom,* recently developed bipolar electrode combined into single unit. End implanted into myocardium has two terminals, 5 mm. apart Swedged-on needle facilitates implantation, after which excess distal wire is cut off flush with myocardial surface. This electrode consists of two fine braided stainless steel wires coated individually with polytetrafluoroethylene insulation and then combined into single sheath of a nonreactive silicon plastic (Silastic).

percutaneous insertion [14] of a wire in the myocardium Insulation of the electrode is not necessary. However, where long-term stimulation is contemplated, we believe it is preferable to expose a small area of the right ventricle myocardium and insert an insulated bipolar electrode directly. This may be done by means of a small incision in the fourth interspace just to the left of the sternum, with the patient under local anesthesia, without entering the pleura

Timing and Degree of Stimulation—In cardiac surgical patients, the electrode is inserted without delay at the time of thoracotomy if complete atrioventricular dissociation is noted or even suspected If complete block is obvious, it has proved advantageous to institute stimulation before taking the patient off the heart-lung machine. The pacemaker stimulus is used as long as the patient remains in complete heart block The rate of stimulation is usually 100 to 120 per minute, or roughly equivalent to what the patient would be expected to have under similar conditions were complete heart block not present.

About two-thirds to three-fourths of the surgical patients regain sinus rhythm within the first two to three weeks of continuous electrical stimulation. When the patient reverts to sinus rhythm, the pacemaker is turned off and careful monitoring of the pulse rate is instituted. (A companion transistorized monitor, with alarm, has been developed This monitor uses the myocardial electrode to augment sensitivity and reliability. The monitor is inserted into the same circuit with the pacemaker to activate the pacemaker automatically should the patient's rate suddenly fall below a predetermined level) After several days, if sinus rhythm has been maintained, the myocardial electrode is removed by gentle traction

Those surgical patients who remain in complete block after this time may usually be weaned from the pacemaker gradually by progressive lowering of the rate of stimulation, supplemented by use of rectally or orally given isoproterenol hydrochloride as previously described [7] If other factors indicate a need, there is no contraindication to the use of digitalis in patients on pacemaker stimulation

The transistor pacemaker in combination with the myocardial electrode has been used in 66 patients at the University of Minnesota Hospitals to date Most of the patients have had complete heart block secondary to surgical procedures, but an increasing number of nonsurgical patients with Stokes-Adams syndrome have been restored to useful activity.

The longest interval of continuous stimulation of a patient's heart by means of a bipolar electrode and the equipment herein described has been 15 months. This patient is still under stimulation, and

the resistance through the electrode gradually rose to about 500 ohms in the first six weeks and has not changed appreciably since

In another patient, a 38-year-old engineer who was unable to work since 1957 because of idiopathic heart block and is now able to return to work, the resistance measured through his bipolar electrode six days after insertion was 230 ohms and the heart was driven by less than 2 5 ma. One month later, these measurements were 366 ohms and less than 3 ma respectively.

Comment

Since the initial description of a patient with complete heart block after closure of a ventricular septal defect who, in 1957, was successfully treated by use of a myocardial electrode and an artificial pacemaker,[8] this method has been universally adopted by cardiac surgeons faced with this complication

The miniaturized equipment here described, as well as the bipolar electrode, has been thoroughly tested and found to facilitate the use of this method by increasing safety and reliability and by providing the possibility of ambulatory treatment. The latter advantage has been particularly useful in extending the benefits of this form of treatment to those nonsurgical patients who sustain complete heart block secondary to coronary arteriosclerosis, drug therapy, or one of the other diverse causes of Stokes-Adams syndrome. In these persons the indication for use of electrical stimulation has been limited to those who are incapacitated despite the conventional forms of medical treatment by either intermittent attacks of syncope or a cardiac output which remains consistently so low that useful work and physical activity have become impossible Not only has the threat of sudden death in these patients been removed, but their physical and emotional rehabilitation has been dramatic Further miniaturization of equipment for such patients is entirely feasible Moreover, experimental work in dogs has indicated the feasibility of implantation of a tiny coil within the myocardium and the use of electromagnetic waves through the intact chest wall from a transmitter on the skin surface This latter method of stimulation by electromagnetic induction has not yet reached the state of practicality necessary for clinical use

With regard to the clinical use of direct myocardial stimulation, two facts are worthy of mention First, the ventricles with a reduced cardiac output due to a slow rate secondary to complete atrioventricular dissociation respond extremely well to repetitive electric stimuli of small magnitude delivered directly to the myocardium On the other hand, an inadequate cardiac output due to a failing myocardium, e g , from anoxia or any of innumerable causes, will not respond to electrical stimuli Even though complete heart block may be present in such patients, it is clearly secondary to the cause of the myocardiopathy and not the primary problem

Secondly, in patients in whom complete block is the primary problem, even though the heart rate and cardiac output are readily restored to adequate levels by internal stimulation, the fact that the induced ventricular and the natural atrial contractions are asynchronous means that the heart is less efficient than it would be under comparable conditions with normal sinus rhythm This reduction in efficiency is not great but it is similar to that which occurs with atrial fibrillation and has been estimated to be about 15%. In the usual patient this reduction is not significant because of the large reserve that exists. In a few surgical patients with complete heart block, however, such as those with a ventricular septal defect and severe pulmonary hypertension due to extensive arteriolar vascular narrowing or in patients with tetralogies with a very hypoplastic pulmonary artery, this reduction in cardiac efficiency might be a decisive factor in the immediate postoperative interval before readjustments have had time to occur. Thus, we have considered the possibility of using the patient's own P wave to trigger the ventricular stimulus, according to a system which has been described.[9] The practical difficulties, aside from the additional complexity of the equipment needed, have been due to the fact that, in the immediate postoperative interval when such a method has its greatest value, the P-wave rate is often unreliable, showing extremes in both directions For the more usual patient, therefore, use of a P-wave pick-up and amplification to synchronize atrial and ventricular contractions does not seem necessary.

The question of how long stimulation can be maintained appears to be related to electrode materials, design, and technique of implantation Suffice it to say that, with the present electrodes, continuous stimulation for periods well over one year has been achieved, without appreciable increase in the impedance after the first six weeks Since these patients are still under stimulation, it is not possible to provide, at this time, an estimate of the average functional interval to be expected with a single electrode If an electrode does fail, another may be implanted We recently have implanted two of the single bipolar electrodes in nonsurgical patients in whom long-term stimulation is anticipated One is brought out through the skin immediately to be used for stimulation, and the other is left buried in the subcutaneous tissue where it can be easily located should the first fail

The possibility of infection along the wire exists, but we believe that this danger can be minimized by tunneling the wire for some distance before bringing it out through the skin.

Summary

In complete heart block the ventricles are extremely responsive to repetitive electrical stimuli of small magnitude delivered by an electrode implanted in the ventricular myocardium. This method has proved to be the most effective method of managing this complication of open-heart surgery and has been universally adopted by cardiac surgeons

A light-weight transistorized pacemaker, with a self-contained battery of long life, has been developed to facilitate continuous electrical stimulation of the heart. This pacemaker may be worn by the patient, making ambulatory treatment practical Safety to the patient has been increased by this unit, since sources of difficulty due to power failure or electrocution due to short circuits are obviated by the use of a battery power source

A single bipolar braided stainless steel electrode, with good duration of function characteristics, has also been described.

Nonsurgical patients incapacitated by complete heart block with low cardiac output have been maintained on continuous stimulation for up to 15 months by means of this equipment It would appear that a small portable pacemaker such as the one herein described may improve the prognosis of many patients afflicted with incapacitating complete atrioventricular dissociation associated with an otherwise adequate myocardium Various refinements and improvements of this equipment are possible, feasible, and under study.

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Mr C W Norman supplied the braided tantalum and stainless steel electrodes with swedged-on needles The polytetrafluoroethylene insulation was supplied as Teflon by Medtronic Laboratories, Inc, Minneapolis 818, who manufactured the pacemaker, cardiac alarm, and electrodes used in this study

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