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Nicholas P. D. Smyth

Tomas Hernandez

Alvin Johnson

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Clinical Experience with Radioisotopic Powered Cardiac Pacemakers

Nicholas P. D. Smyth, MD,* Tomas Hernandez, MD and Alvin Johnson, C V T

Significant increase in the useful lifetime of the implantable cardiac pacemaker has been made possible by the development of a radioisotope power source. This paper reports experience with two models, the AEC-ARCO Nu-5 (fixed rate) and the Medtronic Model 9000 (ventricular inhibited demand). Five of the former models were implanted in 1973, and six of the latter more recently. Both types of units have functioned well.

INCREASING the longevity of the implantable pulse generator is the most important single goal in pacing today. It has been possible to extend greatly the life of the conventional Rubin-Mallory cell by reducing pulse generator output[1,2] or reducing pulse width,[3-5] each combined with reduction in electrode surface area.[6] Rechargeable nickel-cadmium cells and lithium iodide cells are also being studied as sources of longer life from chemical batteries.

The development of the radioisotopic power source, however, has provided the possibility of ten, twenty, or more years of useful power which makes possible the development of a real "lifetime" pacemaker.

During the past year, two radioisotopic pulse generators have become available in the United States for clinical testing under study protocols controlled by the Atomic Energy Commission.

The first involved the AEC-ARCO Nu-5 fixed rate pulse generator and the second, the Medtronic Model 9000 ventricular inhibited demand pulse generator.

Materials and Methods

The AEC-ARCO Nu-5 pulse generator is a fixed rate unipolar unit delivering 73 ±2 pulses per minute of 1.6 ±0.1 millisecond duration and not more than 8 nor less than 4 milliamperes into a 500 ohm load.

*Resident 1951-55. Now at Prince George's General Hospital, Cheverly, MD, and The George Washington University School of Medicine, Washington, DC.

Address reprint requests to Dr. Smyth at 106 Irving Street, NW, Washington, DC 20010.

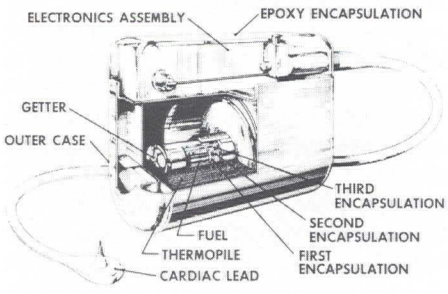

Figure 1
Cutaway drawing of the AEC-ARCO nuclear pulse generator.

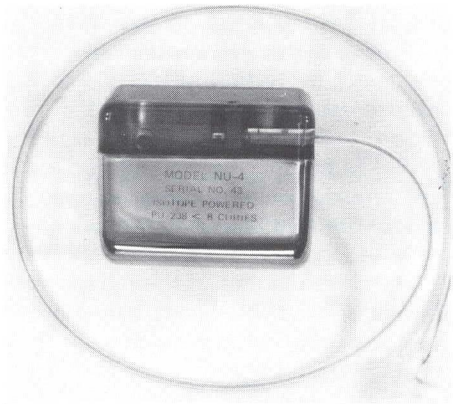

Figure 2
Photograph of complete unit with lead.

The electrical energy is derived by the thermocouple conversion of heat generated from the decay of plutonium-238 (initially 0.4 grams) which has a half life of 87.8 years. There are six tape assemblies of 88 metallic thermocouples each arranged in a series-parallel configuration to deliver approximately 2.2 volts and 230 ±10% microwatts at the beginning of life (Figure 1).

The electronic pulse generator and the electrical energy source are each sealed and then hermetically sealed to each other. Most of the external surface of the unit is titanium, which serves as the anode for pacing; a small area on top, containing the circuitry and lead receptacle is potted in clinical grade epoxy. The unit is designed to fit a unipolar Cordis pacemaker lead (Figure 2).

Maximum specified radiation from the pacemaker is 5 millirads per hour at its surface and less than 0.3 millirads at 5 centimeters from its surface. Of this, neutron contribution is not more than 1.5 millirads per hour at the surface and not more than 0.1 millirad per hour at 5 centimeters from the surface. These maximum specified dose rates in millirads correspond to a maximum specified biological dose rate of 1.2 millirems per hour at 5 centimeters from the surface and 18.5 millirems per hour at the surface. The radiation dose at the surface is 6 mrem/hr and is not considered clinically significant. These are maximum specified dose rates. The unit has demonstrated high reliability in extensive in vitro and in vivo testing.[7]

The clinical protocol requires that the pacers be implanted in patients with complete heart block only, since the AEC-ARCO Nu-5 unit is a fixed rate unit. The patients must have a life expectancy of at least 10 years, and must sign papers allowing recovery of the pulse generator by the AEC at time of death. Follow-up of the patient involves frequent checks of pacemaker rate for the rest of the patient's life. A control series of the patients using conventional pacers is required — one for each nuclear pacer implanted.

The Medtronic Model 9000 is a ventricular inhibited demand bipolar unit (Figure 3). Basic rate is 72 beats per minute. This will drop to 62 beats per minute when the hysteresis mode is operating. Output is 5.5 volts into a 500 ohm load. Sensitivity is 1.5 millivolts and refractory period is 280 milliseconds.

Figure 3
Photograph of Medtronic 9000 nuclear pulse generator.

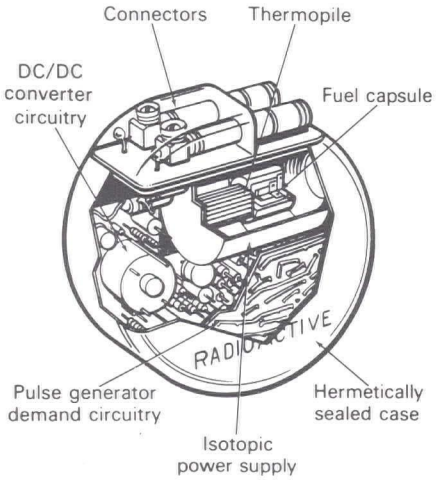

Figure 4
Cutaway drawing of the Medtronic 9000 nuclear pulse generator.

The thermoelectric generator uses Pu 238. Electrical energy is derived from the heat of isotope decay through a thermopile. The resultant voltage is amplified by a DC-DC converter to provide a signal of significant amplitude to capture the myocardium. The isotope is sealed in four metal containers. Radiation emissions are very similar to the AEC-ARCO unit and are not considered any hazard (Figure 4).

Like the AEC-ARCO pacer this unit has undergone extensive testing prior to release for clinical trial. Prior to release for study in the United States some 500 of these units had been implanted in Europe and South America with no known failure up to two years.

The Medtronic protocol allows the insertion of the unit in any patient over the age of 18 years who requires a pacemaker for any rhythm disturbance. The patient must have a life expectancy of 10 years or more. Permanent follow-up and ultimate recovery of the units are required. A control series is required of four patients with conventional battery powered units for each one receiving a nuclear unit.

In June and July of 1973, five AEC-ARCO pulse generators were implanted as replacement units in patients aged 40 to 69, all of whom had been paced for several years, and were known to be in stable third degree heart block. Conventional unipolar pacemakers were inserted in five patients at about the same time as controls. These patients were not all in complete heart block and were older. It was impossible to find a strictly comparable group of patients that could provide a meaningful control group.

Between November 1973 and July 1974, six Medtronic 9000 units were implanted in patients with complete heart block, intermittent heart block and sick sinus node syndrome. Their ages ranged from 39 to 69 years. Five were new implants and one was a replacement.

In all these cases the bipolar unit was converted to the unipolar mode using an anodal ground plate adjacent to the

pulse generator. This was done to maintain comparability with the AEC-ARCO series and with a homogeneous series of 24 patients in whom the Medtronic 5945 unipolar pulse generator had already been implanted.[5] These patients were used for the control group. Their ages and range of disease matched the Medtronic nuclear test series much more closely than was possible in the AEC-ARCO study.

All procedures were done under local anesthesia. Transvenous endocardial leads were used in all 40 patients.

Results

There were no operative or postoperative complications in any of the patients.

The five patients with AEC-ARCO units have been followed for over one year. All are alive and well. One patient in the control series died of causes unrelated to his pacemaker.

Of the six patients with the Medtronic 9000 units, one patient died at home of unknown causes. No autopsy was obtained but the pulse generator was recovered, and returned to the company. There was no evidence of pacer malfunction. Five patients are alive and well. In the control group, four patients died of causes unrelated to their pacers. One was shot to death as an innocent bystander in a service station holdup. Twenty are alive and well.

Discussion

It will be many years before the true value and exact place of the nuclear pacemaker is established. However, it is clear, even at this early stage, that they are reliable. There is widespread public acceptance of these devices. The patients that have them are proud of their "unconventional" pacemakers and there are many disappointed patients who would like to have one but do not meet the current protocol criteria.

By January 1975, the AEC will have decided on the significance of the environmental impact of these devices following a detailed study that has been going on for years. A decision will be made at that time what restrictions if any — other than retrieval — will be imposed on the use of nuclear pacemakers.

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