Clinical Experience with Radioisotopic Powered Cardiac Pacemakers

Nicholas P. D. Smyth
Tomas Hernandez
Alvin Johnson

Follow this and additional works at: https://scholarlycommons.henryford.com/hfhmedjournal

Part of the Analytical, Diagnostic and Therapeutic Techniques and Equipment Commons, Life Sciences Commons, Medical Specialties Commons, and the Public Health Commons

Recommended Citation
Available at: https://scholarlycommons.henryford.com/hfhmedjournal/vol22/iss3/4

This Article is brought to you for free and open access by Henry Ford Health System Scholarly Commons. It has been accepted for inclusion in Henry Ford Hospital Medical Journal by an authorized editor of Henry Ford Health System Scholarly Commons.
Clinical Experience with Radioisotopic Powered Cardiac Pacemakers

Nicholas P. D. Smyth, MD, Tomas Hernandez, MD and Alvin Johnson, CVT

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, or reducing pulse width, each combined with reduction in electrode surface area. 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.
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.

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 pacemaker 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.
Radioisotopic Powered Cardiac Pacemakers

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 main-
tain 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. These patients were
used for the control group. Their ages
and range of disease matched the Med-
tronic 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 post-
operative complications in any of the pa-
tients.

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 ob-
tained but the pulse generator was
recovered, and returned to the com-
pany. 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 pa-
tients 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 de-
cided on the significance of the en-
vironmental impact of these devices fol-
lowing 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.

References

1. Smyth NPD, Keshishian JM, Baker N and
   Tarjan P: Physiological rationale for the
   clinical use of low output pacemakers.
   Medical Annals of DC 43:May, 1974

2. Center S and Tarjan P: The clinical applica-
   tion of low-output pacemakers. J Thorac
   Cardiovasc Surg 64:6, 1972

3. Furman S, Denize A, Escher DJW and
   Schwedel JB: Energy consumption for car-
   diac stimulation as a function of pulse du-

4. Chardack WM, Baken EE, Bolduc L, Giori
   FA and Gage AA: Magnetically actuated
   pulse width control for implantable
   pacemakers. Ann Cardiol Angeiol (Paris)
   20:4, 1972

5. Smyth NPD, Alferness C, Shearon L et al:
   Clinical evaluation of a new pulse
   generator using narrow width for battery
   energy conservation. J Thorac Cardiovasc
   Surg. 68:471, 1974

6. Furman S, Parker W, Esche DJW and Sol-
   omon N: Endocardial threshold of cardiac
   stimulation as a function of electrode sur-

7. Kolenik SA, Hursen TF and Stevens DA:
   Nuclear pacemaker safety criteria. Associa-
   tion for Advancement of Medical In-
   strumentation, 7th Annual Meeting, April
   24-26, 1972

8. Pennington H, Hursen TF, Frommer PL and
   Morrow Ag: Animal implanted nuclear
   powered pacemakers. American Nuclear
   Society Winter Meeting, November 18,
   1970, Washington, DC