The Rise and Fall of the Nuclear Pacemaker

D. John Doyle

(This essay is in the Vancouver style: uniform requirements for manuscripts submitted to biomedical journals)

"The atomic age has moved forward at such a pace that every citizen of the world should have some comprehension, at least in comparative terms, of the extent of this development, of the utmost significance to every one of us. Clearly, if the peoples of the world are to conduct an intelligent search for peace, they must be armed with the significant facts of today's existence."

"Atoms for Peace", D. Eisenhower, 8th December 1953

Introduction

On December 8, 1953, then President Dwight Eisenhower announced plans to harness nuclear technology for nonmilitary purposes in his "Atoms for Peace" program, with the ultimate goal that "the miraculous inventiveness of man shall not be dedicated to his death, but consecrated to his life" [1]. Since that time, atomic research scientists have pursued a number of important research avenues, such as cancer eradication using radiation therapy, food irradiation technology, and medical equipment sterilization using gamma radiation.

Not all of the Atoms for Peace projects made sense. Perhaps among the most ill-conceived unimplemented plans were Bulova's plans for a plutonium-powered wrist watch and Monsanto Research Corporation's plans for a nuclear-powered coffee machine [2]. Perhaps somewhat more practical, but also unimplemented were plans for a nuclear-powered locomotive [3] and even for a nuclear-powered aircraft [4] (First year engineering students would have no problems identifying the numerous potential problems with the notion of an atomic airplane: the reactor powering the aircraft would have to be extensively shielded to prevent the crew from getting radiation sickness, making the plane so heavy that it would never be able to lift off. And, of course, a crash might leave dangerous radioactive waste spread across the landscape.)

Amid such grandiose plans were projects that made a lot of sense at first, only to be eclipsed by even better developments in technology. The nuclear pacemaker was once such project. This essay summarizes that story of the nuclear pacemaker.

Pacemaker Fundamentals

Cardiac pacemakers are implanted chiefly to treat individuals whose hearts beat too slowly, although modern day pacemakers can be programmed treat a number of other cardiac conditions, such as the treatment of congestive heart failure [5]. A slow-beating heart usually occurs as a consequence of a problem with the heart's natural electrical pacing system. By way of nomenclature, an irregularity in the heart's electrical pacing system is called an arrhythmia, or cardiac rhythm disorder. Rhythm disorders can cause the heart to beat too slowly (bradycardia), too fast (tachycardia), very irregularly (as in atrial fibrillation), as well as not beat at all (asystole).

In a normal heart, each heartbeat is initiated in the heart's natural pacemaker (the sinoatrial node), located in the right atrium (Figure 1). The electrical signal from the sinoatrial node then spreads across both atria (the heart's upper chambers), causing the atria to contract in order to pump blood into both ventricles (the heart's lower chambers). This electrical volley then continues from the atria through an area between the atria and ventricles called the atrioventricular (AV) node, which in turn connects to more conduction pathways that relay the electrical signal on to the ventricles, leading to ejection of ventricular blood into the aorta and the pulmonary arteries.

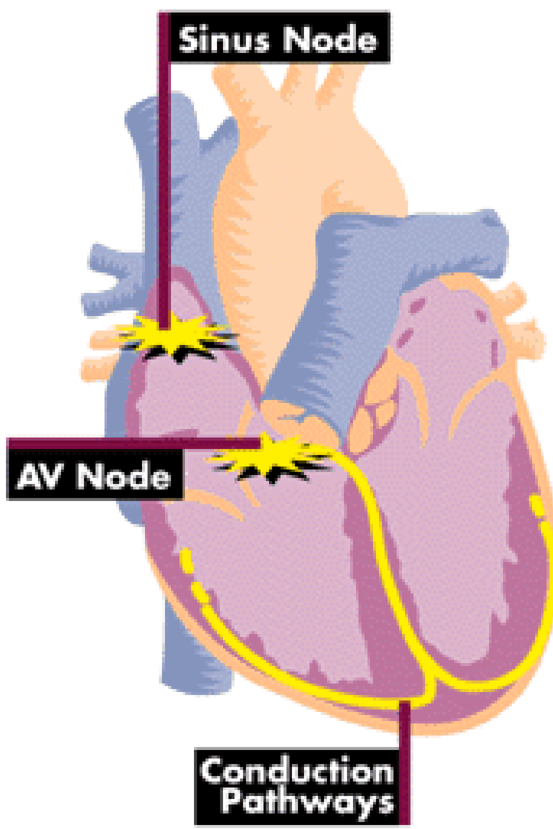

Figure 1. Schematic illustration of the electrical conducting system of the heart.

Source: www.medtronic.com/heartmc/patient/images/hearte.gif

In cases where the heart's natural electrical pacing system has failed, an artificial pacemaker may be inserted surgically to deal with the problem. Using electrodes placed in the right atrium and ventricle and driven by a "pulse generator" usually placed below the clavicle, these units usually last for several years before battery exhaustion takes over. Figures 2 and 3 provide more details in graphical form.

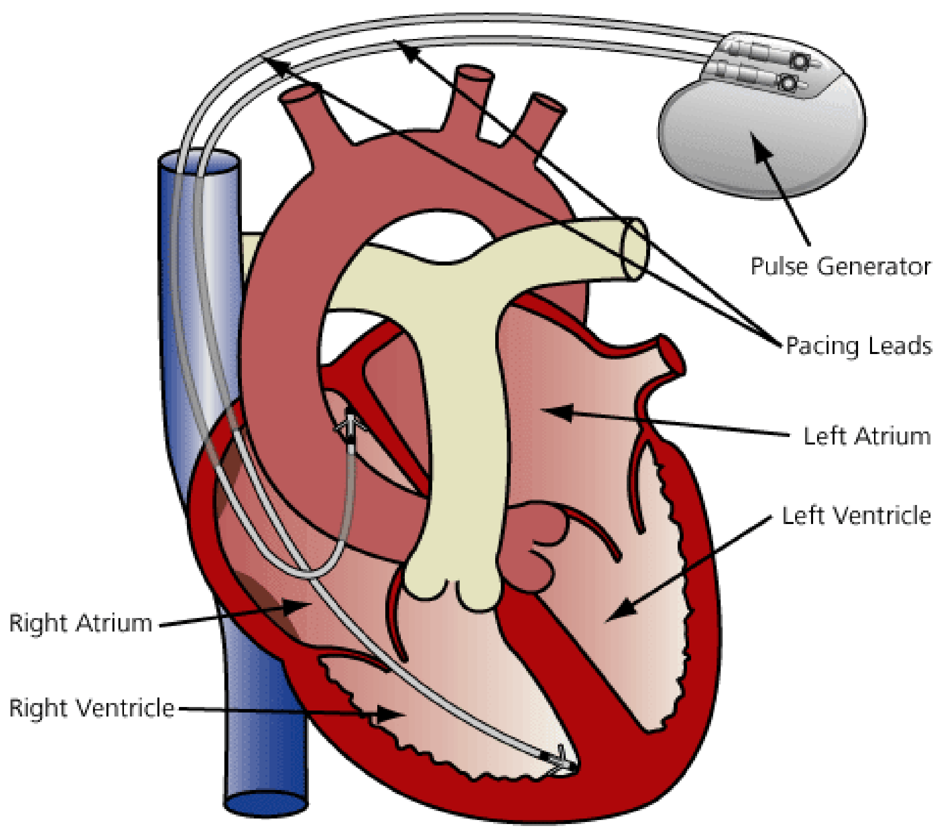

Figure 2. Schematic illustration of pacing electrodes positioned in the right atrium and right ventricle. *Source: http://www.sjm.com/assets/popups/pacemaker.gif*

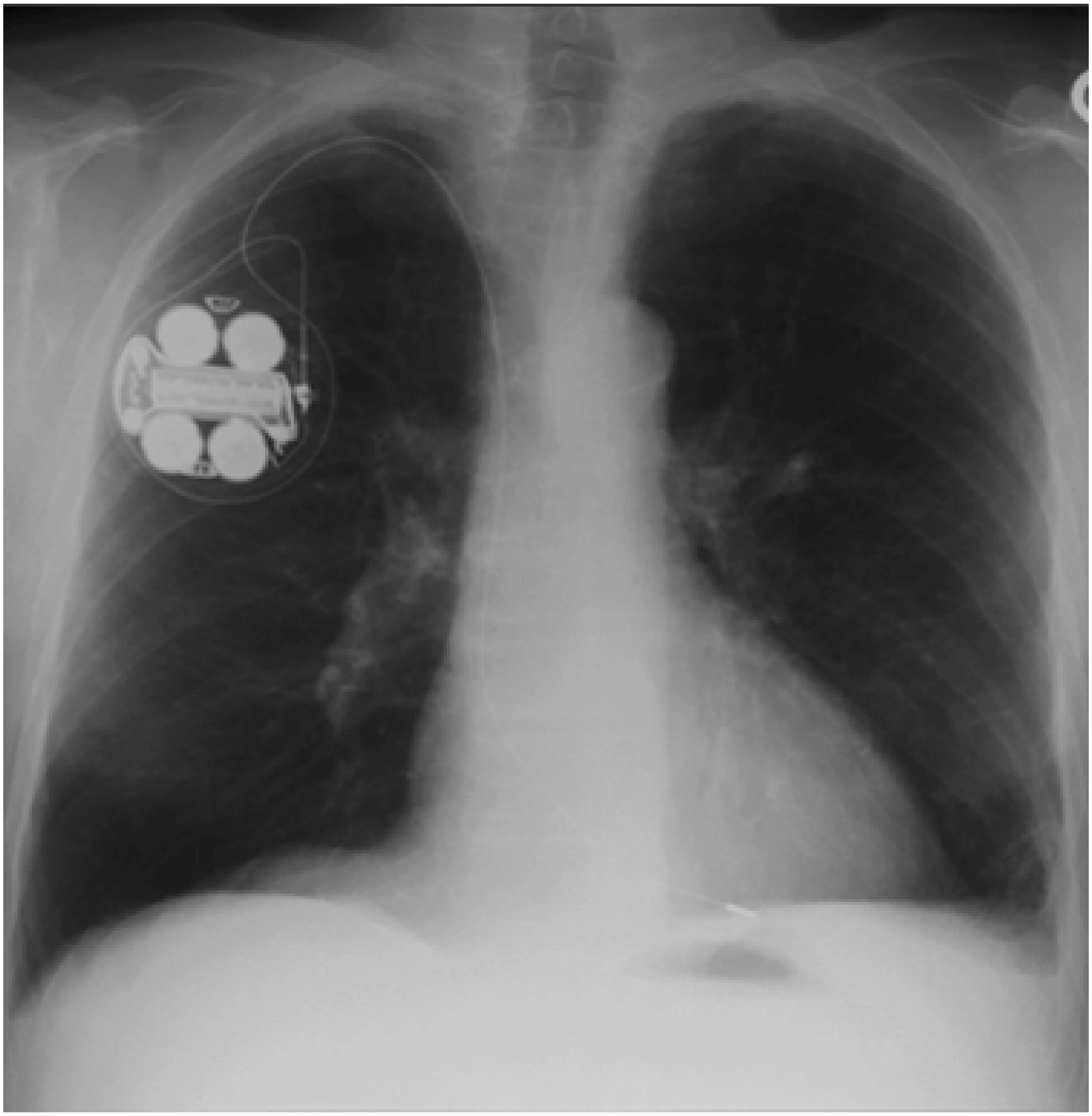

Figure 3. Chest radiograph (X-ray) showing an artificial pacemaker in place.

Source: http://info.med.yale.edu/intmed/cardio/imaging/findings/pacemaker/graphics/rad1.gif

Pacemaker History

The history of the cardiac pacemaker has its genesis in experimental hypothermia. In the late 1940’s and early 1950’s a small number of researchers were exploring the use of whole body hypothermia to permit open heart surgery [6]. (At temperatures below 30 degrees celsius the body’s metabolism is slowed down to the point that the heart can be stopped for extended periods without serious consequences.)

One difficult problem frequently plaguing their efforts was that it was often difficult to restore the heart beat upon re-warming the body. A Canadian electrical engineer, John A. Hopps, was assigned to help solve this problem. He designed a vacuum tube external pacemaker (transistors were not yet commonly available) that utilized an atrial pacing wire (Figure 4). Although effective, the system was large in size and required an external AC power source. In addition, patients could go only travel as far as their extension cord permitted, and loss of power to the unit was a constant concern.

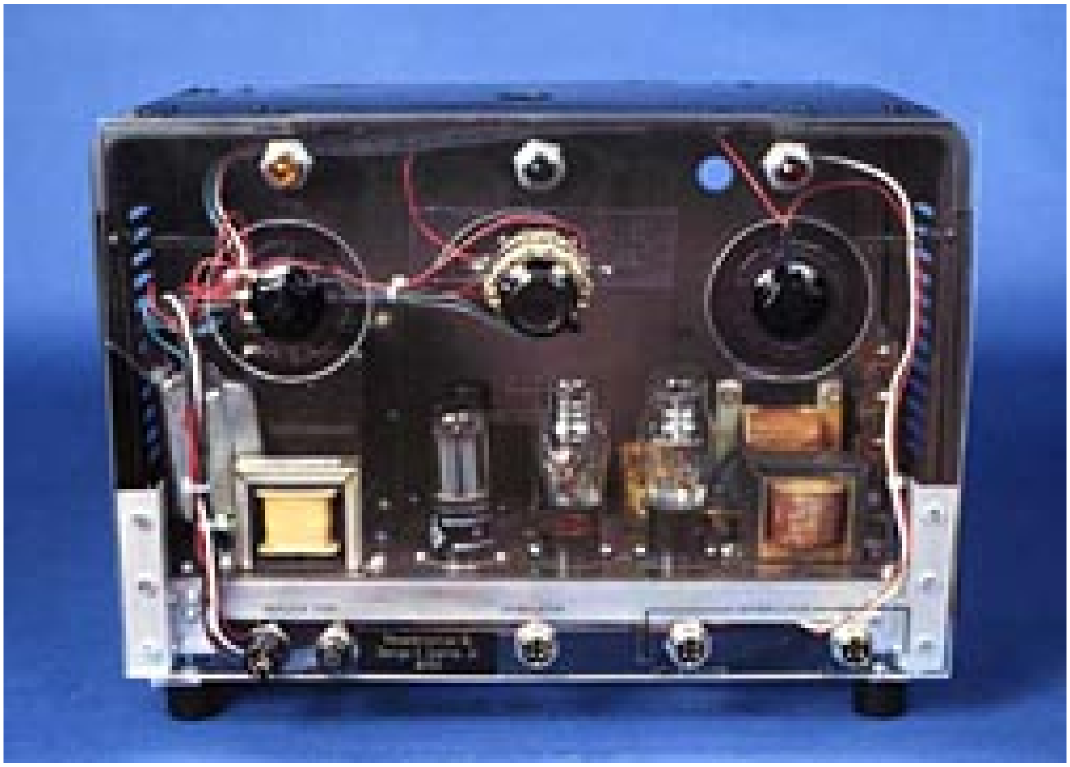

Figure 4: Reproduction of the original Hopps pacemaker. The front panel is of clear plastic to allow visualization of the circuit components.

Source: www.ipej.org/0201/79web.jpg

As developments in experimental cardiac surgery progressed, the need for improved pacemaker technology grew. At the request of the celebrated University of Minnesota heart surgeon Dr. C. Walton Lillehei, in 1957 Earl E. Bakken developed the world's first transistorized, battery-powered, wearable pacemaker. While not implanted, the unit gave patients unprecedented mobility and greatly reduced concerns about power failures. Bakken also founded Medtronic Inc. – now a world leader in pacemaker products and other medical electronic devices.

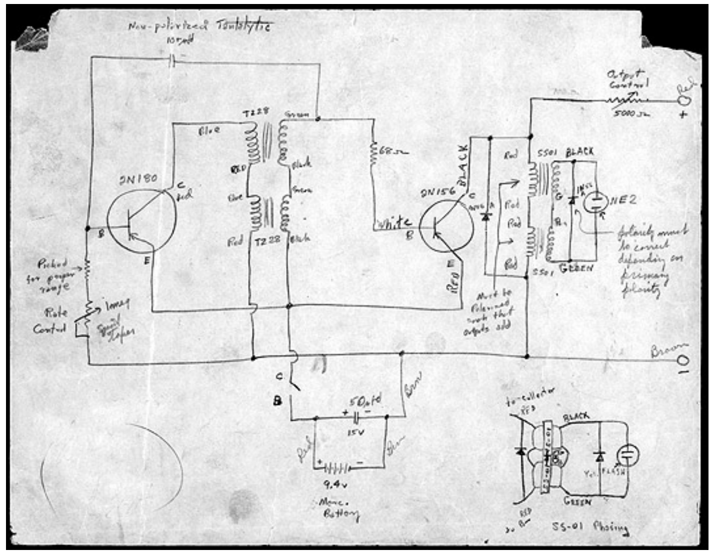

Figure 5a (left): Bakken’s original transistorized pacemaker.

Source: chem.ch.huji.ac.il/~eugeniik/history/bakken_pacemaker1.jpg

Figure 5b (right): Electronic schematic diagram of Bakken’s original transistorized pacemaker.

Source: chem.ch.huji.ac.il/~eugeniik/history/bakken_pacemaker-schematic.jpg

The next development in pacemaker technology involved developing a fully implantable unit. The first implantation into a human was done in 1958 by a Swedish team using a design that used a system of Nickel-cadmium rechargeable batteries that were charged by an external induction coil. According to Medtronic [7] well over 2 million pacemakers have been implanted worldwide since that time. However, in the early days of pacemaker technology, one particularly vexing problem was short battery life, with pulse generators lasting only a year or so. Thus the idea of using a radioactive isotope as a power source (with an expected life of about 20 years) was an exciting notion that captured the hearts and minds of a good many nuclear physicists and biomedical engineers. In 1970 the first nuclear-powered pacemaker was implanted. The first American-made nuclear-powered pacemaker was developed and implanted at Newark Beth Israel Medical Center in Newark, New Jersey in 1972 [8].

Going Nuclear

Given the remarkable developments in nuclear technology in the 1950s and 1960s it is only natural that consideration would be directed towards the development of a nuclear-powered pacemaker. In the 1960s, scientists at the Los Alamos Scientific Laboratory in New Mexico began exploring the feasibility of this goal. The laboratory had an unsurpassed record of excellence in nuclear research – it was founded during World War II as a top-secret research program called the Manhattan Project, aimed at developing the first nuclear bomb.

The key idea behind the design is to incorporate an “atomic battery” into an otherwise conventional implantable pacemaker. Variously known by the terms “atomic battery”, “nuclear battery” or “radioisotope battery”, such a power source is simply a system which utilizes the charged particle emissions from a radioactive isotope to directly or indirectly (e.g., via heating effects) generate electricity.

Figure 6: Medtronic Model 9000 implantable nuclear pacemaker.

Source: dnp.nscl.msu.edu/images/Applications11.gif

According to Parsonnet et al. [9], in the 14 year span between 1973 and 1987 a total of 155 nuclear pacemakers were implanted in 132 patients at the Newark Beth Israel Medical Center. Theoretical concerns that radiation from the units might increase cancer rates in recipients was not supported by their experience, leading the authors to write:

> The frequency of malignancy was similar to that of the population at large and primary tumor sites were randomly distributed. Deaths most commonly were due to cardiac causes (68%). Thus, nuclear pacemakers are safe and reliable and their greater initial cost appears to be offset by their longevity and the resulting decrease in the frequency of reoperations.

In the study period 48 nuclear pacemakers were removed for various reasons: electronic component malfunction (15 units), mode change (12 units), high pacing thresholds (8 units), lead or connector problems (5 units), and power source failure (1 unit). Note that pacemaker explantation surgery for mode change purposes has not been necessary for many years, as they can now be programmed via a special electromagnetic communication device. While the authors write that it is “reasonable to suggest that further use be made of long-lasting nuclear power sources for modern pacemakers and other implantable rhythm-management devices” the clinical reality is that lithium battery technology have now developed to that point that this position is no longer tenable.

On special problem with nuclear-powered pacemakers is that they must be safely recovered after the death of the patient. While it is the responsibility of the implanting hospital to follow the patient and following possible explantation, to return the nuclear pacemakers to the manufacturer for proper disposal, this can be a problem when the patient dies in a facility other than the implanting facility. The following vignette [10] illustrates this:

> Recently, a patient with a nuclear-powered pacemaker (pacemaker) expired in a different hospital from where the pacemaker was implanted. This hospital, not licensed by NRC, explanted the pacemaker and contacted the licensed hospital. The licensee made arrangements to return the pacemaker to the manufacturer. The manufacturer never received the pacemaker and informed the Radiation Safety Officer (RSO) at the licensed facility of the fact. The licensee contacted NRC to report the lost pacemaker. Six weeks had passed between the explantation of the pacemaker and the reporting to NRC. The pacemaker's 178,000 MBq (4.8 curie) plutonium-238 sealed source has not been recovered.

However, eventually the availability of lithium-powered pacemakers with an expected life of 10 or more years, and without the disadvantages of radiation concerns and vexing regulatory paperwork, eliminated the longevity advantage of there units, and the last of these units was implanted in 1988.

Actuarial data collected during their use indicated that these units performed as well. Replacements, when needed, were for mode change reasons, rather than for battery failure. (Pacemaker electronics have now become so sophisticated that changing pacing modes and pacing parameters can be done over a radio frequency link using a handheld programming unit).

Chauvel et al. [11] reported on 325 patients with a mean age of 39 +/- 18 years implanted with pacemakers powered by Pu238 who had their units implanted between April 1970 and July 1982. The mean follow-up period was 12 years. The authors found that these pacemakers performed well, noting that the actuarial survival of the device was 97% at 18.5 years. It was found that during the follow-up period 122 reoperations were necessary in 85 patients: 88 procedures for removal of the entire pacing system and 34 for modifications of the lead system. It was found that “lead dysfunction accounted for 68% of the 122 reoperations, generator failure for 6%, and miscellaneous reasons for 26%.” No radiation-related side effects were found. Based on their experience the authors concluded that the nuclear pacemaker “demonstrated its reliability for long-term cardiac pacing”.

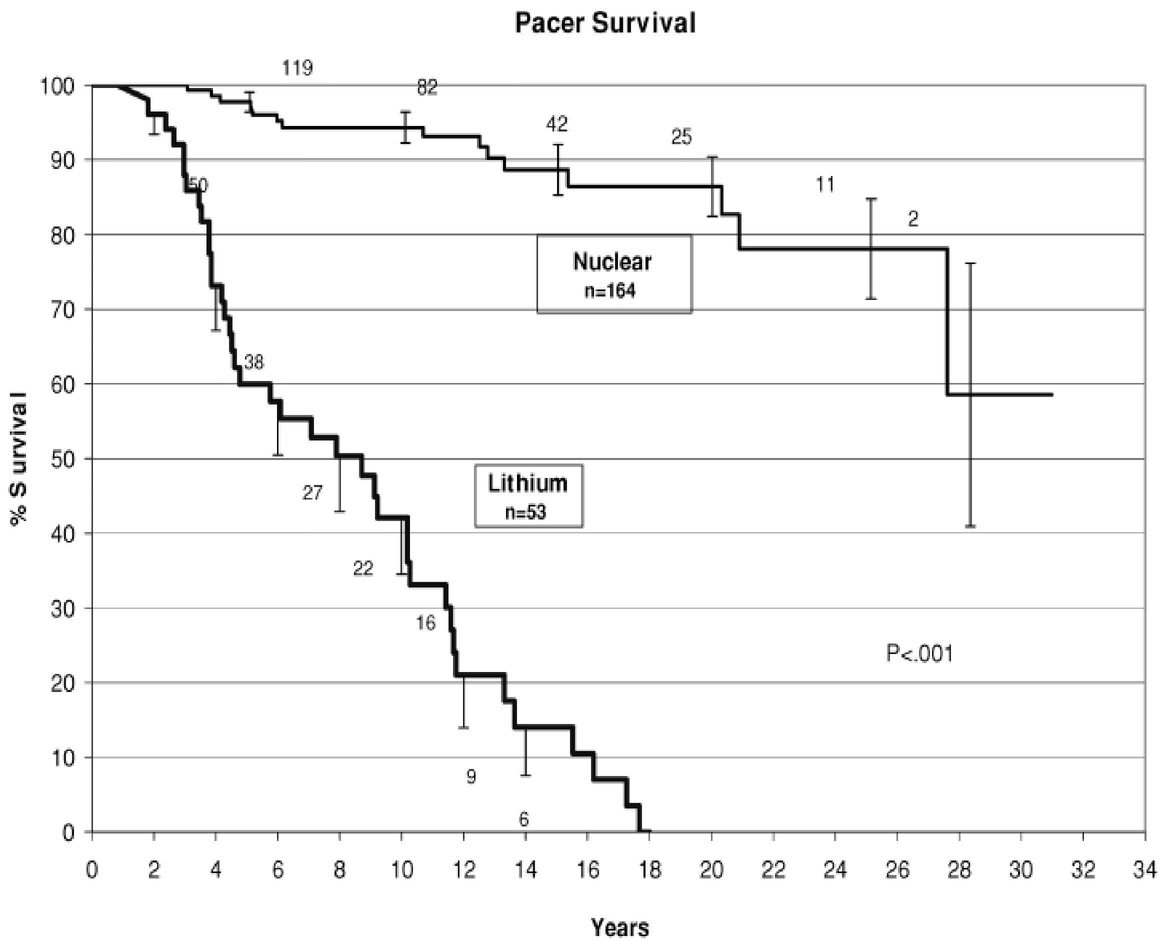

Figure 7: Survival data for nuclear pacemakers (top curve) and for lithium battery powered pacemakers (bottom). The difference in reliability between these competing technologies is obvious [12].

Source: Parsonnet V, Driller J, Cook D, Rizvi SA. Thirty-one years of clinical experience with "nuclear-powered" pacemakers. Pacing Clin Electrophysiol. 2006;29:195-200.

Ethical Issues

In this section I would like to briefly consider some ethical issues pertaining to the nuclear pacemaker. The introduction of new medical technologies inevitably raises ethical issues, especially in the context of protecting the interests of patients who may also serve as experimental subjects. Presumably, those patients who were offered the option of a nuclear pacemaker or a conventional battery-operated pacemaker were provided with the expected details regarding the risks, benefits and alternatives, as normally occurs with any ethical medical intervention.

However, while the potential benefits of a longer-lasting pacemaker and the alternative of using a battery-operated pacemaker are perhaps easily explained to patients, it can sometimes be difficult to get a handle on the specific risks involved. This is because in some cases there may be theoretical risks that may not be readily quantified, such as the risk of developing a malignancy or other serious complication such as radiation fibrosis while being exposed a source of radioactivity over a prolonged period.

Even more difficult would estimating social risks, such as the risk that a patient with a nuclear pacemaker might be kidnapped and murdered with a view to committing a terrorist act by extracting the plutonium fuel and introducing it into (say) the Pentagon’s air intake system. (Inhaled plutonium dust is very carcinogenic: a mere one ten-thousandth of a gram (0.1 milligram) ingested in this manner can cause cancer [13].)

The Future

Although nuclear-powered pacemakers do not appear to have a future, continuing developments in pacemaker technology are inevitable. As an example of a European product that will likely become available in the US, Biotronik has developed an implantable pacemaker / defibrillator that can not only deliver life-saving defibrillation shocks when patients are in ventricular fibrillation, but also adds an ability to monitor the performance of both the heart and the device itself. This product is also able to send daily diagnostic information to clinicians using the mobile phone network as well as immediately in the case of a critical event.

Figure 8: Photograph of the Biotronik Lumax 300 HF-T pacemaker with the ability to send routine and emergency diagnostic information via the mobile phone network and by other means.

Image Source:

http://www.medgadget.com/archives/2006/10/biotroniks_luma.html

References

[1] http://www.eisenhower.archives.gov/atoms.htm

[2] Metzger, H. Peter. The Atomic Establishment. NY: Simon & Schuster, 1972, p. 227

[3] http://www.rachel.org/bulletin/bulletin.cfm?Issue_ID=610

[4] http://www.radiationworks.com/flyingreactor.htm

[5] http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01100.html

[6] Bigelow WG, Callaghan JC, Hopps JA. General hypothermia for experimental intracardiac surgery. Ann. Surg. 1950; 1132: 531-539.

[7] http://www.medtronic.com/brady/patient/pacemaker_history.html

[8] http://experts.about.com/e/a/ar/Artificial_pacemaker.htm

[9] Parsonnet V, Berstein AD, Perry GY. The nuclear pacemaker: is renewed interest warranted? Am J Cardiol. 1990;66:837-42.

[10] http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1998/in98012.html

[11] Chauvel C, Lavergne T, Cohen A, Ducimetiere P, Le Heuzey JY, Valty J, Guize L. Radioisotopic pacemaker: long-term clinical results. Pacing Clin Electrophysiol. 1995;18:286-92.

[12] Parsonnet V, Driller J, Cook D, Rizvi SA. Thirty-one years of clinical experience with "nuclear-powered" pacemakers. Pacing Clin Electrophysiol. 2006;29:195-200.

[13] W. J. Bair, "Toxicology of Plutonium," in *Advances in Radiation Biology*, J. T. Lett, H. Adler, and M. Zelle, Eds. Academic Press, New York, NY, 1974, pp. 255-315.