The First Pacemaker Implant in America

Orestes Fiandra

In January, 1986, as part of the First Inter-American Cardiac Pacing Symposium I had the honor of describing my experience with the first totally implantable pacemaker in America, which was the second pacemaker implanted anywhere in the world.

During my internship and later while working in the hospital emergency department I had often been frustrated by my inability to effectively treat patients with Adams-Stokes seizures. At a time when even external cardiac massage was unknown the only therapeutic option was intravenous or intracardiac administration of drugs such as atropine, epinephrine or sodium lactate. In most instances treatment was unsuccessful or the side effects of the large doses of medication required, were not tolerated.

My interest in cardiac pacing began with reading of Zoll's 1952 initial description of trans-thoracic cardiac stimulation. The possibility of electrical cardiac stimulation was very encouraging as an emergency treatment for patients with Adams-Stokes seizures. Still, we had the residual problem of management of those who, once resuscitated, persisted with atrioventricular block and experienced repeated episodes of cardiac arrest.

In 1954, Professor Clarence Crafoord invited me to train in cardiac catheterization and angiography at the Karolinska Institute in Stockholm. I worked in the department of cardiology of the pediatric clinic under the direction of Professor Bjorn Wallgren. At that time a very close working relationship existed between that department and Elema-Schonander, a Swedish manufacturer which tested much of its medical equipment at the clinic.

I had the privilege of meeting Dr. Rune Elmqvist, a friendly and innovative engineer, who was the director of the Department of Electronics at Elema-Schonander, and joining him in discussing the feasibility of developing an implantable pacemaker. I remember inquiring persistently about the manufacture of an implantable unit, which would use germanium transistors encapsulated in a newly available epoxy resin that had proven effective for insulating underwater cables. He responded that there was no battery available that was sufficiently small and could cope with the high leak rate of germanium transistors. In retrospect, I consider his statement prophetic, i.e., the evolution of implantable pacemakers has been closely tied to the development of new power sources and electronics. When I left Stockholm in 1955 an implantable pacemaker remained a remote possibility despite other important advances in medical equipment.

On October 27, 1956, I was asked to see a 37-year-old lawyer, with an unremarkable personal medical history and a family history of diabetes. She had experienced her first Adams-Stokes episode. The physical examination was normal except for a regular bradycardia. The ECG showed complete heart block. Congenital heart disease, Chagas' disease and other infectious and systemic diseases were eliminated as possible etiologies. Drugs were unavailing and she continued to experience Adams-Stokes attacks, sometimes as many as three a day. Between the attacks she recovered completely and continued her professional activities.

In 1959, the frequency of syncope increased so that I considered the possibility of pacemaker implantation. I disliked use of an external line current powered device, the only one available at the time, as a therapeutic approach for a young and active woman. I then inquired of Dr. Bengt Jonsson, my friend and mentor at Karolinska, whether Dr. Elmqvist had succeeded in producing an implantable pacemaker. His response of July 27, 1959 was discouraging. The first human experience with an implantable pacemaker had failed. The small generator, implanted by Dr. Ake Senning on October 8, 1958 had not worked as expected. Large external pacemakers "...connected to the general current supply..." were still in use in Sweden for the treatment of AV block. I wrote directly to Elmqvist suggesting consider-
ation of recent technological advances, i.e., the silicone transistor which seemed more suitable for an implantable pacemaker than the germanium transistor, and a new epoxy resin (Araldit) produced by Ciba, which had excellent biocompatibility for pulse generator encapsulation. Above all, I trusted Dr. Elmqvist's ability to solve the problems experienced in the first implantable unit.

He confirmed my expectations. He was able to provide an implantable pulse generator powered by two rechargeable nickel-cadmium batteries, each delivering 50 microampere/hours. Recharging was accomplished by a 150 kHz current generated by an external 220 volt unit. The current was transmitted by induction from an external flexible coil 25 cm in diameter (Fig. 1) placed on the skin over the pacemaker, to a coil 50 mm in diameter within the implanted generator. The pacemaker required charging once a week for 12 hours.

The cylindrical unipolar, asynchronous implantable generator consisted of the nickel-cadmium batteries, the electronic circuit and the recharging antenna, all encapsulated in epoxy. It was 52.5 mm in diameter, 17.5 mm thick and weighed 64.3 grams (Fig. 2). The lead had a braided nylon core surrounded by four flat stainless steel bands insulated by a polyethylene coating. The stimulating electrode was a platinum disc 9 mm in diameter, to be sutured to the epicardium through two small holes. The cathodal stimulating surface area was 63.6 square mm (Fig. 3), the anode was a metal ring 10 mm wide on the pacemaker's edge. The ring was not completely circumferential to avoid interruption of the magnetic field created by the charging current.

Dr. Robert Rubio implanted this unit on Feb-
ruary 3, 1960 at the CASMU Clinic of Montevideo, Uruguay. The epicardial electrode was sutured to the left ventricular surface and the pulse generator was placed in the abdominal wall. Her early course was of an increased exercise tolerance and the absence of Adams-Stokes seizures. Infection developed in the thoracic incision and she died of sepsis on October 20, 1960, 9½ months after pacemaker implantation. Despite the outcome, this initial experience with an implantable pacemaker was very encouraging. It was, indeed, the starting point of a prolonged effort to develop pacemaker technology in Uruguay and to make it available to the entire population, regardless of economic status. We concentrated our efforts in two areas.

First, we created a National Fund to provide pacemakers for the entire Uruguayan population. After 14 years we persuaded our health authorities of the benefits of the project. Today, this national fund provides pacemakers and also covers other medical interventions such as cardiac catheterization, cardiac surgery, renal analysis and transplantation and hip prostheses for the entire population. The fund is supported by a monthly contribution of US $0.48 per person from the middle income and wealthy population and a larger government contribution on behalf of the
Figure 3.
indigent population. As a result of this system, 311 pacemaker implants/year/million inhabitants are performed in Uruguay, a figure similar to that of developed countries.

The second project was the creation of a pacemaker industry to supply pacemakers at a reasonable price and to serve as a financial support for research projects in cardiology and pacing. Manufacture of pacemakers started in 1970. Initially we received technical assistance from the Instituto Dante Passanese of Sao Paulo, Brazil where pacemakers were already being manufactured under the direction of Drs. Adibe Jatene and Decio Kormann, to whom we are grateful. In our 16-year experience with pacemaker manufacture we have used mercury, nuclear, and lithium power sources and were the sixth plant to use lithium batteries. We also designed a self anchoring electrode for permanent endocardial stimulation and are in the final research stage of developing a new shape for the endocardial electrode which has already demonstrated very low chronic stimulation thresholds.

Our initial pacemaker implant, in 1960, was the start of this long process. Uruguay, a small (188,000 sq km) South American country, with 2,970,000 inhabitants has the privilege of being one of 17 countries worldwide with an indigenous pacemaker industry as well as being the site of one of the 34 pacemaker factories of the world.

Reference