The Proliferation of Cardiac Pacing: Medical, Technical, and Socioeconomic Dilemmas

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THE RAPID GROWTH of pacing technology calls to mind the cynicism that defines fanciful new therapy as treatment in search of a disease. It has been claimed that pacemakers are too complex, too expensive and too fancy, because surely little more is needed of a pacemaker than its ability to pace the heart. One also hears accusations that pacemakers are being implanted needlessly and in unwarranted numbers.1 Answers to these challenges are badly needed, but largely unobtainable, partly because innovations in pacemakers have come along at such an amazing rate that full evaluation of these accomplishments has not been completed, and partly because the clinical efficacy of a certain pacemaker is hard to prove.

New pacemakers are implanted in the United States at a rate of 308 per million inhabitants, almost twice that of any other country. About 100,000 pulse generators are implanted each year, one-third of which are replacements.2 It has been estimated that there is one pacemaker for every 800 people. If the average pacemaker costs $2500, then the cost of pulse generators alone is around $250 million, excluding electrodes and other hardware and hospital markups. This market is shared by seven American companies (sale of foreign-made pacemakers in the United States is minimal), only two of which have been in existence since the early 1960s (Medtronic and Cordis), and five of which share 90% of the market (Medtronic, Cordis, CPI, Intermedics and Pacesetters). Several large and small companies have fallen by the wayside.3

State of the Art

The generally accepted indication for implanting a permanent pacemaker is symptomatic bradycardia, most often due to fixed or intermittent complete atrioventricular (AV) block. Symptoms are syncope (the classical Adams-Stokes seizure) or lightheadedness proved to be temporally associated with the bradycardia. The spectrum has been broadened to include suspected bradycardia, even when unproved by ambulatory monitoring. Symptoms may also include certain manifestations of low cardiac output, such as confusion and lassitude, and prerenal azotemia. Finally, indications have now been extended to include the prevention or interruption of certain tachyarrhythmias.

In the United States, pacemakers are implanted by almost any physician who claims to have the technical skills to do so, regardless of specialty or training. About half the implanters are general or thoracic surgeons and half are cardiologists.4 There are no guidelines or qualifications for surgical privileges except for the recommendations of the 1974 Inter-Society Commission for Heart Disease Resources (ICHD) Report, which are largely ignored.5 No national accrediting agencies or policies and few hospitals define or enforce surgical privileges for pacemaker implanters. In many other countries, pacemakers are implanted only by acknowledged experts and in regionalized centers.

Almost no one today implants a pacemaker with epicardial (myocardial) wires except when the heart is already exposed in the course of open heart surgery, or on the rare occasions when the transvenous approach is impossible. The percutaneous introducer has somewhat simplified the transvenous technique, but, one hastens to add, at the peril of a few potentially lethal complications, such as pneumo- or hemopneumothorax and massive pulmonary air embolism.

Long-life power sources, particularly some of the lithium cells and radioisotope generators, have substantially extended pacemaker life so that at 7 years, 90% of these pulse generators still function.6 The 50% failure point is many years off, far beyond the life expectancy of the average patient (but certainly not all patients) (fig. 1). Even two-chamber pacers are faring quite well. Of 177 such units in the FDA registry (138 Intermedics 259-01 and 39 Medtronic 5992), there has been 100% survival at 2 years (Bilitch M. et al.: unpublished data of Five Center Study). (Pulse generators with mercury-zinc cells are no longer sold in the United States.) Improvements in battery life have not interfered with continued reduction of pacemaker size; all modern units are small enough to be acceptable to even the smallest and most emaciated patients.

New designs and construction now render the wires almost fracture-free and impervious to damage. Reliable and stable positioning of the electrodes should be achieved in more than 95% of implantations, even in difficult situations.

The role of the atrium in pacing has been debated. A growing interest has been abetted by the perfection of suitable right atrial grasping electrodes and the availability of two-chamber pacemakers. For pacing and sensing both chambers, hardware components of acceptable size, life expectancy and simplicity are appearing on the market.

Physiologic (or adaptive) pacemakers are two-chamber units primarily designed to maintain AV synchrony. Such devices pace the ventricles in synchrony with spontaneous atrial activity, or lacking that, pace the atrium and ventricle in sequence. Several ingenious combined synchronous and sequential pacers have
been developed, but only the AV synchronous and AV sequential have been available long enough to permit clinical appraisal. No one has shown that quality of life, longevity, or adaptability to disease states can be improved by use of these pacemakers; nor have physicians embraced these devices, as evidenced by a 1978 survey that reveals that only 6% of the implants involved the atrium.2

Simple (two functions only) and multiprogrammable pacemakers are universally available, but their usefulness is still being evaluated. There is little argument that output programming has many merits, particularly conserving battery life and reducing skeletal muscle stimulation. Rate adjustments allow the patient with intermittent bradycardia to remain in sinus rhythm as long as possible, and are used to overdrive certain arrhythmias. Sensitivity programming may reduce the tendency of some pacers to sense myopotentials, or may enhance sensing of P or R waves of marginal amplitudes. Less clear is the importance of programmability of other functions, such as refractory period, AV delay, polarity (unipolar or bipolar), and mode, although there are many enthusiasts for such multiprogrammability. The issue of multiprogrammability is so complex that it has prompted the development of a new ICHD coding system, published in Circulation.6 Incidentally, programming has produced its own brand of real and false complications, such as misinterpretation of ECGs and phantom programming; and it has resulted in a profusion of contrivances that are incompatible with one another. Patient follow-up and record keeping have become complex.

Another area that is still evolving is the use of special pacemakers that diagnose, prevent, and treat tachyarrhythmias. No one knows the prevalence of supraventricular or ventricular tachycardia or, more specifically, how often pacemakers will be indicated for their management (rather than standard drug therapy, for example, or surgical interruption of accessory pathways in accelerated AV conduction disorders). The field of electrophysiology is too new to provide answers to these questions, let alone define the problems. Nevertheless, implanted pacemakers can prevent or interrupt arrhythmias in several ways (table 1), and several pacemakers can be purchased for this purpose. The automatic implanted defibrillator is still in an early phase of clinical evaluation; when it has proved to be safe and effective, it will present many intriguing therapeutic possibilities.

No national society or organization has promulgated professional practice standards, although early attempts have begun to appear, such as the ICHD report.5 Standards organizations, such as the International Standards Organization (ISO) and American Association for the Advancement of Medical Instrumentation (AAMI), by design play no role in promoting clinical excellence. The FDA-sponsored Five Center Registry has, since 1974, only served as a professional monitor for pulse generator survival, wire fractures, and early postoperative electrode dislodgement. Their findings on pulse generator survival, summarized bimonthly in PACE, is useful. The North American Society of Pacing and Electrophysiology (NASPE) may play a role in delineating criteria for optimal training and certification of physicians in pacing.

In summary, modern pacemakers are small, highly reliable, long-lasting instruments that are programmable to meet individual needs; some are “physiologic” in that they are designed to maintain AV synchrony. Pacemakers are used in patients who suffer from both slow and fast cardiac arrhythmias; implantations are performed safely and reliably when physicians are properly trained.

Pacemaker Problems

The accusation of “needless” implantation probably would not be heard if symptomatic complete AV block were the only indication for pacing. Complete AV block even without symptoms might be an
accepted indication because one could argue that the first symptom in such cases could be sudden death. Furthermore, the quality of life obviously is far better for patients who do not faint than it is for those who do. Similarly, pacing for tachyarrhythmias is not likely to invoke the cry of needless surgery because extensive preliminary workup and detailed electrophysiologic studies have usually been carried out beforehand.

But for other conditions, the proof of need and efficacy is more elusive. Some of these more controversial areas are asymptomatic second-degree block, recovery from complete AV block after myocardial infarction, bifascicular block with syncope, drug-induced bradycardia, carotid sinus sensitivity, and, most often, the sick sinus syndrome.

Whether pacing is indicated for sick sinus syndrome is a major issue, because this condition alone accounts for 50–80% of all pacemaker implants. (Again, the lower figure is more typical of Europe, Australia and Canada.) This catch-all phrase may encompass sinus bradycardia or arrest, sinus pause, atrial fibrillation, and the bradycardia-tachycardia syndrome. Sick sinus syndrome is an ill-defined condition of multiple and often unproved etiologies and of uncertain prognosis. It is usually associated with nonspecific degeneration of the sinoatrial node and atrium, loss of myocardial cells and fibrosis, and fatty infiltration of the myocardium; it tends to be related to aging. Although electrophysiologic measurements of sinus node recovery time and sinoatrial node conduction time have been used to confirm the diagnosis, these tests are unspecific and highly insensitive; therefore, the diagnosis is usually based rather loosely on one of the simpler ECG manifestations of impaired atrial impulse formation and propagation.

The reason for the reluctance to accept sick sinus syndrome as an indication per se for pacing is that its symptoms are much less dramatic than Adams-Stokes seizures, and rarely if ever causes sudden death; therefore, it is difficult or impossible to prove that a pacemaker has a salutary effect on life expectancy. Moreover, the prognosis of sick sinus syndrome in the absence of pacing is uncertain.

New information is emerging regarding progression of the conduction defects seen in the sick sinus syndrome. It is derived from paced sick sinus patients in whom the implanted pacemaker has been “turned off” by external overdrive pacing. These trials have shown a surprisingly high incidence of progressive AV block (in our series about 20%), which suggests that sick sinus syndrome may be an early manifestation of a panoconduction defect (Parsonnet V: unpublished data). If sick sinus syndrome does progress to complete AV block, one would not expect the prognosis in these patients to differ from that of others with complete AV block. It would explain the almost identical actuarial survival data of our patients with complete AV block and sick sinus syndrome.

The complete AV block of advanced sick sinus syndrome may therefore be indistinguishable from other forms of acquired complete AV block. This insight does not tell us, however, if a pacemaker should be implanted in the “early stages” of the disease. One could propose that any patient with sick sinus should receive a pacemaker, as if the condition were equivalent to complete AV block. However, not enough is known about the natural cause of various types of sick sinus syndrome, and a pacemaker should probably not be implanted unless the patient has symptomatic bradycardia, or has bradycardia-tachycardia proved by electrophysiologic study to be amenable to pacing.

The next most troublesome issue is selecting the appropriate pacing mode. In a recent editorial I expressed a fairly extreme view, stating that almost every patient should receive a bipolar, dual-chamber, multiprogrammable pacemaker, to provide flexibility for changing clinical needs and to maintain AV synchrony. Although the goal may not be close, I maintained that we should strive for the ideal “universal” pacemaker than can maintain physiologic rhythm and rates, adjust to new arrhythmias, interrupt tachyarrhythmias, and transmit electronic, electrocardiographic, and historical information.

Even if such a pacemaker were available, one could not be certain that it would be cost effective. Many unresolved questions require answers:

Is there such a thing as a lifetime pacemaker? The lifetime pacemaker does not exist. Although the life expectancy of a pulse generator is longer than the life expectancy of the average patient, the actual life of the pacing system is far shorter, and other failure modes require pulse generator replacement (fig. 2). Therefore, it may not be cost effective to implant an expensive multiprogrammable pacemaker in everyone.

How often can reoperation be avoided by the use of fully programmable pacemakers? Multiprogram-
mable pacemakers have been implanted in only a relatively small number of patients. But even simple programming (rate and output) has been shown to avert reoperations in 15–20% of patients, and the percentage may increase when multiprogrammable pacers are used. (Parsonnet V: unpublished data; Furman S: personal communication, March 1981). If so, this feature alone will make pacemakers cost effective.

How often is programming truly needed? There are three general categories for adjusting the functions of programmable pacemakers: fine tuning, therapeutic, and troubleshooting. Troubleshooting is the only area where one might say that programming is really needed because this category includes the cases of pacing and sensing failure when the only alternative would be to replace the pacemaker. In the other categories, the definition of need is a matter of personal judgment. For example, at our center we program 100% of the pacemakers because we are organized to do so and have a long-time interest in the field; but most patients have gotten along perfectly well for years without therapeutic fine tuning. How much patients would be improved if all available programming functions were used is conjectural.

How often is two-chamber pacing needed? No one questions the teleologic wisdom of AV synchrony. If AV synchrony could be maintained or restored in everyone at no physical or financial cost, almost every patient would receive this type of unit. But aside from the issues of cost and technical difficulties, there are problems that relate to the desirability of two-chamber pacing.

It has been recommended that dual-chamber pacing be used to alleviate certain symptoms that are related to loss of AV synchrony. For example, the so-called pacemaker syndrome can sometimes be quite severe. This is a symptom complex of periodic and recurrent weakness due to alternating cycles of AV synchrony and asynchrony. Some patients are so keenly aware of ectopic cardiac movements that they may sense even a single unusual beat of any origin. Still others may experience a pronounced thump due to cannon A waves. In these examples, converting the pacemaker to a synchronous system solves the problem. One cannot predict which patient will develop these symptoms, and we do not know their frequency. (Where was the pacemaker syndrome before 1969?) AV synchrony has been shown to improve cardiac output from 15% in normally compliant ventricles to 50% or more in the failing heart. These data may be debated because some believe that the reverse is true — that the strong, healthy ventricle needs the atrial kick to maximize ventricular function, and that the atrial kick plays no role in the noncompliant ventricle. In any event, AV synchrony surely enhances cardiac output; but does it also enhance renal blood flow, relieve azotemia, and improve cerebral function as some authors claim? Little information is available on these issues.

Obviously, it is difficult to assess the value of "physiologic pacing" (maintenance of AV synchrony) because most of the clinical benefits one hopes to identify and measure can only be evaluated in subjective terms. Although interest in studies on physiologic pacing have appeared, no definitive studies have been done on patients during exercise and daily activities. Even the tests done in the laboratory are often abbreviated because one is naturally reluctant to perform the repeated invasive tests that are needed to gain meaningful hemodynamic information.

How often will programming be of benefit when a patient approaches end of life? It is surprising that there is not a single comprehensive study on the need for reprogramming a pacemaker during a patient's intercurrent or terminal illness. The possibility of readjusting pacing modes, altering pacer function, and treating arrhythmias (even ventricular fibrillation) are immense. This aspect of pacing may be of such clinical and therapeutic value that the original costs will have been effective many times over.

How will programming be of benefit when the pacemaker approaches end of life? Figure 1 shows the remarkable longevity of modern pulse generators; after 8 years the 50% survival point has not been reached in any of the quality pacemakers. We do not know how we might use the programming functions when we detect the first signs of the impending end of pacer life, nor do we have experience in how programming might be used for other failure modes.

How can programmability be used for the purpose of routine follow-up? Our own studies show that 15–20% of pacemaker reoperations are avoided by appropriate programming. The capability to shift modes, polarity, refractory period, sensitivity, and the chamber to pace may have an even greater impact on the efficacy of pacemaker therapy and on extension of pacemaker life.

Because of the many imponderables and the inadequacy of the information at hand, it is scarcely possible to define and identify what is meant by unnecessary. Although pacing technology is perhaps ahead of clinical comprehension, it does not follow that implantation of multiprogrammable and two-chamber pacemakers is therefore needless. For the same reason, one cannot conclude that complex pacemakers are too costly.

There is one other dilemma: As has been pointed out, there are no standards for training or for operative privileges in pacemaker implantation. Until the clinical indications for surgery are well defined, the prognosis of various conduction defects thoroughly understood, and the value of pacemakers is exhaustively studied, the best approach would be to treat pacemaker surgery as one treats any other surgical specialty, and that is by the delineation of appropriate training programs and the granting of surgical privileges to the pacemaker implanters by their institutions. In the larger hospitals where there is more than one pacemaker expert, a pacemaker service should be set up as a subspecialty of either medicine or surgery. At the Newark Beth Israel Medical Center, this project has been accomplished with some success.
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While only three physicians had pacemaker privileges during the first 15 years of pacemaker implantation, 10 physicians are now on the pacemaker service. Surgical privileges are determined by a committee on the basis of documented training, experience and continued practice. Weekly pacemaker clinics are attended in rotation by the members of the pacemaker service. At a monthly pacemaker conference, all operations, complications and deaths are reviewed. This is a workable arrangement that can be easily established at any institution.

At smaller hospitals where there may be only one pacemaker surgeon, and an itinerant one at that, similar evidence of training should be required. Lacking that, the hospital should seek referral arrangements with another institution in which adequate facilities and personnel are available.

Ideally, cardiac pacing should be declared a surgical or medical subspecialty, and so recognized by the appropriate national societies. NASPE may be an appropriate nucleus for such an innovation.

In this way, rather than continual reiteration of some of the problems, a peer review process can be established that will automatically provide quality control and resolve these difficult issues.

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