EDITORIALS

The Manufacturer and the Physician: The Brave New World of Intracardiac Pacing

The subject may be the same, but the conclusions are often dramatically different! We urge the readers to compare the views expressed in the three editorials which follow.

“... We are in the horns of an ethical dilemma, to find the middle way will require all our intelligence and all our good will.” Aldous Huxley, in Brave New World Revisited (page 17).

Electrical stimulation of the heart originally introduced for the treatment of complete AV block is currently being used in the correction of many other disturbances of cardiac rhythm and mechanical function. Therefore, the number of patients, physicians and paramedical personnel involved with pacemakers has increased considerably. More information for a larger group of individuals became necessary.

It has been said that the survival of a democracy depends on the ability of a large number of people to make reasonable choices in the light of proper information. This is specially true in the medical profession. However, recent publications have cast doubt as to whether enough (and adequate) data have been supplied by the various pacemaker manufacturers to the large number of physicians (and hence to the patients) involved with these devices. Moreover, the new advances have been communicated in confusing ways. For instance, those who followed closely historical developments in this field must have been puzzled by the different terminology applied when referring to the various types of pacemakers and pacing modes.

Manufacturers have used proper names when referring to the specific types of pulse generators that they have built. In this sense the “name” is helpful since it indicates a particular entity as well as the special characteristics of this entity.

Names have also been used in reference to the various modalities of pacing. Theoretically this could also facilitate the understanding of pacemaker electrophysiology — while in practice it has had the opposite effect. For instance, we introduced the term “demand” in 1964 in reference to a modality of temporary pacing (QRS-inhibited or stimulus-blocking). Later, the word “demand” was also applied to other forms of continuous stimulation, namely QRS-triggered pacing and hence semantic confusion (leading to potential conceptual errors) was introduced in pacemaker electrophysiology.

Concern about etymologies is nothing new. It is found in the Bible (Genesis 17:5 and 17:15 for the changing of the name of Abram to Abraham and Sarai to Sarah). The sophists in ancient Greece carried semantic arguments to incredible extremes. In fact, Plato poked fun at how fanciful the etymologic discussions could get — they usually led nowhere.

Linguistic distortions have also troubled contemporary writers. The deluge of words was the topic of a recent essay published in Time magazine. It is interesting that the author was so concerned with this problem that he coined a new term for it: semantic aphasia (the “tone” deafness to the very meaning of language resulting from the habitual and prolonged abuse or misuse of words).

We must agree with Plato in that arguments regarding the proper use of a term (in this case “demand”) can lead to a “sophistic” discussion. Yet, the reader must be well aware that, although having some common characteristics, these are two different modalities of noncompetitive electrical stimulation. This statement can be tested by simply trying to teach their electrophysiologic characteristics to those learning the fundamentals of pacing. Pacemaker electrophysiology has been further complicated by the manufacturers’ practice of...
supplying insufficient information. That battery life was optimistically over-emphasized is understandable. Inexcusably, various parameters were changed in similar types of pulse generators without due notification. This statement refers specifically to the duration of artificial refractory periods, synchronization times, and escape intervals. Perhaps requesting that these parameters have an exact duration might be expecting too much, and be unnecessary. But variations in refractory periods from 200 to 400 msec, in synchronization intervals from 20 to 150 msec and in escape intervals from 30 to 120 msec;²,⁸ might be enough to mislead the physician into making the wrong decision.

The existence of partial recycling is another example.⁸ Information supplied with QRS-inhibited pacemakers seems to imply that QRS complexes falling outside the pacer’s refractory period should be sensed, or nonsensed if the signal is too low. In former cases, full recycling occurs; in the latter cases, the nonsensed beat appears interpolated between two stimulus artefacts. However, borderline signals can cause a partial recycling in which the postextrasystolic interval is considerably shorter than the expected escape interval.⁸

These variabilities were not stated in the booklets supplied by the manufacturers. It was left for the physicians themselves to observe their existence and to determine their significance—occasionally at the expense of replacing a nonfailing pulse generator.

In the electronic industry, the physician-manufacturer relationship has been different than that in the drug business: it is not often that a practicing doctor indicates to the manufacturer that the composition of a drug is not what the accompanying literature implies!

Although temporary pacing falls in the realm of the clinical cardiologist, implanting pacemakers is the function of the cardiovascular surgeon. When follow-ups are not made in specialized pacemaker clinics, and in view of the complexities involved in determining whether a given electrophysiologic change is (or is not) due to malfunction, one wonders how many normally-operating pacemakers have been replaced! It is understandable, yet not necessarily justifiable, that some physicians have found the “final solution” to all pacemaker problems, namely, replacing the pulse generator (or the total system) when faced with complexities beyond their grasp.

In a recent review, complications were noted in 26 of 64 patients in whom pacemakers were implanted.²² Another group of authors reported that 49 out of 112 patients treated required no intervention but the remaining 63 needed one to five reinterventions for various complications.²³

These facts have led us to question, not whether patients have gained from the use of electronic pacemakers, but whether they have benefited as much as they should. This dilemma is difficult to answer since it has sociologic, economic, humanitarian, and philosophic as well as scientific implications. Is technology being used for the improvement of mankind or for that of the machines and their beneficiaries? Overtchnification, said Huxley, is one of the archenemies of freedom.²⁴

We should, indeed, be proud of our technologic successes. But more and more, it demands an everspringing price from us. A larger number of people, having a greater capacity to acquire, might have a potentially harmful side effect: the concentration of production and distribution in the hands of a few. In this way, a small group can affect our destinies directly through control of the means of production or indirectly by economic determination of what and how we think.²⁴ Particularly in the medical world, patients are encouraged to “consume” in greater quantity and variety than they need. Evidence of this can be gathered from TV commercials or advertisements in lay and medical publications.

A thought-provoking editorial in the New England Journal of Medicine stated that among the many problems of drug advertising, the promotion of psychotropic drugs should be a major area of concern.²⁵ Instead of limiting drug usage for strictly medical problems, the pharmaceutical companies have encouraged the use of drugs for what are problems of everyday living, not traditional mental illnesses.

Industry introduces into products what is called “built-in obsolescence.”²⁵ That is, a “thing” cannot be built to last forever. If things would not wear out, profits would not exist and both manufacturers and employees would be out of work. This, obviously, is the other extreme, which should only be used as an argument to confront the dangers of concentration of power into the hands of a small elite, Big Business or Big Government. Supply and demand is a vicious spiralling circle, still not completely controlled by the medical elite and Big Business. But if the latter two groups become too greedy they will fall prey to Big Government. For everybody’s sake we should take steps to curb these tendencies while we can, for if this happens nobody wins.

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The Cardiac Pacemaker and The Manufacturer’s Responsibility

We are at a pivotal time in the development of cardiac pacemakers. We are beyond early experimental work when each innovation was a pioneering effort to be applauded, and not yet at a period when prolonged stability of design and utility of cardiac pacemakers ensures a slower rate of change. The field is active in new clinical application and still alive with innovation. New energy sources, new pacemaker rhythms and new electrodes can be anticipated with consequent change in pacemaker indications, longevity and complications. Yet, because of their deep involvement in patient care, the manufacturers have inherited both prosperity, and an obligation to the patient and his intermediate, the physician.

This obligation should be as important and honored by each manufacturer as is his balance sheet before the company auditors. Not all live up to that standard. Perhaps the difference is that the auditors have a legal right to examine accounting practices. What is required is a commitment to excellence of manufacture and improvement of design and not only a commitment to change for its sake alone. Obviously that statement can be platitudinous, but a few specific instances may suffice.

Because of the position of cardiac pacing in medicine today we are likely to see new manufacturers entering the field. In each instance that manufacturer will introduce the “best” pacemaker manufactured today. In the present state of the art it is likely that patients and physicians will validate the new pacemaker at their own jeopardy. This is so as the determination of late failures and an estimation of longevity is virtually impossible early after pacemaker implant. As statistically significant numbers of longterm animal implants can be prohibitively expensive, it is likely that such validation will be done in humans. Unfortunately the pacemaker will probably not be the best, but will represent an initial attempt by a new company and a new engineering group to enter a lucrative field.

What are the problems the new manufacturer will face? The design of a battery powered stimulator which emits regular stimuli at a fixed rate (say 70 BPM) is relatively easy. Even the design of a