Some implications for clinical cardiology of recent advances in interventional cardiology

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RECENT YEARS have seen the development of many new techniques and therapies that are useful or potentially useful in the management of patients with cardiovascular diseases. A number of these procedures performed by cardiologists have given rise to the term "interventional cardiology," referring to the more active, interventional role of the physician performing the procedure as compared with the more traditional role of the cardiologist. Among these procedures are the following:

- Coronary arteriography in patients with acute myocardial infarction
- Percutaneous transluminal coronary angioplasty (PTCA)
- Early therapy of patients with acute myocardial infarction with various techniques, including drugs to preserve ischemic or stunned myocardium, thrombolytic agents to dissolve the thrombus usually present, or acute revascularization by PTCA or coronary artery bypass grafting, either in combination with thrombolytic therapy or alone
- Catheter ablation of selective areas of the myocardium in the management of patients with selected varieties of cardiac arrhythmias
- Balloon angioplasty for obstructive valvular heart disease or coarctation of the aorta
- Angioscopy
- Laser ablation of obstructive atherosclerosis
- Retroperfusion of the coronary circulation

The development and the ultimate application of each of these techniques to the practice of clinical cardiology raise a number of questions and problems that need to be addressed by cardiology and, in some instances, by society. Many of these problems are shared by developments in other areas of medicine.

To continue to improve our treatment of patients with cardiovascular disease, medicine must continue to provide an opportunity for the imaginative investigator to have an opportunity to look at a problem in cardiology from a new perspective and to bring new techniques and innovative approaches to bear on the problem. Since many of the recent advances in interventional cardiology are directed toward the diagnosis and treatment of the consequences of advanced coronary atherosclerosis, we need even greater research efforts to understand the pathogenesis of this disease and, ultimately, to prevent its development or even to cause it to regress. Even from a purely financial point of view, such an investment in basic research is eminently justifiable.

The initial development of a new interventional technique of diagnosis or therapy usually requires preliminary animal studies followed by preliminary patient studies. In many instances, large and expensive clinical studies are subsequently necessary to determine the proper clinical usefulness of the therapeutic or diagnostic technique. Such clinical studies not only take much money, but also much time, during which the practicing clinical cardiologist is often beset with difficult clinical decisions in his patient management. One of the difficult clinical decisions the clinical cardiologist must make during this time is whether or not to move ahead and apply the new and unproven therapy or diagnostic technique before adequate clinical studies are completed and published. This dilemma of deciding when to apply new therapies is unavoidable and will always exist as long as we continue to develop new therapies for our patients.

When a new therapy, diagnostic technique, or device is developed in western society, it is sometimes appropriate that there be appropriate financial reimbursement or reward. In some instances, materials or devices are developed than may even be possible for an individual or institution to patent. If an individual or an institution has a special interest in the technique or device, the editor of any medical journal reporting such a technique or device should be fully informed regarding any such potential conflict of interest by the authors or the reviewers when medical articles regarding the new technique or therapy are submitted for publication.

There is also a significant potential for a conflict of interest in the utilization of a new technique for diagnosis or therapy when patients are referred to a physician who decides whether or not the procedure should
be performed who is also the physician who may perform the procedure. Additional potential conflicts arise if the same physician also is responsible for evaluating the effects of the new therapy. It should also be kept in mind that under our traditional fee-for-service financial programs, the physician is reimbursed significantly more if he performs the procedure than if he does not.

It is also necessary to educate both the medical profession and the public regarding the development of new techniques and therapies of interventional cardiology. In view of the potential importance of many reports to both physicians and patients, such reports should not appear in newspapers or magazines or on television before the majority of physicians in the United States have actually received their medical journals. The argument that the actual publication date is several days before the receipt of the publication by most cardiologists is not a satisfactory excuse for the frequent situation in which physicians and patients first learn of such important medical advances in the lay press or on television or radio.

A number of techniques are also increasingly used to educate physicians in addition to traditional medical journals. These include the publication of symposia as supplements to established medical journals, which often are paid for by the sponsoring manufacturer. At times, these symposia have apparently not been subject to the same careful review as articles in refereed journals. In recent years, there has been a proliferation of “throw-away” or free medical journals and newspapers, which often contain superb review articles or news articles but which may also contain material that is not critically reviewed. Television and radio are also now utilized to educate physicians. In general, original data should always be subject to careful peer review before presentation in any format.

The decision of the clinical cardiologist of whether or not to apply a new technique or therapy or to refer a patient is often influenced by many local factors, including the patient population, the local medical and transportation facilities, and the availability of supportive medical and surgical personnel. Occasionally, the financial reimbursement (or the lack thereof) influences the application of new techniques of diagnosis or therapy, as do the potential medical-legal aspects of utilizing new and incompletely established therapies. An additional problem, which is well illustrated by recent developments in the field of coronary angioplasty, is the occurrence of significant changes in the clinical indications for PTCA, in part related to the development of improved, steerable catheters and balloons capable of withstanding higher inflation pressures. These technical developments and increased experience in the last few years with the procedure have significantly enhanced the applicability of PTCA in the therapy of chronic and acute coronary artery disease.

Another problem faced by the clinical cardiologist is the extrapolation of published data regarding a new technique of therapy or diagnosis to local health care facilities because of the difference in skills between the individuals who orginally developed or pioneered the technique or therapy and the skills of those who are beginning to do the procedure locally. In most instances, there is a learning curve of experience. Although the learning curve can sometimes be slightly improved by attendance at postgraduate medical education programs, such courses cannot take the place of formal, hands-on training.

In some instances, it seems reasonable that the application or prescription of a new therapy, procedure, or pharmacologic agent should be regulated or limited, preferably by local hospital committees or appropriate medical groups, to ensure that all physicians who use the new technique have the proper background and training. In the case of some new and potentially hazardous pharmacologic agents, it would seem appropriate that the Food and Drug Administration develop guidelines and special categories of licensure to prescribe these drugs. Thus it would seem reasonable to restrict the prescribing of some pharmacologic agents to specially qualified physicians rather than to allow prescription by all physicians. (In addition to cardiovascular agents, the prescribing of selected drugs used in the treatment of malignancies or psychiatric disorders should probably also be so regulated.) Although the administration of such a program would obviously be difficult, I believe it could and should be established for a limited number of new agents, which might be lifesaving in selected instances but which require special knowledge regarding their use.

An issue with marked implications for clinical cardiologists is the question of when it is appropriate for physicians to be reimbursed for using a new technique or therapy. Initially, it may be appropriate to reimburse only physicians at institutions where the technique has been proved to be of value before approving the technique or therapy for more general reimbursement throughout the nation if there are sufficient studies to justify this recommendation. Ideally, approval should be determined by consultation between the Social Security Administration or commercial insurance companies and cardiologists who do not have a vested interest.
in the technique or therapy. However, it is fully appropriate to have extensive consultations with those individuals who have the greatest experience and qualifications with the technique or therapy but who may nevertheless have unconscious bias or excess enthusiasm.

It is my opinion that the level of financial reimbursement for many interventional procedures in the United States is excessive relative to the level of reimbursement for other types of medical care.

A further implication of the many advances in interventional cardiology is that medicine must train an adequate number of cardiologists to provide these new and valuable advances to our patients. It is now apparent that modern training in adult cardiology requires a minimum of 36 months. For those who wish to perform cardiac catheterization, a minimum of 12 months should be spent in the cardiac catheterization laboratory, during which the trainee should perform at least 300 cardiac catheterizations and coronary arteriograms, including 200 as primary operator. Physicians who wish to perform PTCA should have at least 12 months of additional formal training in coronary arteriography and angioplasty, during which time they should perform at least 125 coronary angioplasty procedures, including at least 75 as primary operator. Lesser amounts of formal training and experience should no longer be considered adequate for individuals to perform PTCA. In addition, physicians who do perform PTCA should perform a sufficient number of procedures each year to maintain proper skills and techniques. Similar standards of training should be developed for other interventional procedures as they become more established.

Finally, there is a need to develop improved techniques for the prompt identification of patients suitable for interventional cardiology and for their prompt transportation to specialized centers for cardiovascular therapy for management, perhaps after initial therapy (i.e., intravenous or intramuscular thrombolytic therapy for acute myocardial infarction) is provided, either by emergency medical techniques or in community hospitals. The actual number of "interventional" cardiologists necessary in the future obviously depends on the value of many forms of therapy that are currently under study, the ultimate value of which is unknown at present. It is unlikely that it will be feasible to provide personnel and facilities for many types of modern interventional techniques in most community hospitals. Rather, patients suitable for such therapy should be transported to specialized centers of cardiovascular therapy.

These personal comments regarding various implications for clinical cardiology of developments in interventional cardiology should be considered in the context of two quotations. The first is ascribed to Goethe:

It is not sufficient that we know, we must also apply; it is not sufficient that we have good intentions, we must also act.

The second quotation is ascribed to Pasteur:

Keep your enthusiasm, but let strict verification be its constant companion.
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