Percutaneous transluminal coronary angioplasty: a word of caution

J. Willis Hurst, M.D.

ANDREAS GRUENTZIG performed the first percutaneous transluminal coronary angioplasty in Zurich in 19771 after years of careful research. He joined the Department of Medicine at Emory University School of Medicine in 1980, where he continued his research until his death in 1985.

I do not personally perform coronary angioplasty, but being intensely interested in it I supported and studied the development of the procedure as Gruentzig and his colleagues, King, Douglas, and Roubin, refined the technique and, by 1985, had applied it to about 5000 patients.

Now, as we are about to embark on an NIH-approved randomized trial of patients with angina and multivessel disease in which the value of coronary angioplasty is to be compared to the value of bypass surgery, it seems appropriate to make these editorial comments.

Gruentzig’s position

Gruentzig wanted the procedure to be safe and useful. He recognized that many problems were yet to be solved and he carefully explored their solution. He was conservative in his statements about the value of the technique but was aggressive in his research efforts to solve the problems associated with it. He did not believe the procedure should be used as a substitute for bypass surgery in all patients. Rather, he preferred to perform the procedure in patients with angina who had single-vessel coronary artery disease for four reasons. First, he often stated something like, “It’s a shame to have a big operation when there is only one small, discrete obstruction in one coronary artery.” He believed, too, that there were well-defined indications for bypass surgery in patients with discrete multivessel coronary disease. Second, he realized that the most serious drawback to coronary angioplasty was the high rate of restenosis (25% to 30% in 6 months). He addressed this problem with a vigorous research effort and stimulated the group at Emory, as well as others, to attack this as a primary problem to be solved. Third, and not generally appreciated, was that Gruentzig was intensely interested in the prevention of the disease. He was familiar with the “natural history” studies that show little deterioration of the survival curve of patients who enter a study with stable angina and single-vessel disease.2 The survival curve of such patients is acceptable until 4 to 5 years have passed, when it turns downward. This, he presumed, occurred because the patients either developed additional lesions in the same vessel or new lesions appeared in the other two coronary arteries. He hoped, if he could identify patients with single-vessel disease and dilate the obstruction successfully, that this would prevent the stepwise evolution of double-vessel and subsequently triple-vessel coronary disease. He did not know the incidence of the disease characterized by the stepwise evolution of obstructions compared with the incidence of the disease appearing in all arteries almost simultaneously.

Fourth, he was concerned that the procedure might be misused by individuals who were poorly trained, blunting the acceptance of the procedure.

Gruentzig, of course, dreamed that the procedure could be used safely in patients with multivessel disease. Before his death, he and his colleagues performed angioplasty in about 1000 patients with multivessel disease at Emory University Hospital. What did he have in mind? I believe he was exploring. But he was exploring very cautiously and would never take chances with a patient. He needed sufficient data to support the safety and possible value of the procedure. Accordingly, he selected the patients very carefully. He did not use the procedure in all types of multivessel disease. An analysis of a subset of these patients with multivessel disease, completed shortly before his death, revealed no major complications in 94.6%. Death occurred in 0.6% of the patients. Myocardial infarction occurred in 1.2%, and emergency coronary bypass surgery was used in 3.6% of the patients. Al-

From the Department of Cardiology, Emory University School of Medicine, Atlanta.
Address for correspondence: J. Willis Hurst, M.D., Candler Professor of Medicine, Chief of Cardiology, Emory University School of Medicine, 1462 Clifton Rd., N.E., Suite 303, Atlanta, GA 30322.
though he had previously called for a randomized trial in which coronary angioplasty would be compared with bypass surgery in patients with angina and multivessel coronary disease, he and his colleagues believed they had sufficient evidence to apply for an NIH grant to implement such a study. Not only has the grant initiated by Gruentzig and his colleagues recently been approved, but the NHLBI has also mounted a multicenter trial, the Bypass Angioplasty Revascularization Investigation (BARI), to examine the question more broadly.

Development of a new procedure

Many new procedures pass through four stages on their way to being accepted or rejected by physicians and patients.

Stage one is initiated because a creative person has an idea that he or she believes would be useful in the diagnosis or treatment of a patient with a certain disease. Gruentzig had the idea many years before he accomplished the feat.

Stage two begins when the individual begins to apply the procedure. Usually the procedure is used in the animal laboratory before it is used in humans. He or she may have the instruments available to implement the new procedure or it may be necessary to develop the tools to accomplish the objective. The tools available in the beginning were inadequate for Gruentzig's needs so he set about developing the balloon catheter and a pressure device required to perform the task. This was tedious work but he persisted until it was accomplished.3

Stage three begins when the creative individual realizes that the crude tools used in the beginning are not satisfactory for the broad use of the procedure and sets about to improve them. Accordingly, Gruentzig and others developed new equipment, including new catheters, and performed the procedure again and again. They gradually developed phenomenal skill and could place the balloon-covered catheter tip into sites that could not have been reached in 1977.

Stage four of the development of a new procedure is devoted to determining its value and the indications for its use. We are just now entering this stage of development.

The clinical value of a procedure is evaluated in terms of the answers to four questions. Does the procedure prolong the lives of the patients? (This question also requires a determination of the number of deaths caused by the procedure and implies that the duration of survival must be compared with other methods known to improve survival.) Does the procedure relieve troublesome symptoms for a significant period of time? (This question implies that the degree of relief produced must be compared with other methods used to relieve symptoms.) Does the procedure prevent serious events from occurring during a significant period of time? (The answer to this requires an estimate of the complications resulting from the procedure and implies that the number of events after angioplasty must be compared with the number of events occurring after other methods of therapy.) Does the procedure create a feeling of security in the minds of patients and their physicians? (This question implies that the feeling of security must be compared with the security associated with other procedures.) It is now time to engage in additional and critical research that will permit us to answer these questions.

The current "state of the art"

Most of the development, thus far, has been almost exclusively limited to the gradual improvement in the technology and skill. There are defensible indications and contraindications but more research is indicated before the technique can be applied, or not applied, to other subsets of coronary disease.

(1) Coronary angioplasty should not be used in patients with left main coronary artery obstruction unless some protection is offered by patent bypass grafts from a previous bypass operation to the anterior descending or circumflex artery. The one exception to this rule is when myocardial ischemia, electrical-mechanical dissociation, and hypotension occur as a complication of coronary arteriography in a patient with left main coronary artery obstruction.

(2) Coronary angioplasty may be used in patients with angina pectoris caused by discrete obstruction of a single coronary artery. One can expect the procedure to relieve angina in most of the patients and that the procedure can be done safely.

(3) Coronary angioplasty may be used to relieve the stenosis in a saphenous vein bypass graft. The effort is more successful when the stenosis site is at a distal anastomatic location. More research is needed to determine the long-range value of the procedure.

(4) Coronary angioplasty may be used to dilate the stenosed artery that is responsible for myocardial infarction. Arterial patency must be achieved during the first few hours after pain caused by myocardial ischemia begins and may be used with or without thrombolytic therapy. More research is needed, however, to determine the exact role of the procedure when it is used in this situation because it may or may not be the definitive procedure for this clinical problem.
(5) Restenosis occurs in 25% to 30% of the patients within 6 months. The figure may be much higher in certain subsets of patients such as patients who have angioplasty for total occlusion of an artery. Accordingly, a major research effort must be directed toward the restenosis problem, which looms as the greatest drawback to an expanded application of the procedure.

(6) The value of the procedure, when it is used in patients with multivessel disease, cannot be determined without a randomized trial. Patients with class I and II angina pectoris who undergo angioplasty should be randomized against medical therapy when the clinical markers, coronary anatomy, and ejection fractions, are similar to those reported in the 1983 Coronary Artery Surgery Study (a compilation in which almost all of the patients were at low risk); patients with angina should be randomized against bypass surgery when the clinical markers, coronary anatomy, and ejection fractions are similar to those reported in the Veterans Administration study of 1973 and 1984 and the European study reported in 1983.

(7) Statements by some, and the behavior of others, suggest that they believe coronary angioplasty is a substitute for surgery in patients with multivessel disease. It may or may not be. The procedure has not been compared with bypass surgery and, until the proper research has been done, it is wise to be cautious in one’s statements about the subject.

(8) The procedure is sometimes used in symptomatic patients with triple-vessel coronary obstruction when the doctor performing the angioplasty dilates a single vessel that is thought to cause the symptoms. Perhaps it is possible to do this in a reliable fashion, but that does not signify that the patient might not live longer if all vessels were bypassed.

(9) Some individuals dilate 10 or more obstructions at a single catheterization. This is a great technical feat but it is not the same as being able to defend that such an approach is superior to other methods of treatment. I would be concerned if less than critical stenoses are dilated. Should such be the case, and if restenosis occurs at the site of dilatation, it is conceivable that the procedure could do harm in such a patient.

(10) Some individuals who perform angioplasty believe it is proper to dilate a coronary artery or arteries every few months for many years. There may be instances when this approach is superior to coronary bypass surgery but such instances must be rare.

(11) Some say that patients do not want bypass surgery so they accept angioplasty. Of course, they don’t want surgery. Neither do they want coronary angioplasty. The fact is, they don’t want to have coronary disease at all. I have learned, however, that patients want a procedure that relieves symptoms, permits them to live longer, prevents events caused by the disease, and gives them and their physician a sense of security. We hope the recently funded randomized study comparing the value of coronary angioplasty with coronary bypass surgery in patients with multivessel disease will clarify which therapy is most beneficial for subsets of patients with this problem. However, until we have the results of the randomized trial, we must offer the procedure that is likely to be the most beneficial to the patient. Our opinion about an individual patient should be supported by scientific data that have been carefully scrutinized by the physicians working in the field. It has been my experience that very few patients will not accept surgery if the physician believes it is best for them in terms of the four objectives just mentioned.

Conclusions

The technique of coronary angioplasty has been refined and, when applied by skilled workers in properly selected patients, is associated with an excellent initial result, low mortality, and an acceptable complication rate. Clearly, the procedure can be used to relieve angina in patients with single-vessel disease.

The high restenosis rate of 25% to 30% within 6 months must be lowered for the procedure to gain total acceptance. Our group and others are addressing this problem.

My plea is a simple one. Let us not confuse the progress made in refining the technique with the value obtained by its use. So far, most of the work has been directed to improving the technique and relieving angina. In fact, most of the work has been related to the first three stages of the four stages a new procedure goes through on its way to acceptance or rejection. The value beyond the third stage of development must be determined by comparing angioplasty with other methods of treatment. Accordingly, within a few weeks we will begin the recently funded randomized study to determine the value of angioplasty in patients with multivessel coronary obstruction.

Gruentzig’s view should be heeded. He was conservative in his statements about the value of the procedure but was aggressive in his research efforts to solve the problems. Let us all hope that this promising procedure is not inappropriately applied before the research has been completed that may justify its expanded use.

References

Percutaneous transluminal coronary angioplasty: a word of caution.
J W Hurst

Circulation. 1987;75:902-905
doi: 10.1161/01.CIR.75.5.902

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/75/5/902.citation