LETTER FROM THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Position on Percutaneous Transluminal Coronary Angioplasty (PTCA)

In 1959, Dr. Mason Sones reported on selective coronary arteriography, a technique that quickly became the standard for precise diagnosis of coronary artery disease. In the early 1960s Drs. Dotter and Judkins introduced the original concept of using a catheter to dilate an atherosclerotic obstruction in a peripheral artery.

Now, almost 2 decades later, the selective coronary catheter is being proposed as a direct therapeutic tool for correction of coronary obstructive lesions, while previously it has only been used for diagnosis.

In 1977, Dr. Andreas Gruntzig and his colleagues in Zurich, Switzerland reported a technique which is now limited to research evaluation, but which might offer promise as a standard therapeutic approach for selected patients. This technique uses a double-lumen dilatation catheter with a balloon with unique expansive characteristics and an appropriate pump to deliver and quickly remove a specified pressure. Using special guiding catheters, the dilatation catheter can be manipulated through the site of obstruction in a coronary vessel under direct fluoroscopic observation. The balloon can then be inflated with subsequent compression of the lesion and dilatation of the functional lumen of the coronary artery. By August 1977, Dr. Gruntzig and his colleagues had used this procedure in 30 patients. In 19 cases the procedure was successful in dilating the affected coronary artery and relieving the patient symptoms. Two acute myocardial infarctions and one case of unstable angina were reported in conjunction with the procedure, but no deaths. Patients with obstructions that could not be dilated by percutaneous transluminal coronary angioplasty (PTCA) were offered bypass surgery.

On the basis of this early reported experience, it appears that PTCA has limited promise as a therapeutic technique for a small number of categories of patients with obstructive coronary disease. It also appears that this technique is technically demanding and involves a definite risk of myocardial infarction and death even when used by skilled, experienced operators who are careful to apply it only when appropriate. Caution against the use of this research technique without such special experience and meticulous case selection should be evident.

To evaluate most completely and expeditiously the promise and limitations of this new technique, the National Heart, Lung, and Blood Institute proposes to establish an initial inventory of investigators who are initiating clinical studies of this research technique in the United States. We have established a preliminary Interim Registry on Percutaneous Transluminal Coronary Angioplasty to be maintained by the Cardiac Diseases Branch, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute. Investigators interested in participating in this Interim Registry are invited to submit a copy of their protocol, including their indications for the procedure, a brief summary of baseline data on the patients studied, and outcome information.

A workshop on PTCA is planned for June 1979 in Bethesda to discuss the technique. This workshop will be a forum for reviewing the preliminary data collected on PTCA in this country by the Interim Registry. Workshop participants may deal more definitively with considerations on the scientific evaluation and indications for the technique and the need for a continuous registry. Inquiries about the PTCA Interim Registry and proposed workshop should be addressed to Dr. Michael B. Mock, Cardiac Diseases Branch, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute, Bethesda, Maryland 20014.

The complexities and cost of conducting cardiovascular research and providing the best care to the patients with cardiac disease demand that the evaluation of any new or potentially promising technique, such as PTCA, be conducted in a rational, scientific manner. They also call for a workable plan for translation of the scientific data at both an appropriate time and manner to the medical community providing care for the patient.

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Circulation. 1979;59:613
doi: 10.1161/01.CIR.59.3.613
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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/59/3/613.citation

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