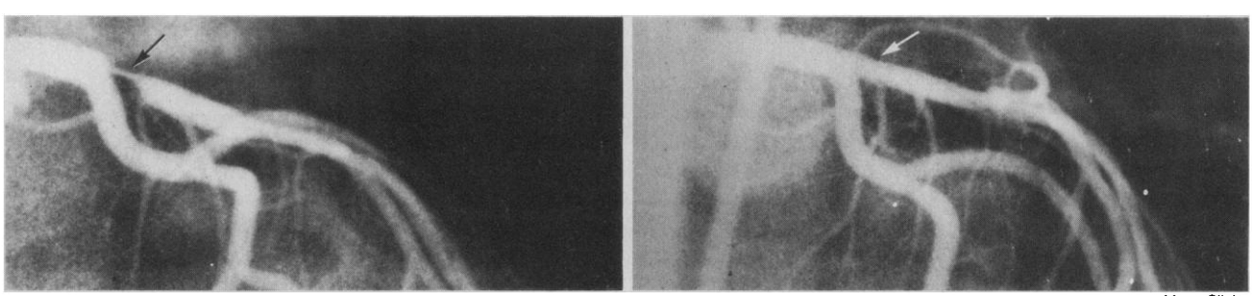
Coronary Treatment Assessed

"It looks very good. We have a technical winner," said David Sabiston of Duke University Medical Center, referring to percutaneous transluminal coronary angioplasty (PTCA), a new method for treating patients with heart disease. "The technique is spreading like wildfire," said Katherine Detre of the University of Pittsburgh.

Sabiston and Detre made their remarks at a workshop* held to assess PTCA. With this technique, partially blocked coronary arteries are opened by using a balloon to squash plaques that are obstructing the arteries. The balloon is threaded through a catheter into the blocked artery, inflated and deflated several times, then removed. When the procedure is successful the plaques remain compressed against the artery wall, blood flow to the heart increases, and the patient no longer suffers from angina pectoris—the chest pains caused by insufficient blood flow to the heart (*Science*, 23 November 1979, p. 917). PTCA can thus allow patients to avoid coronary artery bypass surgery, a procedure in which a vein is grafted onto a blocked artery to bypass the obstruction. The new technique costs about $1000 and requires 2 days of hospitalization, compared to $15,000 and 2 weeks in the hospital for bypass surgery.



Mayo Clinic

Before and after

Marked narrowing of a coronary artery is evident in the angiogram at the left. Two weeks following percutaneous transluminal coronary angioplasty, the artery is open.

The primary source of data discussed at the PTCA workshop was a registry established 2 years ago, when PTCA was first introduced. The registry was begun so that cardiologists could have some means of evaluating the method, thereby avoiding the situation that occurred when coronary artery bypass surgery came into use. No attempt was made to monitor the surgery and it became popular before there was documentation that it was useful.

The PTCA registry began with nine participating medical centers. Now 110 centers are contributing data, but many persons at the workshop felt that the registry is no longer sufficient to answer questions about the usefulness of PTCA. Instead, they called for a clinical trial to be initiated. The registry has, however, provided some information about the results obtained with PTCA. Apparently, the method has succeeded in about 65 percent of the patients on whom it has been tried. However, in about 20 percent of these patients, the arterial blockage reoccurred within a few months of the PTCA procedure.

Patients who have been treated with PTCA have generally had only one easily accessible plaque. The technique has been used on single lesions, explains Ronald Vlietstra of the Mayo Clinic, to facilitate its evaluation. With only one plaque involved, if the blood flow increases and chest pain vanishes after PTCA, the method is clearly a success. When there is more than one plaque, the outcome may not be so clear. Now that they have had experience with PTCA, Vlietstra and others are beginning to use it to push back multiple plaques in two or even all three coronary arteries. As PTCA becomes suitable for a wider variety of arterial blockages, it becomes more competitive with bypass surgery.

Most of the workshop participants agreed that PTCA has reached a stage of development where a randomized, controlled clinical trial comparing the technique to bypass surgery is warranted. But, said William Friedewald, head of the clinical trials branch of the National Heart, Lung, and Blood Institute, "We would all like to do a clinical trial. The question is, can we?" Friedewald argued that because the survival rate for PTCA candidates is high, it would not be feasible to use death as the end point for a trial. Too many patients would be needed to obtain meaningful results. But other possible end points, such as quality of life, exercise tolerance, and blood flow to the heart, are too subjective and easily disputed.

Andreas Grüntzig of Emory University, who introduced PTCA about 2½ years ago when he was at the University of Zurich, agreed that a clinical trial is desirable but added another caution. Doctors who already prefer PTCA may not refer patients for randomization. In fact, when he was developing the method he wanted to randomly assign patients to PTCA or bypass surgery, but physicians told him that they would refer patients only if Grüntzig treated them with PTCA; otherwise they would send the patients directly to bypass surgery. At that point, said Grüntzig, he decided not to randomize.

Yet, according to others at the workshop, the data that can be obtained from a randomized, controlled trial are essential. Paul Meier of the University of Chicago remarked, "If we don't do some sort of clinical trial, it's not as though the problem will take care of itself. We will be making all the decisions that a clinical trial will allow us to make, but we will be making them with less information. If we don't do the trial, what will we do instead?"

—GINA BARI KOLATA

*Workshop on Percutaneous Transluminal Coronary Angioplasty, sponsored by the National Heart, Lung, and Blood Institute and held on 11 and 12 June 1981 at the National Institutes of Health.

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