Editorial Comments

The "Second Generation" NHLBI Percutaneous Transluminal Coronary Angioplasty Registry

Have We Established the Role for PTCA in Treating Coronary Artery Disease?

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The initial National Heart, Lung, and Blood Institute (NHLBI) Percutaneous Transluminal Coronary Angioplasty (PTCA) registry was established when the technique was in its infancy. The initial PTCA registry had the strong endorsement and support of the innovator of coronary angioplasty, Dr. Andreas Gruentzig. The registry tracked the early experience and development of this innovative technique from 1977 to 1981. The goals of the founders of the registry were to define appropriate patients for the procedure and evaluate early success, complication rates, and late follow-up. It was anticipated that the registry data would be used to design a controlled clinical trial to compare the relative clinical effectiveness of coronary angioplasty to more established methods of treating ischemic heart disease—medical treatment and coronary artery bypass surgery. When the results of the initial NHLBI registry were reviewed by a subsequent NHLBI workshop in 1981, it was concluded that the initiation of a controlled trial at that time would be premature because of continuing evolution of coronary angioplasty.

Subsequently, a "new" and more limited NHLBI registry was established to enroll data from 15 centers that had been participants in the "old" registry. This issue of Circulation reports 1-year follow-up data from 1,801 patients enrolled in this new registry. We congratulate the clinical investigators from the 15 participating clinical centers and the Data Center at the University of Pittsburgh School of Public Health led by Dr. Katherine Detre for continuing this important registry experience up to the tenth anniversary of the use of coronary angioplasty for treating coronary heart disease. They have performed in a superlative manner a difficult task of enrolling, following, organizing, editing, analyzing, and reporting a large data set based on patients with ischemic heart disease treated by coronary angioplasty. As we ponder these data, we must ask, have they established the role for PTCA in treating coronary disease?

From the first use of coronary angioplasty, the promise has often been echoed that this less-invasive and initially less-costly procedure might be used in place of coronary bypass. In 1987, the tenth anniversary of PTCA, approximately 190,000 patients underwent PTCA in the United States and approximately 230,000 patients had coronary bypass surgery. Angioplasty as a revascularization procedure had increased 25% over the previous year but did not appear to result in a decrease in the use of the alternative revascularization procedure, coronary artery bypass, which increased 10% from the preceding year. One might conclude from such statistics that angioplasty continues to be used for many patients with single-vessel disease who otherwise may not have had revascularization surgically. The current report from the NHLBI registry by Detre et al confirms that slightly more than half of the patients receiving angioplasty had one-vessel coronary disease.

Because it has been established that most patients with one-vessel disease can be effectively and safely treated by medical therapy, direct comparative data on comparable medically treated patients in a controlled trial would be more informative than outcome data on angioplasty patients alone as reported in this registry. It is noted that within 1 year of initial angioplasty in patients with one-vessel disease the survival rate was 98.7%. One year after the initial successful angioplasty, 20% of the patients required repeat angioplasty and 5% required bypass surgery, and many patients continued taking antiangi-
nal medications. In the Coronary Artery Surgery Study (CASS) randomized trial, the medically treated group enrolled a decade earlier with one-vessel disease had a 99% 1-year survival rate and fewer than 5% had undergone a revascularization procedure during 1 year of follow-up. The new NHLBI registry again has told us how well we can apply coronary angioplasty to patients with one-vessel artery disease, but it does not tell us whether we should. After more than 10 years of registry observations in patients with one-vessel coronary angioplasty, there are no reports from controlled trials comparing medical therapy with coronary angioplasty.

With growing concern about health care expenditures for the treatment of ischemic heart disease, in one opinion the most logical role for coronary angioplasty would be as an alternative revascularization procedure for patients with symptomatic multivessel coronary disease who have failed a medical program or for patients with prior coronary bypass surgery who redevelop symptoms secondary to further progression of obstructive disease in native coronary arteries or grafts. The new registry experience reports a higher incidence of death and myocardial infarction and a greater need for both repeat angioplasty (21.6%) and coronary artery bypass (7.3%) in the first year after initial multivessel coronary angioplasty. Even with appropriate adjustments for known risk factors, the relative risk for death, myocardial infarction, and need for coronary bypass is more than 1.5 times for patients with multivessel disease than one-vessel disease with initially successful coronary angioplasty. It is important also to note that the average number of diseased vessels was 1.8 and that dilation was attempted in 1.3 vessels per patient.

A problem with all registry or data base studies is the “unofficial” comparison of events of registry patients with those of similar patients who had an alternative therapy in studies from a different time and place. We have often seen the results of patients receiving coronary angioplasty in observational studies compared with event rates for coronary bypass patients enrolled in the 1970s in bypass versus medical treatment randomized trials as we had to do in this article in the absence of randomized trial data. The Duke Data Bank for 1984 reported a 99% 1-year survival of surgically treated patients with two-vessel disease. Califf and his colleagues from Duke University further showed that this expected 1-year survival for the average surgically treated patient improved from 84% in 1970 to more than 95% in 1984. Therefore, we share their view that we should not mix and match data from different revascularization techniques, different eras, and from different institutions when we consider the risks and benefits of different coronary revascularization techniques.

In our title we ask whether this “second generation” or new NHLBI PTCA registry established the role for PTCA in treating coronary artery disease? Our answer is a resounding “no.” Our position is that registry studies, even when carried out as effectively as the NHLBI PTCA registry reported in this issue, have great inherent limitations when used to compare this form of treatment with other therapies.

In 1985, in an article on coronary angioplasty versus coronary artery bypass, we asked, “Isn’t it time for a randomized trial?” A randomized clinical trial is the only effective method of providing definitive answers of the relative safety and effectiveness of these two revascularization techniques because the randomization process ensures that patients assigned to the two treatment groups are equivalent in respect to both known and unknown variables. Fortunately, since that time, controlled clinical trials have been initiated. The Veterans Administration is conducting a trial to compare medical treatment with coronary angioplasty, enrolling patients with one- and two-vessel disease. This trial is called Angioplasty Compared to Medicine (ACME).

Two major trials are underway in the United States comparing coronary angioplasty with coronary artery bypass in patients with multivessel disease. The first is a single institutional trial being carried out at the Andreas Gruntzig Center at Emory University called Emory Angioplasty Surgery Trial (EAST). The other trial is a major NHLBI multicenter-controlled study called Bypass Angioplasty Revascularization Investigation (BARI). The data center for the BARI study is the same data center for the NHLBI registry reported on in this issue of Circulation. Thus, as originally planned, experience from the registry is being used to provide an appropriate randomized trial, called for by Dr. Andreas Gruntzig in his initial report on PTCA. We urge all members of the medical community to provide solid support to these important trials during their ongoing recruitment efforts. The successful completion of recruitment and follow-up for the ACME, EAST, and BARI trials must remain a high priority for US cardiologists, cardiovascular surgeons, and health care administrators in the 1990s. In the interim, we urge caution in using observational data from registries and data banks to determine reimbursement guidelines and to make judgments about the relative risk, benefit, and cost of these two major therapeutic procedures for treating advanced ischemic heart disease, which continues to be the major cause of disability and death in the United States.

References


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