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Spencer B. King, III

*J. Am. Coll. Cardiol.* 2000;35;35B-37B

**This information is current as of February 13, 2012**

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**JACC**

*JOURNAL of the AMERICAN COLLEGE of CARDIOLOGY*



# Percutaneous Transluminal Coronary Angioplasty

Spencer B. King, III, MD, MACC

Atlanta, Georgia

This paper is the first report from the Percutaneous Transluminal Coronary Angioplasty (PTCA) Registry of the National Heart, Lung, and Blood Institute (NHLBI). The era of interventional cardiology was born with the performance of the first successful balloon angioplasty by Andreas Gruentzig on September 16, 1977 (1). The background for this extraordinary accomplishment required the development of coronary arteriography, direct coronary bypass surgery and percutaneous peripheral vascular dilation. Gruentzig's willingness to teach the technique in its earliest rudimentary form to all who would come to Zurich was aided by the first set of disciples, including Myler, Stertz, Kaltenbach and others. By 1979, a small number of cases had been accumulated, and the companies manufacturing the devices continued to control the proliferation of the technique by releasing catheters only to those physicians who had visited and observed Gruentzig at work. As more operators began to perform angioplasty in the U.S., it became evident that a more organized evaluation of this fledgling technology could be of great value. After a conversation with Gruentzig and others, Dr. Michael Mook of the NHLBI was instrumental in convening a workshop in June 1979 at the Institute headquarters in Bethesda, Maryland. The outcome of that workshop was the formation of an international registry of PTCA patients that would provide a meaningful evaluation of this new procedure (2). An initial report from the accumulated experience was presented at that workshop, and virtually all of the early practitioners of angioplasty joined that registry.

## Percutaneous Transluminal Coronary Angioplasty: Report From the Registry of the National Heart, Lung, and Blood Institute

Kent KM, Bentivoglio LG, Block PC, Cowley MJ, Dorros G, Gosselin AJ, Gruentzig A, Myler RK, Simpson J, Stertz SH, Williams DO, Fisher L, Gillespie MJ, Detre K, Kelsey S, Mullin SM, Mock MB

From the Emory University Hospital, Atlanta, Georgia.

### ABSTRACT

Data have been collected from 34 centers in the United States and Europe performing percutaneous transluminal coronary angioplasty since September 1977. The procedure was carried out in 631 patients, with an average age of 51 years (range 23 to 76), of whom 80 percent had single vessel coronary disease, 17 percent had double or triple vessel disease and 3 percent had

## 50th Anniversary Historical Article

### INTRODUCTION

In this edition of the *Journal*, we release the tenth in a series of reviews of influential articles that have been previously published in ACC journals, including the *American Journal of Cardiology* (from 1958 to 1982) and *JACC* (from 1983 to the present). The publication of these articles is only one aspect of the ACC's 50th anniversary commemoration, which highlights 50 years of leadership in cardiovascular care and education. The articles are intended to encourage reflection on the remarkable progress made in cardiovascular medicine over time, as well as to acknowledge the amazing prescience of some early investigators in anticipating and, in many cases, later guiding developments in their field.

The working group responsible for selecting these articles and asking reviewers to write editorials solicited suggestions from the ACC's clinical committees and individual members.

The group achieved consensus fairly easily, including whom the group should ask to prepare the accompanying editorials. We initially drew up a list of 14 general areas to cover in this series, but later found that there are several major areas of modern cardiology, prominently molecular cardiology, in which the truly landmark articles have, alas, not yet been published in *JACC*. Therefore, the working group decided not to categorize by subject, but instead, to concentrate on the most important articles.

The working group, a task force of the Subcommittee for the Commemoration of the ACC 50th Anniversary, owes a great deal to Ms. May A. Roustom and the efficient and tireless staff at Heart House for facilitating this project. We also wish to thank all who suggested articles and, most important, the authors who prepared reviews for their willingness to contribute their time and wisdom.

*Influential Articles in JACC Working Group*

Sharon A. Hunt, M.D., F.A.C.C.  
Rick A. Nishimura, M.D., F.A.C.C.  
H.J.C. Swan, M.D., Ph.D., M.A.C.C.  
Michael J. Wolk, M.D., F.A.C.C.

*stenosis of the left main coronary artery. Coronary angioplasty was successful (greater than 20 percent decrease of coronary stenosis) in 59 percent of the stenosed arteries. The mean degree of stenosis was reduced from 83 to 31 percent. Emergency coronary bypass operation was required in 40 patients (6 percent). Myocardial infarction occurred in 29 patients (4 percent). In-hospital death occurred in six patients (1 percent), three with single vessel and three with multivessel disease. Ninety-one patients have been followed up for at least 1 year after coronary angioplasty. Of the 65 patients with an initially successful angioplasty, 83 percent were in improved condition compared with their status before angioplasty. Thus, the initial satisfactory results obtained in a few centers have now been confirmed in many centers using transluminal coronary angioplasty.*

Originally published in the *Journal of the American College of Cardiology*, June 1982.

### Review

This first report from 34 centers in the U.S. and Europe had traced their entire experience with angioplasty. The kind of patients treated reflected Gruentzig's initial recommendations in that 80% had single-vessel disease. With the primitive equipment available, 59% had successful dilation. The complication rates, including emergency operations, myocardial infarction and death, reflected a careful selection of patients, and the first one-year follow-up documented symptomatic improvement.

The NHLBI PTCA Registry was pivotal in the development of interventional cardiology, as it showed for the first time that Gruentzig's experimental procedure could be applied to a broader range of patients by multiple operators. The spirit of collegiality and cooperative assessment of the technique in its early days was perhaps unique. Many of the original investigators of balloon angioplasty have continued to cooperate with the registry, which was moved to the School of Public Health at the University of Pittsburgh under the organizational structure of Dr. Katherine Detre. A subsequent registry was instituted after balloon angioplasty had achieved a more mature status. Patient data were collected in 1985 and 1986 by the NHLBI Registry participants, and these data have been compared with the earlier period (3). Improvements were documented after important technologic advances, including, especially, the development in 1982 of steerable guide wires.

The value of prospectively collected registry data has perhaps been underappreciated in this era of large targeted randomized trials, but these data were essential for understanding the baseline features of patients undergoing angioplasty and their outcomes. This registry, in fact, set the stage for development of randomized trials. Much of the planning and structure of the Emory Angioplasty versus Surgery Trial (4) and the Bypass Angioplasty Revascularization Investigation (5), both sponsored by the NHLBI, were based on data generated from the NHLBI PTCA Registries. As new devices began to be developed in the late 1980s, another

registry, the New Approaches to Coronary Interventions (NACI) Registry, was developed. It has been possible to compare the use and outcome of many of these new devices with the NHLBI Registries and to structure clinical trials to investigate those devices (6). More recently, the registry has evolved into the Dynamic Registry of Percutaneous Coronary Interventions. During defined collection periods, the participating NHLBI sites enter all patients into a defined database. By doing so, a snapshot of interventional cardiology practice can be generated to reflect changes in practice patterns and outcomes. The last two registry collection periods in 1997/1998 and in 1999 show continuing evolution of the method with increased utilization of stenting with concomitant improvement in acute complication rates. These registries will also enable assessment of long-term outcomes based on methodologic changes and in subgroups of great interest including gender, racial and ethnic differences and disease state differences, especially for the diabetic population. In addition to identifying current practice results, the registries will stimulate questions that need further randomized trials. In fact, many of the ongoing trials, including stent trials (Stent or Surgery, ARTS trial) and angioplasty versus medical treatment trials (Veterans Affairs Non-Q-Wave Infarction Strategies in Hospital study [VANQWISH], Coronary angioplasty versus medical therapy for angina [RITA-2], Fragmin during Instability in Coronary artery disease [FRISC II], planned Bypass Angioplasty Revascularization Investigation [BARI II], Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation [COURAGE], and Study of Coronary Revascularization And Therapeutics Evaluations [SOCRATES]), all gained valuable data from understanding the registry results. These registries also have the potential to serve an important postmarketing surveillance function. Currently, new devices must undergo some comparative evaluation before approval by the Food and Drug Administration (FDA), but these evaluations are made on the basis of a carefully defined population of patients. The real-world use of devices cannot be adequately assessed by either the FDA or the device manufacturers because once the device is approved, its utilization is broadened by practitioners. The registry has the potential to collect unselected data that will include the utilization of these new devices and may detect problematic indications or provide data that can enable broader labeling of these devices. It is important to understand what new devices are doing in actual practice in addition to what they did in a controlled preclinical evaluation.

The NHLBI PTCA Registries have resulted in 45 peer-reviewed articles in the medical literature, including the long-term efficacy of PTCA (7), the comparison of changes in interventional technology (3), the incidence and consequence of occlusion of coronary arteries (8), the outcome of coronary angioplasty in women (9), the cause of death in late-term follow-up of patients undergoing angioplasty (10) and the comparison of balloon angioplasty with new late-developing technologies (6). According to the Science Citation Index, publications from the NHLBI

Registries were cited a total of 3,757 times by February 1996. Obviously, these registries have been important in the development of interventional cardiology, and the use of such registries has been adopted by others in an attempt to evaluate the outcome of procedures and disease states. Important examples are the New York State Registry (11) and the National Cardiovascular Data Registry™ of the American College of Cardiology.

## CONCLUSION

The forward-thinking pioneers of interventional cardiology and the leadership of the NHLBI and the Data Center at the University of Pittsburgh are to be congratulated for both their foresight and persistence. The founding of the initial registry formed the basis of this communication, and the continuity of registry activity through the years has enabled an assessment of the dynamic nature of interventional cardiology. Twenty-two years since the first coronary angioplasty by Andreas Gruentzig, these techniques have evolved into an entire subspecialty discipline now recognized by its own board or certificate of added qualification from the American Board of Internal Medicine and have defined residency programs approved by the Accrediting Council on Graduate Medical Education. This first report of outcomes of the NHLBI PTCA Registry established the tradition of collaborative openness in assessing results that Gruentzig espoused so vigorously. This objective, unbiased assessment of ongoing outcomes in interventional cardiology will remain an important part of his legacy.

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**Reprint requests and correspondence:** Dr. Spencer B. King III, Emory University Hospital, F606, 1364 Clifton Road, Atlanta, Georgia 30322.

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