

EDITOR'S PAGE

A Valuable Public Option

When we look back to the beginning of coronary interventions, those of us not chronologically challenged, are amazed at the evolution that has occurred. This is true for many endeavors, but the process of that evolution is seldom chronicled prospectively as it has been for interventional cardiology. When Andreas Gruentzig had done <100 cases in Zurich and the technique had begun to be adopted in the U.S., a major concern arose. A statement from the National Institutes of Health warned of the dangers of performing this experimental procedure. "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." (1). A conference was called at the National Heart, Lung, and Blood Institute (NHLBI) stimulated by Dr. Michael Mock. Several of the early adopters convened and conceived of a registry to keep up with this "experimental technique." The School of Public Health at the University of Pittsburgh became the data center under the direction of the late Dr. Katherine Detre. Andreas was an enthusiastic supporter of this endeavor.

At the American Heart Association's Scientific Session in Orlando (yesterday as I write this), a symposium celebrating the NHLBI Registry was held. The program organized by Dr. David Williams reviewed the contributions of the NHLBI Registry, which the agency has continued to support for 30 years. The first collection of the fledgling experience in 1979 reflected a success rate of 65%, with many patients opting for emergency surgery due to complications of the procedure. There is little wonder that there was concern that unbridled proliferation could become a public health issue. The registry was pivotal in setting a benchmark for new adopters in its first iteration from 1979 to 1981. By 1985, the progress in angioplasty, largely driven by improved devices and steerable guidewires, stimulated a second wave of the registry. A third wave was necessary when many new devices of the late 1980s and early 1990s were introduced. Surprising to many of us, the new devices were shown to be not as effective as balloon angioplasty, and with the exception of stents, most of them were dropped from the tool box. Many of the original sites that participated in the registry continued to collect the required detailed data and perform the meticulous follow-up throughout the subsequent registries. Since women were under-represented, a registry limited to women was commissioned and showed important gender differences.

A common method was used in performing these registries. Approximately 15 hospitals enrolled consecutive patients having percutaneous coronary intervention (PCI) until a cohort of approximately 2,000 cases was collected. These biopsies of the practice of PCI were continued under the name "Dynamic Registry." Now more waves of that registry have studied the outcome during the stent era and the drug-eluting stent era. By comparing these waves we can clearly see the evolution of the method in real time. Over 100 publications, many in the leading journals, have led to extensive citations resulting from this important work. Young investigators have developed a keen interest in outcomes research and over 150 unique investigators have authored these manuscripts.

There are other registries that make major contributions, and each of them has different capabilities to address important questions. Single-site registries, such as the Duke and Emory



Spencer B. King III,
MD

Editor-in-Chief,
*JACC: Cardiovascular
Interventions*

A statement from the National Institutes of Health warned of the dangers of performing this experimental procedure.

At the American Heart Association's Scientific Session in Orlando . . . a symposium celebrating the NHLBI Registry was held.

The registry was pivotal in setting a benchmark for new adopters in its first iteration. . .

By comparing these waves we can clearly see the evolution of the method. . .

Interventional cardiology continues to evolve and the changes need to be compared to what has gone on before.

databases, can perform a longitudinal follow-up with their own patients. The New York State database has become a benchmark for the country in studying very large populations of patients with systematic data collection from all laboratories in the state, and outcomes can be tied to vital statistics data and administrative databases. The American College of Cardiology (ACC), through the National Cardiovascular Data Registry (NCDR), has the largest cardiac database with voluntary participation and careful collection of hospital outcomes. Hopefully, future legislation will enable longitudinal follow-up with unique identifiers. A recent federal grant will enable a collaborative outcomes study coupling the NCDR registry and the registry of the Society of Thoracic Surgeons. Each registry has strengths that augment randomized trials and extend observations well beyond those restricted to randomized trial participants. Most of these randomized trials in our field are very expensive and are undertaken by industry in order to gain Food and Drug Administration approval and labeling. These are necessary but they often do not address the questions that are most clinically important to us and our patients.

At the 30-year celebration of the NHLBI registry, the future was a major point of discussion. Interventional cardiology continues to evolve and the changes need to be compared to what has gone on before. Some coming trends are structural heart disease interventions, left main stenting (now a Class IIb indication in the 2009 American College of Cardiology/American Heart Association focused guideline update for ST-elevation MI and PCI [2]), radial access interventions with same-day discharge, and genomic variations and their impact on interventions (personalized medicine), as well as numerous

others. Important questions regarding the performance and outcome of these procedures should not wait for an economic imperative of industry to be addressed. The answers are important for our patients and those treating them, as well as those paying for the care. Until now, private payers have not contributed to these efforts. They should, as they would get a very big bang for their buck. Meanwhile, we can be thankful that the government has stepped up for the past 30 years and enabled a talented group at the coordinating center, headed by Dr. Sheryl Kelsey and a very small army of dedicated investigators and coordinators, to define the progress of interventional cardiology, to identify some of its foibles, and to provide objective evidence of the value of our future endeavors. Congratulations to all of you!

Address for correspondence to:

Spencer B. King III, MD
Editor-in-Chief, *JACC: Cardiovascular Interventions*
Saint Joseph's Heart and Vascular Institute
5665 Peachtree Dunwoody Road, NE
Atlanta, Georgia 30342
sbking@sjha.org

REFERENCES

1. Levi RI, Jesse MJ, Mock MB. NHLBI position on percutaneous transluminal coronary angioplasty (PTCA). *Am J Cardiol* 1979;43:867.
2. Kushner FG, Hand M, Smith SC Jr., King SB III. 2009 focused update of the ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction (updating the 2004 guideline and 2007 focused update) and the ACC/AHA/SCAI guidelines on percutaneous coronary intervention (updating the 2005 guideline and 2007 focused update): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2009;54:2205-41.