Editorial

National Heart, Lung, and Blood Institute Percutaneous Transluminal Coronary Angioplasty Registry as a Standard for Comparison of New Devices

When Should We Use It, and What Should We Compare?

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The ongoing National Heart, Lung, and Blood Institute Percutaneous Transluminal Coronary Angioplasty (PTCA) Registry is a continuation of the registry originally established for studying the safety and efficacy of PTCA when it first became available for nonsurgical coronary revascularization. The 1979–1981 registry consisted of the consecutive cases performed by the pioneers in the field. To study long-term efficacy, the registry was extended to include a minimum 5-year follow-up. During these 5 years, there were important improvements in dilatation equipment, which had a major impact on case selection and outcome. Documentation of this rapid technological improvement was accomplished by the same investigators who entered a new series of consecutive cases in the registry between August 1985 and May 1986. The multicenter nature of the data base, the excellence of the cooperation among the participating centers, the completeness of the follow-up, and the existence of an independent coordinating center to assess the results enabled the registry to become the standard for evaluation of coronary angioplasty during this time. To our knowledge, there is no other source from a large multicenter experience reporting annual, updated results of PTCA and straddling two important phases in its history.

The registry has always attempted to provide objective reports to the cardiology community; as an outgrowth, the PTCA registry could now play a role in the evaluation of new devices that are extensions or alternatives to balloon angioplasty. The registry has received requests for comparison data when Food and Drug Administration approval is sought for new percutaneous devices. However, several caveats are required to ensure that in these circumstances, the PTCA registry data are used properly and that any comparisons or inferences that are made are scientifically valid and clinically meaningful.

At the present time in the PTCA registries, 5–9-year follow-up of the 1979–1981 cohort has been completed, and the 1985–1986 cohort is in the fifth year of follow-up. Both cohorts of patients have been characterized at baseline and during follow-up at annual intervals. In each cohort, a subgroup of patients had PTCA performed in the setting of acute myocardial infarction (defined as within 10 days before PTCA); however, most analyses reported by the registry exclude these acute myocardial infarction patients unless they are the topic of a specific analysis addressing PTCA for acute myocardial infarction. Between 1979 and 1981 and 1985 and 1986, there...
were not only major improvements in dilatation equipment and in their successful application but also major changes in patient selection criteria. Patients in the 1985–1986 registry were generally older, and more candidates had unstable angina syndromes, multivessel disease, and ejection fraction of less than 50%. In the 1985–1986 registry, PTCA was frequently performed for more than one lesion, for more than one vessel, and for chronically occluded vessels. These changes have important implications for any comparative studies.

Both the early and later cohorts of patients continue to be of great interest to the cardiology community for several reasons. In the new registry, PTCA was performed with the use of steerable guide wires and low-profile catheters, whereas catheter systems in the early registry were more primitive. These early generation devices used in 1979–1981 are perhaps analogous to the developing new devices used today. Naturally, in evaluating the efficacy of PTCA, we have been most interested to determine whether the improvement in outcome has indeed paralleled improvement in technology and operator experience. When assessing the 1-year outcome of PTCA, we found that the simple, crude comparisons of the results from the two different registry periods led to misleading conclusions without special attention to the marked changes in patient characteristics from one registry to the other. Fortunately, the two registries measured and recorded patient characteristics in a uniform manner so that it was relatively easy to make the adjustment necessary to obtain a fair comparison. After appropriate adjustments, a significant improvement in outcome could be demonstrated.

When PTCA registry results are used in a comparison with results obtained by new devices, the situation may be quite similar to our experience of comparing results from the two registry periods; that is, differences in patient characteristics may have an important impact, confounding the effect on outcome that may be attributed to the type of device used. Thus, direct comparison of the outcome obtained by new devices with the outcome obtained by balloon devices may lead to erroneous conclusions. The type of patients who are included in most of the device studies are often truly “ideal” angioplasty patients, among whom the current rate of emergency bypass surgery is generally felt to be less than 1% and the success rate is thought to be more than 95%, rates even better than those in the registry 5 years ago. For these reasons, the investigators of the PTCA registries caution all those who are going to use PTCA Registry results as standards for comparison with new devices that crude comparisons could be grossly invalid. To make a fair comparison between registry results and results with new devices, patient characteristics must be carefully balanced between the patient groups, and identical definitions must be used in all respects. For example, we must take into account the proportion of patients with multivessel disease, whether the patients have had prior PTCA or bypass graft surgery, the proportion of patients who have unstable graft surgery, the proportion of patients who have unstable angina, and whether patients have had a recent myocardial infarction, as well as other characteristics that may have an influence on outcome. Likewise, the definition of outcomes must be identical. Recent review of the literature on abrupt vessel closure revealed a wide variation from report to report in what was meant by periprocedural closure. Only when comparisons of patient and procedural characteristics as well as definitions are carefully described in a side-by-side comparison can the appropriate analyses be performed in a way that could provide meaningful comparisons. There are several circumstances when even this simple principle cannot be applied: when a new device is applied to types of lesions that have not been deemed suitable for PTCA due to low probability of success or high probability of complications; when the effectiveness of a new device is measured by a device-specific outcome, such as the debulking of atheroma mass, which clearly has no parallel with PTCA; or when new devices are used to achieve a different purpose from that of PTCA.

The PTCA registry results represent the averages of more than 16 experienced centers, and these results are generalizable. Although the PTCA registry centers were among the most experienced, the results represent what can be seen today—5 years later—in general PTCA practice. New device results may not yet be representative of what can be expected in general interventional practice. Furthermore, because of the large sample sizes, the PTCA registry results are estimated with good precision. We expect that using the recently established New Approaches to Coronary Intervention (NACI) registry vehicle, new device investigators will soon also accumulate large sample sizes from a variety of centers experienced in using the given devices. In the NACI registry, these new devices will be assessed in a standardized format designed to accommodate the various modes for each device used and with built-in possibilities for randomized trials comparing the devices with PTCA. We advocate careful statistical adjustment for the differences in the patient groups undergoing new device procedures compared with PTCA. This can reduce, but not eliminate, the biases that occur when the new device results are compared with PTCA registry results. Although it may be necessary for the time being to use external data bases such as the PTCA registry for comparisons, evidence obtained by this method will not have the same weight as that obtained by randomized comparisons.

In summary, the PTCA registry investigators encourage the cardiology community to study new devices in a critical, scientific fashion. Some comparisons with PTCA will be important in studying these techniques, but such comparisons should be performed with extreme care regarding possible confounding effects resulting from differences in patient selection and aims of the treatment. Ultimately,
randomized clinical trials are needed to compare PTCA with new device alternatives.

References


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