Pulmonary-Artery Catheters — Peace at Last?
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The history of the use of the pulmonary-artery catheter (PAC) illustrates a great deal about physicians’ often uncritical acceptance of technology in clinical applications. In 1956, Forssmann, Cournand, and Richards were awarded the Nobel Prize in Physiology or Medicine for the development of heart catheterization and consequent discoveries in cardiac pathophysiology. Forssmann performed the first right heart catheterization, on himself, in 1929. The catheterization work of Cournand and Richards at the Bellevue Hospital Chest Service began in the 1940s, and it initiated a new era in cardiopulmonary physiology, providing important insights into hemodynamics, gas exchange, and heart–lung interactions. Their studies provided a sound scientific basis for the development of new approaches to diagnosis and therapy. In 1970, Swan and Ganz introduced the balloon-tipped flow-directed pulmonary-artery catheter. This catheter made bedside measurements of sophisticated hemodynamic and gas-exchange variables feasible for the first time. Its popularity was instantaneous, but its widespread use, without clinical trials to establish benefit, was decried in a then controversial and now prophetic editorial by Robin.2

The modern PAC was introduced six years before the enactment of the Medical Device Amendments (1976) to the Food, Drug, and Cosmetic Act of 1938, which led to development of the current Center for Devices and Radiological Health of the Food and Drug Administration (FDA). If the PAC had come into commercial use just a decade later, it would have undergone more scrutiny than it did in 1970 and the current controversy about its appropriate use might not have occurred. As it is, years have been spent in debating the usefulness and dangers of PACs.

In 1996, a large, prospective, observational cohort study of PAC use in critical care settings indicated that PAC use might increase mortality as well as morbidity.3 The response to this study triggered a multidisciplinary workshop sponsored by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health and the FDA, to examine the use of catheters and clinical outcomes.4 The workshop called for the development of educational programs by professional societies and for clinical trials in several areas in which PAC use was extensive. The study reported on by Wheeler and colleagues5 in this issue of the Journal is an outgrowth of the response to the workshop report by the Acute Respiratory Distress Syndrome (ARDS) Clinical Trials Network of the NHLBI. This study is part of the Fluid and Catheter Treatment Trial (FACTT), the results of which have been reported by Wiedemann et al. (available at www.nejm.org).6

The study was well designed and executed. A factorial design was used, in which patients in a defined population with ARDS were randomly assigned to receive either a PAC or a central venous catheter (CVC) and to either a liberal or a conservative strategy of fluid management. The primary end point was mortality at 60 days. Criticisms of earlier studies were addressed in this one by extensive training of study personnel in the performance and interpretation of measurements of vascular pressure obtained by means of the PAC, the use of rigorous algorithms to guide treatment in response to the catheter-derived data, and the use of the two strategies of fluid management. A total of 1000 patients were recruited, and compliance with the study protocol was excellent. No difference in 60-day mortality was found between the PAC group and the CVC group.
There was an increase in the PAC group in the frequency of atrial arrhythmia and ventricular arrhythmia, occurring during the insertion of the catheter, but this increase did not affect the primary end point.

Large-scale clinical trials, particularly those involving critically ill patients, are difficult to design and perform. No study is likely to be perfect or to answer all questions. Sometimes, during the course of a study, accepted practice changes, coloring views of the study’s relevance. Such factors may lead to some criticism of the study by Wheeler and colleagues, but it remains a well-controlled trial that answers the important question of whether use of the PAC affects outcomes. Given our current treatment methods, there is no difference in outcomes between patients with ARDS who are treated by means of a CVC and those treated by means of a PAC. This study can be added to other recent, prospective, controlled trials of PAC use in patients with congestive heart failure and those undergoing high-risk surgery, which have found no benefit. Thus, after 20 years, Robin has been vindicated.

Although the conclusion now must be that the routine use of the PAC is not necessary in ARDS, congestive heart failure, and some surgical settings, this does not mean that there is no role for the PAC. In the present study, patients with severe chronic obstructive pulmonary disease (COPD), clinically significant pulmonary hypertension, or dependence on dialysis were excluded. It is possible, even probable, that information obtained by means of the PAC may be useful in the care of some of these patients. Clinical practice is rarely exclusively dichotomous; a range of responses based on each patient’s situation will always be appropriate. In addition, right heart catheterization has an established role in the diagnosis of congenital heart disease and pulmonary arterial hypertension. The information derived from right heart catheterization has a prognostic value in idiopathic pulmonary arterial hypertension (formerly known as primary pulmonary hypertension) and can be used to determine and adjust drug treatments known to influence survival. It can also help to distinguish pulmonary arterial hypertension from pulmonary veno-occlusive disease — a distinction that can have therapeutic consequences.

The bottom line with respect to PAC use is that it should no longer be part of the routine management of a number of conditions for which it has been widely used. It still has a role in diagnosis and in certain types of treatment, particularly the treatment of patients with suspected pulmonary arterial hypertension and right ventricular dysfunction. PACs may also have a role in populations of patients not included in the study by Wheeler and colleagues, such as those with severe COPD or with conditions requiring complex fluid management. In any setting in which the PAC is used, the catheter should be used for the shortest time practical in order to minimize the possible development of infectious and thrombotic complications. We also need to keep an open mind with regard to the future. The present results are based on PAC use with current treatment. Were an effective new treatment to become available that depended on information obtained by means of a PAC, this equation could change.

Generally speaking, well-controlled trials of the use of devices are essential and must temper enthusiasm for what is new and exciting. Such studies not only provide the best possible information but also, in many ways, honor the goals of Courmand and Richards — to place medicine on a firm foundation of scientific knowledge.

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