SEARCHING FOR EVIDENCE TO SUPPORT PULMONARY ARTERY CATHETER USE IN CRITICALLY ILL PATIENTS

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IN ONE ARTICLE IN THIS ISSUE, SHAH AND COLLEAGUES present a meta-analysis of randomized clinical trials comparing treatment of patients with and without PAC in the setting of high-risk surgery, general ICU treatment, hospitalization for advanced heart failure, and the acute respiratory distress syndrome (ARDS) and/or sepsis. The authors identified and analyzed 13 trials meeting predefined criteria published between 1985 and 2005, with 6 of the trials published between 2001 and 2004; 5051 patients were randomized in total across these 13 trials. The authors used a random-effects model applied to the aggregate data to estimate the odds ratios for death, number of days hospitalized, and use of vasoactive drugs. Although PAC was associated with greater vasoactive drug use, no impact on mortality or time in the hospital was observed between the groups randomized to PAC use or not.

Although a critical reader would note that this meta-analysis incorporated rather heterogeneous patient populations and clinical problems, the lack of effect of PAC on key end points of mortality or time spent recovering from acute illness or surgery is striking. Another potential criticism of this meta-analysis of PAC—germane to the studies themselves—is that some (but not all) of these investigations by design randomize clinicians to using a PAC or not in the treatment of the patient, but do not provide 2 ex-

See also pp 1625 and 1664.
plicit protocols for care based on PAC-generated data or the alternative. Assessment of a monitoring technology such as PAC in a vacuum—that is, as a monitor devoid of an effective evidence-based strategy based on data from the monitor that is known to improve outcome—is unlikely to show benefit.\footnote{Hall JB. Use of the pulmonary artery catheter in critically ill patients: was invention the mother of necessity? JAMA. 2000;283:2577-2578.} This argument often is labeled as the assessment of "efficacy" (the technology linked to explicit treatment protocols dictated by the study) vs “effectiveness” (the technology used as a monitor and without explicit guidance to the clinician). Both of these questions are important—first, can clinicians guide an effective treatment modality better with PAC? And second, widely used as a monitoring modality, will PAC help clinicians globally improve care for complex surgical patients or critically ill medical patients? The meta-analysis by Shah et al\footnote{Shah MR, Hasselblad V, Stevenson LW, et al. Impact of the pulmonary artery catheter in critically ill patients: meta-analysis of randomized clinical trials. JAMA. 2005;294:1664-1670.} would suggest that the answer to each question is no, at least to date and with regard to mortality and hospital length of stay.

The other article on PAC in this issue of JAMA reports the results of the Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE), a multicenter randomized controlled trial evaluating the safety and efficacy of PAC in the treatment of patients with acute heart failure.\footnote{ESCAPE Trial. JAMA. 2005;294:1625-1633.} The results of this trial were incorporated in the meta-analysis conducted by Shah et al.\footnote{Shah MR, Hasselblad V, Stevenson LW, et al. Impact of the pulmonary artery catheter in critically ill patients: meta-analysis of randomized clinical trials. JAMA. 2005;294:1664-1670.} The ESCAPE trial was terminated early (at enrollment of 433 patients of a planned 500) when a significant number of excess adverse events were noted in the PAC group, and it was determined that any benefit of PAC on the primary end point of days alive out of the hospital at 6 months was not likely to be observed. Interestingly, there was an improvement in exercise capacity and quality of life in patients treated with PAC, observed largely during the time following discharge from hospital. In this trial, the use of PAC data or alternatives in the non-PAC group were not explicitly linked to treatments (that is, there was not explicit control by protocol of diuretic or vasoactive drug use), but in both groups the goals of treatment were resolution of clinical congestion with the added targets in the PAC group of a pulmonary capillary wedge pressure of 15 mm Hg and right atrial pressure of 8 mm Hg.

For the relatively homogeneous group of patients with acute or chronic left ventricular failure, PAC use did not improve survival or shorten time in the hospital. The benefits of PAC perceived by the patient (better long-term symptom relief) seem offset by a greater number of complications in the early phase of treatment. It is possible that some of the benefit of PAC in terms of symptom control is a placebo effect, because patients and clinicians could not be blinded to the use of the invasive catheterization. Is there a future for the use of PAC in the routine treatment of patients with heart failure? As suggested by the authors, it seems more reasonable to seek means of achieving the same symptom relief with non-PAC strategies than holding out PAC as the best way to achieve long-term symptom control in these patients.

What is the evidence for the broader issue of PAC use in the ICU and perioperative setting? The data collected to date certainly do not support routine use of the catheter in any patient group, and the currently available information could be viewed as justifying “pulling the pulmonary artery catheter” from routine use, a suggestion made almost 10 years ago.\footnote{Pinsky MR, Vincent JL. Let us use the pulmonary artery catheter correctly and only when we need it. Crit Care Med. 2005;33:1119-1122.} One important additional trial is nearing completion and evaluates the use of PAC in patients with ARDS.\footnote{ARDSnet. Prospective, randomized multicenter trial of pulmonary artery catheter (PAC) vs central venous catheter (CVC) for management of acute lung injury (ALI) and acute respiratory distress syndrome (ARDS). Prospective, randomized multi-center trial of “fluid conservative” vs “fluid liberal” management of acute lung injury (ALI) and acute respiratory distress syndrome (ARDS). Available at: http://www.ardsnet.org/factt.php. Accessed August 2005.} This trial, supported by the National Institutes of Health and conducted by the ARDS Network, compares treatment of patients with and without PAC and for each group compares a “fluid conservative” approach (favoring a reduction of edemagenesis in this form of low-pressure pulmonary edema) vs a “fluid liberal” strategy (favoring a generous ventricular preload and perfusion of peripheral organs). Of all PAC studies reported to date, this trial is the only one capable of simultaneously assessing the benefits, if any, of both the monitoring modality (comparing PAC to routine central venous catheterization) and the strategy guided by the monitoring. Should there be a positive result attributable to PAC in this trial, a specific niche for this technology may remain in critical care.

If the results of this soon-to-be-completed trial show no benefit of PAC monitoring, it is likely that the available data will indicate that it is time to remove the catheter from widespread use, or at the very least relegate this former common monitoring tool to salvage therapy of an extremely small and select number of patients. The need to question the routine use of this monitoring modality was quite real and the results of the last 5 years of study most valuable. Once again the community of critical care physicians has been edified by the approach of “Don’t just do something, stand there! And then think about it. . . .”\footnote{Financial Disclosures: None reported.}

REFERENCES