Pulmonary Artery Catheter for Coronary Artery Bypass Graft: Does It Harm Our Patients? Primum non Nocere

Eugene A Hessel
Ioanna Apostolidou

Available at: http://works.bepress.com/nanette_schwann_lvhn/29/
Pulmonary Artery Catheter for Coronary Artery Bypass Graft: Does It Harm Our Patients? Primum non Nocere

Eugene A. Hessel, MD,* and Ioanna Apostolidou, MD†

Bedside balloon flotation pulmonary artery catheters (PAC) were introduced in 1970 by Drs. Swan and Ganz. Shortly thereafter, PACs became a core component of managing critically ill patients and patients undergoing cardiac surgery. PACs are used for diagnostic and monitoring purposes, and generate detailed information about cardiac filling pressures, cardiac output, and mixed venous oxygen saturation. The availability of these data has generally been believed to allow for hemodynamic optimization of patients that ultimately improve patient outcome.

In the mid 1980s, studies questioned the benefit and even raised concern about the danger of PACs, leading some to recommend their abandonment. This concern was brought to a zenith by the landmark observational study by Connors et al. that found an increased mortality associated with use of PACs in patients admitted to intensive care units (ICU). This led to the conduct of several fairly large randomized controlled trials that did not confirm an increased mortality associated with use of PACs, but also did not find benefit with their usage. However, the latter studies did not address PAC use in patients undergoing cardiac surgery. Other studies, though, have challenged the universal need for PACs and safety of PACs in patients undergoing coronary artery bypass graft (CABG) surgery. Nonetheless, PACs continue to be widely used, often routinely, in a large number of surgeries despite lack of strong evidence of their benefit. The risk–benefit calculation of PAC use in cardiac surgery patients has become particularly pressing in recent years, with the availability of new, less invasive technologies including transesophageal echocardiography (TEE) and less invasive methods for cardiac output monitoring.

Thus, clinicians caring for patients undergoing cardiac surgery are left with conflicting and incomplete data on which to base their decision on PAC use in individual patients. In this issue of Anesthesia & Analgesia, Schwann and colleagues present the findings of a prospective, observational study on the effect of PAC use on fatal and nonfatal outcomes in 5065 patients who underwent CABG surgery at 70 international centers between November 1996 and June 2000. The authors report that PAC use was associated with a 68% greater risk of the composite outcome of death (any cause), or cardiac, cerebral, or pulmonary dysfunction in comparison with non-PAC use. Patients monitored with a PAC suffered twice the risk for all-cause mortality (3.5% vs 1.7%) and a similarly increased rate of adverse cardiac, cerebral, and renal outcomes. Patients who had PACs received inotropic drugs more frequently, received larger volumes of IV fluids after surgery, and experienced longer time to tracheal extubation and longer hospitalization in the ICU than did those who did not have PACs placed during surgery.

How should this study impact the current approach to perioperative care for patients undergoing CABG surgery? First, let us review the strengths of this paper. It included a large patient sample size undergoing surgery under “real-world” clinical practices, and it included patients from a diverse cross-section of centers around the world. This aspect of the study would support the external validity of the study. At the same time, the study has numerous weaknesses that are mostly acknowledged by the authors. For example, the data presented are >10 years old, which begs the question of their relevance to current clinical practice given advances in knowledge, technology, and alternative monitoring approaches.

An important limitation of this study is the fact that the study was observational, relying on propensity analysis to provide matched groups. Propensity scoring, like logistic regression analysis, is a way to adjust a comparison between groups that differ at baseline in some characteristic. Propensity scoring has the advantage of being able to adjust simultaneously for many characteristics in an attempt to generate a control group at equal risk for receiving a PAC (even when they did not). The authors chose 36 covariates to estimate the propensity scores but left out important covariates, including preoperative drug therapy (β-blockers, statins, antihypertensive agents, aspirin, diabetic agents) and participating institution. The latter is particularly troublesome given that the rate of PAC insertion varied from 1% to 99% among centers, suggesting differences among institutions not accounted for in the
propensity score. The authors did acknowledge that institution was not included in the propensity score, but believe that they have adequately adjusted for this by adding a random effect (institution) in the analysis of the outcomes (general estimating equations). It has been argued that clustering by institutions should not be ignored. 

Regardless, it is increasingly recognized that large prospectively randomized trials necessary to evaluate the safety and efficacy of many common interventions are impractical, are expensive, and may not reflect common clinical practice. Thus, clinicians often must make decisions on the basis of analysis of observational studies. Although the sophisticated statistical approach used in this study is state of the art, in the end the readers can never be absolutely assured whether there was or was not a bias whereby more severely ill patients received a PAC. The parallelism between the current study and the study by Connors et al. is striking. The latter also used propensity analysis in their large observational study of use of PACs in patients in ICUs and also observed a 20%–40% increase in mortality in patients receiving PACs versus those who did not. Yet 6 subsequent randomized controlled trials found no increase in mortality in patients receiving PACs in the ICU9–14 In fact, only observational studies using various methods to balance populations have observed increased mortality associated with PAC use.8,23–25 This difference raises questions on whether propensity scoring of observational data can draw the same conclusions about PAC use in cardiac surgery patients as do data from a randomized trial.

Another concern with the current study is the exclusion of patients receiving TEE, a group that constituted >1/3 of their patients. It would be instructive to have data on whether TEE use impacted their observed adverse effects of PACs on the composite outcome. The reader may also question the purported mechanism of the observed increase in mortality associated with PAC use. The authors suggest that PAC use resulted in “more frequent and more intensive hemodynamic interventions” as the basis for the results. It seems remarkable that a 3% (200 mL) increase in fluid administration, a 7% (200 mL) increase in fluid balance, or a 16% increase use of inotropes (58% versus 50%) would cause a doubling in mortality.

Other possible explanations for the apparent increased mortality associated with PAC use include complications due to the PAC per se, misuse/interpretation of data, and finally the possibility that PACs were used by less skilled physicians who relied on technology rather than clinical skills for patient management. Increased mortality directly due to a PAC (i.e., complications of insertion, arrhythmias, pulmonary hemorrhage, infection) seems unlikely, although unfortunately the authors of this paper provided no data in this regard. A summary of the complications rate associated with use the PAC in the 2641 patients in the PAC arms of the 6 major randomized controlled trials observed a low rate of serious complications from PAC use and no deaths.5–14 The authors of the current study asserted that it was unlikely that the PACs were misused or misinterpreted, but multiple studies suggest that even physicians experienced in cardiac and critical care are often ill-informed about interpretation of data derived from a PAC.27,28 This is a particular concern because in the past 10 years (after this study was performed), physicians have become more aware that static filling pressures (e.g., pulmonary artery occlusion pressure and central venous pressure) are unreliable clues to preload (ventricular filling) and fluid responsiveness, and have come to rely more heavily on TEE and other dynamic indices for such information.29 In interpreting the results of this study, the reader will note that the study population was relatively low risk. About 87% were first-time isolated CABG procedures, and the overall mortality was 2.6%. This is not a group of patients in whom use of a PAC would be expected to improve outcome, and hence potential for harm is greater. There is also no information provided about the indication/rationale for placing the PAC (e.g., routine, or because the patient was considered high risk, or because it is a preoperative problem). Lastly, it is ironic that, with the current enthusiasm for “goal-directed therapy,” often relying on less reliable technology than the PAC, the current paper suggests that use of the PAC is associated with worse outcome. This may simply be further evidence that what is important is how the instrument/data are interpreted and used (therapeutic algorithms) and not the instrument itself.

While acknowledging the important limitations of the study by Schwann et al.,21 we simply should not ignore the warning that it raises. This study should generate attention and discussion in the scientific and clinical community. How do the authors of this editorial believe we should respond to this important study? First, each of us must carefully consider the appropriateness of using PAC for a given patient rather than using it routinely. There is considerable evidence to support the fact that in low-risk patients, CABG surgery can be accomplished with excellent results without a PAC.17,18,31 In low-risk patients the likelihood of improving outcome is low, while still exposing the patients to the risks inherent in use of the PAC even though they may be low. Finally, it is our opinion, as recommended in the editorial by Dalen and Bone22 which accompanied the Connors et al. study,9 that this study from Schwann et al.21 demands that one or more large high-quality randomized clinical trials (with strict therapeutic goals included) be conducted to either confirm or refute their findings that use of PACs during CABG surgery causes harm. To fail to do so is not in the best interest of our patients nor of our specialty. Primum non nocere.

DISCLOSURES
Name: Eugene A. Hessel, MD.
Contribution: This author helped write the manuscript.
Attestation: Eugene A. Hessel approved the final manuscript.
Name: Ioanna Apostolidou, MD.
Contribution: This author helped write the manuscript.
Attestation: Ioanna Apostolidou approved the final manuscript.
This manuscript was handled by: Charles W. Hogue, Jr., MD.

ACKNOWLEDGMENTS
We appreciated the biostatistical expertise that Drs. Nathan Pace and William Thomas provided in the preparation of the editorial.
REFERENCES


