Letter

Pulmonary Artery Catheterization in Critically Ill Neonates

The recent article by Yoshizato and Hagler in the April 1989 issue of the *Proceedings* (pages 387 to 391) raises several serious issues that are inapparent from a simple reading of the report. In nine critically ill neonates, pulmonary artery catheters were placed by using two-dimensional echocardiographic guidance. The purpose was to administer a pulmonary artery vasodilator, tolazoline (Priscoline), directly into the pulmonary artery. Of the nine patients, two (22%) died in the pericatheterization period. One death was attributed to respiratory failure and the second to renal failure in an infant with "minor" blood loss.

The risk-to-benefit ratio of pulmonary flow catheters is currently an area of substantial controversy in adult medicine.[1,2] Whatever the ultimate outcome of this controversy, investigators almost universally agree that (1) the balance between risks and benefits has not been established by an appropriate randomized clinical trial, (2) a considerable number of complications occur, and (3) some of these complications, such as right-sided myocardial injury, can be uncovered only by postmortem examination.[3]

I assume that these issues would be even more relevant in critically ill neonates. The use of pulmonary artery vasodilators in adults is also an unsettled issue.[4] Again, the balance between risk and benefit has not been determined by an appropriate randomized clinical trial, nor do I believe that such a test has been used for administration of drugs through the pulmonary artery.

In light of these issues, the article by Yoshizato and Hagler prompts the following legitimate questions: (1) Were autopsies performed on the infants who died? (2) What was the nature of the institutional review that approved the catheterization and the intra-pulmonary artery use of tolazoline? (3) What process was involved in obtaining informed consent from the parents? (4) Did this process include an explanation to the parents that the investigators themselves did not know the true risk-to-benefit ratio of the procedure being performed? (5) What were the parents told about the deaths of their children? (6) Were any of these issues raised during the peer review process of the manuscript?

On the surface, it appears that an unproven instrument was used in a particularly vulnerable group of patients to give an unproven drug by an unproven route of administration.

Eugene Robin, M.D.
Division of Respiratory Medicine
Stanford University School of Medicine
Stanford, California

REFERENCES

1. Mathay M, Robin E, Morin M, Winterbauer R: A pulmonary artery catheter should be used in patients with respiratory failure. *In* Debates in Medicine. Vol 2. Edited by G Gitnick. Chicago, Year Book Medical Publishers, 1989, pp 168-197
2. Robin ED: Defenders of the pulmonary artery catheter (letters to the editor and responses). Chest 93:1059-1066, 1988
3. Rowley KM, Clubb KS, Walker Smith GJ, Cabin HS: Right-sided infective endocarditis as a consequence of flow-directed pulmonary-artery catheterization: a clinicopathological study of 55 autopsied patients. N Engl J Med 311:1152-1156, 1984
4. Glanville AR, Burke CM, Theodore J, Robin ED: Primary pulmonary hypertension: length of survival in patients referred for heart-lung transplantation. Chest 91:675-681, 1987

Dr. Hagler replies

The letter from Professor Robin raises several questions relative to the placement of pulmonary artery catheters in critically ill neonates. In his letter, he questioned the risk-to-benefit ratio of pulmonary artery catheters as an area of substantial controversy in adult medicine. Indeed, the Food and Drug Administration (FDA) recently published the recommendations of a task force convened by the FDA in an effort to minimize the serious complications sometimes seen with use of central venous catheters.[1] They emphasized the following complications: infection, pneumothorax, hemothorax, hydrothorax, vessel and cardiac perforation, cardiac tamponade at-

tributable to pericardial effusion, dysrhythmia, and air embolus. My coauthor and I certainly agree with their conclusions that central venous catheterization should be performed only when the potential benefits seem to outweigh the inherent risks of the procedure. We would point out that these guidelines apply not only to pulmonary artery catheters but also to central venous catheters in general. The report also concludes that central venous catheterization must be performed only by trained personnel well versed in anatomic landmarks, safe technique, and potential complications. Similarly, we emphasized in our report that this procedure should be performed by experienced pediatric cardiologists capable of performing echocardiography and also cardiac catheterization.

We would like to reemphasize several points that were also discussed in our report. We indicated that the purpose of the report was to describe a reproducible and effective technique for placement of a pulmonary artery catheter in critically ill neonates solely with the use of echocardiographic guidance and echocardiographic contrast effect to verify its location in the main pulmonary artery. We point out that a clinical decision for infusion of α-adrenergic agonists such as tolazoline for the treatment of persistent fetal circulation had been established. Thus, the purpose of the report was not to prove the utility of this therapy. The risk-to-benefit ratio that we considered in the report was heavily weighted to the use of echocardiographic guidance to avoid transfer of critically ill neonates to the cardiac catheterization laboratory for placement of a pulmonary artery catheter. As we pointed out, the use of echocardiography in catheter guidance had been clearly established clinically in previous reports. These techniques can be safely applied as well to critically ill neonates. Clearly, with a heavily weighted benefit with the use of two-dimensional echocardiographic guidance, no need exists for institutional review. For all the infants included in that study, parents were advised about the anticipated benefits of infusion of tolazoline and the need for placement of the pulmonary artery catheter.

As with any controversial subject in medicine, the extremely negative aspects can be highlighted, and Professor Robin has taken this stance in his assessment of pulmonary artery catheter placement and infusion of vasodilators. As we mentioned in the article, the effect of central versus peripheral infusion of tolazoline remains to be clarified in a double-blind protocol. In such controversial areas, it may be impossible to know the *true* risk-to-benefit balance of such procedures. Such a situation, however, does not imply that these procedures should be abandoned or not performed at all. We believe that much of Professor Robin's pessimism reflects the differences in the use of pulmonary artery vasodilators in adults with fixed pulmonary vascular beds in contrast with their use in neonates with persistent fetal resistance and a very highly reactive pulmonary vascular bed. Certainly, the parents of our patients were aware of many of the uncertainties in the care of such critically ill neonates.

We believe that the results of our study represented an excellent outcome in such critically ill neonates. Although two deaths occurred in the peri-catheterization period among a total of nine neonates, clearly many of the infants in this study had dramatic improvement during the course of the tolazoline infusions. As we reported, one infant who died was so critically ill with sepsis and respiratory distress syndrome that she died of respiratory failure before the catheter could be manipulated beyond the right atrium. Postmortem findings were not available in this patient. The second infant died of renal failure several days after placement of the pulmonary artery catheter. In this infant, cardiac examination showed no evidence of right-sided myocardial injury, thrombus, or vegetation. The parents were indeed advised of the details of the deaths of their children and the treatment methods used in this highly fatal condition. During the peer review of the manuscript, we also emphasized that the purpose of the report was not to assess the benefit of central versus peripheral infusion of tolazoline.

Thus, we strongly object to Professor Robin's casual dismissal of this method as an unproven technique. We believe that our study demonstrates that when a clinical decision for the need of a central pulmonary catheter has been made, two-dimensional echocardiographic guidance may be applied for the placement of such pulmonary artery catheters in critically ill neonates safely, effectively, and reproducibly. Finally, we emphasize that the guidelines recommended by the FDA task force should be carefully followed.

Donald J. Hagler, M.D.

REFERENCE

1. Precautions necessary with central venous catheters. FDA Drug Bull 19:15-16, July 1989