

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.
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REFERENCES

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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-