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In Reply:—We appreciate the comments by Drs. Hammer and Krane. Indeed, we believe that the pressurized infusion was the main cause of the localized arterial hypoxemia, because the high pressure reversed the normal arterial/venous pressure gradient, causing the transfusion to flow directly across the shunt. The shunting was so immediate and dramatic that we immediately suspected an anatomic shunt rather than retrograde flow through capillary beds. This was mentioned as a possible theoretical explanation for venoarterial admixture in general. The postoperative arteriography demonstrated the suspected abnormal anatomic venoarterial connection.

It is likely that all pediatric anesthesiologists believe that small distal veins should not be used for rapid transfusion. However, in this case, both peripheral lines were 18-gauge catheters. These are by no means small catheters, particularly in an 8.7-kg patient! Why were they placed so distally? Because these distal veins were much larger than the antecubital veins in this patient, possibly because of arterialization of the veins secondary to the anatomic shunts.

According to Poiseuille's law, resistance to flow is affected by both radius and length of the catheter used. An 18-gauge, 3.2-cm catheter will allow much more rapid transfusion than an 18-gauge 8-cm catheter; in situations involving massive hemorrhage, this difference in flow can be critical.

We appreciate reiteration of the point that calcium chloride can be very irritating to small veins and tissues; when distal administration of calcium is considered, calcium gluconate is less damaging.

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Ethics for Non-emergencies

To the Editor:—I read with great interest the recent editorial by Pearson[1] with its thoughtful and provocative analysis of the problems of obtaining informed consent when a potential subject's condition precludes this action. Pearson correctly details the Food and Drug Administration's criteria for exempting a clinical investigation from the requirement for obtaining informed consent. Although I agree with his analysis, I do not believe that the study[2] that formed the basis for his editorial satisfied the requirements for "deferred consent" or came within the aegis of the Food and Drug Administration's exemption.

I refer specifically to Pearson's fourth prerequisite for permitting emergency research without a patient's consent: "the investigation could not be performed without the waiver." This stipulation implies that the condition being studied will be sudden and unanticipated and will mandate immediate action. The first sentence of the abstract in the article by Balser *et al.*[2] clearly demonstrates that the pathology being investigated was neither sudden nor unanticipated. Rather, it was predictable and reasonably foreseeable: "Postoperative supraventricular tachyarrhythmia is a common complication of [cardiac] surgery."

Accordingly, each patient should have been enrolled in this study *before surgery*, at which time informed consent easily could have been obtained in a nonemergent setting. Thereafter, if the arrhythmia developed in a patient who satisfied the other requirements for entrance into the randomization procedure, there would have been no ethical problems in conducting the investigation.

I am concerned that an unduly low threshold for waiving requirements for informed consent risks impairing the role of institutional review boards in the implementation of this important provision of federal regulations. This very well may result in imposing inflexible requirements for informed consent in a truly emergent setting, thereby interfering with the acquisition of important knowledge.

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The views and opinions expressed herein are those of the author and do not necessarily reflect those of the National Institute on Drug Abuse (NIDA), NIDA's Intramural Research Program, or its institutional review board.

References

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