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Hematocrit trial

To the Editor:

We read with interest the report by Ootaki and associates,¹ as well as the correspondence by Shuhaiber² in reference to the article by Habib and colleagues.³ Ootaki and coworkers¹ applied a transfusion protocol in which blood was not transfused during cardiopulmonary bypass unless hematocrit was less than 15%. They found that patients with a hematocrit of less than 20% had a higher lactate level than patients with a higher hematocrit but imply that this has no functional significance.

In their critique of the article by Habib and associates,³ which emphasized the value of the lowest hematocrit as a predictor of outcome, Shuhaiber² implied that a hematocrit of 20% is a useful transfusion trigger. They also called for a prospective randomized study of hematocrit, as did Habib's group.

At the 2002 meeting of the American Association for Thoracic Surgery, we presented the results of a prospective randomized trial of 2 hemodilution strategies.⁴ This study was shut down by the Data and Safety Monitoring Board of the National Institutes of Health because of a strongly positive outcome. Infants who had a mean hematocrit of $27.8\% \pm 3.2\%$ ($n = 73$) had significantly better motor skills at 1 year of age relative to patients whose lowest hematocrit on bypass was $21.5\% \pm 2.9\%$ ($n = 74$). A significantly greater percentage of patients at 1 year of age were classified as developmentally delayed with respect to motor skills relative to patients perfused at a higher hematocrit. The lactate level 1 hour after bypass was significantly lower with the higher hematocrit.

The findings of our prospective randomized study are consistent with several previous reports derived from our laboratory work in this area.⁵⁻⁷ Studies using near-infrared spectroscopy suggest that acute hemodilution during cardiopulmonary bypass results in cerebral hypoxia. It is important to remember, before discarding the significance of our clinical trial as being irrelevant to adults because it was performed in infants, that the mature brain is significantly more sensitive to

hypoxic injury than the neonatal and infant brain. Nevertheless, we strongly endorse the call for a prospective randomized trial of hematocrit in adults undergoing cardiopulmonary bypass, including sensitive end points such as assessment for cognitive dysfunction. In the meantime, we strongly recommend that a hematocrit of at least 25% and preferably closer to 30% should be used during cardiopulmonary bypass.

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Randomized prospective trial for blood transfusion during adult cardiopulmonary bypass surgery

To the Editor:

Hemoglobin dilution is an expected physiologic response during cardiopulmonary bypass (CPB) surgery. Current controversy, however, centers around this ques-

tion: what is a safe hematocrit level during CPB before the patient sustains less than an expected outcome? The main reason for the lack of consensus regarding blood transfusion may stem from the lack of a direct cause (hematocrit level) and effect (morbidity and mortality) relationship or an association or both causality and association. Although it has been found that low preoperative hemoglobin levels are correlated with poorer outcome,¹ it does not mean that correcting this number will result in improved outcome. This same argument holds true for intraoperative hematocrits with the understanding that new-onset intraoperative anemia is reversible and mainly caused by dilution, whereas preoperative anemia is pathologic and mainly caused by nondilutional processes. Also, despite understanding the reversibility concept, most decisions of intraoperative transfusion stem from personal and institutional experience, with no defined dimensions. In May 2004, the National Heart, Lung, and Blood Institute working group published an executive summary regarding future directions in cardiac surgery.² Creating a cardiovascular surgery clinical research network was one of the pillars, and I hope that the working group and the National Institutes of Health-sponsored workshop for neurocognitive changes after cardiac surgery will consider this trial an important direction toward filling an existing critical gap.

Why Is a Hematocrit Trial Timely?

The patient's physiologic status must be the underlying cause for a transfusion, and the outcome of the transfusion (effect) must also be considered. The practicing surgeon, including those in training, is currently confused with the paradigm of cause and effect that seems to argue that mortality is higher among patients with low hematocrit ($<25\%$ in women and $<23\%$ in men^{3,4}) and high hematocrit ($>34\%$).⁵ Randomization is lacking in the adult cardiac surgery group thus far, despite a clear benefit of increased hematocrit for neurologic outcome in pediatric heart surgery (mean intraoperative hematocrit: 27.8% vs 21.5%).⁶

Moreover, despite the benefit of increased oxygen-carrying capacity with increased hematocrit, we must be aware that blood transfusions expose patients to a variety of potential cellular and hu-