

Improved cerebral oxygen saturation and blood flow pulsatility with pulsatile perfusion during pediatric cardiopulmonary bypass

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The Materials and Methods section, under “Patients and study design,” begins with the following erroneous sentence:

“With Penn State IRB approval and parental informed consent, and under the guidance of a Data Safety Medical Board (DSMB) in addition to FDA clinicaltrials.com database registration, 238 patients were enrolled between March 2007 and February 2010 in a randomized trial comparing intra- and early postoperative physiologic measures as monitored by NIRS and TCD after receiving pulsatile or nonpulsatile perfusion during hypothermic CPB for surgical repair of CHDs.”

In fact, the patient data were pooled from two institutional board-approved protocols at our institution. The first, and primary, protocol—aimed at determining the physiologic impact of pulsatile versus nonpulsatile perfusion—incorporated parental informed consent. The second IRB protocol, from which we utilized only neuromonitoring data, was part of an ongoing quality-based study that collected said neuromonitoring information as part of standard-of-care procedures during hypothermic cardiopulmonary bypass. The number of subjects whose neuromonitoring information was incorporated from this second protocol represented a minority in terms of the overall subject population.

In addition, “clinicaltrials.com” should have read “clinicaltrials.gov.”

The text should therefore have read as follows:

“With Penn State IRB approval and parental informed consent, and under the guidance of a Data Safety Medical Board (DSMB) in addition to FDA clinicaltrials.gov database registration, 145 patients were enrolled between March 2007 and February 2010 in a randomized trial comparing intra- and early postoperative physiologic measures as monitored by NIRS and TCD after receiving pulsatile or nonpulsatile perfusion during hypothermic CPB for surgical repair of CHDs. Data from 93 additional subjects, for whom neuromonitoring information during hypothermic CPB for surgical repair of CHDs was available as standard of care, were added to this data set to yield a final sample size of 238 patients.”