

No reduction in death or severe brain injury with cerebral oximetry monitoring in extremely preterm infants, finds study

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An international team of 100 researchers at 70 sites in 17 countries has found no reduction in death for treatment guided by cerebral oximetry



monitoring in extremely preterm infants.

In the paper "Cerebral Oximetry Monitoring in Extremely Preterm Infants," published in the *New England Journal of Medicine*, researchers report on the outcome of a phase 3 trial in which 1,579 extremely preterm infants were studied to assess the effectiveness of treatments informed by cerebral oxygen level monitoring versus no monitoring in an intensive care environment for the first 72 hours after birth. Infants were eligible for enrollment if they were less than 28 weeks gestational age at birth, if a decision had been made to provide full life support, and if the initiation of cerebral oximetry monitoring within six hours after birth was possible.

Infants in the oximetry group (n=772) underwent cerebral oximetry monitoring for 72 hours after birth, measured with Medtronic's INVOS small adult sensor. An elastic bandage fixed a probe with near-infrared light sources and sensors to the infant's head. A signal indicating the hemoglobin oxygen saturation percentage was continuously displayed. The signal primarily displayed information from veins in the cortex and subcortex directly beneath the probe.

Treatment guided by cerebral oximetry monitoring for the first 72 hours after birth was not associated with a lower incidence of death or severe brain injury at 36 weeks' postmenstrual age than usual care. Death or severe brain injury had occurred in 272 of 772 infants (35.2%) in the cerebral oximetry group, compared with 274 of 807 infants (34.0%) in the usual-care group.

Serious adverse events assessed were death, severe brain injury, bronchopulmonary dysplasia, retinopathy of prematurity, necrotizing enterocolitis, and late-onset sepsis. The incidence of serious adverse events did not differ between the two groups, as statistical significance thresholds (+/- 7.5%) were unmet. In considering why the additional



intervention failed to provide an added benefit, the researchers speculate about potential issues in the trial.

The authors point to the <u>training program</u> they designed to establish competence with the system as a possible weakness. The training was optional and involved hospitals with little or no experience with cerebral oximetry, which could have resulted in a lack of appreciation for the additional monitoring data.

The time frame could have had an impact as monitoring was not performed in the delivery room or during the first few hours in the neonatal intensive care unit and was involved for only 72 hours.

Additionally, the main target of cerebral oximetry is a hypoxic-ischemic brain injury, so factors not detectable by oximetry may have been responsible for death or severe brain injury in many of these extremely preterm infants.

Adverse reactions were also reported, including severe skin damage and physical injury associated with the oximetry device. While the <u>patient interaction</u> with the device is fairly limited (sensor taped to the forehead), the wires connecting sensors to the monitoring unit may have caused the critical displacement of endotracheal tubes or endovascular lines.

Clinical interventions aimed at improving the respiratory or cardiovascular status and oxygen transport that occurred in reaction to oximetry monitoring may have needed to be better managed, leading to adverse results.

While the cerebral oximetry device may have provided useful information in some scenarios, the study highlights the difficulty in adding interventions to the highly complex environment of an intensive



care unit and infant patients already undergoing multiple interventions.

More information: Mathias L. Hansen et al, Cerebral Oximetry Monitoring in Extremely Preterm Infants, *New England Journal of Medicine* (2023). DOI: 10.1056/NEJMoa2207554

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