Traumatic brain injury study finds standard of care not a significant improvement

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This is the intensive care unit at Hospital Luis Vernanza in Ecuador, one of the study sites. Credit: University of Washington/Neurological Surgery.

For patients with a traumatic brain injury, the default standard of care has just been turned on its head by a group of researchers at the University of Washington working with colleagues at six hospitals in Bolivia and Ecuador.

In a study published in the New England Journal of Medicine Dec. 12, the researchers found that intracranial pressure monitoring – the standard of care for severe traumatic brain injury – showed no significant difference than a treatment based on imaging and clinical examination.
"Within this field, this is a game changer," said Randall Chesnut, a UW Medicine neurosurgeon based at Harborview Medical Center in Seattle and principal investigator of the study. "We've been treating a number not a physiology."

The study is the first international randomized controlled trial on traumatic brain injury the NIH has funded and is the first study of its type in Latin America.

In the trauma world, getting a patient's intracranial pressure less than 20 mm (millimeters of mercury) was the bellwether for treatment, even if it meant taking off a patient's skull.

Raised intracranial pressure means that both nervous system (neural) and blood vessel (vascular) tissues are being compressed and could result in permanent neurologic damage or death.

"We suspect that one major issue is that 20 is not a magic number and that patients require a more complicated method of treatment," said Chesnut.

**The Study**

In the randomized control trial, 324 patients over the age of 13 treated in intensive care units at four hospitals in Bolivia and two hospitals in Ecuador were randomly assigned to one of two specific protocols – intracranial pressure monitoring (ICP) or imaging and clinical exam. They were evaluated by a combination of survival time, impaired consciousness, three and six-month functionality and six-month neuropsychological status assessed by a blinded examiner. This composite measure was based on percentile performance across 21 measures of functional and cognitive status (0-worst to 100-best).
The results surprised researchers. The composite measure for intercanial pressure monitoring was a median of 56 versus 53 for imaging and clinical exam – very little difference.

Chesnut said this study should make clear that multimodality monitoring should be more commonplace. For patients, he said, this translates to more focused treatment, less unnecessary treatment and a shorter stay at the intensive care unit.

**Impact of TBI**

Traumatic brain injury management advancement has been limited by lack of recognition of the importance of this disease, so this study brings new energy into what researchers call an "orphan disease."

Around the world, traumatic brain injury has a huge impact on the quality of life.

Traumatic brain injury is the leading cause of death among young people (15-29), according to the World Health Organization (WHO), and is the leading cause of death associated with road traffic crashes.

Worldwide, an estimated 1.2 million people are killed in road crashes each year and as many as 50 million are injured, according to WHO. Projections indicate that these figures will increase by about 65 percent over the next 20 years unless there is new commitment to prevention. Injuries, and specifically traumatic brain injury, are projected to be a top five killer by 2020.

**NIH Study**

The study is part of a five-year $3.2M grant from the National Institutes of Health (NIH) Fogarty International Center and the National Institute
on Neurologic Diseases and Stroke (NINDS) to evaluate overall outcomes in order to understand the care traumatic brain injury patients receive and how this care affects outcomes.

Chesnut said the idea for the study came from Bolivian intensive care specialists who weren't sure that, if they had the money, they should spend it on costly monitors (upwards of $700 each). Since many Latin American countries do not routinely use ICP monitors, the study was conducted in Bolivia and Ecuador.

The study grew from a passionate core of physicians in Latin America who wanted to help survivors of traumatic brain injuries, but were hindered by scientific knowledge on how to treat these patients. The physicians formed the Latin Brain Injury Consortium and have teamed with Chesnut and his colleagues to look for answers.

**Other Findings**

In other findings, researchers came across orphan patients – meaning they were orphaned from ICU because there was no available bed. In Latin America, due to ethical considerations, patients are treated on first-come, first-serve basis and there is no accommodation to ration beds according to need.

The next phase of research will include setting standards for treating traumatic brain injury patients, testing the protocol based on a consensus, and then retesting it, said Chesnut.

Provided by University of Washington

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