A Blood Test for Brain Injury Approved by FDA

By Julianna LeMieux — February 19, 2018

There are millions of traumatic brain injury (TBI) - related emergency department visits in the U.S each year.

For each one of these visits, be it from a car crash or football tackle, a two part standard examination is done to test for TBI. First is the 15-point Glasgow Coma Scale (see details below in note #1) followed by a CT scan of the head to look for the presence of intracranial lesions.

The Food and Drug Administration (FDA) recently approved a blood test that may revolutionize the diagnosis of TBI. It's called the Brain Trauma Indicator and is marketed by Banyan Biomarkers Inc.

What is TBI?

TBI is caused by either a bump, blow or jolt to the head or can be caused by something that penetrates the head. Regardless of the cause, normal brain functioning is disrupted, the severity may range from mild to severe. Effects from TBI can range from impaired thinking or memory, movement, sensation or emotional functioning. Seventy-five percent of all TBIs that occur are categorized as more mild TBIs or concussions. Many patients with these mild concussions end up with a negative CT scan, as well.

What does the blood test measure?

The Brain Trauma Indicator blood test measures the levels of two proteins, UCH-L1 and GFAP. Upon brain injury, these proteins are released from the brain into the blood. If found at elevated levels, brain damage with intracranial lesions, normally otherwise only visible on a CT scan, is suggested.

The blood test can be done immediately, with results coming back in a few hours, allowing for
health care professionals to send those patients who are blood test positive to the CT scan to confirm and gather more information on the damage. A blood test negative patient could head home to rest.

The FDA reviewed and authorized for marketing the Banyan Brain Trauma Indicator in fewer than 6 months as part of its Breakthrough Devices Program [1].

How well does the Brain Trauma Indicator work?

To give approval, FDA used data from a clinical study of 1,947 individual blood samples from adults with suspected TBI and compared blood test results with CT scan results. How did the blood test perform? It was able to predict the presence of intracranial lesions on a CT scan 97.5 percent of the time and those who did not have intracranial lesions on a CT scan 99.6 percent of the time.

“Helping to deliver innovative testing technologies that minimize health impacts to patients while still providing accurate and reliable results to inform appropriate evaluation and treatment is an FDA priority. Today’s action supports the FDA’s Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging—an effort to ensure that each patient is getting the right imaging exam, at the right time, with the right radiation dose,” said FDA Commissioner Scott Gottlieb, M.D. “A blood-testing option for the evaluation of mTBI/concussion not only provides health care professionals with a new tool, but also sets the stage for a more modernized standard of care for testing of suspected cases. In addition, availability of a blood test for mTBI/concussion will likely reduce the CT scans performed on patients with concussion each year, potentially saving our health care system the cost of often unnecessary neuroimaging tests.”

This test was developed in collaboration with the US Department of Defense and will be incredibly useful both for civilians in the United States and for the military overseas.

Notes:

The 15 point scale is as follows. Patients are scored in each of three categories and the scores are added together to give a total of 15 points - indicating the severity of the brain injury. (taken from http://www.traumaticbraininjury.com/symptoms-of-tbi/glasgow-coma-scale/ [2])

I. Motor Response
6 – Obeys commands fully
5 – Localizes to noxious stimuli
4 – Withdraws from noxious stimuli
3 – Abnormal flexion, i.e. decorticate posturing
2 – Extensor response, i.e. decerebrate posturing
1 – No response

II. Verbal Response
5 – Alert and Oriented
4 – Confused, yet coherent, speech
3 – Inappropriate words and jumbled phrases consisting of words
2 – Incomprehensible sounds
1 – No sounds

III. Eye Opening
4 – Spontaneous eye opening
3 – Eyes open to speech
2 – Eyes open to pain
1 – No eye opening

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