ABSTRACT SUMMARY

World's First Clinical Implementation of a Mild Traumatic Brain Injury Blood Test in the Emergency Department[1]

Authors: Linda Papa, MD.CM, MSc; Jay G. Ladde, MD; Josef G. Thundiyil, MD, MPH; Susan A. Miller, MD; Chrissy VanDillen, MD; John O'Brien, MD; Chris Hunter, MD, PhD; Jesus V. Roa, MD; Joshua G. Briscoe, MD; Tory Weatherford, MD; Sara Y. Baker, MD; Jillian Davison, MD; Steve Leech, MD; Kurt Weber, MD; Philip A. Giordano, MD

This summary is based on a conference abstract authored by Dr. Linda Papa, MD.CM, MSc, and colleagues, presented at SAEM 2025. It reflects preliminary findings from a single-center study that has not been peer-reviewed or published. The content is for informational purposes only and is not intended to guide clinical decisions.

BACKGROUND AND OBJECTIVES:

- In 2024, *i-STAT TBI*, the whole-blood point-of-care (POC) test was FDA-cleared to help clinicians determine the need for a CT scan in adult patients with suspected mild traumatic brain injury (TBI) (GCS 13-15) who present to the emergency department (ED) within 24 hours of injury.
- On August 13, 2024, Orlando Health became the first hospital in the world to implement the test.
- During this time, Orlando Health evaluated the impact of *i-STAT TBI* on clinical performance measures including CT ordering rates, ED length of stay, and test performance for identifying CT lesions.

STUDY DESIGN:

- Prospective, single-single center study at the only Level I Trauma Center in Orlando, Florida.
- Adult trauma patients with suspected mild TBI presenting within 24 hours of injury collected from Aug. 13, 2024 to Nov. 1, 2024.
- Evidence-based clinical algorithm was created that combined clinical decision rules (CDR) and *i-STAT TBI* to guide emergency physicians (EP) in determining the need for a CT scan.
- The decisions to perform *i-STAT TBI* and the CT scan were solely at the discretion of the treating EP.
- Primary outcome measure was the CT ordering rate.
- Secondary outcome measures included total length of stay in the ED (LOS), time from being placed in a room to discharge (RD), and time from being seen by an MD to discharge (MD).
- Tertiary outcome was the detection of intracranial lesions on CT scan.

RESULTS AND CONCLUSION:

- *i-STAT TBI* was performed on 205 patients (mean age 40 [SD 17] and 121 (59%) male).
- Physicians performed CT scans in 48 patients. A reduction of 70% from prior to implementation.
- The ED LOS was significantly lower in patients without CT performed (328 min.) vs. those with CT performed (453 min.).
- Time of RD was also significantly reduced in patients without CT performed (300 min) vs. those with CT performed (429 min.).
- Similarly, MD time was significantly lower in patients with out CT performed (298 min) vs. those with CT performed (429 min).
- Sensitivity (100%), negative predictive value (NPV) (100%), and specificity (28%).
- In a single level I trauma center, the *i-STAT TBI* cartridge reduced the CT scan rate by 70% and reduced emergency department length of stay by over 2 hours, while maintaining high sensitivity and negative predictive value.

Reference:

1. Papa et al. "World's First Clinical Implementation of a Food and Drug Administration-Approved Traumatic Brain Injury Whole-Blood Test in the Emergency Department." Society for Academic Emergency Medicine Abstract (2025)

Intended Use:

The i-STAT TBI test is a panel of in vitro diagnostic immunoassays for the quantitative measurements of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) in whole blood and a semi-quantitative interpretation of test results derived from these measurements, using the i-STAT Alinity instrument. The interpretation of test results is used, in conjunction with other clinical information, to aid in the evaluation of patients, 18 years of age or older, presenting with suspected mild traumatic brain injury (Glasgow Coma Scale score 13-15), which may include one of the following four clinical criteria: 1) any period of loss of consciousness, 2) any loss of memory for events immediately before and after the accident, 3) any alteration in mental state at the time of accident, and/or 4) focal neurological deficits, within 24 hours of injury, to assist in determining the need for a CT (computed tomography) scan of the head. A 'Not Elevated' test interpretation is associated with the absence of acute traumatic intracranial lesions visualized on a head CT scan.

The test is to be used with venous whole blood collected with EDTA anticoagulant in point of care or clinical laboratory settings by a healthcare professional.

i-STAT TBI and the *i-STAT Alinity System* is for *in vitro* diagnostic use. This material is intended for a U.S. audience only.
For complete product information, visit www.globalpointofcare.abbott.

Abbott