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Clinical Trial of VEUPLEX℠ TBI Assay to Help Diagnose Traumatic Brain Injury by Quantifying Glial Fibrillary Acidic Protein and Ubiquitin Carboxy-Terminal Hydrolase L1 in the Serum of Patients Suspected of Mild TBI by Fluorescence Immunoassay

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Abstract : The clinical sensitivity of the “VEUPLEXTM TBI assay”, a clinical trial medical device, in mild traumatic brain injury was 28.6% (95% CI, 19.7%-37.5%), and the clinical specificity was 94.0% (95% CI, 89.3%). -98.7%). In addition, when the results analyzed by marker were put together, the sensitivity was higher when interpreting the two tests together than the two tests, UCHL1 and GFAP alone. Additionally, when sensitivity and specificity were analyzed based on CT results for the mild traumatic brain injury patient group, the clinical sensitivity for 2 CT-positive cases was 50.0% (95% CI: 1.3%-98.7%), and 19 CT-negative cases. The clinical specificity for cases was 68.4% (95% CI: 43.5% - 87.4%). Since the low clinical sensitivity for the two CT-positive cases was not statistically significant due to the small number of samples analyzed, it was judged necessary to secure and analyze more samples in the future. Regarding the clinical specificity analysis results for 19 CT-negative cases, there were a large number of patients who were actually clinically diagnosed with mild traumatic brain injury but actually received a CT-negative result, and about 31.6% of them showed abnormal results on VEUPLEXTM TBI assay. Although traumatic brain injury could not be detected in 31.6% of the CT scans, the possibility of actually suffering a mild brain injury could not be ruled out, so it was judged that this could be confirmed through follow-up observation of the patient. In addition, among patients with mild traumatic brain injury, CT examinations were not performed in many cases because the symptoms were very mild, but among these patients, about 25% or more showed abnormal results in the VEUPLEXTM TBI assay. In fact, no damage is observed with the naked eye immediately after traumatic brain injury, and traumatic brain injury is not observed even on CT. But in some cases, brain hemorrhage may occur (delayed cerebral hemorrhage) after a certain period of time, so the patients who did show abnormal results on VEUPLEXTM TBI assay should be followed up for the delayed cerebral hemorrhage. In conclusion, it was judged that it was difficult to judge mild traumatic brain injury with the VEUPLEXTM TBI assay only through clinical findings without CT results, that is, based on the GCS value. Even in the case of CT, it does not detect all mild traumatic brain injury, so it is difficult to necessarily judge that there is no traumatic brain injury, even if there is no evidence of traumatic brain injury in CT. And in the long term, more patients should be included to evaluate the usefulness of the VEUPLEXTM TBI assay in the detection of microscopic traumatic brain injuries without using CT.

Keywords : brain injury, traumatic brain injury, GFAP, UCHL1
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