NEW APPROACHES FOR CONCUSSION DIAGNOSTICS

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INTRODUCTION

There is not a definite laboratory test for the detection of traumatic brain injury (TBI). Especially mild injuries and concussions (a typical event in the sports) remain undiagnosed and untreated. An easily available test would help a physician to assess the severity of a brain injury and to make decisions e.g. on patient's ability to return to play.

Medicortex Finland Oy is developing a comprehensive solution for the detection and management of TBI. The company is developing a rapid diagnostic method* relying on glycan based biomarkers discovered in body fluids, and in addition, multifunctional drug molecules* for the treatment of TBI and for halting the secondary cascade.

*Patent applications of these innovations are in the PCT process.

METHODS

Preclinical studies

In the preclinical animal models a controlled cortical impact was carried out to exposed dura of anesthesized laboratory rats. Animals were allowed to recover from the operation, and samples of body fluids were drawn after given times. The samples were analyzed with a biochemical binding assay where the binding intensity is quantified and visualized with a fluorescent reporter.

Clinical trial

Medicortex is running a clinical trial in collaboration with Turku University Hospital (Tyks). Samples of body fluids are collected from 16 patients within 24 hours after the injury and from 12 healthy controls. The samples will be analyzed with a biochemical binding assay and a biomarker profiling assay.

RESULTS

Preclinical results

TBI rats have shown remarkable increase in the level of particular biomarkers in comparison to Sham rats. Results in urine and cerebrospinal fluid (CSF) are shown in Figures 1 and 2.

Clinical results

The trial is still ongoing. The final results of the binding assay, profiling and data analysis are expected to be available in Q1/2017. The outcome of the clinical trial will be a significant proof-of-concept, confirming the presence and the diagnostic indication of the discovered biomarker in the human subjects.

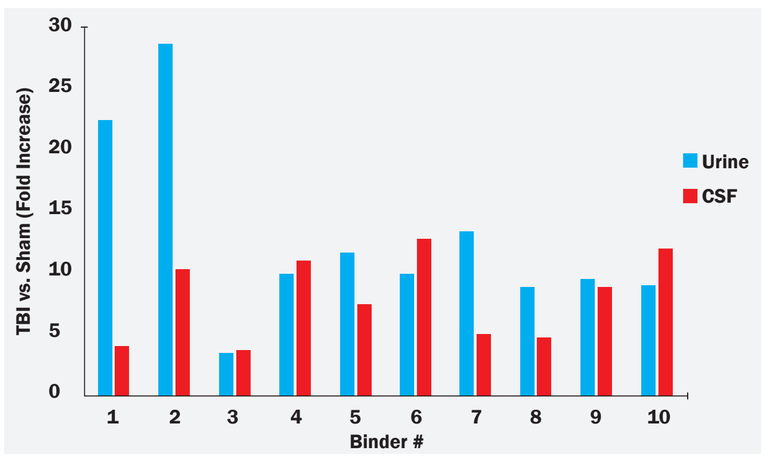

Figure 1. Increase of the biomarker levels in TBI rats compared to Sham rats. Data are shown for urine and CSF that were drawn from the rats at 24 h post operation.

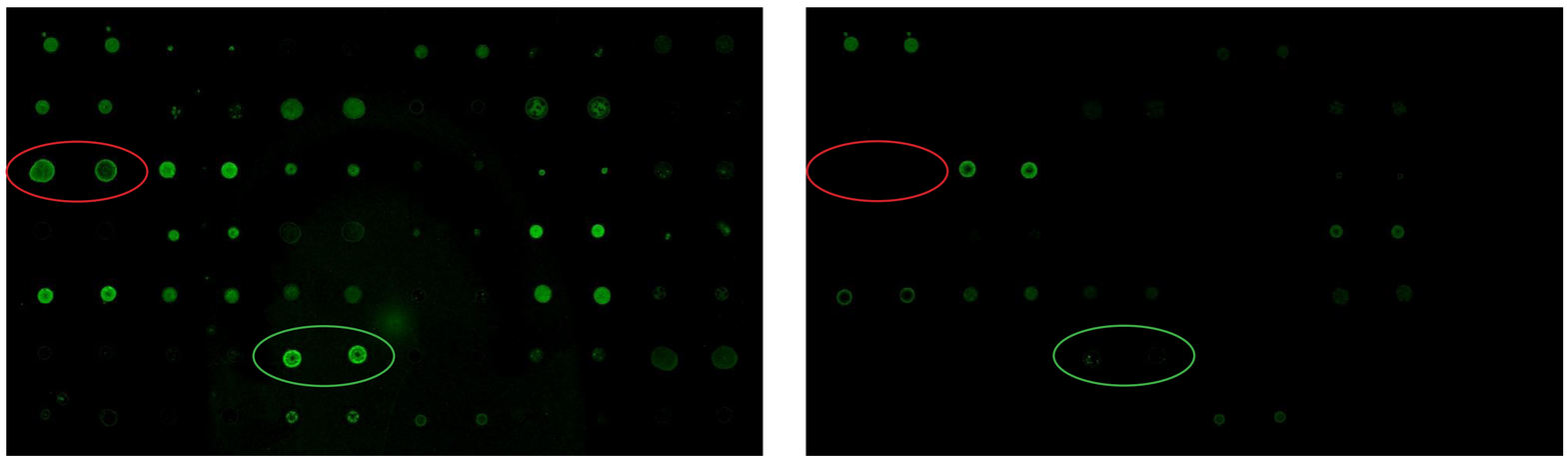

Figure 2. Binding of the biomarkers on the array is visualized by fluorescent reporters. Particular binders show much higher intensity in TBI samples (left) compared to Sham samples (right).

CONCLUSIONS

Blows to the head and collisions occur frequently in active sports, and the athletes and coaches do not always recognize brain injuries. Emergency department doctors, paramedics and sport, organizations would greatly benefit from an easily accessible diagnostic test for the detection of brain injury.

In the Medicortex's approach the type of the biomolecule used for the detection, and the fact that it can be detected in non-invasive samples of body fluids, allow for the development of a new rapid diagnostic test for TBI. It would be helpful for confirming or ruling out a TBI, even at the site of an accident, and indicating a need for further medical intervention.