

FEATURE

A biomarker could tackle one of worst diseases in sports

By Jacob Bell • Feb. 13, 2017

Super Bowl LI was full of firsts. It was the first time the big game had gone into overtime; the first time a quarterback added a fifth championship ring to his collection; the first time Lady Gaga jumped from the rafters of NRG Stadium — at least to the public's knowledge.

But in the days leading up to the New England Patriots' victory, a different team was working toward another potential first, one that could also have far-reaching implications for the National Football League and its players. Diagnostics company Exosome Sciences and its founder, Jim Joyce, are helping that team, which intends to conduct an early-stage study to find the first biomarker for spotting chronic traumatic encephalopathy (CTE).

A ticking clock

CTE is a neurodegenerative disease spawned from continual head trauma. As such, military personnel, as well as professional and college athletes who play contact sports like boxing, football or hockey, have a higher risk of developing the illness. Patients with CTE may demonstrate confusion and memory loss, impaired motor skills, depression or suicidal thoughts.

There are currently no Food and Drug Administration-approved treatments for the disease. In fact, the only way to know whether someone even has CTE is to examine their brain postmortem, in part because traditional tools such as magnetic resonance imaging (MRI) and computerized tomography (CT) scans don't pick up on concussions.

The lengthening list of people in the football community who have died from CTE or who have retired early for fear of developing CTE has put a

spotlight on it in recent years. Results from a Department of Veterans Affairs and Boston University study found that among 91 former, deceased football players, 87 – or almost 96% – tested positive for the disease. Joyce, who played football at the University of Maryland, said that the death of his former teammate Tom McHale from CTE in 2008 fueled his drive to address the obstacles to diagnosing it.

Exosome, which opened in 2013, announced in late January it would undertake a Phase 1 study investigating a potential biomarker called plasma exosomal tau, or TauSome for short.

Biomarkers are any substance or characteristic that reflects what's going on in a patient's body. In the case of TauSome, data published in 2016 from Boston University's DETECT study, a preclinical trial of 78 former NFL players, found those players had higher levels of the exosome than a control group, and that the higher levels also correlated with poorer performances on memory tests. Notably, the tau protein bound in TauSomes is also linked to a number of other neurodegenerative diseases, including Alzheimer's and dementia.

"The really important takeaway on this is that until there's an actual biomarker and you can monitor changes and levels of that biomarker to look at disease progression, it's not really possible to advance therapies because you don't really have a way to evaluate whether someone is responding to therapy," Joyce said.

Game on

Exosome's clinical trial looks to enroll 200 former NFL players before the end of June. The company hasn't initiated the formal recruitment process yet, but Joyce said he was confident that number could be reached. In the meantime, Exosome has focused on education efforts, conducting more than 35 interviews for media outlets and radio stations including ESPN and CBS in the days leading up to the Super Bowl, according to Joyce.

"These are the types of interviews that are really helpful ... to create momentum to educate people. I mean, we're just at the start of educating people about the importance of participating in this program," he said.

To that end, Joyce's team also met with Bart Oates, the current head of the New York/New Jersey chapter of the NFL alumni association, as well as John Beck and Joe Wesley, the former presidents of the Miami and Houston chapters, respectively, to give them information about the study that they could then pass onto their groups' members.

When the trial does commence, testing will take place in several locations throughout the U.S. Most of the sites will be in locales with large numbers of previous players, including Southern California, South Florida and New Jersey. Another site will be the Translational Genomics Research Institute in Phoenix.

Uncharted territory

Exosome isn't the only one looking to develop a diagnostic for CTE.

The National Institutes of Health gave \$16 million in December 2015 to Boston University and a few other research centers for a longitudinal study looking at how CTE may change the brain, as well as risk factors for the disease. The NFL, amid criticism that it wasn't doing enough to address the mental and neurological health risks posed by playing football, forked over \$100 million to Harvard University for two CTE investigational projects, and also helped to fund the DETECT study.

It's difficult to say whether drugmakers and the larger healthcare sector will follow suit and increase investment in exosome diagnostics as a whole. Some reports, for example, anticipate steady growth for the global exosome diagnostics market, with a nearly 38% CAGR between 2016 and 2022, yet also expect the market to reach just \$367 million by that latter year. And though investors have shown interest in exosome treatments in lucrative therapeutic areas like cancer, CTE's small patient population may make it a harder strategic sell.

"While there's a lot of coverage in the media, in reality it's a very rare disease condition, and so there's not a lot of interest from a business standpoint to create solutions," Joyce said. "So we really emphasize to these former players that it's important to step back onto the field and participate in these clinical studies."

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