

Research collaboration ids Serum biomarkers that Predict preclinical IBD development & complications

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Years before inflammatory bowel disease (IBD) is diagnosed and symptoms exist, biomarkers are already circulating that can help predict risk not only of disease development but also of complications, according to research published online last week, which will also appear in the June 15, 2016 print issue of *Alimentary Pharmacology & Therapeutics*. This publication reports the first findings from the PREDICTS (Proteomic Evaluation and Discovery in an IBD Cohort of Tri-service Subjects) study—a CRADA (Cooperative Research And Development Agreement) between the Mount Sinai Health System, the Naval Medical Research Center, Mayo Clinic, Prometheus Laboratories Inc. and Janssen Pharmaceuticals.

"Acquiring mechanistic information on pre-clinical IBD can potentially uncover key pathogenic events, lead to the development of new therapeutic targets and inform predictive algorithms that could be used to define at-risk populations in whom to test these approaches," said Jean-Frédéric Colombel, MD, co-senior author, and Co-Director of The Susan and Leonard Feinstein Inflammatory Bowel Disease Clinical Center at Mount Sinai. "This study adds an additional piece of evidence into 'life before IBD,' a major focus of research at Mount Sinai, since exploring the pre-clinical phase of [inflammatory bowel disease](#) may offer some new insights in the origin of IBD and hopefully prevention."

Using clinical data obtained from the Defense Medical Surveillance

System (DMSS)—the main data repository of the US armed forces, containing military and medical information from more than 7 million armed forces members' careers since 1990—researchers identified patients with a diagnosis of Crohn's disease, and then retrieved their pre-diagnostic serum samples from the Department of Defense Serum Repository. For each patient, up to four serum samples from pre- and post-disease initiation were obtained—the first sample being from the patient's initial diagnosis, and the others being serum samples stored from the three preceding biennial periods—to assess the presence of antimicrobial antibodies. These markers have previously been shown to circulate in patients' serum years before diagnosis and have been associated with more severe disease when identified at the time of or shortly after diagnosis; however, this was the first study demonstrating these markers and their progression using multiple samples at different time points before diagnosis.

In each of the samples, researchers measured a panel of antibodies directed against microbial epitopes—the specific piece of the antigen to which an antibody binds. With access to multiple samples from before the patients' diagnoses, researchers were able to demonstrate for the first time not only that these markers were present in serum up to six years before diagnosis (65 percent of patients tested positive for at least one marker in the earliest serum samples), but also that the number of positive markers increased up to diagnosis. Furthermore, those individuals with higher number of positive antibodies, and with higher titers, developed more frequent complications (such as need for surgery, strictures, or fistulae and abscesses) at or around the time of diagnosis.

"This study represents an important addition to research being performed on the pre-clinical stage of IBD," said co-senior author Joseph A. Murray of the Mayo Clinic. "This is the first time that a longitudinal assessment of antimicrobial markers in serum was performed. Furthermore, it is also the first time that a link between these

markers in a pre-clinical phase and future risk for disease complications has been made. These findings suggest that it may be possible to identify a population of patients not only at high risk for IBD, but also for complicated disease in which preventive strategies or intensive monitoring could be applied. Further research into this stage of pre-clinical disease will likely lead to better understanding and identification of key events involved in disease pathogenesis."

The research is still ongoing, and soon data from 1,000 patients with Crohn's disease, 1,000 with ulcerative colitis, and 500 controls will be available. Furthermore, beside antimicrobial markers, other possible pre-clinical markers, such as proteomic profile and exposure to infectious agents including virus, will be explored.

More information: R. S. Choung et al, Serologic microbial associated markers can predict Crohn's disease behaviour years before disease diagnosis, *Alimentary Pharmacology & Therapeutics* (2016). [DOI: 10.1111/apt.13641](https://doi.org/10.1111/apt.13641)

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