RAID-Dx is a new non-invasive method providing a positive diagnosis for irritable bowel syndrome (IBS) and differential diagnosis from inflammatory bowel disease (IBD). The test is based on a patented technology capable of detecting specific bacterial signatures for these pathologies through a stool sample.

Application

Aimed at patients presenting abdominal pain and altered bowel habits, meeting Rome IV criteria, and who need to perform a differential diagnosis between IBS and IBD.

Clinical evidence

RAID-Dx has been tested in a clinical trial where 84 IBS and IBD patients and healthy subjects recruited at the Doctor Josep Trueta University Hospital, Santa Caterina Hospital, Germans Trias i Pujol University Hospital, Bellvitge University Hospital and Teknon Medical Centre. The RAID-Dx test may lead to a reduction of 75% inblank colonoscopies from patients misdiagnosed with IBS.

Sensitivity, specificity, positive and negative predictive values obtained through the RAID-Dx:

Table-1: The IBS patients included had an active clinical status with diarrheal behaviour, met Rome IV criteria and had had a recent colonoscopy without significant macroscopic lesions. The IBD patients had clinical activity (Harvey-Bradshaw Index > 4 for Crohn's Disease patients and Mayo Partial index> 1 for patients with ulcerative colitis). In addition, IBD patients had also had a recent colonoscopy showing inflammatory activity (SES-CD> 0 and endoscopic Mayo> 0, for Crohn's disease and ulcerative colitis patients respectively). Each patient provided a stool sample prior to the bowel cleansing required for the colonoscopy in order to ensure appropriate colon conditions. A specific microbiological signature, consisting of six bacterial markers, was analysedfor each stool sample. RAID-Dx was able to differentiate between IBS and IBD patients using sensitivity and specificity values, predictive positive value and a predictive negative value higher than the faecal calprotectin.

IBS vs. IBD results	RAID-Dx	Faecal calprotectin (50 µg/g)
Sensitivity (%)	88.2	51.5
Specificity (%)	89.2	92.2
Positive predictive value (%)	79.0	80.9
Negative predictive value (%)	94.3	74.6

Use

To use RAID-Dx, a stool sample must be collected with a collection kit following the corresponding instructions. The sample should be sent at room temperature within 24-48 hours after its deposition. Within seven days you will receive the report and diagnosis based on the bacterial signature.

Current diagnosis

IBS is a functional disorder affecting up to 15-20% of the world's population. Currently, there is no solid diagnostic test for this pathology. Its diagnosis is based on the characteristic symptomatology as systematized in the Rome IV criteria. The overlapping symptomatology of IBS with other intestinal disorders such as IBD is very frequent. Although the Rome IV criteria are mandatory, they are not sufficient to establish a diagnosis. The procedure to be followed consists of carrying out a series of clinical tests to support the diagnosis of IBS. Firstly, basic laboratory tests including faecal calprotectin (inflammatory parameter) are performed. When the laboratory tests come back normal, but inflammatory parameters appear slightly elevated, IBD is suspected and imaging tests such as a colonoscopy are performed. All of these procedures are invasive and expensive and most of the times they do not offer a definitive answer to diagnose the patient. IBS continues to be one of the main reasons for normal colonoscopies within the digestive services of health systems, demonstrating that a specific marker for diagnosis is urgently needed.

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