miRFec: a non-invasive method for colorectal cancer screening

CLINIC/Ciber/Idibaps/UB

Dr. Antoni Castells

PROFILE

The *Gastrointestinal and Pancreatic Oncology Research Team* belongs to the leading biomedical research center in Spain **IDIBAPS** and to the Centro de Investigación Biomédica en Red (**CIBER**). The goal of the group is to improve current preventive, diagnostic and therapeutic approaches through the understanding of molecular mechanisms involved in gastrointestinal and pancreatic neoplasms. Major contributions include evaluation of CRC screening strategies and identification of biomarkers for both hereditary and sporadic cancers.

SPEAKER

Dr. Antoni Castells' research activity is focused on colorectal cancer (CRC) prevention. He is co-coordinator of the CRC Screening Program of Barcelona and leads the Spanish COLONPREV project (N Engl J Med 2012; J Natl Cancer Inst 2013). He is a founding member of the Alliance for the Prevention of CRC, and is on the advisory board for CRC screening of the International Digestive Cancer Alliance and of the World Gastroenterology Organization Task Force on Digestive Oncology, among others.

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PRODUCT

miRFec: non-invasive method for colorectal cancer screening.

MECHANISM OF ACTION

miRFec is a new non-invasive diagnostic method based on the combination of three fecal biomarkers (two microRNAs and hemoglobin) that is able to identify individuals with CRC or its precursor lesion –advanced adenoma (AA)– with better performance than the current non-invasive method FIT (only based on fecal hemoglobin).

Indeed, it shows higher sensitivity for AA, thus representing an attractive approach for CRC prevention, and higher specificity that results in a reduction of false-positives from FIT, thus reducing the number of unnecessary colonoscopies. Therefore, miRFec could improve effectiveness and cost-effectiveness of population-based CRC screening programs

By analyzing the whole miRNome in 124 tissues from CRC or AA patients, we found 200 and 324 miRNAs significantly deregulated in CRC and AA tissues, respectively. More precisely, 7 and 5 of these miRNA were found to be detectable and also deregulated in feces. Indeed, MIR421 and MIR27a-3p were significantly upregulated in fecal samples from patients with CRC or AA (n=767).

miRFec is based on the combination of fecal levels of these miRNAs and hemoglobin, showing that is more accurate than fecal hemoglobin concentration alone. Analysis of these two miRNAs might be added to current fecal test –FIT– for a better detection of CRC or AA, resulting in a widely distributable and cost-effective tool for population-based CRC screening.

TARGET INDICATIONS

The miRFec has been designed for population-based, CRC screening in average-risk population (i.e. men and women older than 50 years-old). Other potential applications include diagnosis of CRC, screening of familial CRC, colonoscopy triage or prioritization on individuals with a fecal immunochemical test (FIT) positive result, and surveillance of patients with colorectal polyps and cancer.

CURRENT STATUS

- The results obtained so far are published in two articles in high-impact scientific journals (Identification and Validation of microRNA Profiles in Fecal Samples for Detection of Colorectal Cancer. Duran-Sanchon S, et al. Gastroenterology 2020 Mar;158:947-957; Fecal MicroRNA-Based Algorithm Increases Effectiveness of Fecal Immunochemical Test-based Screening for Colorectal Cancer. Duran-Sanchon S, et al. Clin Gastroenterol Hepatol 2020:S1542-3565(20)30262-7).
- In summary, we studied **767 individuals** with a FIT positive result who underwent colonoscopy examination. In this cohort, miRFec was able to differentiate patients with CRC from those with normal colonoscopy or non-significant lesions with an AUC of 90% and is application would have avoided 34% of unnecessary colonoscopies.