MicroRNA Signature to Predict Progression of Barrett's Esophagus to Esophageal Dysplasia or Adenocarcinoma

A set of 33 micro-RNAs (miRNAs) is associated with the likelihood of progression of Barrett's esophagus to esophageal dysplasia or adenocarcinoma within seven years. Because Barrett's esophagus confers a 5-fold elevated risk for esophageal cancer, all patients diagnosed with Barrett's esophagus are monitored yearly with invasive and costly procedures. However, only about 1% of Barrett's esophagus patients progress to adenocarcinoma suggesting that a large number of patients are being monitored unnecessarily. Our technology can help predict which Barrett's esophagus patients are unlikely to progress, leading to about $4000 per patient per year savings on unnecessary medical monitoring.

COMMERCIAL OPPORTUNITY

- Barrett's esophagus is a pathological condition in which the normal esophageal epithelium is replaced with the columnar epithelium, presumably due to a chronic exposure to stomach acid (acid reflux). Barrett's esophagus is diagnosed in 5-15% of people seeking care for acid reflux. Overall, ~3M Americans have been estimated to suffer from Barrett's esophagus .
- Barrett's esophagus confers a 5-fold increased risk for esophageal adenocarcinoma—a deadly disease with mortality rates exceeding 85%. Because there is no method to predict which patients will progress to esophageal cancer, all of them are monitored yearly with gastroesophagoduodenoscopy (GED) and biopsies which are uncomfortable, time consuming, costly, and produce false positive results.
- Our technology can help distinguish which Barrett's esophagus patients are at high or low risk for progression to esophageal cancer based on the miRNA expression in the fresh frozen or paraffin embedded biopsy sample. Those patients deemed "low risk" can be spared from rigorous monitoring.
- With the average cost of GED at $2700 and a biopsy ranging anywhere $1100-4000 per procedure, our test could save an average of $4000 per patient per year, not including the cost to treat side effects (bleeding, infections etc), as well as additional unnecessary testing for false positives.
- NeoSITE, a FISH assay, marketed by NeoGenomics, Inc. is used to help physicians diagnose Barrett's esophagus patients by determining whether they are likely to have low-grade dysplasia, high-grade dysplasia or esophageal adenocarcinoma. NeoSITE however is not a replacement for a test to predict those Barrett's esophagus patients likely or unlikely to progress within 7 years.

TECHNOLOGY

Nanostring miRNA analysis was performed on existing formalin-fixed paraffin embedded tissue blocks from patients with Barrett's esophagus which later progressed to low-grade dysplasia, high-grade dysplasia, and/or esophageal adenocarcinoma (n=5) and from patients with Barrett's esophagus which remained stable without progression to dysplasia and carcinoma for >7 years (n=4). Expression of 800 miRNAs was tested in 11 retrospectively collected samples obtained from Moffitt patients. 33 miRNAs had expression that was statistically significantly (p-values <0.05; log rations fold changes >=1). associated with the risk of progression to dysplasia and eventually, esophageal cancer. The principal component analysis using 33 selected miRNAs showed that the first component accounts for almost 90% of variation.

PUBLICATION/PATENT

- Patent application filed March 16, 2014 for Drs. Coppola and Qu

CONTACT

Haskell Adler PhD MBA
Senior Licensing Manager
Haskell.Adler@Moffitt.org
(813) 745-6596

LICENSING OPPORTUNITY

MOFFITT CANCER CENTER

13MB080.2014.08