

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



A set of 19 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. The 19 miRNAs can help predict with over 95% accuracy which Barrett's esophagus patients are unlikely to progress, avoiding the cost of 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, about 3 million 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.
- These miRNAs 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

Formaldehyde fixed paraffin embedded (FFPE) tissue from 24 BE patients was processed and RNA quantified using the HTG EdgeSeq™ platform to measure gene expression. The expression profiles of 13 patients who did not progress was compared to that of 11 patients who developed cancer within 7 years. Analysis revealed 19 miRNAs that are predominantly downregulated ($p < 0.04$) in those patients that progressed to cancer, while these remained comparably unchanged in the patient group that did not progress. The signature is 95.8% accurate at distinguishing non-progressing from likely-to-progress patients (95% CI: 87.2-100).

PUBLICATION/PATENT

- A provisional patent application was filed for Dr. Coppola on November 22, 2016.

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LICENSING OPPORTUNITY

