Biomarkers for Detection of Barrett’s Esophagus

Brief Description of Technology

Minimally invasive detection method using methylated DNA biomarkers for determining the presence of Barrett’s Esophagus and risk of developing esophageal adenocarcinoma (EAC).

Technology Overview

Many patients with Barrett’s esophagus (BE) go undiagnosed under current screening recommendations. However, this condition is the strongest risk factor for esophageal cancer with a 10-30 fold increased risk of EAC compared with the general public. It is estimated that 95% of patients with a new diagnosis of EAC do not have a previous diagnosis of BE and are not under surveillance. Thus, noninvasive detection methods for BE can help to identify many of those going undiagnosed.

Researchers in the Grady Lab have identified four CpGs associated with two genes, B3GAT2 and ZNF793, that are aberrantly methylated in BE and developed assays for each biomarker. Clinical validation studies showed BE could be detected from a mixed cell population collected via an esophageal balloon in these assays. These biomarkers are further being validated in a Phase 1 trial as part of the Barrett’s Esophageal Translational Research Network (BETRNet). Identification of those with BE will allow for better EAC surveillance and early treatment.

Applications

- Determination of BE presence or risk
- Monitoring strategies for those at risk of EAC

Advantages

- Clinically validated molecular diagnostic that can be used on FFPE or endoscopic brushing specimens
- Highly sensitive and specific detection
- Non-invasive and low cost assay for the detection of BE

Market Overview

BE is expected to affect about 1.3-5.6% of the US population. Of those individuals diagnosed with BE, about 5-10% will develop EAC. EAC is one of the fast growing cancers in the world. EAC affects approximately 17,000 people each year in the US and in 2012, there were over 450,000 new cases worldwide. EAC has a poor prognosis with a combined 5-year survival rate of 10-15% with those caught early having a survival rate of 40%. In the US, $1.6 billion was spent on EAC-related expenditures in 2016 with $0.7 billion occurring in the last year of life.