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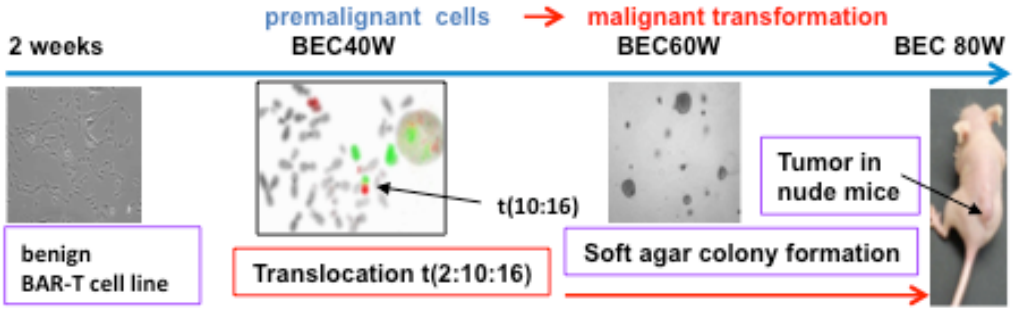
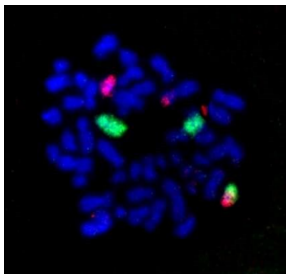
Clinical Validation of FISH Assay for Early Detection of Esophageal Cancer



Manisha Bajpai, Ph.D., is Assistant Professor of Medicine in the Division of Gastroenterology and Hepatology, Rutgers Robert Wood Johnson Medical School. Her research is focused on the development of novel biomarkers for diagnosis of pre-cancerous conditions of the Gastrointestinal tract.

Co-Inventors: Kiron M. Das, MD, PhD and Hana Aviv, PhD



Top Image: *The in-vitro model demonstrates chromosomal changes from healthy Barrett's to malignancy due to exposure to acid and bile mix for 60wks.* ***Adjoining image:*** *Translocations as visualized by FISH assay objectively showing translocation events (Chr 2 Red and Chr10-Green).*

Intellectual Property: Published PCT application PCT/US17/21405

Innovation Summary: Barrett's Esophagus (BE) mostly develops in patients with gastroesophageal reflux disease (GERD); and may develop into esophageal adenocarcinoma (EA) following the metaplasia→dysplasia→cancer sequence. Although patients with BE have a 120-fold higher risk of developing EA, only 30% actually develop cancer, others just have benign BE. However, there are no tools available to predict if the BE will clinically progress to EA or remain benign. The current standard of care is to determine the stage of disease histologically and if dysplastic, surgically remove the tissue indiscriminately. This not only increases the cost of medical care from post-surgical complications but also affects the quality of life of the BE patients who are not at risk for EA. Dr. Bajpai's team has discovered several chromosomal translocation events that appear before malignant transformation of the BE cells in a human gastroesophageal reflux disease model [1,2]. In pilot studies, with the help of novel DNA probes and fluorescence in-situ hybridization (FISH) assay, Dr. Bajpai and her team detected these events in human EA and not in the benign BE tissues. These results may one day enable the screening of patients with Barrett's epithelium for the risk of developing esophageal adenocarcinoma.

The team is now developing a kit based screening method that would be run on small biopsy samples retrieved from patients during an endoscopic exam, similar to those used for histological determination of BE disease stage. This innovative new FISH assay based kit will provide an objective cancer risk screening tool to complement the gold standard histological method that suffers from subjectivity.

Advantages:

- Objective test for cancer risk in BE patients
- Can be combined with traditional pathology procedures
- Early detection of cancer, allowing early intervention and expanding treatment options

Market Applications: Stratification of high-risk BE patients and early detection of esophageal adenocarcinoma

Potential Social and Economic Impact:

- Gastro-esophageal reflux disease (GERD) affects about 20 percent of the U.S. population3 and chronic GERD poses a significantly higher risk (120 fold) of BE progressing into fatal Esophageal adenocarcinoma4. Earlier detection, at the stage of pre-adenocarcinoma would produce more favorable patient outcomes.
- The annualized mean net costs in the initial year of diagnosis of cancer of the esophagus in men 65+ is estimated to be $79,822 with continuing costs of $6,450 per year5.
- Patients that do not present with the translocation events (low risk) may be able to avoid unnecessary invasive exams and procedures. This would reduce healthcare costs and improve the quality of life of patients.

Next R&D Steps:

- Further clinical validation on human tissue samples
- Development of a kit and pathology workflow

References:

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2. Bajpai M, Aviv H, Das KM. Prolonged exposure to acid and bile induces chromosome abnormalities that precede malignant transformation of benign Barrett's epithelium. Mol Cytogenet. 2012 Nov 29;5(1):43.

3. El-Serag HB, Petersen NJ, Carter J, et al. Gastroesophageal reflux among different racial groups in the United States. Gastroenterology. 2004;126:1692–1699.

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5. https://costprojections.cancer.gov/annual.costs.html#f1