

Blood Based microRNA Assay to Detect Malignant Intraductal Papillary Mucinous Neoplasms (IPMNs)



IPMNs are a type of pancreatic cyst that can transform into pancreatic cancer, a deadly disease with an overall 5-year survival of 6%. Advances in CT and MRI have increased the number of IPMNs discovered each year in the US to about 75,000. For many IPMNs that meet the current guidelines for resection, it is not possible to determine if they are malignant or benign. Clinicians tend to be cautious, resulting in approximately 2,600 unnecessary and risky surgeries for benign cysts, to ensure resection of the majority of malignant cysts. By evaluating a circulating microRNA signature in a patient's blood sample, our test can help to predict whether a patient's IPMN is benign or malignant, so that patients with benign lesions would not be subjected to unneeded surgery.

COMMERCIAL OPPORTUNITY

- There are about 35,000 patients with IPMNs that do not meet consensus guidelines for resection who will undergo surveillance (with CTs and MRIs). Over 5 years, about 10% (3,500) of these patients will develop features that according to the guidelines suggest resection. However, only about 27% (~875) of these cysts have been shown to be malignant upon resection, suggesting that approximately 73% (~2,625) will have undergone unnecessary treatment, at a cost of about \$120,000 per surgery.
- The blood based microRNA assay could be utilized to determine malignancy, once patients display the radiologic features suggesting resection, and the assay could be used annually thereafter to monitor for the cysts for malignant transformation potential.
- This market is attractive as evidenced by PathFinder TG Pancreas, a diagnostic that had \$10M in annual sales when it was acquired by PDI and renamed PancreaGen. This assay, to determine pancreatic cyst malignancy, is covered by Medicare. However, PancreaGen requires an invasive cyst tissue biopsy, whereas our diagnostic assay is non-invasive.
- Blue Cross Blue Shield has stated that: “the diagnosis of cystic pancreatic lesions is usually performed by endoscopic, ultrasound-guided fine-needle aspiration sampling of the fluid and cyst wall for cytologic examination and analysis. Cytologic examination of these lesions can be difficult or indeterminate due to low cellularity, cellular degeneration, procedural difficulties, etc. Ancillary tests (e.g., amylase, lipase, carcinoembryonic antigen levels) often are performed on cyst fluid to aid in diagnosis, but results still may be equivocal. Information provided by additional testing modalities would, therefore, be potentially useful.”

TECHNOLOGY

800 miRNAs were evaluated using pre-operative blood plasma from 42 pathologically-confirmed IPMN cases (21 malignant, 21 benign). We generated a 5 microRNA signature that discriminated between the 21 malignant (high-grade dysplasia and invasive carcinoma) and 21 benign (low- and moderate-grade dysplasia) IPMNs (AUC=73.2; 95% CI, 57.6 – 88.9, P = 0.005). Components of this microRNA signature are confirmed to be gene suppressors and pancreatic cancer regulators by validated microRNA:target interactions, pathway enrichment analysis, and literature.

PATENT/PUBLICATION

- PCT filed on 3/31/2015 for Drs. Wey and Malafa.
- J. Permut-Wey et al., *Can Prev Res*; Online Aug. 27, 2015 & *PLoS One* 2015;10 (1): 1-18.

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