BARREGEN™
ESOPHAGEAL CANCER RISK CLASSIFIER

An Innovative Tool for Barrett's Esophagus Patients

GERD IM IND LGD HGD EAC

DNA-based Molecular Pathology Test

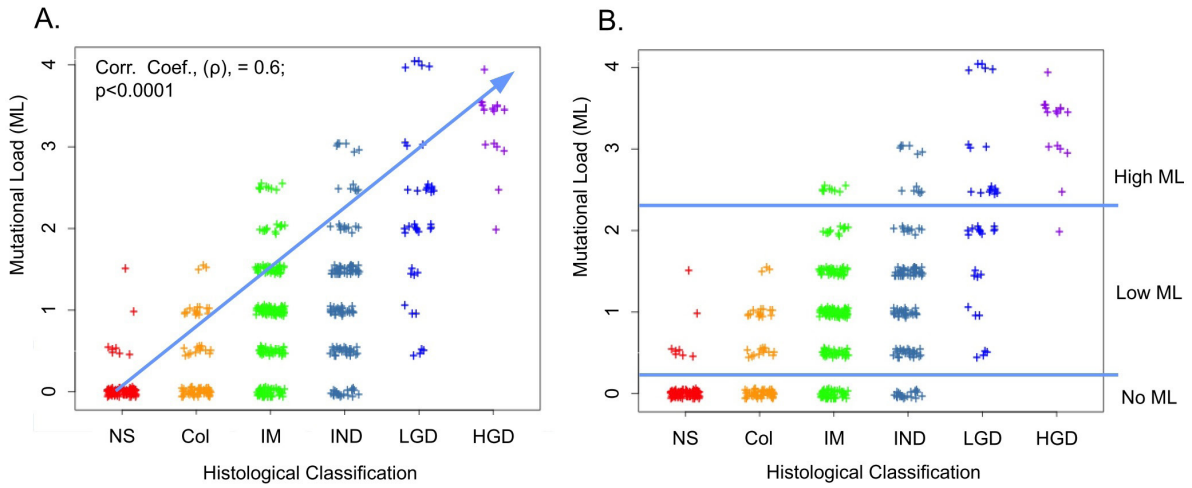
Barrett's Esophagus is a precancerous condition typically caused by Gastroesophageal Reflux Disease (GERD). BE is diagnosed by endoscopic appearance of columnar mucosa at the distal esophagus confirmed as intestinal metaplasia by a pathologist. Various progressive histological stages of BE exist, ranging from initial intestinal metaplasia histology to indefinite for dysplasia, low-grade dysplasia (LGD), high-grade dysplasia (HGD), and then esophageal adenocarcinoma (EAC). Differentiating the presence and grade of dysplasia from reactive histological changes remains a challenge among pathologists, resulting in high inter-observer variability in the diagnosis of levels of dysplasia[1]. BarreGEN can help diagnose the presence of dysplasia and assess risk of cancer in patients with BE.

BarreGEN™

Studies have shown that the BarreGEN assessment for mutational load is able to identify subsets of patients with non-dysplastic (i.e. intestinal metaplasia) and LGD histology who have the same level of genomic instability as those who have HGD and EAC[1,2]. These studies support the use of ML in identifying dysplasia and suggest that ML may be useful in assessing risk for developing HGD or cancer in the future. Consistently, a recent longitudinal validation study has shown that ML can identify patients with non-dysplastic or LGD histology who will develop cancer in ~3-4 years, distinguishing them from those who will not progress in this timeframe with 90% accuracy (96% sensitivity and 87% specificity)[3].

Take the Confusion out of Staging Barrett's Esophagus with BarreGen

BarreGEN can help support the need for cancer preventative treatments, such as ablation, and support justification for when such treatments may not be necessary. It does so by helping to diagnose dysplasia and assessing risk of dysplasia or cancer in the future. When used in such way, studies have shown that BarreGEN is cost effective compared to other patient management surveillance and ablation strategies[4].



ML in microdissected targets by histological classification: NS = normal squamous epithelium, Col = columnar, non-Barrett's epithelium, IM = intestinal metaplasia, IND = indefinite for dysplasia, LGD = low grade dysplasia, HGD = high grade dysplasia. Reprinted from Ellsworth et al. BMC Gastroenterology 2012, 12:181

References:

1. H. S. Khara et al., Assessment of mutational load in biopsy tissue provides additional information about genomic instability to histological classifications of Barrett's esophagus. J Gastrointest Cancer 45, 137 (Jun, 2014).
2. E. Ellsworth et al. Cumulative Mutational Change in Dysplastic and Non-Dysplastic Barrett's Esophagus. Gastroenterology 142, S (2012).
3. S. Eluri et al., The Presence of Genetic Mutations at Key Loci Predicts Progression to Esophageal Adenocarcinoma in Barrett's Esophagus. Am J Gastroenterol 110, 828 (Jun, 2015).
4. A. Das, K. Callenberg, M. Styn, S. Jackson, Endoscopic ablation is a cost effective cancer preventative therapy in patients with Barrett's Esophagus who have elevated genomic instability. Endoscopy International Open DOI: 10.1055/s-0042-103415, (2016).

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