CLINICAL SUMMARY

TissueCypher
▸ Barrett's Esophagus

AGA Clinical Practice Update

AGA Clinical Practice Update on new technology and innovation for surveillance and screening in Barrett's esophagus: Expert review

V. Raman Muthusamy, MD, MAS, Sachin Wani, MD, C. Prakash Gyawali, MD, Srinadh Komanduri, MD, MS, for the CGIT Barrett's Esophagus Consensus Conference. *Clin Gastroenterol Hepatol*. 2022; https://doi.org/10.1016/j.cgh.2022.06.003

BACKGROUND

The purpose of this best practice advice (BPA) article from the American Gastroenterological Association is to provide an update on advances and innovation regarding the screening and surveillance of Barrett's esophagus.

The AGA Clinical Practice Update (CPU) recognizes TissueCypher's ability to look beyond morphologic changes to identify high- and low-risk non-dysplastic Barrett's esophagus (NDBE) patients. Best Practice Advice Statement #9 supports the clinical use of TissueCypher for risk stratification of patients with NDBE and cites validation data showing the progression rate of a patient with NDBE and a high-risk TissueCypher test result is 6.9%, similar to the progression rate in patients with low-grade dysplasia. The CPU proposes a new care pathway indicating that TissueCypher may be used for risk stratification of both newly diagnosed patients with Barrett's esophagus and patients under surveillance.

BEST PRACTICE ADVICE STATEMENT #9

Tissue systems pathology-based prediction assay [TissueCypher] may be utilized for risk stratification of patients with nondysplastic BE.

Access the complete AGA Clinical Practice Update published in Clinical Gastroenterology and Hepatology by scanning the QR code.

CITED EVIDENCE

- TissueCypher is validated to risk stratify BE patients for progression to HGD/EAC with 4.7-fold increased risk in high-risk vs low-risk patients
- NDBE patients with a TissueCypher high-risk test result progressed at a rate similar to LGD (6.9%)
- Markov modeling suggests that TissueCypher based risk stratification becomes cost-effective after 5 years
- A pooled analysis by Mayo Clinic demonstrated that a TissueCypher high-risk score in NDBE patients was a strong independent predictor for progression to HGD/EAC (OR, 14.2; 95% CI, 5–39; P < .001)

IMPLICATIONS OF USING TISSUECYPHER FOR PATIENT MANAGEMENT:

- Identifies high-risk BE patients, including those that are NDBE, that are highly likely to progress to EAC, thereby enabling early intervention, high quality repeat endoscopy, or more frequent surveillance to prevent EAC
- Identifies BE patients at very low risk of progression, thereby avoiding unnecessary procedures or surveillance endoscopies to be more efficient with limited healthcare resources

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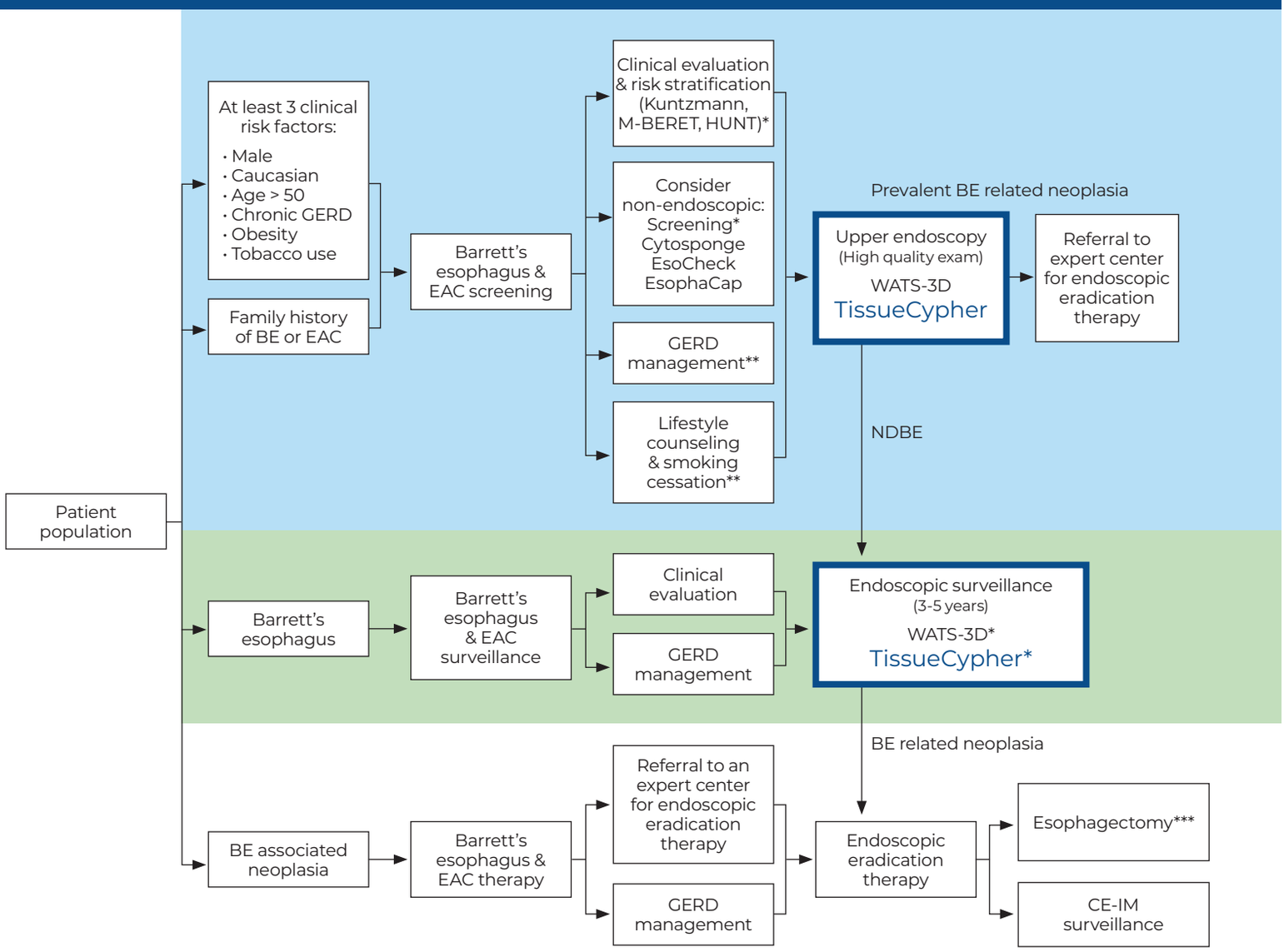
AGA Clinical Practice Update Suggested Care Pathway



Detection of prevalent neoplasia

Surveillance of NDBE to improve risk stratification

*May be utilized as per BPA in this document
**When clinically appropriate
***For T1b or higher stage cancers by EMR or neoplastic disease refractory to EET

Figure 1. Adapted from the suggested Barrett's esophagus care pathway proposed in the AGA Clinical Practice Update. This pathway highlights the use of TissueCypher during screening to detect prevalent disease and during Barrett's esophagus surveillance.

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