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RESULTS FROM A RANDOMIZED CONTROLLED TRIAL: INTRODUCING A PRECISION MEDICINE DIAGNOSTIC TOOL INCREASES ADHERENCE TO GUIDELINES IN PATIENTS WITH BARRETT'S ESOPHAGUS

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Introduction

- Gastroenterological societies have established recommended guidelines for management of BE. However, low adherence to these guidelines leads to both overuse of endoscopic surveillance and endoscopic eradication as well as under-use of care leading to reduced detection of dysplasia and esophageal adenocarcinoma (EAC).[1–2]
- The TissueCypher Barrett's Esophagus Assay is a commercially-available, validated test that predicts risk of progression to high-grade dysplasia (HGD) or EAC within 5 years.[3-7]
- This study aimed to assess the ability of this test to improve physicians' ability to assess the risk of developing HGD/EAC in BE patients and improve adherence to guideline-recommended management strategies for patients with BE.

Methodology

- 259 physicians were randomized to 3 arms (Table 1), and given a set of clinical performance and value (CPV) vignettes (Table 2) to evaluate in round 1.
- In round 2, education on TissueCypher was provided to Intervention arms 1 and 2, test results were supplied to Intervention 1, and optionally ordered by Intervention 2.
- A quality-of-care percentage (0-100%) score was generated from the CPVs based on American College of Gastroenterology (ACG)[8] and American Society of Gastrointestinal Endoscopy (ASGE)[9] guidelines.
- A fixed effects difference-in-difference model was used to assess the impact of the test.

Table 1: Physician Cohorts

Arm	Physicians (n)	Round 1	Round 2
Control	90	No Test results	No Test Results
Intervention 1	91	No Test results	Test results supplied
Intervention 2	78	No Test results	Test results ordered optionally

Table 2. Clinical Performance and Value (CPV) vignettes

Clinical Performance and Value (CPV) vignettes		
	Clinical Factors Risk	TissueCypher Risk Class
Case A	High	High
Case B	Low	High
Case C	High	Low

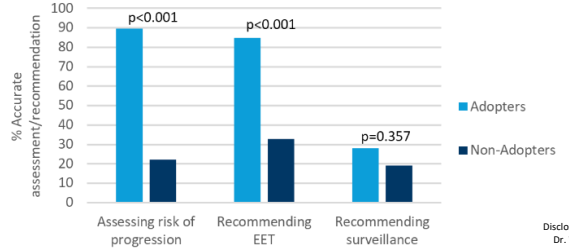
Results

Table 3. Physicians who received the TissueCypher test results performed better than the control group in determining patient risk

Accuracy of Assessing a BE Patient's Risk of Progression to HGD/EAC				
	Arm	Round 1	Round 2	Difference in Difference
Case A	Control	28.30%	26.10%	–
	Intervention 1	19.40%	77.50%	+60.2%, p<0.001
	Intervention 2	27.6%	40.90%	+15.5%, p=0.176
Case B	Control	12.00%	8.30%	–
	Intervention 1	10.20%	72.20%	+65.6%, p<0.001
	Intervention 2	9.4%	25.30%	+19.6%, p=0.020
Case C	Control	19.60%	25.60%	–
	Intervention 1	30.50%	69.10%	+32.6%, p=0.008
	Intervention 2	25.6%	45.20%	+13.6%, p=0.286

- Physicians in intervention group 2 ordered the test results in 21.9% of their cases
- Those who ordered the test performed similarly to or better than intervention 1, and those who did not order the test performed similarly to the control group.

Figure 1. TissueCypher adopters in Intervention 2 were significantly more likely to accurately assess a patient's risk of progression and recommend EET when appropriate.



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Summary & Conclusions

- Quality-of-care scores improved significantly across all patient cases after physicians were given the TissueCypher test results.
- Quality of care was significantly increased for variant B cases (patients presented at a clinically lower risk, but the test indicated a high risk of progression).
- Directional improvements in quality of care due to use of the test were also observed for variant A cases (patients' risk factors and/or endoscopic findings placed them at a higher risk for progression that was confirmed by the test) and variant C cases (patients presented at a clinically higher risk but the test showed a lower risk of progression).
- These improvements indicate that the test has the potential to significantly optimize current surveillance programs and reduce management variability.
- Additionally, the test results can assist in preventing under-surveillance for high-risk patients and avoid excessive surveillance and/or invasive treatment for those at low risk.
- Overall, the findings of this study demonstrated the significant impact and clinical utility of the TissueCypher Barrett's Esophagus test to improve risk assessment for all clinical variants evaluated in this study.

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