RESULTS FROM A RANDOMIZED CONTROLLED TRIAL: INTRODUCING A PRECISION MEDICINE

DIAGNOSTIC TOOL INCREASES ADHERENCE TO GUIDELINES IN PATIENTS WITH BARRETT’S ESOPHAGUS

Highlights

- 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 resection 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.

Methods

- 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 arms 1 and 2, and 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) [1] and American Society of Gastrointestinal Endoscopy (ASGE) [2] guidelines.
- A fixed effects differences-in-difference model was used to assess the impact of the test.

Table 1: Physician Cohorts

<table>
<thead>
<tr>
<th>Arm</th>
<th>Physicians (n)</th>
<th>Round 1</th>
<th>Round 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>90</td>
<td>No Test Results</td>
<td>No Test Results</td>
</tr>
<tr>
<td>Intervention 1</td>
<td>91</td>
<td>No Test Results</td>
<td>Test results supplied</td>
</tr>
<tr>
<td>Intervention 2</td>
<td>78</td>
<td>No Test Results</td>
<td>Test results ordered optionally</td>
</tr>
</tbody>
</table>

Table 2. Clinical Performance and Value (CPV) vignettes

<table>
<thead>
<tr>
<th>Clinical Factors Risk</th>
<th>TissueCypher Risk Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case A</td>
<td>High</td>
</tr>
<tr>
<td>Case B</td>
<td>Low</td>
</tr>
<tr>
<td>Case C</td>
<td>High</td>
</tr>
</tbody>
</table>

Accuracy of Assessing a BE Patient’s Risk of Progression to HGD/EAC

<table>
<thead>
<tr>
<th>Case</th>
<th>Control</th>
<th>Intervention 1</th>
<th>Intervention 2</th>
<th>Difference in Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>28.30%</td>
<td>19.40%</td>
<td>27.6%</td>
<td>+60.2%, p&lt;0.001</td>
</tr>
<tr>
<td>Case B</td>
<td>12.00%</td>
<td>10.20%</td>
<td>9.4%</td>
<td>+65.6%, p&lt;0.001</td>
</tr>
<tr>
<td>Case C</td>
<td>19.60%</td>
<td>10.50%</td>
<td>25.6%</td>
<td>+32.6%, p=0.008</td>
</tr>
</tbody>
</table>

• 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.

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

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References


Disclosure: CPV, QURE Healthcare’s proprietary simulated case tool, were used to collect data and score the responses. Otherwise, there are no disclosures.

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