AN INNOVATIVE MUCOSAL IMPEDANCE DEVICE DIFFERENTIATES ACTIVE EOSINOPHILIC ESOPHAGITIS FROM INACTIVE DISEASE, NERD, AND CONTROLS

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Disclosures

• Vanderbilt Institutional Review Board approved this study
• Vanderbilt University holds the patent with Sandhill Scientific Inc. for the device
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Background

• Eosinophilic esophagitis (EoE), gastroesophageal reflux disease (GERD), and non-erosive esophageal reflux disease (NERD) are common diseases of both adult and pediatric patients
• Share clinical and histological features
• Require multiple endoscopies with biopsies or pH-impedance monitoring
Introduction

There is a need for an accurate means of diagnosing chronic mucosal changes due to EoE, GERD, and NERD

- Timely
- Inexpensive
- Reduced Risks

Cellular Level

Inflammation compromises the esophageal epithelial barrier

Normal  Eosinophilia  Spongiosis
Mucosal Impedance (MI) Device
MI is a measurement of current across the epithelium which can distinguish normal vs inflamed mucosa
Validated by adult studies
- Focused on GERD
- No histologic confirmation

Hypothesis
We hypothesize that mucosal impedance measurement in pediatric patients will differentiate histologically-proven active EoE from inactive EoE, GERD/NERD, and normal.

Secondary Hypothesis
We hypothesize that higher eosinophil counts and more severe degrees of spongiosis will have decreased electrical impedance compared to normal histology.
Methods

• Cross Sectional Study
• 83 pediatric patients
• Ages 1 year - 18 years
• Vanderbilt Pediatric Gastroenterology Clinic

Methods

• MI measurements (in Ω)
  • Endoscopic placement
  • 2 cm, 5 cm and 10 cm above the squamocolumnar junction
  • Provide instantaneous measurements

• Routine biopsies
  • 2 cm, 5 cm and 10 cm above the squamocolumnar junction

Methods

• Pathologists blinded to MI measurements reviewed biopsies per routine protocol
• Spongiosis was graded on an ordinal visual scale (normal, mild, moderate or severe).

<table>
<thead>
<tr>
<th>Spongiosis</th>
<th>Normal</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
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</thead>
<tbody>
<tr>
<td></td>
<td><img src="image1.png" alt="Cell" /></td>
<td><img src="image2.png" alt="Cell" /></td>
<td><img src="image3.png" alt="Cell" /></td>
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</tbody>
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Final Diagnosis

Pediatric Patients: N=83

- NERD/GERD N=21
- Active EoE N=15
- Inactive EoE N=7
- Control N=26
- Other Abnormal Histology N=14

MI by Final Diagnosis

<table>
<thead>
<tr>
<th>N</th>
<th>Active EoE</th>
<th>Inactive EoE</th>
<th>NERD/GERD</th>
<th>Control</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 cm</td>
<td>83</td>
<td>1018</td>
<td>3243</td>
<td>2612</td>
<td>1089</td>
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<tr>
<td>5 cm</td>
<td>82</td>
<td>1212</td>
<td>2682</td>
<td>2979</td>
<td>1415</td>
</tr>
<tr>
<td>10 cm</td>
<td>83</td>
<td>1572</td>
<td>2396</td>
<td>3820</td>
<td>2278</td>
</tr>
</tbody>
</table>

a, b, c represent the lower quartile a, the median b, and the upper quartile c for continuous variables. 
N is the number of non-missing values.
Conclusions

1) MI measurements provide immediate results of esophageal mucosal inflammation in pediatric patients.

2) Active EoE patients have significantly lower MI measurements than other patients.

3) MI measurements inversely correlate with eosinophil counts and spongiosis severity.

4) This novel device has the potential to provide immediate, less invasive disease monitoring in pediatric patients with EoE, thus significantly reducing costs and risks of repeated endoscopic evaluation.
Significance and Future Potential

- Sedated endoscopy with biopsies
- Dietary or Topical Steroid Treatment
- Repeat sedated endoscopy with biopsies
- Food Challenge
- Repeat sedated endoscopy with biopsies
- Symptomatic

EoE

GERD/NERD

Acid Blockade Treatment

- Multichannel Intraluminal Impedance

- Current potential
- Future potential

X- Current potential
X- Future potential