Taking Acid-Reducing Medicine With Aspirin Offers Moderate Benefits in Patients With Barrett’s Esophagus

Summary includes updated data not in the abstract
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ASCO Perspective
“The risk of esophageal cancer weighs on patients with Barrett’s esophagus. For these patients, this regimen reduces serious complications of acid reflux disease and the risk of dying from all causes, including esophageal cancer, and with little to no side effects. It’s an approach that people with Barrett’s should consider and discuss with their doctors,” said ASCO Expert Andrew Epstein, MD.

CHICAGO – Findings from an updated analysis from a randomized phase III trial show that taking a high dose of the acid-reducing medicine esomeprazole (Nexium®) with low dose aspirin for at least seven years can moderately reduce the risk of developing high grade dysplasia (a pre-cancerous lesion) or esophageal cancer, or delay death from any cause in people with Barrett’s esophagus.

The authors estimate that development of these outcomes could be delayed by using these
simple, over-the-counter medicines. Esophageal cancer is an uncommon cancer, but very
difficult to screen for and treat – less than 1 in 5 (19%) of patients survive 5 years after
diagnosis.

The findings will be featured in a press briefing today and presented at the 2018 American
Society of Clinical Oncology (ASCO) Annual Meeting.

“Based on these data, we believe people with heartburn should talk with their doctor about
their risk of Barrett’s esophagus, but they should not self-medicate with these medications,”
said lead study author Janusz Jankowski, MD, PhD, Deputy Vice Chancellor, Royal College of
Surgeons, Ireland and Consultant Clinical Adviser, National Institutes for Health and Care
Excellence, UK. “We hope that the National Institute for Health and Care Excellence in the UK
and national bodies in other countries will consider our findings when developing guidelines
for esophageal cancer prevention.”

About Esophageal Cancer and Barrett’s Esophagus

Esophageal cancer accounts for only 1% of cancers diagnosed in the United States, but it is
more common in other parts of the world. Esophageal adenocarcinoma is the most common
type of esophageal cancer in the West, accounting for two-thirds of all esophageal cancers.
Esophageal cancer is the seventh leading cause of death from cancer in the world.

Barrett's esophagus can develop in some people who have chronic gastroesophageal reflux
disease (GERD) or inflammation of the esophagus called esophagitis, even when a person
does not have symptoms of chronic heartburn. Damage to the lining of the esophagus causes
the squamous cells in the lining of the esophagus to turn into glandular tissue. People with
Barrett's esophagus are more likely to develop adenocarcinoma of the esophagus, but the
risk of developing esophageal cancer is still fairly low.

It is estimated that Barrett's esophagus occurs in only 2% of adults in Western countries, but
experts believe that it may be underdiagnosed. Although people with this condition have a
much higher risk for esophageal cancer compared to the general population, their absolute
risk is still very small – the lifetime chance of developing the disease is only 2%.

It is estimated that 80-90% of esophageal cancers are preceded by Barrett's esophagus, but
most of the time cancer is diagnosed before Barrett's esophagus, because prior endoscopy
has not been undertaken properly or at all. Prior research has suggested that acid reduction with standard-dose proton pump inhibitors might prevent progression of Barrett's esophagus to cancer. There is also evidence from observational studies that aspirin is effective in preventing gastrointestinal cancers, including esophageal cancer.

**About the Study**

The ASPECT trial randomly assigned 2,563 people with Barrett's esophagus to four treatment groups:

- High dose proton pump inhibitor esomeprazole
- High dose esomeprazole with low dose aspirin
- Standard dose (e.g., low dose) esomeprazole
- Standard dose (e.g., low dose) esomeprazole with low dose aspirin

The primary endpoint was time to death from any cause, diagnosis of esophageal cancer or diagnosis of high-grade dysplasia (precancer) (three combined events). The analysis adjusted for patient’s age and duration of Barrett’s esophagus.

**Key Findings**

Patients were followed for a median of 8.9 years, and high dose esomeprazole had a statistically significant benefit on the combined endpoint compared to standard dose esomeprazole (p=0.0459). The most effective treatment was high dose esomeprazole with low dose aspirin.

Aspirin showed no benefit compared to no aspirin in the primary analysis. However, there was a weak effect when researchers censored for prior NSAID use.

**Safety Precautions**

The treatments were safe overall, with serious side effects reported in only 1% of patients. Although both medicines are generally very safe, precautions should be taken before starting this regimen, noted Dr. Jankowski.

The most common side effect of proton pump inhibitors is diarrhea. People with heart disease should be aware that these drugs can interact with various heart medications. Other, much more rare risks include *Clostridium difficile* infection and osteoporosis. The most serious side effects of aspirin include allergic reactions, bleeding in the stomach, and bleeding in the
brain (particularly for people with high blood pressure). In addition, people who are already taking another non-steroidal anti-inflammatory drug (NSAID), should not be taking aspirin.

**Next Steps**

Although this was the largest chemoprevention randomized controlled trial in Barrett's esophagus and it had the longest follow-up, more research is needed, noted Dr. Jankowski. The research was conducted in only five countries with mostly White populations, so it is not known if this chemoprevention strategy would be as effective in Black and Asian people, as genetic ancestry can affect treatment efficacy. In addition, the researchers would like to follow patients on this study to see if 9-10 years of chemoprevention is even more effective and whether there is an increased risk for side effects with longer treatment.

This study received funding from Cancer Research UK.

**Study at a Glance**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Barrett's Esophagus/Esophageal Cancer</th>
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</thead>
<tbody>
<tr>
<td><strong>Trial Phase, Type</strong></td>
<td>Phase III, Randomized, Chemoprevention</td>
</tr>
<tr>
<td><strong>Patients on Trial</strong></td>
<td>2,563</td>
</tr>
<tr>
<td><strong>Intervention Tested</strong></td>
<td>Proton pump inhibitor and aspirin</td>
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<tr>
<td><strong>Primary Finding</strong></td>
<td>Taking a high dose of esomeprazole with low dose aspirin for at least seven years can moderately reduce the risk of developing high grade dysplasia or esophageal cancer, or delay death from any cause in people with Barrett’s esophagus.</td>
</tr>
<tr>
<td><strong>Secondary Finding(s)</strong></td>
<td>N/A</td>
</tr>
</tbody>
</table>

View the full abstract.

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