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PR Q&A

Cytosponge™* Cell Collection Device

Q: What is the goal of the Cytosponge™* cell collection device procedure?

A: The Cytosponge™* cell collection device is a minimally invasive way to collect cells from the surface of the esophagus.[1]

Q: How does the Cytosponge™* cell collection device work?

A: The Cytosponge™* cell collection device is a small capsule-shaped device the size of a multivitamin. A thin string is connected to a sponge inside the capsule. A patient swallows Cytosponge™*, which after some time dissolves and the sponge expands in the stomach. The string is then gently pulled to retract the sponge. As it's retracted, the sponge collects cells from the entire length of the esophagus. The procedure can be performed in less than 10 minutes.[2]

Q: What do physicians do with the cell samples collected with the Cytosponge™* cell collection device?

A: The Cytosponge™* cell collection device is placed in a jar of preservative and sent to a pathologist for analysis.

Q: Are there any recent US clinical studies supporting the use of Cytosponge™* cell collection device in patients?

A: In a recent pilot study of 191 patients in the US:

- **91 percent** of Cytosponge™* cell collection device procedures provided adequate samples of esophageal cells.
- **65 percent** of patients indicated a preference of Cytosponge™* cell collection device compared to endoscopy.
- Nearly all (**99.5% percent**) were able to successfully swallow the device.
- **93 percent** of patients indicated a willingness to undergo a repeat Cytosponge™* cell collection device procedure.[3,4]

Q: What are some benefits of using the Cytosponge™* cell collection device?

A: The Cytosponge™* cell collection device provides health care providers and patients with a minimally invasive way to collect esophageal cell samples. Additionally, the procedure can be performed in under 10 minutes without the use of sedation.[2,3]

Q: Is the Cytosponge™* cell collection device suitable for use in all patients?

A: No, Cytosponge™* cell collection device is not appropriate for everyone. Patients should talk to their doctor about the Cytosponge™* cell collection device and their esophageal health to determine if the test is right for them.

Q: Do patients need to do any special preparation prior to undergoing a procedure with the Cytosponge™* cell collection device?

A: Yes. Patients should fast for four hours prior to procedure. Other considerations including patients taking antithrombotic agents should be discussed between the patient and healthcare provider.

Q: Are there any risks or side effects associated with the Cytosponge™* cell collection device?

A: Yes. Like other medical devices, there is a risk of complications. Potential complications include: mucosal laceration or perforation requiring secondary intervention, major and minor bleeding, airway obstruction, infection, aspiration, intestinal obstruction, tissue damage, allergic reaction, dysphagia, pain. Secondary intervention including endoscopy and/or surgery may be required to treat any of the potential complications listed.

Q: What happens if the string connected to the sponge breaks during the procedure?

A: In the event that the sponge detaches from the string, an endoscopic retrieval procedure may be necessary.

Q: Is the Cytosponge™* cell collection device more cost-effective than endoscopy tests?

A: Based on the 2018 reimbursement for EGD, the Cytosponge™*cell collection device is less expensive than endoscopy with biopsy for collection of cells from the surface of the esophagus.[5]

Q: What patients are at most risk for esophageal disease?

A: People who experience reflux symptoms or heartburn may be at a higher risk for esophageal diseases.[6]

Q: What are the signs and symptoms of GERD?

A: People with GERD may not realize they have it because symptoms can be associated with other conditions. Common reflux symptoms may include chronic heartburn; regurgitation; chest pain; chronic cough, sore throat and/or hoarseness; sleep disturbances; belching, gas and bloating; and nausea.[7,8] Early detection of reflux symptoms is critical. If left untreated, GERD can lead to more serious diseases.[9]

References

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3. Assessment of a Minimally Invasive Esophageal Cytology Collection System in Patients with Barrett's Esophagus or GERD Symptoms (CASE II). Clinical Study Report- COVB2710467 May 2018 (Data on file).
4. Shaheen et al. A Multicenter Study of the Adequacy and Accuracy of Cytosponge™*, First Report in an American Population with Barrett's Esophagus and GERD. AGA Abstracts, 2019. S-223.
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6. Peery et al. Burden of Gastrointestinal, Liver, and Pancreatic Diseases in the United States. Gastroenterology, 156(7), pp. 254-272.
7. GERD Symptoms: Typical and Atypical. https://www.gerdhelp.com/about-gerd/symptoms/. Accessed on July 22, 2019.
8. What are symptoms of GER and GERD? http://www.niddk.nih.gov/health-information/digestive-diseases/acid-reflux-ger-gerd-adults/symptoms-causes. Accessed on July 22, 2019.
9. Dymedex Market Development Consulting, Strategic Market Assessment, GERD, October 30, 2014. References 1-3, 6-15, 22, 23, 25, and 34 from the full citation list. Access at http://www.medtronic.com/giclaims.

Cytosponge™* cell collection device

In England, the devices and diagnostic tests are sold separately by Medtronic and Cyted respectively. Medtronic sells Cytosponge devices and separately Cyted sells and performs the labaratory-based immunohistochemical testing for detection of intestinal metaplasia and/or dysplasia in oesophageal cells, which have been collected by the Cytosponge. Neither party is responsible for the goods or services provided by the other party. For the avoidance of doubt, no sample processing, staining or any other laboratory-based immunohistochemical analysis are conducted by Medtronic.

Indications for Use: The Cytosponge™* cell collection device is indicated for use in the collection and retrieval of surface cells in the esophagus for cytological and histological analysis.

Contraindicated for: Patients with symptoms of dysphagia or history of swallowing disorders. Patients with known or suspected anatomical abnormalities of the esophagus or stomach. Patients that have undergone esophageal or gastric dilation, ablation, biopsy, mucosal resection or other invasive medical procedures within the previous two months. Pregnancy. Patients with known or suspected portal hypertension and/or gastric or esophageal varices. Patients taking anti-thrombotic agents (e.g., anticoagulants, antiplatelet agents) that cannot be temporarily discontinued.

Risk Information: Potential complications of the Cytosponge™* include: Mucosal laceration or perforation requiring secondary intervention, major and minor bleeding, airway obstruction, infection, aspiration, intestinal obstruction, tissue damage, allergic reaction, dysphagia, pain. Secondary intervention including endoscopy and/or surgery may be required to treat any of the potential complications listed above.

Important: Always refer to the Instructions For Use (IFU) packaged with the product for complete instructions, indications, contraindications, warnings and precautions.

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