Healthcare Improvement Scotland | SHTG Advice on health technologies

# Plain Language Summary

## Capsule sponges for detecting Barrett's oesophagus and early oesophageal cancer | November 2023

### Key messages

- Capsule sponges are a potential alternative or precursor to endoscopy for diagnosing Barrett's oesophagus or early stage oesophageal cancer.
- Using capsule sponge tests has been shown to improve access to endoscopy for patients who are at the greatest risk of a serious diagnosis and to reduce endoscopy waiting lists.
- Capsule sponge tests are likely to misdiagnose approximately 28% of patients tested. Endoscopy has been reported to miss between 21% and 23.5% of early oesophageal cancers in patients with Barrett's oesophagus.
- The majority of patients asked found capsule sponge tests an acceptable alternative to endoscopy.
- The use of capsule sponge tests for patients with chronic reflux symptoms referred for an endoscopy led to savings for the NHS in Scotland.
- Please note that all the evidence on capsule sponges relates to the Cytosponge™ device which is no longer used in NHSScotland.

### What are acid reflux, Barrett's oesophagus and oesophageal cancer?

The oesophagus is the tube that carries food from your mouth to your stomach.

Acid reflux is a common condition where acid from the stomach leaks up into the oesophagus. Symptoms include heartburn and an unpleasant taste at the back of the mouth. Some people with long-term reflux can develop a condition called Barrett's oesophagus.

People with Barrett's oesophagus develop patches of abnormal tissue in the oesophagus. In a small number of people, this abnormal tissue can develop into oesophageal cancer.

Oesophageal cancer usually does not cause any symptoms when the tumour is small. The majority of patients are diagnosed with symptoms of advanced disease, such as difficulty swallowing and weight loss, and their outlook is very poor.

## What are endoscopies and capsule sponges?

An endoscopy is a procedure where a thin flexible tube with a light and camera at one end is used to examine the oesophagus. During an endoscopy tissue samples can be collected for testing. People with long-term reflux or Barrett's oesophagus often have endoscopies.

Capsule sponges are an alternative to endoscopies. We considered the evidence for two capsule sponges: Cytosponge™ and Endosign®. These devices are similar in design and function. Each device consists of a sponge packed inside a small capsule and attached to a piece of string.

During a capsule sponge procedure, the patient swallows the capsule and string with a drink of water. Once it has been swallowed, the capsule dissolves and the sponge expands in the stomach. After about 5 minutes, the sponge is pulled up from the stomach using the string. As it comes up the oesophagus the sponge collects tissue samples for testing. Patients can be offered a numbing throat spray to reduce discomfort when removing the sponge.

Tissue samples collected by the sponge are sent to a laboratory where they are tested for signs of Barrett's oesophagus or the early stages of cancer.

## Why is this important?

Most people who are diagnosed with oesophageal cancer in Scotland have advanced disease. Only 5–40% of people with advanced disease survive for 5 years after diagnosis.

People with long-term reflux or Barrett's oesophagus are at increased risk of developing oesophageal cancer. Since most people with these conditions will not get cancer, giving them regular endoscopies places a lot of pressure on endoscopy services.

During the COVID-19 pandemic, many endoscopies were cancelled resulting in long waiting lists. Capsule sponge tests could help reduce waiting lists and are less invasive for patients.

## What we did

We looked at whether capsule sponges were effective, safe and acceptable alternatives to endoscopy for diagnosing Barrett's oesophagus and early oesophageal cancer. We calculated the effects on the NHS budget of introducing capsule sponge tests in Scotland. We analysed data from Scottish patients who had a Cytosponge™ test between 2020 and 2023.

## What we found

### Patients with long-term reflux

We found that Cytosponge™ tests would misdiagnose 28 out of 100 people with long-term reflux.

- 19 out of 100 people would be wrongly told they did not have Barrett's oesophagus.
- 9 out of 100 people would be wrongly told they did have Barrett's oesophagus.

In an analysis of English NHS data, 78% of patients tested with Cytosponge™ could be taken off the endoscopy waiting list based on their test result. This analysis also found that Cytosponge™ testing provided value for money.

We calculated that testing using the Endosign® device in patients with reflux who are referred for an endoscopy could save the NHS £700,000 in a year and £3.3 million within 5 years. The NHS would probably not see these savings in cash terms, but the capacity of current healthcare staff to treat patients may increase.

### Patients with Barrett's oesophagus

We found that Cytosponge™ could misdiagnose 27 out of 100 people with Barrett's oesophagus.

- 11 out of 100 people would be wrongly told they did not have pre-cancerous changes in their oesophagus or cancer.
- 16 out of 100 people would be wrongly told they did have pre-cancerous changes in their oesophagus or cancer.

Recent studies suggest that endoscopy (the alternative test for these patients) may miss approximately one in five early oesophageal cancers.

In our analysis of Scottish NHS data, patients generally waited less time after their Cytosponge™ test to begin treatment (9 months) compared with patients receiving treatment after an endoscopy (39 months).

One study found that in Scotland, 91% of people whose test result suggested they had a high risk of cancer had an urgent endoscopy within 12 months of their test. Half of these people had an endoscopy within 3 months of their test.

We found two studies that looked at whether Cytosponge™ test results could be used to decide whether to take people off the endoscopy waiting list. Approximately 65% of patients who were thought to have a low risk of cancer were able to be taken off endoscopy waiting lists.

### Safety

Safety incidents involving the Cytosponge™ include the string breaking, oesophageal bleeding, a sore throat, indigestion, reflux, oesophageal discomfort or stomach pain.

Between December 2022 and June 2023, 13 patients worldwide (five of them in Scotland) reported the Cytosponge™ became detached from the string during their procedure. All nine patients had an urgent endoscopy to retrieve the sponge.

Small numbers of patients with Barrett's oesophagus (5.7%) or reflux (2.1%) are unable to swallow the Cytosponge™.

### Acceptability

Capsule sponge testing was generally acceptable to patients, with 80% willing to have the test again. Concerns about the test related to being unable to swallow the capsule and getting the sponge back out.

Patients found the Cytosponge™ test was more acceptable than endoscopy without sedation, but less acceptable than endoscopy with sedation.

## What is our conclusion?

The data suggests that Cytosponge™ potentially misdiagnoses approximately one in four people with long-term reflux or Barrett's oesophagus. This might be an overestimate and more research is needed on the accuracy of capsule sponge tests and endoscopies.

We were unable to determine whether capsule sponge tests improved access to endoscopy services or reduced endoscopy waiting lists in Scotland. Data from NHS England suggests that capsule sponge tests could reduce waiting lists and demand for endoscopy services.

Analysis of Scottish and English NHS data suggest that capsule sponge testing in people with long-term reflux referred for an endoscopy is good value for money. The NHS would probably not see savings in cash terms, but the capacity of current healthcare staff to treat patients may increase.

Safety incidents associated with Cytosponge™ are infrequent and minor. In 2023, several cases of the string breaking off the sponge were reported. This has led to NHSScotland switching to using the Endosign® device.

Patients generally find capsule sponge tests to be an acceptable alternative to endoscopy.

### Limitations of the evidence

All the evidence on capsule sponges is for the Cytosponge™ device. Since the EndoSign® device is similar, we have assumed that the evidence can apply to both devices. This needs to be confirmed in research on the EndoSign® device.

Almost all the studies we found were published by people involved in developing the Cytosponge™ and founding the Endosign® manufacturing company. This suggests a potential conflict of interest in all of these studies.

## What next?

The Cytosponge™ and EndoSign® devices will be considered for national rollout in NHSScotland.

This plain language summary has been produced based on an SHTG Assessment in November 2023