

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures

Patient Organisation Submission

IP2010 Laparoscopic insertion of a non-active implant for gastro-oesophageal reflux disease

Thank you for agreeing to give us your views on this procedure or operation and how it could be used in the NHS.

When we are developing interventional procedures guidance we are looking at how well a procedure or operation works and how safe it is for patients to have.

Patient and carer organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of having the procedure or operation
- the outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.)
- the expectations about the risks and benefits of the procedure or operation.

To help you give your views, we have provided this template, and ask if you would like to attend as a patient expert at the bottom of the form. You do not have to answer every question – they are there as prompts. The text boxes will expand as you type, the length of your response should not normally exceed 10 pages.

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

About you	
1. Your name	Fiona Labrooy
2. Name of organisation	Heartburn Cancer UK
3. Job title or position	COO
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	Heartburn Cancer UK is a charity which provides support to patients and their families, raises awareness of the dangers of persistent heartburn, promotes the importance of early diagnosis and provide input to research projects that improve patient outcomes.
<p>5. How did you gather the information about the experiences of patients and carers to help your submission?</p> <p>(For example, information may have been gathered from one to one discussions with colleagues, patients or carers, telephone helplines, focus groups, online forums, published or unpublished research or user-perspective literature.)</p> <p>Information has been collected through our support groups and contact with patients and their families via phone, email, Messenger and our social media pages.</p>	

Living with the condition

6. What is it like to live with the condition or what do carers experience when caring for someone with the condition?

Gastro-oesophageal reflux disease can be a chronic condition with a huge impact on patients' and their families' quality of life. Common symptoms of GORD include chest pain (heartburn), chest tightness, regurgitation, and swallowing difficulties, but it can also cause other symptoms, due to acid reflux that can irritate the airways and lead to respiratory symptoms such as asthma, chronic cough and sore throat.

These symptoms affect their personal and working lives. Many patients do not sleep properly and need to adapt their sleeping habits, some having to raise the head of the bed and some even sleeping in chairs. To try and minimise this, patients often will not eat anything past late afternoon and must limit certain types of food posing severe restrictions and having a significant negative impact on their social lives. A person's oral health can also be affected due to acid reflux causing tooth decay which also affects self-confidence.

Due to such restrictions and altered habits, people with GORD may miss family occasions and celebrations, in turn affecting their friends and relatives. Caregivers or families of GORD patients can feel hopeless in helping those with reflux disease as they see their loved ones suffer potentially severe symptoms upsetting their everyday life without a satisfactory treatment. In the end, patient's well-being, quality of life, and productivity are significantly affected by this disease.

Advantages of the procedure or operation

7. What do patients (or carers) think the advantages of the procedure or operation are? Why do you consider it to be innovative?

Based on the current available data and our experience, RefluxStop surgery offers several meaningful advantages over PPIs and other surgical options. Firstly, it seems to be effective at controlling GORD symptoms whilst resulting in fewer unwanted side effects compared to other surgical options and secondly, it is designed to be durable and designed to last a lifetime. With good control of symptoms, patients are able to stop taking daily PPI medication, which they may otherwise need for the rest of their lives. Since there are now thought to be negative consequences of taking PPIs lifelong, this is also a great advantage if patients are able to discontinue medication. Thirdly, RefluxStop can be used in patients with poor oesophageal function and it is the only good surgical option for these patients.

The innovation, to our understanding, is the way the surgery is performed. Surgeries like fundoplication wrap part of the stomach around the oesophagus to try to keep it in position and can often have side effects such as bloating or difficulty swallowing. This surgery (RefluxStop) puts an implant onto the stomach to try to keep it in the correct position so that acid is unable to reflux up into the oesophagus. It doesn't wrap anything around the oesophagus, as is done in other surgeries, so it is thought to not have the same side effects.

An effective treatment that has fewer side effects and allows patients to stop taking daily PPIs or similar medications represents a great advantage for patients' quality of life. An added benefit is reducing the burden of regular prescription charges.

8. Does this procedure have the potential to change the current pathway or patient outcomes? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes, it is likely to result in a change in PPI and other GORD medication use, which patients are often heavily reliant upon for years even after other anti-reflux surgery. Reduction in medication use appears likely based on reported data. The surgery successfully alleviates most of the severe patients' symptoms, based on the results available so far. Reduction in medication requirements would be beneficial for patient quality of life and convenience but is also important as recent scientific studies have reported associations between the long-term use of PPIs and a range of possible side effects, which is understandably a concern for patients.

Importantly, it has the potential to significantly reduce readmissions, burdensome hospital visits and interventions in the postoperative period due to a very low rate of side effects such as dysphagia requiring oesophageal dilatation compared to existing surgical treatments. So far there have been very few adverse effects that are usually seen with other types of anti-reflux surgery. All of this could mean that the patient requires less medical input for

control of symptoms and side effects, which would reduce use of medical resources and a better experience for the patient.

Disadvantages of the procedure or operation

9. What do patients (or carers) think the disadvantages of the procedure or operation are?

The disadvantages in comparison to medical treatment are that it entails having an operation, with the general risks associated with that. Usually the surgeon explains these to the patient before they agree to surgery. However, many patients with severe or chronic GORD see this as a minor disadvantage in exchange for a much improved quality of life. In addition, some patients may not like the idea of a foreign body inside them or will be concerned about the implant moving to a different part of the body.

Patient population

10. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why.

Based on available data, RefluxStop device can be used in patients with GORD symptoms who do not respond well to medical treatment, or are unable or unwilling to take medical treatment, for example due to side effects or patient preference.

However, due to the fact that there is nothing encircling the oesophagus, it is particularly suitable for patients with poor swallowing function and has been shown to be effective at reducing or eliminating GORD symptoms without causing unwanted side effects. This group of patients (with poor swallowing or motility function) do not have other suitable surgical choices because they are at risk of more severe swallowing difficulties after operations like fundoplication, so it will be an enormous relief for these ineffective motility patients to finally have a treatment option.

There is also growing evidence that the procedure works well even in patients with large hernias, who are another group that is prone to complications after standard anti-reflux surgery. Therefore, this procedure can help not only general GORD patients, but also patients with more complex surgical needs – ineffective swallowing issues and large hernias.

Safety and efficacy

11. What are the uncertainties about how well this procedure works and how safe it is?

RefluxStop surgery has been performed in multiple centres in the UK, Germany, Switzerland, Austria, and other European countries since 2017. It is our understanding that well over 800 patients have received RefluxStop surgery and the results so far have been encouraging with a very low rate of side effects or problems related to the device (around 1%). Although current data looks very promising, the longer-term effect of this treatment will be further tested with time. Our understanding is that more research is underway, and additional long-term data will be available in the near future.

Equality

10. Are there any potential [equality issues](#) that should be taken into account when considering this topic?

In our understanding, none. RefluxStop is suitable for anyone who is eligible for anti-reflux surgery.

Other issues

11. Are there any other issues that you would like the Committee to consider?

Although GORD is considered a generally benign condition, the impact of the disease is grossly underestimated, resulting in profound limitations on lifestyle habits and quality of life, plus the risk of the patient developing Barrett's oesophagus and then potentially oesophageal cancer.

Improving the management of GORD can reduce the risk of developing Barrett's oesophagus and, consequently, lower the risk of oesophageal cancer and associated mortality. As the available clinical data supports RefluxStop is an effective treatment option for GORD patients, we support introduction of this treatment in NHS hospitals and would like to see it made available as broadly as possible across the UK so that every eligible patient has this choice of treatment.

Key messages

12. In no more than 5 bullet points, please summarise the key messages of your submission.

1. GORD is a serious and debilitating condition that significantly impacts patients' lives, mental health (including anxiety and depression), overall well-being, and work productivity. Globally, GORD affects 1 billion people, including 20% of the UK population suffering from this condition. According to a 2019 study, there has been a staggering 77% increase in the prevalence of GORD over the past 30 years.
2. More than one-third of patients with GORD do not have satisfactory control of symptoms with medical therapy (e.g. PPIs), leaving a large number of inadequately treated patients in need of urgent alternative treatments.
3. In recent years, attention has been drawn to many possible side effects of long-term PPI use, which is a growing concern among patients. Conventional surgical options are not suitable for all patients and that could change with the addition of novel procedures, such as RefluxStop.
4. RefluxStop surgery aims to correct the underlying structural abnormalities that cause reflux and uses an implant to keep the repaired anatomy in position. This is thought to minimise the unwanted side effects of surgery. To date, RefluxStop surgery has been effective at controlling patients' symptoms without safety concerns.
5. Untreated, or inadequately treated, GORD can lead to severe loss of quality of life and other life-threatening conditions such as oesophageal cancer. Therefore, it is more urgent for NHS England to prioritise GORD treatment solutions and ensure these long-neglected patients get immediate access to well-deserved necessary care before it's too late, costing lives and a tremendous burden on the healthcare system.

Committee meeting

13. Would you be willing to attend the interventional procedures committee meeting to provide the view from your organisation in person?

I would have been willing but unfortunately I am unable to attend on the earmarked date.

Thank you for your time.

Please return your completed submission to helen.crosbie@nice.org.uk and ip@nice.org.uk.

