

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	Maggie Robinson
2. Name of organisation	OPA Cancer Charity
3. Job title or position	Manager
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	Raising awareness of GORD/Acid Reflux and supporting patients with oesophageal and gastric cancer including their carers, and families. Donations are from Charitable Trusts and general public. 14479 Subscribers
5. How did you gather the information about the experiences of patients and carers to help your submission? (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.) One to one discussion with colleagues, patients, online forums, videos, and user perspective literature	

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?

The burden of Gastro-oesophageal reflux disease (GORD) is vastly underestimated. This disease often affects patients' lives causing daily suffering, pain, and discomfort with substantial impact on mental health and quality of life.

The disease is burdensome with regurgitation of acid often causing heartburn with substantial pain. The acid may damage tissue causing difficulty swallowing and sometimes affects the vocal cords and lungs, causing symptoms such as chronic cough, asthma, sore throat, and dental erosion.

Patients are often required to restrict their eating and social habits in an attempt to manage adverse symptoms. A patient must adapt her/his entire life to limit the consequences of the disease. It is difficult to go to restaurants or visit friends for dinner because food restriction may be severe and the pain can occur suddenly. For some, lying horizontally causes symptoms, resulting in difficulty sleeping, which is often a serious problem and sitting up while sleeping is not unusual.

Family members are also impacted by GORD causing a significant burden to society at large. The patient's carer or family may feel helpless and distressed as they witness severe and chronic suffering without effective management. For some, symptoms may be present persistently with little relief. Waking up many times during the night affects not only the patient's well-being, but also their partner may experience lack of sleep. The limitation in social life affects the whole family.

All of these aspects have significant effects, not only on well-being and quality of life, but also on work output and productivity toward society.

Medical treatment does not hinder regurgitation of stomach fluid only reduces the acidity in the fluid, thereby treating the symptoms not the cause of the disease and is therefore needed for a lifetime.

One issue is that PPI medical treatment has serious side effects when used long-term that could lead to death, with the 4 most common reasons for death; digestive cancer, heart disease, chronic kidney disease and overgrowth of bacteria and parasites.

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?

The key advantages of RefluxStop surgery are elimination or reduction of GORD symptoms directly after surgery with fewer side effects and better resolution of symptoms, as compared to PPI therapy or other types of anti-reflux surgery surrounding the esophagus.

Medical treatment with PPI is plagued with severe long-term complications and the treatment is lifelong. In addition, we know that 30-40% of sufferers are not helped by PPI medical therapy.

Although PPI medication works well on a short-term basis for some GORD patients, they simply reduce the acidity of stomach contents flowing back into the oesophagus without treating the root cause of reflux disease itself while also subjecting patients to serious long-term side effects and even an increased risk of gastrointestinal malignancies overall. The concept of requiring medication on a daily basis with potentially significant side effects does not appeal to many, particularly when considering that PPIs do not address the root cause of disease and provide only temporary relief.

For the first time in decades, this new surgical technique can address the root cause of reflux disease symptoms. RefluxStop surgery can eliminate the necessity for daily medication, potentially for the remainder of a lifetime. Symptoms are usually imminently resolved or improved after surgery, allowing for normalisation of lifestyle, including resumption of normal dietary habits, decreasing sleep disturbance, return to work (if applicable), return to personal interests, social activities, and much more; a crucial consideration for patients.

Existing surgical options do not address the cause of reflux disease and only treat an isolated aspect of the overall problem. They provide limited relief at the cost of a significant side effect profile since they compress the oesophagus, leading to issues such as difficulty swallowing, gas-bloating, and more.

Effective control of reflux disease has enormous knock-on effects that are often subordinated with conventional care, including mental health, quality of life, and return to the patient's healthy role in life.

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, RefluxStop surgery has shown very promising results. Since the procedure actually treats the root cause of reflux disease, patients finally have the option to appropriately treat GORD and experience long-term relief. Patients do not need daily medication that does not provide adequate relief or may cause long-term serious effects. This procedure can lead to optimal outcomes in terms of symptom improvement without major side effects like difficulty swallowing that occurs with other types of anti-reflux surgery. This procedure can also reduce unnecessary hospital and doctor visits due to

optimized symptom control and the lower likelihood of requiring further intervention.

Disadvantages of the procedure or operation

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

The disadvantages are similar to those of any other operation (i.e., anaesthesia, staying in hospital overnight, absence from work, need for pain medication after surgery). These disadvantages are highly likely to be far outweighed by the benefits of RefluxStop surgery, such as symptom control, improved quality of life, and less reliance on medication.

Patient population
<p>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.</p> <p>Yes, RefluxStop surgery can benefit existing GORD patients eligible for anti-reflux surgery and, for the first time, extends the treatment option to help previously untreatable patient groups. For example, GORD patients with ineffective oesophageal motility (i.e., poor contraction of the oesophagus), have a weaker food transportation and therefore often have swallowing difficulties. This patient group therefore predisposes to a much higher risk of side effects after existing anti-reflux surgery, surrounding and compressing the esophagus and most often worsening their symptoms such as difficulty swallowing. NICE guidelines do not recommend surgery for these patients.</p> <p>RefluxStop treats acid reflux without surrounding and compressing the food passageway and according to several hospitals' results, provides excellent clinical outcomes for dysmotility patients. This surgery may be of particular benefit to these patients since the procedure uses a novel and unique mechanism of action that does not cause these effects.</p> <p>Furthermore, RefluxStop when invaginated in the stomach wall acts like a mechanical stop to reduce reherniation also in large hiatal hernia patients. This patient group has a very high recurrence rate of reherniation and new treatment options are needed.</p> <p>Additionally, RefluxStop surgery is also suitable for any GORD patient who is intolerant to or does not wish to receive medical therapy, or in whom medication does not work well.</p>
Safety and efficacy
<p>11. What are the uncertainties about how well this procedure works and how safe it is?</p> <p>It is reported that more than 800 patients have been treated with this procedure in the UK and Europe over the last few years. Clinical studies show this surgery is safe and effective in GORD patients with very promising long-term results.</p> <p>As several NHS hospitals in the UK are conducting this procedure, we hope to see a plethora of available data in the near future.</p>
Equality

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

GORD subjects society to a tremendous social and economic burden that is only growing in magnitude at an increasing rate, with over 1 billion sufferers worldwide. GORD may affect persons of any gender, age, race, or socioeconomic background.

There are boundless waiting queues for “elective care” treatments in the NHS England. Although GORD may not cause life-threatening conditions immediately, an enormous burden on patient ability to work and productive contribution to society exists and is vastly underestimated. As a result, a large number of patients are left untreated and exposed to significant risk factors that lead to personal harm and broader economic impacts. Therefore, it is of utmost importance for the UK NHS to provide equitable access to timely and effective treatment for GORD and avoid the potentially catastrophic long-term impacts on society.

Furthermore, there is an issue of chronic GORD patients remaining on ineffective medical treatment in the long term due to a lack of consideration for surgical options. Often, management is suboptimal in these patients and they are cycled between primary and secondary care clinics without a satisfactory solution.

Other issues

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

The impact of GORD is vastly underestimated, perhaps because it is chronic in nature and not considered to be life-threatening, yet it has profound effects that limit normal habits and impair quality of life. Furthermore, the disease is much more serious than is generally understood. According to Cancer Research UK, oesophageal cancer is the [seventh](#) most common cause of cancer death in the United Kingdom (2016). Each year in the UK around [9,000 people are diagnosed](#) with oesophageal cancer, and over [8,000 die from it](#), according to Cancer Research UK. Most of these deaths are likely be caused by acid reflux and PPI therapy.

An effective, definitive treatment would be a pronounced step forward in the management of reflux disease. While GORD is considered benign, it predisposes to the premalignant lesions of Barrett's oesophagus and, in turn, to oesophageal cancer. The frequency of this malignancy is increasing rapidly, at a rate higher than for any other solid tumor. More specifically, the frequency of oesophageal adenocarcinoma has increased almost 800% in the last few decades. The overall mortality rate of oesophageal cancer within 5 years of diagnosis approximates 90%, an astonishing proportion. Despite this insight, very little has been done to appropriately mitigate the malignancy risks associated with GORD. Moreover, management of GORD with PPIs does not seem to diminish malignancy risk as per the literature and have been associated with an increased risk of gastrointestinal cancers overall.

Key messages

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

1. GORD is very distressing, painful, and can severely impact quality of life, including sleep disturbance and lost productivity. It affects patients' and their families' mental wellbeing and social life.
2. Taking daily medication does not work for 30-40% of users and exposes patients to a significant risk of long-term side effects including cancer and death. Many do not wish to continue medication for the remainder of their lives, particularly when medication does not definitively treat the underlying condition.
3. The existing surgical treatment options do not address the root cause of GORD and have risks of side effects that also negatively affect quality of life. For example, patients managed with conventional anti-reflux surgeries often experience difficulty swallowing, inability to belch and vomit, gas-bloating, high surgical failure rates, and high reoperation rates.
4. RefluxStop surgery directly addresses the underlying anatomic and physiologic abnormalities of GORD, unlike other treatment mechanisms, to relieve symptoms while minimising side effects of conventional options. Since it treats the cause of acid reflux without affecting the food passageway, it provides treatment for dysmotility patients who have no well working treatment today. In addition, RefluxStop is likely to provide better outcomes in patients with large hiatal hernia since it acts like a mechanical stop.
5. RefluxStop surgery has demonstrated promising results thus far in terms of symptom improvement and few side effects, if any, allowing patients to discontinue daily medication.

Committee meeting

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

Yes an OPA representative would be willing to attend to provide a view from patient perspective

Thank you for your time.

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