NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

Balloon cryoablation for treating Barrett's oesophagus

The oesophagus is a muscular tube that connects the mouth to the stomach. With Barrett's oesophagus, the cells lining the lower part of the oesophagus become more like the cells lining the intestines. The changed cells can become cancerous.

Cryoablation involves putting a balloon into the oesophagus through a flexible tube with a camera on the end (an endoscope). The balloon is inflated using very cold gas. The cold gas freezes the abnormal cells and destroys them. The aim is to try and remove the affected tissue and lower the chance of cancer developing.

Guidance development process

NICE interventional procedures guidance evaluates procedures used for treatment or diagnosis. It provides evidence-based recommendations about how safe and effective these procedures are. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible care. By reviewing clinical evidence and considering patient outcomes, NICE aims to improve patient safety and treatment choices in the NHS.

Find out more on the NICE webpage on interventional procedures guidance.

NICE is producing this guidance on balloon cryoablation for treating Barrett's oesophagus in the NHS in England. The interventional procedures advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for consultation with the stakeholders. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If committee meets again, it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on balloon cryoablation for Barrett's oesophagus. The recommendations in section 1 may change after consultation.

More details are available in NICE's interventional procedures programme manual.

Key dates:

Closing date for comments: 09 October 2025

Second committee meeting: 13 November 2025

1 Recommendations

1.1 More research is needed on balloon cryoablation to treat Barrett's oesophagus in adults before it can be used in the NHS.

1.2 This procedure should only be done as part of formal research and a research ethics committee needs to have approved its use.

What this means in practice

There is not enough evidence to know if this procedure is safe or effective. Balloon cryoablation to treat Barrett's oesophagus in adults should only be done as part of formal research.

Auditing of outcomes

Data on safety and outcomes should be collected for everyone having the procedure and entered into the C2 CryoBalloon Ablation International Research Database Registry..

Who should be involved with the procedure

Patient selection and the procedure should be done by an appropriately constituted multidisciplinary team of gastroenterologists, pathologists and surgeons with specific training in this procedure.

What research is needed

More research, in the form of longer-term prospective studies, is needed on:

- patient selection (including people with different Barrett's oesophagus segment -lengths, people without previous RFA treatment, and people whose Barrett's oesophagus is resistant to RFA who are having balloon cryoablation as a secondary treatment)

- longer-term efficacy outcomes, such as time to recurrence and freedom from dysplasia and internal metaplasia, especially compared with standard care (radiofrequency ablation), for the cryoablation duration used in NHS practice
- safety outcomes (in particular, stricture formation), for the cryoablation duration used in NHS practice.

Why the committee made these recommendations

There is little good-quality evidence on the safety and efficacy of this procedure. All the evidence comes from observational studies. The results suggest that, in some people, balloon cryoablation may cause less pain and be better tolerated or more appropriate than radiofrequency ablation. In the short term, it also appears to be as effective as radiofrequency ablation in terms of cancer prevention and recurrence. But it has not been directly compared with radiofrequency ablation in a randomised controlled trial. Also, long-term data is lacking. So, more research is needed on long-term clinical effectiveness and safety, and for different populations.

2 Information about the procedure

2.1 Balloon cryoablation for Barrett's oesophagus aims to destroy the abnormal cells lining the oesophagus. Sedation is usually used, which is commonly conscious sedation but may be general anaesthesia. A balloon catheter is inserted through an endoscope, aligned with the abnormal tissue and inflated. Nitrous oxide gas is then sprayed through a radial diffuser head within the balloon, which is aimed at the abnormal tissue. The balloon freezes and the extreme cold destroys the abnormal tissue. The nitrous oxide gas remains fully contained within the balloon, which exits the body through the proximal end of the catheter.

2.2 The ablation sequence is repeated until all the abnormal tissue is destroyed. Multiple ablations can be done in 1 session without removing the balloon. Repeat endoscopy is usually scheduled 8 to

12 weeks after the procedure to check whether the abnormal tissue has been destroyed. If any of the tissue is found, retreatment may be considered.

2.3 The procedure is usually done in an outpatient setting, but is sometimes done in an inpatient setting. The choice of setting may vary by care provider and patient needs.

2.4 Medicines such as a histamine2--receptor antagonist or proton pump inhibitor may be recommended for some people having cryoablation. The aim of this medication is to improve the success rate of the procedure. It may also help to lower the chance of Barrett's oesophagus returning in the long term.

2.5 The identified evidence all used the C2Cryoballoon Ablation system (PentaxMedical, Redwood City, California, USA).

3 Committee discussion

The condition

3.1 The oesophagus is a muscular tube connecting the mouth and stomach. In Barrett's oesophagus, the cells lining the lower part of the oesophagus change, becoming more like the cells lining the intestines (intestinal metaplasia). The changed cells can become abnormal (dysplastic) over time. There is a small chance of the abnormal cells becoming cancerous. Treatment may be offered to try and remove the affected tissue. This aims to lower the cancer risk.

Current practice

3.2 Management of Barrett's oesophagus may include lifestyle changes, acid-suppressing medicines, endoscopic mucosal resection, endoscopic submucosal dissection, ablative therapies and surgery. Ablative therapies include radiofrequency ablation, photodynamic therapy, argon plasma coagulation, laser ablation,

multipolar electrocoagulation and cryotherapy. People with Barrett's oesophagus whose cells are dysplastic may be offered ablative therapy, but which one depends on the grading of the dysplasia.

3.3 NICE's guideline on the monitoring and management of Barrett's oesophagus and stage 1 oesophageal adenocarcinoma recommends offering radiofrequency ablation to people with low-grade dysplasia confirmed by 2 separate endoscopies. Endoscopic resection of visible lesions should be offered as first-line treatment to people with high-grade dysplasia. Endoscopic ablation may be offered after the initial resection to treat any residual Barrett's oesophagus.

Unmet need

3.4 Treatment options for Barrett's oesophagus may not always be feasible or suitable. Radiofrequency ablation should be avoided in people with severe comorbidities (such as cardiopulmonary disease) or in people unable to stop anticoagulation therapy. It may also be unfeasible because of an uneven Barrett's oesophagus surface or because of oesophageal strictures precluding passage of the radiofrequency ablation catheter. Endoscopic resection may be unsuitable for people with coagulation disorders, portal hypertension and people unable to stop anticoagulation therapy. It may also be difficult for longer Barrett's oesophagus segments or if there is no endoscopically visible lesion.

3.5 Cryoablation may be an option for some people who cannot have radiofrequency ablation. It may cause less pain than radiofrequency ablation in some people. In addition, it may be better tolerated or more appropriate than radiofrequency ablation or endoscopic resection for some people with comorbidities.

Innovative aspects

3.6 The cryoballoon is configured in both cylindrical and pear shapes, as well as different sizes, to allow for more tailored treatment. The pear-shaped balloon may be preferred for people with narrowing at the distal oesophagus or gastroesophageal junction. It may also be used when there is difficulty in stabilising the position of the cylinder because of a pre-existing or new stenosis.

The evidence

3.7 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 9 sources, which was discussed by the committee. The evidence included 1 meta-analysis and 8 observational studies (4 prospective cohort and 4 retrospective analyses). It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.8 The professional experts and the committee considered the key efficacy outcomes to be freedom from dysplasia and metaplasia, and recurrence of Barretts oesophagus at follow-up endoscopies.

3.9 The professional experts and the committee considered the key safety outcomes to be pain, stricture formation and perforation.

3.10 Five commentaries from people who have had this procedure were received. The views of these people were mostly positive, with some negative views about sedation noted.

Committee comments

3.11 Patient pathways and indications for cryoablation use are not clear. Prospective studies have focused on groups with an unmet need, such as people who are resistant to radiofrequency ablation. More

evidence is needed clearly identifying the patient pathway and across wider population groups to address uncertainties about who would most benefit from the procedure.

3.12 In the UK, the procedure is currently only done for people with short Barrett's oesophagus segment lengths. When length was reported, the evidence base was limited to lengths of 6 cm or less. The safety and efficacy of the procedure for longer segment lengths is not clear from the evidence.

3.13 There may be a role for cryoablation for people who are resistant to radiofrequency ablation. But most of the identified evidence only included people who had not had this treatment. So, evidence for cryoablation as a secondary treatment is limited, and more evidence is needed on the safety and efficacy of this use.

3.14 While most short-term safety data seems reassuring, longer-term issues with strictures need further exploration. A comparative study with standard care (radiofrequency ablation) would be useful.

3.15 Current research includes only a small sample of people. Longer-term outcome data on balloon cryoablation in more people would be beneficial, looking at:

- how many people remain free from dysplasia and metaplasia
- the length of time before any recurrence.

Ideally, this would be in the context of a comparison with standard care (radiofrequency ablation) in a randomised control trial.

3.16 The committee was pleased that a UK registry evaluating the Focal C2 CryoBalloon Ablation System for Barrett's oesophagus-related neoplasia has been established. But data on only a small cohort of people with Barrett's oesophagus has been included to date. Also,

results from the registry have not yet been published in a full-text peer-reviewed journal article. Recruitment of more people to the cohort would be useful, and publication of outcomes in peer-reviewed journals could be used to inform future decisions.

3.17 The committee are aware of different cryoablation durations being used from the included research. Research on outcomes using the same cryoablation duration as that employed within the UK would be useful.

Equality considerations

3.18 The prevalence of Barrett's oesophagus is related to age, typically affecting adults over 50.

3.19 Barrett's oesophagus is between 2 to 4 times more common among men than women, across all ages.

3.20 Barretts oesophagus is more common among those from White backgrounds.

3.21 The committee noted that there are only certain centres in the UK that offer balloon cryoablation ablation. So, people living further from these centres may not have access to this procedure.

4 Committee members and NICE project team

This topic was considered by NICE's interventional procedures advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Simon Bach

Vice chair, interventional procedures advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Aleix Rowlandson

Technical lead

Amy Crossley

Technical adviser

Corrina Purdue

Project manager

Emily Eaton Turner

Associate director

ISBN: [to be added at publication]