

Balloon cryoablation for Barrett's oesophagus

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg811

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG682.

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 and effective. Balloon cryoablation to treat Barrett's oesophagus in adults should only be done as part of formal research.

Auditing of outcomes

Healthcare professionals doing this procedure should collect data on safety and outcomes of the procedure. Enter details about everyone having the procedure into the [C2 CryoBalloon Ablation International Research Database Registry](#). Review data on outcomes and safety regularly.

Who should be involved with the procedure

Patient selection should be done by a multidisciplinary team including gastroenterologists, pathologists and surgeons. This procedure should only be done by gastroenterologists 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
 - who have not had radiofrequency ablation
 - who cannot have radiofrequency ablation
 - whose Barrett's oesophagus is resistant to radiofrequency ablation and who are having balloon cryoablation as a secondary treatment
- longer-term efficacy outcomes compared with radiofrequency ablation, such as:
 - time to recurrence

- freedom from dysplasia and internal metaplasia
- safety outcomes, including:
 - the formation, severity and longer-term impact of strictures
 - serious adverse events, such as perforation.

Studies should compare standard care (radiofrequency ablation) with balloon cryoablation done using the duration used in NHS practice, currently 8 seconds.

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 for 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 for 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 abnormal 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 reduce the risk of Barrett's oesophagus returning in the long term.

3 Committee discussion

The interventional procedures advisory committee considered evidence on balloon cryoablation for Barrett's oesophagus from several sources. This included a review of efficacy and safety evidence and responses from stakeholders. Full details are available in the [project documents for this guidance](#).

NICE did a rapid review of the literature on the efficacy and safety of this procedure. The evidence included 1 meta-analysis and 10 observational studies (5 prospective cohort analyses and 5 retrospective analyses). The evidence informing this guidance was on only 1 device. 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.

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 risk of the abnormal cells becoming cancerous. Treatment may be offered to try to remove the affected tissue. This aims to reduce 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 The professional experts and the committee considered the key efficacy outcomes to be freedom from dysplasia and metaplasia, and recurrence of Barrett's oesophagus seen at follow-up endoscopies.
- 3.8 The professional experts and the committee considered the key safety outcomes to be pain, stricture formation and perforation.
- 3.9 Five commentaries from people who have had this procedure were received. The commentaries were mostly positive, with some negative views on sedation.

Committee comments

- 3.10 Indications for balloon cryoablation are not currently clear. Prospective studies have focused on groups with an unmet need, such as people who have resistance to radiofrequency ablation. More evidence is needed to clearly identify suitability across wider population groups and address uncertainties about who would benefit most from the procedure.
- 3.11 There may be a role for cryoablation for people whose Barrett's oesophagus is resistant to radiofrequency ablation. But most of the identified evidence only included people who had not had radiofrequency ablation. So, evidence for cryoablation as a secondary treatment is limited, and more evidence is needed on the safety and efficacy of this use.

- 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 The committee was aware that the technology and procedures are evolving, and it may be possible to treat longer segments in the future. But there is potential for overlapping lesions to form when treating longer segments. This may be more likely to cause strictures. Evidence is needed on balloon cryoablation for treating longer segments to show that no serious adverse events occur. This should have sufficient follow up to ensure the full impact of any safety or adverse events is captured.
- 3.14 While most short-term safety data seems reassuring, evidence on the formation, severity and longer-term impact of strictures on people having the procedure needs further exploration. A comparative study with standard care (radiofrequency ablation) would be useful.
- 3.15 Current research includes only a small number of people. Longer-term outcome data in more people would be beneficial, looking at:
- how many people remain free from dysplasia and metaplasia
 - the length of time before any recurrence
 - serious adverse events (such as perforation).
- Ideally, this would be a comparison with standard care (radiofrequency ablation) in a randomised control trial.
- 3.16 The committee considered evidence comparing cryoballoon ablation with radiofrequency ablation up to 4.4 years post procedure. Safety and efficacy were comparable. But the results were uncertain because of the retrospective design, small sample sizes and limitations of propensity score matching. The reliability of propensity score matching was reduced because of prognostic differences between groups (such as segment length) and limited overlap in baseline characteristics. Some recurrences happened towards the end of follow up suggesting that longer follow up may be needed. The direction of effect

demonstrated by the hazard ratios differed according to the type of recurrence, and the confidence intervals were wide. So it was not clear if there was similar, less or greater risk of recurrence among people who had balloon cryoablation, compared to people who had radiofrequency ablation. This meant the committee could not be sure about non-inferiority conclusions. Larger, UK-based studies and randomised designs are needed to strengthen confidence.

- 3.17 The committee was aware that a UK registry evaluating C2 CryoBalloon for Barrett's oesophagus-related neoplasia has been established. But to date only a small cohort of people with Barrett's oesophagus has been included and results from the registry have not yet been published in a full-text peer-reviewed journal article. Recruiting more people to the cohort would be useful, and publishing outcomes in peer-reviewed journals could inform future decisions.
- 3.18 The committee was aware of different cryoablation durations being used from the included research. Research on outcomes using the cryoablation duration used in the NHS would be useful.

Equality considerations

- 3.19 The prevalence of Barrett's oesophagus is related to age, typically affecting adults over 50.
- 3.20 Barrett's oesophagus is 2 to 4 times more common in men than women, across all ages.
- 3.21 Barrett's oesophagus is more common in people of White ethnicity.
- 3.22 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

Richard Body

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 consultant clinical adviser, a project manager and an associate director.

Aleix Rowlandson

Technical lead

Amy Crossley

Technical adviser

Anthony Akobeng

Consultant clinical adviser

Corrina Purdue

Project manager

Emily Eaton Turner

Associate director

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