Barrett's oesophagus: ablative therapy

Clinical guideline
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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

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.
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Introduction

Barrett’s oesophagus develops as a consequence of chronic gastro-oesophageal reflux disease. It is characterised by abnormal changes in the oesophageal lining that may, in some patients, become dysplastic and lead to oesophageal cancer. Oesophagectomy (surgical removal of the oesophagus) is the standard NHS treatment for high-grade dysplastic Barrett’s oesophagus or intramucosal cancer (including T1a); however, it is associated with significant mortality and morbidity. Consequently less invasive surgical techniques, such as endoscopic mucosal resection, and ablative treatments have been developed and are being used as alternatives for patients who are unsuitable for surgery or who express a preference for less invasive options. However, in the past there has been uncertainty whether ablative therapy for Barrett’s oesophagus is both clinically and cost effective compared with other management options.

Radiofrequency ablation is one of the ablative therapies currently being used. This has a standard depth of ablation that is set by the manufacturer. Photodynamic therapy has a greater depth of ablation than radiofrequency ablation, irrespective of the photosensitiser used (although only one photosensitiser (porfirmer sodium) is presently licensed in the UK). However greater depth of ablation is associated with higher rate of complications but clinicians do not control the depth and is dependent on the ablative therapy used.

Previously no evidence-based guideline has addressed the use of ablative therapies for the treatment of Barrett’s oesophagus in England and Wales, which may lead to variation in practice. This clinical guideline covers the use of ablative therapies (argon plasma coagulation, laser ablation, multipolar electrocoagulation, radiofrequency ablation and photodynamic therapy) and endoscopic mucosal resection compared with oesophageal surgery, and surveillance with proton-pump inhibitors for treating Barrett’s oesophagus with high-grade dysplasia or with early intramucosal cancer in adults (18 years and older) in secondary care.
Patient-centred care

This guideline offers best practice advice on the care of adults with a diagnosis of Barrett's oesophagus with high-grade dysplasia or with intramucosal cancer.

Treatment and care should take into account patients' needs and preferences. People with a diagnosis of Barrett's oesophagus with high-grade dysplasia or with intramucosal cancer should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent and the code of practice that accompanies the Mental Capacity Act. In Wales, healthcare professionals should follow advice on consent from the Welsh Government.

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.
1  Guidance

The following guidance is based on the best available evidence. The full guideline gives details of the methods and the evidence used to develop the guidance.

For the purposes of this guideline, the term 'endoscopic mucosal resection' is used interchangeably with 'endoscopic resection'.

1.1  List of all recommendations

Before considering endoscopic therapy as an alternative to surgery, a confirmed diagnosis of high-grade dysplasia or intramucosal cancer in Barrett’s oesophagus should be agreed by a designated specialist multidisciplinary team for oesophago-gastric cancer.

Key principles of care

1.1.1  All treatments for high-grade dysplasia and intramucosal cancer in Barrett’s oesophagus should be performed by specialist oesophago-gastric cancer teams with the experience and facilities to deliver the treatments recommended in this guideline.

Endoscopic therapies

1.1.2  Consider offering endoscopic therapy as an alternative to oesophagectomy to people with high-grade dysplasia and intramucosal cancer (T1a), taking into account individual patient preferences and general health. Endoscopic therapy is particularly suitable for patients who are considered unsuitable for surgery or who do not wish to undergo oesophagectomy.

Endoscopic mucosal resection

1.1.3  Consider using endoscopic mucosal resection alone to treat localised lesions.

1.1.4  Use circumferential endoscopic mucosal resection with care because of the high incidence of stricture formation.

1.1.5  If residual or recurrent disease is suspected, consider additional or repeated therapy with appropriate follow-up using:
• endoscopic mucosal resection with further pathological assessment or
• ablative therapy (radiofrequency ablation or photodynamic therapy) or
• endoscopic mucosal resection and ablative therapy (radiofrequency ablation, argon plasma coagulation or photodynamic therapy).

Ablative therapies

1.1.6 Consider using radiofrequency ablation alone or photodynamic therapy alone for flat high-grade dysplasia, taking into account the evidence of their long-term efficacy, cost and complication rates.[1]

1.1.7 Do not use argon plasma coagulation, laser ablation or multipolar electrocoagulation alone, or in combination with each other, unless as part of a clinical trial.

Endoscopic mucosal resection in combination with ablative therapies

1.1.8 If using endoscopic mucosal resection, consider following with an additional ablative therapy (radiofrequency ablation, argon plasma coagulation or photodynamic therapy) to completely remove residual flat dysplasia, taking into consideration the side-effect profiles[1].

Patient and carer support and information

1.1.9 Give patients verbal and written information about their diagnosis, available treatments, patient support groups and the uncertainty of the long-term outcomes of ablative therapies. Give patients time to consider this information when making decisions about their care.

1.1.10 Discuss the multidisciplinary team’s views on the range of appropriate treatments with the patient.

1.1.11 Offer patients the opportunity to see the same specialist healthcare team more than once to agree treatment.

1.1.12 Advise patients who have endoscopic therapy that they will need lifelong care and repeated endoscopies.
Recommendation linked to IPG344 and IPG350.
2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available from our website – click on 'How this guidance was developed'.
3 Implementation

NICE has developed tools to help organisations implement this guidance.
4 Research recommendations

We have made the following recommendations for research, based on our review of evidence, to improve NICE guidance in the future.

This guideline focuses on the use of ablative and excisional therapies to treat high-grade dysplasia or intramucosal cancer in patients with Barrett's oesophagus. Therefore, the natural history of Barrett's oesophagus, including oesophageal reflux disease, diagnosis and assessment, and progression to cancer was not reviewed systematically. The Guideline Development Group noted that treatment should only be considered after a confirmed diagnosis and full assessment, and they acknowledged that research to support diagnosis and prognosis was needed. The research recommendations below focus on treatment-related questions.

4.1 Progression to dysplasia

What is the likelihood of Barrett's oesophagus progressing to dysplasia and cancer? What are the significant influencing factors?

Why this is important

Surgical treatment of high-grade dysplasia is the most effective method of treatment; however, there are significant but rare adverse effects. Ablative and excisional therapies are also successful but have an increased risk of recurrence. It is therefore important to identify patients with the highest risk of developing high-grade dysplasia, both before and after surgery, or ablative and excisional therapies. Long-term observational studies are needed to identify the risk of progression and predictive factors (for example age, sex, extent or distribution of disease, or previous treatments).

4.2 Markers of treatment success

Do anatomical, pathological and molecular markers indicate successful ablation of Barrett's oesophagus and/or the risk of recurrence of high-grade dysplasia after ablative and excisional treatment?

Why this is important

High-grade dysplasia in Barrett's oesophagus can recur after ablative and excisional therapies; however, it is not known if there are anatomical, pathological and molecular markers associated
with the success of treatment or recurrence of high-grade dysplasia. Studies to identify markers associated with long-term treatment success are needed.

4.3 **Effectiveness of treatment**

What is the effectiveness of ablative and excisional therapies for the treatment of high-grade dysplasia or intramucosal cancer in Barrett's oesophagus?

**Why this is important**

Many cases were reviewed for this guideline; however, high quality evidence from randomised clinical trials on the benefit of ablative and excisional therapies was lacking. Randomised controlled trials (or well designed studies with a follow-up of at least 5 years or a central register) of ablative and excisional therapies compared with surgery, and compared with other ablative and excisional therapies are required to determine the relative benefits, costs, and impact on quality of life.

4.4 **Follow-up after treatment**

What is the most appropriate process of follow-up after the treatment of high-grade dysplasia or intramucosal cancer in Barrett's oesophagus?

**Why this is important**

Barrett's oesophagus can recur after ablative and excisional therapies. Evidence for the most appropriate follow-up is lacking so research should establish how patients should be monitored after ablative and excisional therapies. This should include randomised controlled trials (with a follow-up of at least 5 years) to evaluate the effectiveness and optimal timing of different follow-up approaches such as universal surveillance, endoscopy if symptoms recur.

4.5 **Information needs**

What are the information needs of patients considering treatment for high-grade dysplasia or intramucosal cancer in Barrett's oesophagus?

**Why this is important**

Patients with Barrett's oesophagus deciding on the treatment of high-grade dysplasia or intramucosal cancer need information to make an informed choice. Substantial literature exists
concerning their general information needs, but there is very little relating to the point of treatment choice.

Research is required into the delivery of information to patients who are considering ablative and excisional and other treatments for high-grade dysplasia in Barrett’s oesophagus. This should include randomised controlled trials of different methods to support shared decision-making, with a process evaluation to identify barriers and facilitators for both patients and healthcare professionals.
5 Other versions of this guideline

5.1 Full guideline

The full guideline, 'Barrett's oesophagus: Ablative therapy for the treatment of Barrett's oesophagus', contains details of the methods and evidence used to develop the guideline.

5.2 Information for the public

NICE has produced information for the public explaining this guideline.

We encourage NHS and voluntary sector organisations to use text from this information in their own materials about Barrett's oesophagus.
6 Related NICE guidance

Published

- Endoscopic submucosal dissection (ESD) of oesophageal dysplasia and neoplasia. NICE interventional procedure guidance 355 (2010).

- Photodynamic therapy for Barrett's oesophagus. NICE interventional procedure guidance 350 (2010).

- Epithelial radiofrequency ablation for Barrett's oesophagus. NICE interventional procedure guidance 344 (2010).


7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations. Please see our website for information about updating the guideline.
Appendix A: The Guideline Development Group and the Short Clinical Guidelines Technical Team

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A short clinical guidelines technical team was responsible for this guideline throughout its development. It prepared information for the Guideline Development Group, drafted the guideline and responded to consultation comments. The following NICE employees made up the technical team for this guideline.

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The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

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About this guideline

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

The guideline was developed by the Short Clinical Guidelines Technical Team. The team worked with a group of healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, who reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in The guidelines manual. This guideline was developed using the short clinical guideline process.

We have produced information for the public explaining this guideline. Tools to help you put the guideline into practice and information about the evidence it is based on are also available.

Changes after publication

20 December 2011: Layout changed to match other NICE guidelines.

May 2013: Minor maintenance.

Your responsibility

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, 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, and informed by the summary of product characteristics of any drugs they are considering.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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