NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Barrett's oesophagus: ablative therapy for the treatment of Barrett's oesophagus

1.1 Short title

Barrett's oesophagus – ablative therapy

2 The remit

The Department of Health has asked NICE: "To prepare a short clinical guideline on ablative therapy for the treatment of Barrett's oesophagus."

3 Clinical need for the guideline

3.1 Epidemiology

a) Barrett's oesophagus is an acquired condition that develops as a consequence of chronic gastro-oesophageal reflux. It is common, being found in 15–20% of people undergoing upper gastrointestinal endoscopy for symptoms of chronic gastro-oesophageal reflux. The condition is characterised by the replacement of the normal cells that make up the mucus membrane (squamous mucosa) in the lower oesophagus with column-like cells (columnar mucosa). It is identified through endoscopy and confirmed by a microscopic examination of the cells that shows a columnar-lined oesophagus. Barrett's oesophagus progresses from no dysplasia to low-grade dysplasia to high-grade dysplasia.

b) Barrett's oesophagus is considered to be a major risk factor for adenocarcinoma of the oesophagus. The incidence of oesophageal

adenocarcinoma has increased considerably over the past two decades; it now represents up to 79% of all oesophageal malignancies. Oesophageal cancer has a poor overall 5-year survival rate of around 9%, a level that has not significantly improved over the past decade.

3.2 Current practice

a) Because Barrett's oesophagus is associated with an increased risk of adenocarcinoma of the oesophagus, surveillance endoscopy has been used in people with Barrett's oesophagus with the aim of detecting high-grade dysplasia or early cancer in order to offer earlier treatment. Traditional treatment has been surgical, with oesophagectomy (removal of the oesophagus) if high-grade dysplasia or adenocarcinoma is detected. Oesophagectomy is associated with significant mortality and morbidity. Less invasive surgical techniques, including endoscopic mucosal resection (EMR), have been developed. Other treatments, known as ablative therapies, have also been developed; these destroy the abnormal cells without the need to remove the whole oesophagus. There are also ongoing trials on the use of preventive drugs, using proton pump inhibitors and aspirin to reduce the development of oesophageal cancer.

b) Ablative therapy destroys the abnormal cells of the Barrett's oesophagus, and the cells grow back as normal squamous cells. Ablation is used in conjunction with acid suppression, usually with proton-pump inhibitors. Residual columnar cells have been reported occurring beneath the squamous re-growth, so ablation therapy aims to destroy the abnormal cells to a depth that eliminates the deeper columnar mucosal cells as well as the surface layer, without causing excess damage to the underlying muscle or surrounding tissue. Ablative therapies currently in use include: argon plasma coagulation (APC), photodynamic therapy (PDT), laser ablation, cryotherapy, multipolar electrocoagulation

(MPEC), and radiofrequency ablation (RFA). Because these therapies are designed to cause destruction of the Barrett's oesophagus tissue, the balance needs to be achieved between destroying the abnormal cells to a sufficient depth to ensure ablation while minimising adverse effects (such as narrowing of the oesophagus) and allowing cell re-growth. There is uncertainty as to whether: a) ablative therapy for Barrett's oesophagus is both clinically and cost effective compared with other management options for Barrett's oesophagus; b) any one of the ablative therapies is more clinically and cost effective than other ablative therapies. Furthermore the long-term benefits and harms of treatment need to be established.

c) There is currently no evidence-based guideline available in England, Wales and Northern Ireland that addresses ablative therapy for the treatment of Barrett's oesophagus.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

a) Adults (age 18 and older) with a diagnosis of Barrett's oesophagus with high-grade dysplasia or with intramucosal cancer.

4.1.2 Groups that will not be covered

a) Children (younger than 18).

b) Adults with a diagnosis of Barrett's oesophagus with no dysplasia or with low-grade dysplasia.

c) Adults with other gastrointestinal conditions, including gastro-oesophageal reflux disease.

4.2 Healthcare setting

a) Secondary care.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) The clinical and cost effectiveness of ablative therapy for Barrett's oesophagus compared with the following management options:

- oesophageal surgery
- endoscopic mucosal resection
- surveillance and proton-pump inhibitors.

b) The clinical and cost effectiveness of the following individual ablative therapies compared with other ablative therapies:

- argon plasma coagulation (APC)
- photodynamic therapy (PDT)[1]
- laser ablation
- multipolar electrocoagulation (MPEC)
- radiofrequency ablation (RFA) [1].

c) The depth of tissue destruction needed for ablation to be effective.

[1] These two therapies are currently covered by NICE interventional procedure guidance under 'special arrangements'; they will be covered by this guideline only if the status changes to 'normal arrangements' during guideline development.

d) The information and support needs of patients undergoing or considering undergoing ablative therapy.

4.3.2 Clinical issues that will not be covered

a) Diagnosis and assessment of Barrett's oesophagus.

b) Other forms of management for Barrett's oesophagus, including oesophageal surgery, unless they are being used as comparators for the ablative therapies.

c) Diagnosis and treatment of gastro-oesophageal reflux disease.

d) Treatment of dyspepsia.

4.4 Main outcomes

a) Risk of progression to oesophageal adenocarcinoma in people who have had ablative therapy for Barrett's oesophagus.

b) Risk of recurrence of Barrett's oesophagus, including the development of high-grade dysplasia, after ablative therapy.

c) Reported adverse effects of ablative therapy, immediate and long term.

d) Health related quality of life.

e) Resource use and costs.

4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and costs will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see section 6, 'Further information').

4.6 Status

4.6.1 Scope

This is the final scope.

4.6.2 Timing

The development of the guideline recommendations will begin in June 2009.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be updated

None.

5.1.2 NICE guidance to be incorporated

- Circumferential epithelial radiofrequency ablation for Barrett's oesophagus. NICE interventional procedure guidance 244 (2007). Available from www.nice.org.uk/IPG244
- Photodynamic therapy for high-grade dysplasia in Barrett's oesophagus. NICE interventional procedure guidance 82 (2004). Available from www.nice.org.uk/IPG82

5.1.3 Other related NICE guidance

- Endoscopic augmentation of the lower oesophageal sphincter using hydrogel implants for the treatment of gastro-oesophageal reflux disease. NICE interventional procedure guidance 222 (2007). Available from www.nice.org.uk/IPG222
- Photodynamic therapy for early oesophageal cancer. NICE interventional procedure guidance 200 (2006). Available from www.nice.org.uk/IPG200
- Thoracoscopically assisted oesophagectomy. NICE interventional procedure guidance 189 (2006). Available from www.nice.org.uk/IPG189

- Endoluminal gastroplication for gastro-oesophageal reflux disease. NICE interventional procedure guidance 115 (2005) Available from www.nice.org.uk/IPG115
- Endoscopic injection of bulking agents for gastro-oesophageal reflux disease. NICE interventional procedure guidance 55 (2004). Available from www.nice.org.uk/IPG55
- Dyspepsia. NICE clinical guideline 17 (2004). Available from www.nice.org.uk/CG17

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website).

- Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease. NICE interventional procedure guidance. Publication expected March 2009.

6 Further information

Information on the guideline development process is provided in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders' the public and the NHS'
- 'The guidelines manual'.

These are available from the NICE website (www.nice.org.uk/guidelinesmanual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).