NICE guidance

Photodynamic therapy for Barrett's oesophagus

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg350

1 Guidance

This guidance replaces the previous guidance on Photodynamic therapy for Barrett's oesophagus, 82, August 2004.

1.1 Current evidence on the efficacy of photodynamic therapy (PDT) for patients with Barrett's oesophagus with high-grade dysplasia (HGD) is adequate, provided that patients are followed up in the long term. There are no major safety concerns, although there is a risk of oesophageal stricture, and photosensitivity reactions are common. This procedure may be used in patients with Barrett's oesophagus with HGD provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Current evidence on the efficacy and safety of PDT in patients with Barrett's oesophagus with either low-grade dysplasia (LGD) or no dysplasia is inadequate in quality and quantity, and the balance of risks and benefits is not clear. Therefore, for these patients, the procedure

should be used only with special arrangements for clinical governance, consent and audit or research.

1.3 Clinicians wishing to undertake PDT in patients with Barrett's oesophagus with either LGD or no dysplasia should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
- Audit and review clinical outcomes of patients with Barrett's oesophagus other than HGD having PDT (see section 3.1).

1.4 Patient selection should be carried out by a multidisciplinary team experienced in the management of the condition.

1.5 PDT for Barrett's oesophagus should only be carried out by endoscopists with specific training in this procedure.

2 The procedure

2.1 Indications and current treatments

2.1.1 Barrett's oesophagus is characterised by abnormal epithelium of the oesophagus. In some patients metaplasia and dysplasia could progress to oesophageal adenocarcinoma.

2.1.2 Cancer risk is higher for patients who have Barrett's oesophagus with HGD (some of whom may already have developed early-stage cancer) than for those with LGD or no dysplasia. Patients with HGD are usually offered oesophagectomy, or frequent endoscopic surveillance and re-biopsy (to detect neoplastic changes early) followed by oesophagectomy. Endoscopic treatments aiming to remove or ablate abnormal epithelium include endoscopic mucosal resection and different

ablative treatments.

2.1.3 Patients with LGD or no dysplasia are usually offered regular endoscopic surveillance and re-biopsy (with the aim of detecting potential progression to HGD or cancer).

2.2 Outline of the procedure

2.2.1 PDT is carried out as an inpatient procedure, with the patient under intravenous sedation. A photosensitising agent is injected intravenously and is activated by illuminating the selected area with a laser inserted into the oesophagus. The photosensitising agent absorbs the light and forms high-energy oxygen molecules that cause necrosis of the Barrett's epithelium through a photochemical effect. For extensive Barrett's oesophagus, more than 1 treatment session may be required.

2.2.2 Patients are advised to avoid exposure to bright light and direct sunlight for several weeks after the procedure to minimise risk of photosensitivity reactions.

> Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 A randomised controlled trial (RCT) of 208 patients with HGD treated by PDT and omeprazole or omeprazole alone reported absence of HGD in 75% (104/138) and 36% (25/70) of patients respectively at 18-month follow-up ($p < 0.0001$) and in 48% and 4% of patients at 5-year follow-up ($p < 0.0001$).

2.3.2 An RCT of 72 patients without dysplasia treated by PDT or argon plasma coagulation (APC) reported complete response (reversal of columnar to squamous epithelium) in 50% (17/34) and 97% (33/34) of patients respectively at 12-month follow-up ($p < 0.0001$).

2.3.3 The RCT of 208 patients treated by PDT and omeprazole or omeprazole alone reported adenocarcinoma development in 15% (21/138) and 29% (20/70) of patients respectively during 5-year follow-up.

2.3.4 The Specialist Advisers listed key efficacy outcomes as reversal of dysplasia and metaplasia, and prevention of progression to adenocarcinoma.

2.4 Safety

2.4.1 One patient died 3 days after PDT treatment, with transmural oesophageal necrosis without perforation, in an RCT of 40 patients (13 with single-dose PDT vs 13 with two-dose PDT vs 14 with APC).

2.4.2 Oesophageal stricture was reported in 36% (49/138), 3% (1/34), 33% (20/60), 15% (2/13), and 27% (35/131) of patients treated by PDT in RCTs of 208, 72, 60, 26 and a non-randomised controlled trial of 199 patients respectively. Most were treated successfully with dilatation but 2 patients had perforation requiring oesophagectomy, as a result of dilatation.

2.4.3 Dysphagia was reported in 19% (absolute figures not stated) of patients treated by PDT in the RCT of 208 patients (symptom timing not stated).

2.4.4 Photosensitivity reactions within 90 days occurred in 69% of patients in the PDT arm of the RCT of 208 patients (absolute figures not stated). Photosensitivity reactions occurred in 15% (5/34) and 15% (2/13) of patients in RCTs of 72 and 26 patients respectively, and in 60% (77/129) of patients in the non-randomised controlled trial of 199 patients.

2.4.5 In the RCT of 72 patients treated by PDT or APC, buried glands were reported in 24% (4/17) and 21% (7/33) of patients respectively (difference reported as 'not-significant').

2.4.6 Specialist Advisers listed anecdotal adverse events as pain and inflammation, ulceration and severe hypotension after PDT with 5-aminolevulinic acid. They considered theoretical adverse events to include decompensation in patients with cirrhosis of the liver, and skin

and retinal damage due to photosensitisation.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure for LGD or no dysplasia make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

3.2 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Other NICE recommendations on photodynamic therapy

Further recommendations have been made as part of the clinical guideline on Barrett's oesophagus - ablative therapy published in August 2010, as follows:

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.

Clinical and cost-effectiveness evidence was reviewed in the development of this guideline which has led to this more specific recommendation. More information is available.

The IP guidance on photodynamic therapy for Barrett's oesophagus remains current, and should be read in conjunction with the clinical guideline.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It updates and replaces NICE interventional procedure guidance 82.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

4 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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 which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation