

Photodynamic therapy for early-stage oesophageal cancer

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg200

1 Guidance

- 1.1 Current evidence on the safety of photodynamic therapy (PDT) for early-stage oesophageal cancer appears adequate. PDT appears efficacious in reducing tumour bulk in carefully selected patients with small early-stage tumours. However, the current evidence is of poor quality and relates only to short-term outcomes; it is therefore not adequate to support the use of this procedure without special arrangements for consent, audit and clinical governance.
- 1.2 Clinicians wishing to undertake PDT for early-stage oesophageal cancer should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's [information for patients](#) ('Understanding NICE guidance') is recommended.

- Audit and review clinical outcomes of all patients having PDT for early-stage oesophageal cancer (see section 3.1).

1.3 Further research will be useful, and clinicians are encouraged to enter patients into well-designed trials and to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Oesophageal cancer is a common cancer that is increasing in incidence. The most common histological types are adenocarcinoma and squamous cell carcinoma. Oesophageal cancer may cause difficulty in swallowing (dysphagia), weight loss, hoarseness, chronic cough and chest pain. The depth of penetration of the tumour determines the tumour stage; tumours that are superficial or have penetrated only the submucosa are defined as early-stage cancer. The treatment objective in early-stage oesophageal cancer is cure.

2.1.2 Oesophagectomy (surgical removal of the oesophagus) is the most radical treatment option for early-stage oesophageal cancer. However, it is a major operation, with the potential for mortality and serious morbidity. Some patients may be reluctant to accept oesophagectomy and others may be unfit for the treatment. Selection criteria for this procedure are not well defined. Less invasive treatments include laser ablation, radiation therapy and chemotherapy.

2.2 Outline of the procedure

2.2.1 A photosensitising agent is administered by intravenous injection and is then activated by exposing the tumour to light, usually with a low-power laser introduced through an endoscope. The photosensitising agent absorbs energy from the light (a photochemical effect), forming high-energy oxygen molecules that destroy tumour cells. A number of different photosensitising agents have been used in PDT for oesophageal

cancer. Treatment can be performed on an outpatient basis and is usually done under sedation.

2.3 Efficacy

- 2.3.1 Some studies reported results for PDT as monotherapy and some for PDT in combination with other treatment modalities, making comparison of outcomes difficult.
- 2.3.2 The definition of complete response or remission varied between the studies, but it was most frequently defined as no evidence of tumour on endoscopy together with negative biopsy findings. Across case series, complete response was achieved in 37% (23/62), 75% (18/24), 81% (43/53), 97% (32/33) and 100% (18/18) of patients. However, the follow-up time varied between studies, and some patients received repeat PDT sessions. Where reported separately for subgroups, the response rate was 67% (22/33) for stage T1a tumours and 91% (20/22) for in situ squamous cell carcinomas.
- 2.3.3 In one case series, 5-year disease-specific survival was 72% in 56 patients treated with PDT monotherapy. In a case series of 38 patients, nine of whom received repeat PDT sessions, mean disease-free survival was 32 months. In another case series, 54% (13/24) of patients were alive without recurrence at a mean follow-up of 21 months. In a case series of 18 patients treated with PDT, mean overall survival was 60.5 months. Finally, in another case series of 21 patients, the mean local-progression-free survival period was 60 months. For more details, refer to the 'Sources of evidence' section.
- 2.3.4 The Specialist Advisers were divided in their opinions as to whether this procedure is established practice, or novel and of uncertain safety and efficacy.

2.4 Safety

- 2.4.1 Oesophageal stenosis or stricture following PDT occurred in 7% (3/41), 8% (2/24), 11% (2/18), 13% (5/38), 25% (6/24) and 35% (43/123) of

patients, although the photosensitising agent and type of light source varied between studies. In one case series, chronic stenosis was reported to have occurred in 4% (5/123) of patients.

- 2.4.2 Two case series each reported development of oesophagotracheal fistula following PDT in 8% of patients (2/24 and 3/38).
- 2.4.3 The most frequently reported complication reported in relation to PDT for early oesophageal cancer was skin photosensitivity, which was reported in 0% (0/24), 8% (5/62) and 13% (16/123) of patients. Where specifically reported, second-degree sunburn occurred in 3% (1/38), 5% (5/102) and 13% (3/24) of patients. However, the timing of adverse events resulting from skin photosensitivity following administration of the photosensitiser was not always recorded. For more details, refer to the 'Sources of evidence' section.
- 2.4.4 The Specialist Advisers stated that adverse events may include death, photosensitivity, strictures, acute neuropathy, chest pain, low-grade fever, oesophageal or lung perforation, nausea, atrial fibrillation, congestive heart failure, skin reaction, recurrence/progression of cancer, pleural effusion, hypotension, pneumonia, oesophagitis and haemorrhage.

2.5 Other comments

- 2.5.1 It was noted that different photosensitising agents may have different safety and efficacy profiles.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. The Institute has identified relevant audit criteria and developed an [audit tool](#) (which is for use at local discretion).

Andrew Dillon
Chief Executive
December 2006

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of photodynamic therapy (PDT) for early-stage oesophageal cancer', May 2006.

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 Changes since publication

The guidance was considered for reassessment in December 2009 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please contact us.

18 January 2012: minor maintenance.

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.

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.

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.