

# Photodynamic therapy for early-stage oesophageal cancer

## 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 (available from [www.nice.org.uk/IPG200publicinfo](http://www.nice.org.uk/IPG200publicinfo)).
- 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.

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### This guidance is written in the following context

This guidance represents the view of the Institute, which 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.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

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), available from [www.nice.org.uk/IPG200](http://www.nice.org.uk/IPG200)

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## Information for patients

The Institute has produced information describing its guidance on this procedure for patients ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from [www.nice.org.uk/IPG200publicinfo](http://www.nice.org.uk/IPG200publicinfo)

## 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.

Available from: [www.nice.org.uk/IP339overview](http://www.nice.org.uk/IP339overview)

## Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1168. 'Understanding NICE guidance' can be obtained by quoting reference number N1169.

The distribution list for this guidance is available at [www.nice.org.uk/IPG200distributionlist](http://www.nice.org.uk/IPG200distributionlist)

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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