

Palliative photodynamic therapy for advanced oesophageal cancer

Interventional procedures guidance

Published: 24 January 2007

www.nice.org.uk/guidance/ipg206

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of palliative photodynamic therapy (PDT) for advanced oesophageal cancer is of poor quality but appears adequate to support the use of this procedure to relieve symptoms in patients with a poor prognosis. Clinicians wishing to use this procedure should ensure that normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Palliative PDT for advanced oesophageal cancer should only be performed in specialist centres with regular experience in surgery for oesophageal cancer.

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 stage of the cancer; tumours that extend beyond the submucosa, or that have spread to other organs, are in the advanced stage. The treatment objective for such tumours is relief of symptoms, particularly dysphagia, and maintenance of quality of life.
- 2.1.2 There is a range of palliative treatment options for advanced oesophageal cancer, including external-beam radiation, chemotherapy and endoscopically administered interventions: tube or stent placement, electrocautery, plasma/laser

coagulation and brachytherapy.

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 palliative photodynamic therapy (PDT) for oesophageal cancer. Treatment can be performed on an outpatient basis and is usually done under sedation.

2.3 Efficacy

2.3.1 Most studies described patients as having advanced oesophageal cancer, although the definitions used were not always well described.

2.3.2 In a randomised controlled trial, the response rate was significantly higher after PDT (32%) than after laser ablation (20%; $p < 0.05$) at 1-month follow-up. In the same study, the complete local response rate (defined as absence of tumour at endoscopy) at 1-month follow-up was 8% (9 out of 110) in the PDT treated group and 2% (2 out of 108) in the laser-ablation group (p value not stated). In several case series, the complete response rate varied from 0% (0 out of 14) to 7% (6 out of 84) at 6 to 8 weeks' follow-up.

2.3.3 A randomised controlled trial comparing PDT with laser ablation found that there was no statistically significant difference in improvement of dysphagia between the treatments. One case series of 215 patients (85% of whom were available for evaluation) showed that PDT reduced dysphagia, measured on a 5-point scale, from a median score of 3 points at baseline to 2 points at follow-up ($p < 0.0001$). A second case series showed an improvement in mean dysphagia score on the same scale from 4 points at baseline to 2.8 points following PDT. A third case series found that 5% (4 out of 84) of patients had dysphagia to semi-liquid diet

(purée) at 6 to 8 weeks after PDT; all other patients had milder symptoms. A fourth case series reported that PDT produced a statistically significant improvement in the minimum oesophageal diameter from 6.2 mm to 11.1 mm ($p < 0.0001$).

- 2.3.4 Mean survival following PDT was reported in four studies as 4.8 months, 9.5 months, 9.7 months and 13.9 months. Where survival by stage was reported separately, mean survival varied from 12 months for patients with stage II cancer to 3.5 months for those with stage IV cancer. For more details, see the [overview](#).
- 2.3.5 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 The most common complication relating to PDT in one case series was skin photosensitivity, which occurred after 6% (19 out of 318) of treatments; second-degree sunburn was reported in one of 215 patients (<1%). Another case series of 128 patients reported no serious reactions resulting from exposure to sunlight.
- 2.4.2 A randomised controlled trial reported that the incidence of oesophageal perforation was significantly lower with PDT (1%) than with laser ablation (7%; $p < 0.05$). The rate of oesophageal perforation reported in one study was 2% (5 out of 215), and in a second case series of 128 patients there were two cases (2%) each of fistula of the trachea and fistula of the left main bronchus. Stricture following PDT was reported in 2% (5 out of 215), 3% (4 out of 128) and 7% (6 out of 84) of patients, requiring dilatation in some cases. For more details, refer to the [overview](#).
- 2.4.3 The Specialist Advisers stated that adverse events may include photosensitisation, perforation of the oesophagus or left main bronchus, worsening oesophageal motility, stricture, herpes zoster, nausea, erythema, pain, fever, pleural effusion, respiratory complications and abscess at the treatment site.

2.5 Other comments

- 2.5.1 It was noted that the available evidence only compared PDT with laser.
- 2.5.2 It was noted that the available evidence did not indicate whether patients should be re-treated with PDT if it had been previously used to treat early-stage disease.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

The Institute has produced [information for the public on this procedure](#). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

ISBN: 978-1-4731-6240-2

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).