NICE guidance

Palliative photodynamic therapy for advanced oesophageal cancer

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg206

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 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% (9/110) in the PDT treated group and 2% (2/108) in the laser-ablation group (p value not stated). In several case series, the complete response rate varied from 0% (0/14) to 7% (6/84) at 6–8 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% (4/84) of patients had dysphagia to semi-liquid diet (purée) at 6–8 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, refer to the 'Sources of evidence' section.

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% (19/318) 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% (5/215), 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% (5/215), 3% (4/128) and 7% (6/84) of patients, requiring dilatation in some cases. For more details, refer to the 'Sources of evidence' section.

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.

Andrew Dillon
Chief Executive
January 2007

3 Further information

Sources of evidence

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

'Interventional procedure overview of palliative photodynamic therapy for advanced oesophageal cancer', May 2006.

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.

4 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. Information about the evidence it is based on is also available.

Changes since publication

17 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.