



Interstitial photodynamic therapy for malignant parotid tumours

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www.nice.org.uk/guidance/ipg259

1 Guidance

- 1.1 Current evidence on the safety and efficacy of interstitial photodynamic therapy (PDT) for malignant parotid tumours is inadequate in quantity.

 Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake interstitial PDT for malignant parotid tumours should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information. In addition, the use of the Institute's <u>information for patients</u> ('Understanding NICE guidance') is recommended.

- Audit and review clinical outcomes of all patients having interstitial PDT for parotid malignancies (see section 3.1).
- 1.3 Further publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 The parotid glands are salivary glands located in front of the ears. Rarely, primary malignant tumours can develop in the parotid glands (although benign tumours are more common). Patients with malignant parotid tumours typically first present with painless, localised swelling on one side of the face.
- 2.1.2 Conventional treatment for malignant parotid tumours involves surgical excision. Superficial parotidectomy with careful dissection and preservation of the facial nerve is the most common surgical treatment. Superficial parotidectomy can also be used to establish a definitive diagnosis of the tumour. If malignancy is diagnosed, more extensive surgery may be required. Radiotherapy and chemotherapy may also be used in the treatment of malignant parotid tumours.

2.2 Outline of the procedure

2.2.1 PDT involves initial administration of a photosensitising agent by intravenous injection. A few days later, the procedure is performed under local or general anaesthetic. A number of needles are inserted into the parotid tumour, either percutaneously or transorally, with the use of ultrasound, computed tomography or magnetic resonance imaging guidance. The required number and length of the needles depend on the size and position of the tumour. A beam splitter is used to divide a primary laser beam of appropriate wavelength into a small number of optic fibres, which are passed through the needles to deliver laser light into the tumour. Light dosimetry calculations are made based on the dose of light required and the output of the laser. After the deepest

portion of the tumour has been treated, the needles and laser fibres are pulled back in 1 cm decrements, each withdrawal being followed by further illumination. The illumination of the photosensitive agent results in the formation of high-energy, cytotoxic oxygen molecules.

2.2.2 After administration of the photosensitising agent, patients need to follow a regimen of controlled re-exposure to ambient light over a period of 2 to 3 weeks.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, refer to the Sources of evidence.

2.3 Efficacy

- 2.3.1 One report described two patients with refractory parotid tumours treated with PDT. One of these patients, a 42-year-old woman with a stage T4 adenoid cystic carcinoma of the parotid gland, had a complete response to PDT at 4 weeks and was alive and well with no evidence of recurrence at 15-month follow-up. The other patient was described as responding to treatment but no additional information was provided. A second report described a single patient with a parotid tumour, who was still alive 3 years after treatment.
- 2.3.2 The Specialist Advisers considered the main efficacy outcome to be local tumour control.

2.4 Safety

- 2.4.1 No complications attributable to PDT were described for the two patients in the report (see 2.3.1).
- 2.4.2 The Specialist Advisers considered theoretical adverse events to include photosensitisation that may result in burns to non-treated areas, allergic reactions to the photosensitising agent, nerve and blood vessel damage, bleeding and delayed healing.

2.5 Other comments

2.5.1 The Committee noted that PDT may be used for patients whose parotid tumours are refractory to other forms of treatment or for those with recurrent parotid tumours.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).
- 3.2 NICE has produced interventional procedures guidance on palliative photodynamic therapy for both <u>early-stage</u> and <u>advanced</u> oesophageal cancer, <u>photodynamic therapy for high-grade dysplasia in Barrett's oesophagus</u>, <u>photodynamic therapy for localised inoperable endobronchial cancer</u>, <u>photodynamic therapy for advanced bronchial carcinoma</u>, <u>photodynamic therapy for bile duct cancer</u>, and <u>photodynamic therapy for non-melanoma skin tumours</u>.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced <u>information on this procedure for patients and carers</u> ('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 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 <u>summary of this guidance for patients and carers</u>. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

11 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 <u>Healthcare Improvement Scotland</u>.