NICE guidance

# Interstitial photodynamic therapy for malignant parotid tumours

Interventional procedures guidance
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## 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 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 NICE's information for the public 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. NICE 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 Photodynamic therapy (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, see the overview.

## 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 section 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 photodynamic therapy (PDT) for early-stage oesophageal cancer, palliative PDT for advanced oesophageal cancer, epithelial radiofrequency ablation for Barrett's oesophagus, PDT for localised inoperable endobronchial cancer, PDT for advanced bronchial carcinoma, PDT for bile duct cancer and PDT for non-melanoma skin tumours.

## Sources of evidence

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

## Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.