National Institute for Health and Clinical Excellence

Photodynamic therapy for brain tumours

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NICE interventional procedure guidance 290

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NHS Evidence has accredited the process used by the NICE Interventional Procedures Programme to produce interventional procedures guidance. Accreditation is valid for three years from January 2010 and applies to guidance produced since January 2009 using the processes described in the 'Interventional Procedures Programme: Process guide, January 2009' and the 'Interventional Procedures Programme: Methods guide, June 2007'

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Contents

1 Guidance

1.1 Current evidence on the safety and efficacy of photodynamic therapy (PDT) for brain tumours is limited in both quality and quantity. Therefore, this procedure should only be used in the context of randomised controlled trials with well-defined inclusion criteria (specifying the tumour type for inclusion in the trial) and treatment protocols, and with collection of both survival and quality of life outcomes.

2 The procedure

2.1 Indications and current treatments

2.1.1 Brain tumours may be primary tumours or metastases from tumours elsewhere in the body. Primary brain tumours are graded using a World Health Organization (WHO) classification from I (least aggressive) to IV (most aggressive). Patients with high-grade tumours often have a poor prognosis.

2.1.2 The symptoms of a brain tumour are determined by its location and size. Depending on its location in the brain, a tumour can cause limb weakness or speech disturbance. Any brain swelling caused by a tumour can result in raised intracranial pressure, which can lead to headache, vomiting and reduced consciousness.

2.1.3 Some patients can be treated by surgical resection, with the aim of reducing symptoms and improving prognosis. Non-surgical treatment options include chemotherapy and radiotherapy. A combination of these treatments may be used, or surgery may be followed by chemotherapy and radiotherapy.

2.2 Outline of the procedure

2.2.1 Photodynamic therapy is usually carried out with the patient under general anaesthesia, at the same operation as surgical resection, when as much of the tumour has been removed as possible. A photosensitising agent is injected, usually intravenously, although direct injection into the tumour is also possible. The photosensitising agent is activated by illuminating the selected area with a laser source. The photosensitising agent absorbs the light and forms high-energy oxygen molecules that interact with the brain tissue to cause tumour necrosis through a photochemical effect. Occasionally, repeated PDT sessions are performed after surgery via access maintained through the skull. To minimise the risks associated with skin photosensitivity, patients are advised to avoid exposure to bright light and direct sunlight for several weeks after the procedure.

2.2.2 This guidance refers to the therapeutic use of PDT and not to PDT-guided resection.

2.2.3 Various devices and photosensitising agents can be used for this procedure.

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 detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 A randomised controlled trial (RCT) of 27 patients with newly diagnosed glioblastoma and a Karnofsky score of 60 or greater (on a scale where 100 is 'perfect health' and 0 is 'death') reported an increase in mean survival in 13 patients who received PDT after surgery compared with 14 patients treated by surgical resection alone (52.8 weeks and 24.1 weeks respectively; $p = 0.001$). A case series of 112 patients treated by PDT following surgical resection reported median survival of 30 weeks in patients with gliomas and 24 weeks in patients with metastatic carcinoma (follow-up not stated). A case series of 136 patients treated by PDT following surgical resection reported that median survival from initial diagnosis was 76.5 months for patients with primary anaplastic astrocytoma and 14.3 months for patients with glioblastoma multiforme ($p = 0.001$), with a minimum follow-up of 3 years. Duration of survival was not associated with the location of the tumours in the brain ($p = 0.54$). A case series of 26 patients with recurrent glioblastoma (WHO grade IV) treated by PDT following surgical resection reported median survival of 8.5 months.

2.3.2 The case series of 26 patients reported that median time to disease progression was 6 months.

2.3.3 The RCT of 27 patients reported an improvement in mean Karnofsky score from 60 to 80 points in the PDT after surgery group but no change from 70 points in the surgical resection group (follow-up not stated; $p < 0.05$).

2.3.4 The Specialist Advisers considered key efficacy outcomes to include overall and progression-free survival, completeness of resection and quality of life.

2.4 Safety

2.4.1 In the case series of 112 patients, 3% (3/112) died after the operation, 1 of pulmonary embolism and 2 of tumour cavity haemorrhage. Deep vein thrombosis occurred in 4% (4/112), infection (not otherwise specified) in 4% (4/112), and cerebrospinal fluid leak in 1% (1/112) of patients (no further details stated).

2.4.2 The case series of 26 patients reported transient oedema of the treated area in 4% (1/26) of patients.

2.4.3 Across three case series, sunburn due to light exposure occurred at a rate of between 2% (2/112, 2/136) and 8% (2/26).

2.4.4 The Specialist Advisers considered adverse events associated with PDT for brain tumours to include cerebral oedema, raised intracranial pressure, hypersensitivity reactions and skin photosensitisation. They stated that additional theoretical adverse events include damage to the normal brain and cerebral blood vessels, stroke, and compromising of further treatments by increasing the sensitivity of the brain to their toxic side effects.

3 Further information

3.1 NICE has published technology appraisal guidance on temozolomide for the treatment of recurrent malignant glioma (brain cancer) and carmustine implants and temozolomide for the treatment of newly diagnosed high grade glioma, and service guidance for improving outcomes for people with brain and other central nervous system tumours.

Information for patients

NICE has produced information on this procedure for patients and carers ('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 summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

7 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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