



Transpupillary thermotherapy for age-related macular degeneration

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www.nice.org.uk/guidance/ipg58

1 Guidance

- 1.1 Current evidence on the safety and efficacy of transpupillary thermotherapy for age-related macular degeneration does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake transpupillary thermotherapy for agerelated macular degeneration should take the following action.
 - 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. Use of the Institute's information for the public is recommended.

- Audit and review clinical outcomes of all patients having transpupillary thermotherapy for age-related macular degeneration.
- Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

- 2.1.1 Age-related macular degeneration (AMD) is characterised by damage to the central part of the retina (the macula) resulting in progressive loss of central vision. Peripheral vision is not affected so individuals retain some useful vision. The prevalence of macular degeneration increases with age.
- 2.1.2 Ninety percent of people with AMD have dry (atrophic) macular degeneration, characterised by thinning of the macular retina. The other 10% have wet (exudative or neovascular) macular degeneration, characterised by the growth of abnormal new blood vessels in the choroid layer underneath the retina. These new vessels can leak fluid and cause scarring, which can threaten vision. They can be classified using fluoroscein angiography into 'classic' if they can be seen clearly and 'occult' if they cannot. Wet macular degeneration usually occurs in people who already have dry macular degeneration. Of these two conditions, wet macular degeneration progresses more quickly and vision loss is more severe.
- 2.1.3 Laser therapy is used to coagulate new vessels in wet macular degeneration. However, the procedure itself may permanently impair vision, especially if the vessels are very close to the fovea (subfoveal vessels). Recurrence is common. Laser therapy appears to work only in people with classic neovascular macular degeneration.
- 2.1.4 Other new treatments for macular degeneration include surgery to remove new vessels, radiotherapy, photodynamic therapy, and new

drugs that suppress new vessel formation (antiangiogenic drugs).

2.2 Outline of the procedure

2.2.1 Transpupillary thermotherapy uses laser energy to coagulate vessels in wet macular degeneration and is intended to alter the progression of the disease and to preserve vision. This procedure uses a lower-power, more diffuse beam than standard laser treatment. It may be used to treat patients with occult new vessels.

2.3 Efficacy

- 2.3.1 All studies identified were uncontrolled and relatively small with a mean follow-up of no greater than 10 months. The majority of patients in the studies had occult or predominantly occult subfoveal new vessels. Visual acuity improved in 0% (0/12) to 32% (9/28) of eyes and deteriorated in 9% (5/57) to 43% (12/28) of eyes in the studies identified. For more details, refer to the 'Sources of evidence' section.
- 2.3.2 A Specialist Advisor considered that optimal treatment protocols have yet to be established.

2.4 Safety

- 2.4.1 The main safety findings reported in the studies reviewed were: large submacular haemorrhage in the first 2 months, 6% (3/49 patients); postoperative haemorrhage, 5% (3/66 eyes); and macular infarction, 1% (1/77 patients). For more details, refer to the 'Sources of evidence' section.
- 2.4.2 The Specialist Advisors considered there to be a risk of unwanted thermal damage to the retina and pigment epithelium.

3 Further information

3.1 The Committee will wait for the results of the current randomised

controlled trial (TTT4CNV, co-ordinated at the New England Eye Centre, Tufts University School of Medicine, USA) and reconsider the procedure following its publication.

Andrew Dillon Chief Executive May 2004

Sources of evidence

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

'Interventional procedure overview of transpupillary thermotherapy for age-related macular degeneration', December 2002.

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 Changes since publication

The guidance was considered for reassessment in June 2007 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please contact us.

28 January 2012: minor maintenance.

5 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>. Information about the evidence it is based on is also available.

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.