

Transpupillary thermotherapy for age-related macular degeneration

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg58

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 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 age-related 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 information for the public is recommended.
 - Audit and review clinical outcomes of all patients having transpupillary thermotherapy for age-related macular degeneration.
- 1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE 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 fluorescein 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 of 12) to 32% (9 of 28) of eyes and deteriorated in 9% (5 of 57) to 43% (12 of 28) of eyes in the studies identified. For more details, refer to the [sources of evidence](#).
- 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 of 49 patients); postoperative haemorrhage, 5% (3 of 66 eyes); and macular infarction, 1% (1 of 77 patients). For more details, refer to the sources of evidence.
- 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.

Sources of evidence

The evidence considered by the interventional procedures advisory committee is described in the [overview](#).

Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Update information

Minor changes since publication

January 2012: minor maintenance.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).