Issue date: **May 2004**

NHS
National Institute for Clinical Excellence

Transpupillary thermotherapy for age-related macular degeneration

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 Institute's *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. 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.

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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 (see below).

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 (see below).

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

Information for the Public

The Institute has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available, in English and Welsh, from www.nice.org.uk/IPG058publicinfo.

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.

Available from: www.nice.org.uk/ip061overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0571. *Information for the Public* can be obtained by quoting reference number N0572 for the English version and N0573 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL www.nice.org.uk/IPG058distributionlist

Published by the National Institute for Clinical Excellence, May 2004 ISBN: 1-84257-635-6

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N0571 1P 20k May 04 (HOBBS)