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National Institute for Clinical Excellence

Radiotherapy for age-related macular degeneration

1 Guidance

1.1 Current evidence shows radiotherapy for age-related macular degeneration to have little efficacy. There are also concerns about its safety. It is suitable for use only within good quality research studies approved by a research ethics committee, specifying the dose of radiation used and with explicit patient consent. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute is not undertaking further investigation at present.

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 age-related macular degeneration 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. The vessels 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. Recurrence is common. Standard 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, macular translocation, photodynamic therapy and new drugs that suppress new vessel formation (antiangiogenic drugs).

2.2 Outline of the procedure

2.2.1 This procedure involves the use of radiotherapy to destroy the new vessels formed in patients with wet neovascular AMD. The beam of radiotherapy is angled to avoid damage to the optic nerve and structures in the other eye.

2.3 Efficacy

2.3.1 Three randomised controlled trials (RCTs) reported radiotherapy as having no significant benefit on visual acuity when compared with sham treatment or observation. Two RCTs found that radiotherapy reduced loss of visual acuity when compared with very low dose (effectively sham) radiation or observation

Interventional Procedure Guidance 49

only. However, the dose of radiation used varied among the studies, ranging from 2 Gy to 20 Gy. For more details, refer to the Sources of evidence (see below).

2.3.2 The Specialist Advisors considered trials to have shown little or no benefit from using radiotherapy, and that any effect was likely to be modest. One Specialist Advisor also noted that all patients in the UK being treated with this procedure were enrolled in clinical trials.

2.4 Safety

2.4.1 In the RCTs identified, the main complication reported was cataract which ranged from 2% (1/51 eyes) to 67% (28/42 eyes). Other potentially serious complications reported were: vitreous haemorrhage (1/42 eyes) and retinal detachment (1/42 eyes). For more details, refer to the Sources of evidence (see below).

2.4.2 One Specialist Advisor considered the main safety concerns of this procedure to be radiation retinopathy, dry eyes and cataract.

2.5 Other comments

2.5.1 Current evidence does not show the procedure to be efficacious.

2.5.2 The efficacy of this procedure may be related to the dose of radiation administered, but there is insufficient evidence to support this hypothesis.

3 Further information

3.1 The Institute has issued guidance on the use of photodynamic therapy for age-related macular degeneration (www.nice.org.uk/pdf68_PDTGuidance.pdf) and macular translocation for age-related macular degeneration (www.nice.org.uk/IPG048guidance).

Andrew Dillon
Chief Executive
March 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/IPG049publicinfo.

Sources of evidence

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

Interventional procedure overview of radiotherapy for macular degeneration, December 2002.

Available from: www.nice.org.uk/IP081overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0490. *Information for the Public* can be obtained by quoting reference number N0491 for the English version and N0492 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/IPG049distributionlist

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