Radiotherapy for age-related macular degeneration

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg49

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. However, 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.

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.

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 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 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 section.

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 section.

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 and macular translocation for age-related macular degeneration (replaced by NICE interventional procedure guidance 339, 'Limited macular translocation for wet age-related macular degeneration', and interventional procedure guidance 340, 'Macular translocation with 360° retinotomy for wet age related macular degeneration')

Andrew Dillon
Chief Executive
March 2004

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.

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 Changes since publication

The guidance was considered for reassessment in January 2011 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 summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.