

Epiretinal brachytherapy for wet age-related macular degeneration

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg415

1 Guidance

- 1.1 Current evidence on the efficacy of epiretinal brachytherapy for wet age-related macular degeneration (AMD) is inadequate and limited to small numbers of patients. With regard to safety, vitrectomy has well-recognised complications and there is a possibility of subsequent radiation retinopathy. Therefore this procedure should only be used in the context of research. Research studies should address whether epiretinal brachytherapy reduces the progression of wet AMD and whether it can reduce the number of injections of anti-vascular endothelial growth factor agents (anti-VEGF) required. Long-term outcomes should be reported.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 AMD is the most common cause of blindness in developed countries. A proportion of patients with AMD have wet AMD. Wet AMD is characterised by the abnormal growth of blood vessels in the choroid layer underneath the macular part of the retina. These vessels can threaten vision if they leak and cause scarring.
- 2.1.2 Current treatments for wet AMD include laser photocoagulation, photodynamic therapy and intravitreal injections of anti-VEGFs. Patients with advanced disease may benefit from optical aids such as magnifying glasses, eccentric viewing training and implantation of miniature lens systems.

2.2 Outline of the procedure

- 2.2.1 Epiretinal brachytherapy for wet AMD aims to slow down the growth of blood vessels that cause wet AMD by administering beta radiation therapy targeted at the abnormal, leaking vessels.
- 2.2.2 The procedure is usually carried out with the patient under local anaesthesia, and is normally used in combination with an anti-VEGF agent. A vitrectomy is performed, and an intraocular epiretinal probe is placed in the vitreous cavity, over the fovea. Beta radiation is delivered by the probe. The radiation dose received by the patient is less than the dose received during a typical chest X-ray. The sclera is closed with an absorbable suture and the eye is patched. Prophylactic antibiotics and steroids are usually administered.
- 2.2.3 A number of different devices are available for this procedure.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#)

2.3 Efficacy

- 2.3.1 A case series of 34 patients treated by epiretinal brachytherapy (concomitant treatment not described) reported that 63% and 50% of patients receiving 24 Gy and 15 Gy of radiation respectively gained 1 or more letters of visual acuity at 12-month follow-up (absolute figures not given). In the same study, visual acuity improved by more than 15 letters in 21% and 0% of patients respectively (absolute figures not given).
- 2.3.2 A different case series of 34 patients treated by epiretinal brachytherapy plus anti-VEGF injections reported a gain of 8.9 letters in best-corrected visual acuity after the procedure; 38% (13/34) of patients demonstrated a clinically significant improvement of 3 lines or more at a median follow-up of 12 months. At 36-month follow-up, the mean change in visual acuity was a gain of 3.9 letters (n = 19); 21% (4/19) of patients had gained 15 letters or more.
- 2.3.3 The Specialist Advisers listed key efficacy outcomes as retention of visual acuity, number of anti-VEGF injections required, and time to recurrence of AMD.

2.4 Safety

- 2.4.1 The case series of 34 patients treated by epiretinal brachytherapy plus anti-VEGF injections reported that 25% (6/24), 50% (12/24) and 54% (7/13) of phakic eye patients developed cataracts at follow-up periods of 12, 24 and 36 months.
- 2.4.2 The case series of 34 patients treated by epiretinal brachytherapy alone reported that there were no radiation-induced toxicity adverse events at 12-month follow-up. The other case series of 34 patients, treated by epiretinal brachytherapy plus intravitreal VEGF therapy, reported non-

proliferative radiation retinopathy in 1 patient at 36-month follow-up. These changes were not considered to have an adverse effect on visual acuity.

2.4.3 Retinal tear was reported in 6% (2/34) and 3% (1/34) of patients in the 2 case series.

2.4.4 The case series of 34 patients treated by epiretinal brachytherapy plus anti-VEGF injections reported raised intraocular pressure in 6% (2/34) of patients (follow-up not stated).

2.4.5 The Specialist Advisers listed anecdotal or reported adverse events as cataract formation, retinal haemorrhage, retinal detachment, infective endophthalmitis, and radiation retinopathy. They considered theoretical adverse events to include radiation optic neuropathy and radiation-induced malignancy.

2.5 Other comments

2.5.1 The Committee noted that a number of controlled clinical trials are currently in progress.

3 Further information

3.1 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('[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.

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 procedures guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

Changes after publication

May 2012: minor maintenance

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](#).

Accreditation

