

Epiretinal brachytherapy for wet age-related macular degeneration

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg415

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 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 Age-related macular degeneration (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-vascular endothelial growth factor agents (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.

2.3 Efficacy

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](#).

- 2.3.1 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 out of 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 out of 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 out of 24), 50% (12 out of 24) and 54% (7 out of 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 out of 34) and 3% (1 out of 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 out of 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

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

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

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Endorsing organisation

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