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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating wet age-related macular degeneration (AMD) using localised radiotherapy

NICE 'HealthTech guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how a type of localised radiotherapy called brachytherapy can be used in the NHS to treat people with wet AMD. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe wet AMD or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 6.

What has NICE said?

Currently there is not enough evidence about how well this procedure works, and the available evidence is limited to small numbers of patients. There are well-recognised complications and a possible risk of damage to the retina (the light-sensitive area at the back of the eye) as a result of exposure to radiation.

For these reasons, NICE has said that this procedure should only be carried out as part of a research study (also called a clinical trial). The research should look at whether the procedure slows the progression of wet AMD and whether it can reduce the need for other treatments. Research should also look at long-term results.

Other comments from NICE

There are a number of clinical trials in progress.

Treating wet AMD using localised radiotherapy

This procedure may not be the only possible treatment for wet AMD. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The medical name for this procedure is 'epiretinal brachytherapy for wet age-related macular degeneration'.

The procedure is not described in detail here – please talk to your specialist for a full description.

In the eye, the retina covers the inside of the back wall of the eyeball and is the layer of cells responsible for creating vision. Macular degeneration affects the area of the retina responsible for detailed vision (the macula). Because degeneration usually occurs in older people it is also known as 'age-related macular degeneration' or 'AMD'. There are two types – 'dry' and 'wet'. The wet form is caused by bleeding at the back of the eye from new blood vessel growth, and the loss of vision can be quicker than the dry form.

Current treatments for wet AMD include laser treatment, photodynamic therapy and injections of drugs called antivascular endothelial growth factors (anti-VEGFs), which work by blocking a substance that causes new blood vessels to grow in the eye. For people who have advanced AMD, magnifying glasses, eye exercises called ‘eccentric viewing training’, and implanting artificial lenses can also be useful.

This procedure aims to slow down the growth of blood vessels that cause wet AMD by treating the abnormal, leaking blood vessels with radiation. The procedure is usually carried out with the patient under local anaesthesia, and anti-VEGF treatment is usually given at the same time. The surgeon first makes tiny incisions in the white of the eyeball to remove the vitreous humour, which is the clear jelly-like fluid from the inside of the eye. This procedure is called a vitrectomy. A probe is inserted into the eyeball, and moved into the correct position. Radiation is then delivered through the probe. The radiation dose is less than that received during a typical chest X-ray. After the procedure absorbable stitches are used and an eye patch applied. Antibiotics and steroids are usually given to prevent infection and inflammation.

What does this mean for me?

Your doctor can only offer you this procedure as part of a research study (also called a clinical trial).

NICE has recommended that some details should be collected about every patient who has this procedure in the UK. Your doctor may ask you if details of your procedure can be used in this way. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Summary of possible benefits and risks

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at two studies on this procedure.

How well does the procedure work?

In one study 34 patients were treated with one of two different doses of radiation and their sight was tested after a year. Fifty per cent who had the lower dose and 63% who had the higher dose had clearer vision (they could see 1 or more letters better in an eye test). In patients treated with the higher dose, 21% had vision that improved by more than 15 letters. No patients treated with the lower dose had this much improvement.

In another study, 34 patients were treated with the procedure and anti-VEGF injections. After having the procedure their vision improved by 8.9 letters in the eye test. In 13 of these patients, vision improved substantially – by 3 or more lines on the eye test. After 36 months, in 19 patients vision had improved by 3.9 letters on average, and in 4 of these patients vision had improved by 15 letters or more.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the main success factors were retaining clear vision, the number of anti-VEGF injections needed, and how long it takes for AMD to come back.

Risks and possible problems

In the first study of 34 patients treated with the procedure and anti-VEGF injections, cataracts developed in 25% of patients after 12 months, in 50% of patients after 24 months and in 54% of patients after 36 months. 1 patient had radiation-related damage to the retina,

seen after 36 months. This did not have an effect on the patient's vision, and had not worsened 43 months after the procedure.

In the other study of 34 patients treated with the procedure alone, 1 year after the procedure none of the patients treated had any side effects as a result of the radiation treatment.

Three patients out of a total of 68 patients in the two studies had a tear in their retina.

Two patients out of 34 treated with the procedure and anti-VEGF injections had raised pressure inside their eye, which can be a risk factor for glaucoma.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that cataracts, bleeding inside the eye, the retina becoming detached, infection, and damage to the retina caused by the radiation treatment are all possible problems. In theory, other problems could include cancer and damage to the optic nerve caused by the radiation treatment.

More information about wet AMD

NHS Choices may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on AMD, visit the NICE website.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. HealthTech guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'epiretinal brachytherapy for wet age-related macular degeneration'. This leaflet and the full guidance aimed at healthcare professionals are available at http://guidance.nice.org.uk/HTG279

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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