

Retrobulbar irradiation for thyroid eye disease

Interventional procedures guidance

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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 Recommendations

- 1.1 Current evidence on the safety and efficacy of retrobulbar irradiation for thyroid eye disease appears adequate to support the use of this procedure in patients for whom other treatments are inadequate or associated with significant side effects. Normal arrangements should be in place for consent, audit and clinical governance.
- 1.2 Patient selection should be made with the involvement of a multidisciplinary team that includes an ophthalmologist, a clinical oncologist and an endocrinologist.

2 The procedure

2.1 Indications

- 2.1.1 Thyroid eye disease (also known as dysthyroid eye disease, Graves' eye disease, Graves' ophthalmopathy and thyroid orbitopathy) affects the extraocular muscles and other orbital tissues. It is the most common cause of unilateral or bilateral proptosis in adults, due to enlarged eye muscles and an increase in the fatty tissue behind the eyes.
- 2.1.2 Other symptoms include diplopia, soreness and grittiness of the eyes, with increased watering and photophobia. Most patients have mild symptoms that are controlled by conservative means. In patients with more severe disease, the eyelids may not close properly and this can result in corneal exposure and ulceration. In addition, the increased orbital tissue may cause optic nerve compression with resultant damage to sight.

- 2.1.3 Steroid medication is the most commonly used treatment for thyroid eye disease. This decreases inflammation in the eye muscles and orbital tissue. Often, high-dose systemic corticosteroids are required, but these have significant side effects. If active eye disease recurs after treatment, other therapeutic options may need to be considered.
- 2.1.4 Surgical orbital decompression aims to relieve severe pressure on the optic nerve. Various surgical procedures may be used to make room in the eye socket for the swollen and thickened orbital tissue. This allows the bulging eyeball to return to its normal position.
- 2.1.5 Radiation therapy targeted at the tissue behind the eyeball aims to decrease orbital inflammation. It may be used alone or in combination with steroids.

2.2 Outline of the procedure

- 2.2.1 Patients are commonly treated on an outpatient basis. The patient is placed in a supine position, and the head fixed with a full head shell. Irradiation is targeted at the retrobulbar contents of the orbit, delivered in about 10 sessions over a 2-week period.

2.3 Efficacy

- 2.3.1 A randomised controlled trial of irradiation versus sham therapy in 88 patients with mild, untreated thyroid eye disease found a greater response rate with irradiation, using a composite outcome measure of eye function and physical properties ($p=0.02$, 52% versus 27%).
- 2.3.2 In a randomised controlled trial of 60 patients, improvement in eye motility was achieved in 82% of patients (14 of 17) following irradiation, and in 27% of patients (4 of 15) following sham therapy ($p=0.004$). At 24 weeks, mean eye elevation was improved by 4.9° more in the patients treated with irradiation ($p=0.01$). There were no significant differences in proptosis or eyelid swelling between the study arms.

- 2.3.3 When irradiation was compared with prednisolone in a randomised controlled trial, there were no significant differences in eye function between the treatment arms, as measured by proptosis, visual acuity or eyelid aperture size. Self-reported eye-evaluation scores were also similar at 24 weeks.
- 2.3.4 A randomised cross-over trial of 42 patients, with either the left or the right eye treated first, found no significant differences between eyes treated with irradiation and those receiving sham treatment in the outcomes of muscle volume and proptosis at 3 months following treatment. For more details, refer to the [sources of evidence](#).
- 2.3.5 The specialist advisors noted that efficacy was hard to assess because of the natural history of the condition.

2.4 Safety

- 2.4.1 Two case series with long-term follow-up of 7.2 and 11 years recorded the incidence of cataracts to be 10% and 11% (22 of 197 and 21 of 204), and reported retinopathy in 1% (2 of 197 and 2 of 204) of patients. One series found tumours in 5% of patients (10 of 197) treated with irradiation but none of these were in the area treated. Another case series found no malignant tumours in the head or neck in 157 patients followed up for a median 11 years. Mucosal thickening or polyps in the paranasal tissue were recorded in 34% (53 of 157) of patients followed up by CT scans. For more details, refer to the sources of evidence.
- 2.4.2 The specialist advisors noted that theoretical adverse events include short-term exacerbation of thyroid eye disease, dry eye, cataract, retinopathy (particularly in diabetic patients) and carcinogenesis.

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 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 Update information

Minor changes since publication

January 2012: Minor maintenance.

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Endorsing organisation

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