NICE guidance

Implantation of an opaque intraocular lens for intractable double vision

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 Guidance

1.1 Implantation of an opaque intraocular lens (IOL) for intractable double vision is technically similar to standard cataract surgery. It is indicated only in highly selected patients. In this context the evidence on safety and efficacy, which is limited to a small number of patients, appears adequate for the procedure to be used provided that normal arrangements are in place for clinical governance and audit.

1.2 During the consent process clinicians wishing to undertake implantation of an opaque IOL for intractable double vision should take the following actions:

- Ensure that patients and their carers understand that the removal of the natural lens required for this procedure is irreversible. If removal of the implanted opaque IOL were ever required, then damage to ocular structures would be a risk. They should provide them with clear information. In addition, the use of NICE's information for the public is recommended.

1.3 Patients should only be offered implantation of an opaque IOL when all alternative treatment options for their double vision have proved inadequate.

2 The procedure

2.1 Indications and current treatments

2.1.1 Double vision (also known as diplopia) occurs when a person sees two images of a single object instead of one. It most commonly results from the eyes pointing in different directions. Binocular double vision may be caused by disorders affecting the eye muscles or other conditions such as brain tumours, diabetes, thyroid disease or severe head injury. This form of double vision may stop if either eye is covered. Occasionally, people may have monocular double vision (one eye only), which is usually caused by a type of cataract. The procedure described in this guidance is not used for monocular double vision.

2.1.2 Treatment of binocular double vision depends on its underlying cause and prognosis. It may include wearing a patch over one eye, use of filters on spectacles, use of an opaque contact lens in one eye, eye muscle botulinum toxin injection or eye muscle surgery. Some patients, particularly children, may be able to ignore the double vision.

2.2 Outline of the procedure

2.2.1 Implantation of an opaque lens for intractable double vision is carried out with the patient under local or general anaesthesia. Two different techniques can be used. One technique involves removal of the natural lens by phacoemulsification or extracapsular surgery (to extract the lens in fragments or in one piece, respectively, similar to standard cataract surgery). An opaque intraocular lens (IOL) is then inserted through the corneal incision and placed in the capsular bag or sulcus (cleft). In the alternative technique, a specially manufactured tinted IOL, called an iris claw lens, is surgically attached to the iris in the anterior chamber of the eye. The lens has a claw-like mechanism that attaches to the iris tissue by pinching it. Using this technique, the eye's natural lens is kept in place.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 In a case series of 12 patients, the mean visual function score after implantation of an opaque IOL was 92 (measured by the 14-item Visual Function scale [0 to 100 from maximum disability to no disability]) at a mean follow-up of 21 months (preoperative score not measured). One patient in the case series of 12 patients reported persistence of double vision that resolved with medical treatment. Case reports of six patients, including two patients with intractable double vision, stated that all patients had improved symptoms (not otherwise stated) after opaque IOL implantation at a mean follow-up of 14 months. Case reports of two patients described improvement in double vision in both patients after implantation of an opaque IOL (duration of follow-up not stated). In a case report of one patient, double vision resolved completely after implantation of an opaque IOL and a good result was reported to be maintained at 14-year follow-up.

2.3.2 The case series of 12 patients reported that mean patient satisfaction score following the procedure was 3.4 (on a scale ranging from 0 [unhappy] to 4 [very satisfied]).

2.3.3 The Specialist Advisers considered the key efficacy outcomes to be eradication of or improvement in symptoms of diplopia without discomfort to the eye. They stated that there were no concerns about the efficacy of the procedure.

2.4 Safety

2.4.1 In the case series of 12 patients, one IOL broke during insertion; another IOL was successfully implanted into the eye 6 months later (mean follow-up 21 months).

2.4.2 The case series of six patients reported mild IOL subluxation (partial dislocation of the lens) in one patient with leukocoria (time of occurrence not stated). However, this did not adversely affect patient satisfaction.

2.4.3 The Specialist Advisers stated that there is concern about the blocking of vision in a functioning eye, since development of a sight-threatening condition in the other eye would leave the patient with impaired vision, and it is difficult to reverse the procedure. They considered theoretical adverse events to include failure to recognise pathology (such as a malignant tumour) in the implanted eye because the fundus is obscured from examination by the opaque lens, dislocation of the opaque lens and raised intraocular pressure. They considered that an iris claw IOL presents a theoretical risk of damage to the natural lens of the eye.

3 Further information

3.1 NICE has published interventional procedures guidance on implantation of accommodating intraocular lens (IOLs) during cataract surgery.

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.