NICE guidance

Insertion of hydrogel keratoprosthesis

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg69

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 safety and efficacy of insertion of hydrogel keratoprosthesis does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to undertake insertion of hydrogel keratoprosthesis should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having insertion of hydrogel keratoprosthesis.

1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty.

1.4 The manufacturer of the synthetic hydrogel cornea implant used in this procedure maintains a registry [link broken, Feb2012]. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 The cornea is the transparent part of the coating of the eyeball, that covers the iris and pupil and admits light to the interior of the eye. Injury or disease of the cornea can make it opaque, hindering the passage of light and resulting in loss of vision. Diseases that can cause the cornea to deteriorate include keratoconus, bullous keratopathy and herpetic eye disease.

2.1.2 A corneal transplant is the standard treatment when the cornea becomes damaged by injury or disease. This procedure involves the removal of a disc comprising the majority of the cornea using a trephine, and replacing it with a corresponding disc from the cornea of a donor eye. In penetrating keratoplasty, a disc the entire thickness of the cornea is removed and replaced with a disc of equivalent thickness. Some patients cannot undergo the standard procedure using donor tissue for several reasons, such as disease severity, severe involvement of the conjunctiva, objection to the use of donor tissue, failed past donor tissue transplants, or when measures required to prevent graft rejection are medically contraindicated. For these patients, penetrating keratoplasty using an artificial cornea or keratoprosthesis is an option.

2.2 Outline of the procedure

2.2.1 The implantation of a synthetic hydrogel cornea is a two-stage surgical procedure. The first stage involves making a partial thickness incision at the junction of the cornea and sclera, to allow an intralamellar pocket to be created within the cornea. The superficial flap is then reflected to allow a portion of the central part of the posterior lamella to be removed using a trephine, and the synthetic hydrogel cornea to be inserted into the intralamellar pocket. The superficial flap is repositioned and the incision closed. In most cases, the operation is completed by forming a flap of tissue from the conjunctiva, which is used to cover the surface of the front of the eye. This may cause changes in the cosmetic appearance of the eye.

2.2.2 The second stage of the procedure is performed 12 weeks later, and involves removing the conjunctival cover and the superficial flap of the cornea, exposing the synthetic hydrogel cornea to light. The eye may still not appear completely 'normal' after this stage of the operation.

2.3 Efficacy

2.3.1 Evidence on the efficacy of this procedure was based on small, uncontrolled studies with short-term follow-up. Initial results indicated that visual acuity improved (although it was still poor) or remained the same in most patients. In a report of 41 patients with a mean preoperative visual acuity of hand movements, mean best corrected visual acuity for 21 patients at 12 months follow-up was 20/300. An improvement of this degree is likely to be valuable to patients. The authors of this report also stated that among the 41 patients undergoing implant of a synthetic cornea, 26 implants remained in situ (63%) at a mean follow-up of 16 months. However, patient selection criteria have changed since the first trial of this procedure, and it is unclear what impact this will have on efficacy outcomes. For more details, see the overview.

2.3.2 The Specialist Advisors considered that this procedure should be restricted to those individuals who cannot be treated with established procedures and who have no useful vision in the other eye.

2.4 Safety

2.4.1 Stromal melting is a frequent complication for all keratoprostheses and is common following this procedure. In a review of 41 non-herpetic patients, 42% (17 patients) developed a stromal melt. In this particular review, the number of patients requiring device removal as a result of this complication was unclear; however, in another series, the same authors reported that 13% (5/40) implants were removed because of melting. Other complications included cellular depositions on the device itself (22%), development of retroprosthetic membranes (7%), and retinal detachment (5%). The literature seemed to suggest that certain patients were at increased risk of complications, namely patients with

herpetic eye disease and smokers. For more details, see the overview.

2.4.2 The Specialist Advisors considered that the long-term complication rate of this procedure is still unknown. Although endophthalmitis is thought to be the most significant potential complication of any artificial cornea, the Advisors noted that this had not yet been reported following this procedure.

2.5 Other comments

2.5.1 Data were based on small numbers of patients.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for the public

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.