NICE guidance

Trabeculotomy ab interno for open angle glaucoma

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 Current evidence on the safety and efficacy of trabeculotomy ab interno for open angle glaucoma is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection should be carried out in units that specialise in glaucoma treatment that can offer a range of treatment options.

1.3 NICE encourages the collection and publication of further data on long-term efficacy.

2 The procedure

2.1 Indications and current treatments

2.1.1 Open angle glaucoma is a chronic condition associated with elevated intraocular pressure (IOP). Early stages are usually asymptomatic but as the condition progresses it leads to visual impairment and, if untreated, blindness.

2.1.2 Treatment usually involves eye drops containing different pharmacological agents that reduce the production or increase the absorption of aqueous humour. Surgical procedures such as trabeculectomy and laser trabeculoplasty may also be used.

2.2 Outline of the procedure

2.2.1 Trabeculotomy ab interno for open angle glaucoma aims to reduce IOP by removing a portion of the trabecular meshwork to improve drainage of aqueous humour. It avoids the creation of a subconjunctival bleb associated with traditional trabeculectomy.

2.2.2 With the patient under local (intracameral) anaesthesia, a scleral incision is made and viscoelastic is inserted into the anterior chamber. Electrical ablation (aided by a goniolens) is used to remove a strip(s) of the trabecular meshwork. The eye is then irrigated and the viscoelastic aspirated from the anterior chamber. The incision is sutured.

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 1,688 patients reported a reduction in mean IOP from 23.5 mmHg preoperatively to 16.4 mmHg at 5-year follow-up (number of patients at 5 years not stated).

2.3.2 A non-randomised comparative study of 828 patients treated by trabeculotomy ab interno alone (n=538) or trabeculotomy ab interno plus phacoemulsification (n=290) reported procedural success (defined as final IOP less than 21 mmHg and a 20% reduction in IOP in 2 consecutive visits after 3 months postoperatively and no secondary glaucoma incision surgery) in 65% (349 out of 538) and 87% (252 out of 290) of patients respectively at 12-month follow-up ($p<0.001$).

2.3.3 A non-randomised comparative study of 259 patients (114 trabeculotomy ab interno with phacoemulsification and intraocular lens insertion procedures versus 145 phacoemulsification and intraocular lens insertion only procedures) reported procedural success (defined as no additional glaucoma surgery, IOP less than 21 mmHg and IOP reduced by 20% below baseline on the last 2 consecutive 3-month follow-up visits) in 80% and 46% of patients respectively at 24-month

follow-up.

2.3.4 A case series of 53 patients reported complete overall success of the procedure (defined as IOP of 21 mmHg or less without the use of medication) in 91% of patients at 24-month follow-up (absolute figures not stated). The same study reported a significant reduction in mean IOP from 25.6 mmHg to 15.0 mmHg at 24 months ($p<0.005$).

2.3.5 Case series of 1,688, 53 and 21 patients reported reductions in the mean number of glaucoma medications used by patients after the procedure: from 3 to 1 at 5-year follow-up; 3 to less than 1 at 24-month follow-up; and 2 to less than 1 at mean follow-up of 25.3 months respectively.

2.3.6 The case series of 1,688 patients reported that 10% (162 out of 1,688) of patients required an additional procedure during the 5-year follow-up. This included 96 trabeculectomies (6% of patients), 41 aqueous tube shunts (2%) and 14 repeat ab interno trabeculotomy procedures (1%).

2.3.7 The non-randomised comparative study of 828 patients treated by trabeculotomy ab interno alone (n=538) or trabeculotomy ab interno plus phacoemulsification (n=290) reported a need for secondary glaucoma procedures in 32% (175 out of 538) and 8% (24 out of 290) of patients respectively at 12-month follow-up.

2.3.8 The Specialist Advisers listed the key efficacy outcome as reduction in IOP.

2.4 Safety

2.4.1 The case series of 1,688 patients reported an increase in IOP of more than 10 mmHg after the procedure in 6% (96 out of 1,688) of patients (follow-up not stated).

2.4.2 The case series of 53 patients reported temporary IOP elevation (not otherwise described) in 23% (12 out of 53) of patients.

2.4.3 The case series of 1,688 patients reported hypotony (defined as an IOP of less

than 5 mmHg) 1 day after the procedure in 1% (24 out of 1,688) of patients (follow-up not stated; not otherwise described).

2.4.4 The case series of 1,688 patients reported corneal Descemet's limited membrane tear in 4 patients (timing of event not stated).

2.4.5 The case series of 53 patients reported moderate cataract with no influence on visual acuity in 11% (6 out of 53) of patients and cataract with a loss of 1 line of visual acuity on the Snellen chart in 6% (3 out of 53) of patients at 24-month follow-up.

2.4.6 The Specialist Advisers listed adverse events reported in the literature or anecdotally: hyphaema (blood in anterior chamber) and potential damage to the iris and lens (if performed on phakic eyes without concurrent cataract extraction). They considered theoretical adverse events to include trabecular meshwork scarring, which could render the procedure ineffective after 6 to 12 months.

2.5 Other comments

2.5.1 The Committee noted that compliance with glaucoma medication is often poor and that the usual surgical treatment is trabeculectomy. It seemed plausible that alternative procedures, such as this one, might offer advantages to selected patients.

2.5.2 The Committee noted concerns about the possibility of failure of the procedure in the long term but was advised that this would not preclude further surgical treatment.

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.