

Trabeculotomy ab interno for open angle glaucoma

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 gonioscope) 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.

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, available at www.nice.org.uk/guidance/IP/860/overview

2.3 Efficacy

- 2.3.1 A case series of 1688 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% (349/538) and 87% (252/290) of patients respectively at 12-month follow-up ($p < 0.001$).

Interventional procedure guidance 397

This guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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- 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 1688, 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 1688 patients reported that 10% (162/1688) 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% (175/538) and 8% (24/290) of patients respectively at 12-month follow-up.
- 2.3.8 The Specialist Advisers listed the key efficacy outcome as reduction in IOP.
- 2.4.2 The case series of 53 patients reported temporary IOP elevation (not otherwise described) in 23% (12/53) of patients.
- 2.4.3 The case series of 1688 patients reported hypotony (defined as an IOP of less than 5 mmHg) 1 day after the procedure in 1% (24/1688) of patients (follow-up not stated; not otherwise described).
- 2.4.4 The case series of 1688 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% (6/53) of patients and cataract with a loss of 1 line of visual acuity on the Snellen chart in 6% (3/53) 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.

2.4 Safety

- 2.4.1 The case series of 1688 patients reported an increase in IOP of more than 10 mmHg after the procedure in 6% (96/1688) of patients (follow-up not stated).

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

- 3.1 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See

www.nice.org.uk/guidance/IPG397/publicinfo

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N2552 for this guidance, N2553 for the 'Understanding NICE guidance' or N2554 for the large print version of the 'Understanding NICE guidance'.

This guidance represents the view of NICE, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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