

Canaloplasty for primary open-angle glaucoma

1 Guidance

- 1.1 Current evidence on the safety and efficacy of canaloplasty for primary open-angle glaucoma is inadequate in both quality and quantity. Therefore, this procedure should only be used in the context of research or formal prospective data collection. Clinicians are encouraged to collaborate in the collection and publication of data.
- 1.2 Further publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Glaucoma describes a group of conditions in which there is progressive damage to the optic nerve. It is often associated with an abnormal rise in intraocular pressure. Normal intraocular pressure helps the eye to keep its shape and is maintained by the production and drainage of aqueous humour. Schlemm's canal, the main drainage channel for aqueous humour, is situated in the angle between the iris and the cornea. In primary open-angle glaucoma, the most common type of glaucoma, the outflow of aqueous humour via Schlemm's canal is not obstructed by the peripheral iris. The early stages of primary open-angle glaucoma are usually asymptomatic, but loss of peripheral and central vision occurs over time.
- 2.1.2 Treatment for glaucoma aims to lower the intraocular pressure. In primary open-angle glaucoma, treatment is usually with drugs, delivered as eye drops. If these are inadequate then surgical trabeculectomy, or sometimes laser trabeculoplasty, may be used. Trabeculectomy involves creating a new drainage passage for

aqueous humour to leave the eye by creating a flap from the outer layer of the eye (sclera) which covers a small hole communicating with the anterior chamber of the eye. Other surgical alternatives include viscocanalostomy and deep sclerectomy. These are non-penetrating techniques that avoid permanent, full-thickness penetration into the anterior chamber of the eye. In viscocanalostomy, a block of sclera is removed to leave a thin membrane through which aqueous humour drains away. A thick fluid (a viscoelastic) is then injected into Schlemm's canal to dilate it. Deep sclerectomy is a similar procedure but usually involves the insertion of an implant under the scleral flap to facilitate aqueous drainage.

2.2 Outline of the procedure

- 2.2.1 Canaloplasty is a non-penetrating surgical technique for glaucoma which aims to restore the natural drainage of fluid from the eye. Canaloplasty may be performed under local or general anaesthetic. A superficial hinged flap of sclera is made and a deeper flap excised, exposing Schlemm's canal. A microcatheter with an illuminated tip is introduced into the canal and advanced around its entire circumference. As the catheter tip advances, viscoelastic fluid is injected into the canal to dilate it. After catheterisation of the entire canal length is complete, a suture is tied to the tip of the microcatheter, which is withdrawn, pulling the suture into the canal. The suture is cut from the microcatheter and tied in a loop encircling the inner wall of the canal. The suture is tightened, so distending the trabecular meshwork with the aim of widening the canal. The superficial flap is sutured. A special ultrasound imaging system is used to help identify the canal and to visualise the instruments in the canal before, during and after the surgery.

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

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 details, refer to the Sources of evidence.

2.3 Efficacy

- 2.3.1 In a case series of 94 patients, successful circumferential catheterisation of Schlemm's canal was achieved in 88% (83/94) of patients, and a suture was successfully placed in the canal in 79% (74/94) of patients. Mean intraocular pressure was reduced from 24.7 mmHg at baseline to 15.3 mmHg at 12-month follow-up ($p < 0.05$). (The normal upper limit for intraocular pressure is 21 mmHg.) The mean number of drugs to lower the intraocular pressure was reduced from 1.9 at baseline to 0.6 at 12-month follow-up. Furthermore, 88% (50/57) and 96% (46/48) of patients with successful suture placement had intraocular pressures of 21 mmHg or lower after 3 months and 6 months, respectively (with or without drugs to lower intraocular pressure). Four patients had poor intraocular pressure control after canaloplasty and required subsequent trabeculectomy.
- 2.3.2 The Specialist Advisers considered key efficacy outcomes to include control of intraocular pressure, preservation of the visual field and ocular comfort.

2.4 Safety

- 2.4.1 The case series of 94 patients reported ocular-related complications including hyphema (the presence of blood in the anterior chamber) (3%), elevated intraocular pressure (3%), detachment of Descemet's membrane (1%), hypotony (abnormally low intraocular pressure) (1%), choroidal effusion (1%) and exposed closure suture (1%) (absolute figures not reported).

- 2.4.2 In the same case series, the loss of two or more lines of best corrected visual acuity was reported in 25% (18/71) of patients at 1-month follow-up, 7% (5/68) of patients at 3-month follow-up and 9% (4/47) of patients at 12-month follow-up. The authors noted that the decline in visual acuity in these patients was related to disease processes not associated with the canaloplasty procedure.
- 2.4.3 The Specialist Advisers considered theoretical adverse events to include anterior chamber perforation, tearing of Descemet's membrane resulting in corneal opacification or retinal damage, intraocular inflammation caused by the suture, cataract formation, sustained increases in intraocular pressure, hypotony, and bleb formation or suture exposure with endophthalmitis.

3 Further information

- 3.1 The Institute is currently developing a clinical guideline on glaucoma (www.nice.org.uk/guidance/index.jsp?action=byID&o=11644).

Information for patients

NICE has produced information on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. See www.nice.org.uk/IPG260publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview, available at www.nice.org.uk/ip651overview

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1576 for this guidance or N1577 for the 'Understanding NICE guidance'.

This guidance represents the view of the Institute, 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.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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