

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Ab interno canaloplasty for open-angle glaucoma

Open-angle glaucoma is a progressive condition that causes increased pressure in the eye. This damages the nerve that connects the eye to the brain and may lead to permanent sight loss. This procedure involves making a small cut in the eye (ab interno) and inserting a tiny tube into the channel that drains fluid from the eye. The tube widens the drainage channel (canaloplasty), then gel is injected into it and the tube is removed. The gel keeps the channel wider for a few days then dissolves, leaving the channel permanently wider to allow excess fluid to drain away. The aim is to reduce pressure in the eye.

NICE is looking at ab interno canaloplasty for open-angle glaucoma.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 24 May 2022

Target date for publication of guidance: October 2022

1 Draft recommendations

1.1 Evidence on the safety of ab interno canaloplasty for open-angle glaucoma shows no major safety concerns. Evidence on the efficacy is limited in quality and quantity, particularly in the long term. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out [what special arrangements mean on the NICE interventional procedures guidance page](#).

1.2 Clinicians wanting to do ab interno canaloplasty for open-angle glaucoma should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers as appropriate) clear information to support [shared decision making](#), including [NICE's information for the public](#).
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into [NICE's interventional procedure outcomes audit tool](#) (for use at local discretion).
- Enter details about everyone having ab interno canaloplasty for open-angle glaucoma onto a suitable registry and review local clinical outcomes.
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
 - Regularly review data on outcomes and safety for this procedure.
- 1.4 Patient selection and treatment should be done by glaucoma specialists with training and experience in the technique.
- 1.5 Report any problems with a medical device using the [Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme](#).
- 1.6 Further research should report:
- details of patient selection, including concurrent procedures, severity of glaucoma and concomitant therapy
 - long-term efficacy and safety outcomes.

2 The condition, current treatments and procedure

The condition

- 2.1 Glaucoma is usually a chronic condition that is typically associated with raised intraocular pressure (IOP). The most common type of glaucoma in the UK is primary open-angle glaucoma. It leads to progressive damage to the optic nerve. Early stages are usually asymptomatic. But, as the condition progresses it can cause visual impairment and, if untreated, blindness.
- 2.2 In a healthy eye, aqueous humor drains through the trabecular meshwork (into Schlemm's canal) and through the uveoscleral outflow pathway. In glaucoma, this drainage becomes impaired either from resistance in the trabecular meshwork pathway (primary

open-angle glaucoma) or from obstruction by the iris (primary closed-angle glaucoma).

Current treatments

- 2.3 Treatment usually involves eye drops containing medicines that either reduce the production of aqueous humor or increase its drainage. Surgical procedures such as trabeculectomy, deep sclerectomy, trabeculotomy, stenting, canaloplasty, or laser trabeculoplasty may be used.

The procedure

- 2.4 Ab interno canaloplasty aims to reduce IOP by improving the drainage of aqueous fluid from the eye in people with open-angle glaucoma. It is done under local or general anaesthetic. Unlike traditional (ab externo) canaloplasty, which is done by cutting through the conjunctiva and sclera, ab interno canaloplasty uses an internal approach through a clear corneal or limbal incision. A microcatheter is introduced into the canal through a small opening in the trabecular meshwork and advanced around its entire circumference. As the catheter tip is withdrawn, viscoelastic fluid is injected into the canal to dilate it. The microcatheter is then removed. The viscoelastic fluid disperses down the collector channels of the eye within 2 to 3 days. The aim is to permanently dilate the canal to allow increased drainage of aqueous humor from the eye and thereby lower IOP. Some devices allow canaloplasty to be done simultaneously with trabeculotomy. Canaloplasty is often done concurrently with phacoemulsification (cataract surgery).

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive

literature search and detailed review of the evidence from 6 sources, which was discussed by the committee. The evidence included 6 before-and-after studies. It is presented in the [summary of key evidence section in the interventional procedures overview](#).

Other relevant literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduction in IOP, reduction in glaucoma medicine use, preservation of peripheral vision and patient-reported outcomes including quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding within the eye, infection, loss of vision, hypotony and need for further surgery.
- 3.4 Three commentaries from people who have had this procedure were discussed by the committee.

Committee comments

- 3.5 Glaucoma is a common chronic condition. This underpinned the committee's recommendation on collecting and reporting further data on outcomes and safety, particularly in the long term.
- 3.6 The committee was informed that this procedure is for people with mild-to-moderate glaucoma.
- 3.7 More than 1 device is available for this procedure.
- 3.8 The committee was informed that people with glaucoma need lifelong follow up and some may need to continue using glaucoma medicine after the procedure.

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Chair, interventional procedures advisory committee

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