

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Ab externo canaloplasty for primary open-angle glaucoma

Primary open-angle glaucoma is a progressive condition that causes long-term increase of pressure in the eye. This damages the nerve that connects the eye to the brain (optic nerve) and may gradually lead to permanent loss of sight. This procedure involves inserting a tiny tube into the main drainage canal, to widen it. The tube is then removed and a stitch is placed in the canal to keep it open. The aim is to reduce pressure in the eye.

The National Institute for Health and Care Excellence (NICE) is examining ab externo canaloplasty and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about ab externo canaloplasty.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.

- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 23 June 2017

Target date for publication of guidance: September 2017

1 Draft recommendations

- 1.1 Current evidence on the safety and efficacy of ab externo canaloplasty for primary open-angle glaucoma is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
- 1.2 Ab externo canaloplasty for primary open-angle glaucoma should only be done by clinicians with specific training in the procedure.

2 Indications and current treatments

- 2.1 Primary open-angle glaucoma is a chronic condition associated with elevated intraocular pressure. It leads to progressive damage to the optic nerve. Early stages are usually asymptomatic but as the condition progresses it causes visual impairment and, if untreated, blindness.
- 2.2 Treatment is usually eye drops containing drugs that either reduce the production of aqueous humor or increase its drainage. Surgical procedures such as trabeculectomy, drainage tubes, deep sclerectomy, viscocanalostomy, or laser trabeculoplasty may also be used.

3 The procedure

- 3.1 Ab externo canaloplasty is a surgical technique that aims to reduce intraocular pressure, by improving drainage of aqueous fluid from the eye. It is done under local or general anaesthetic. A superficial hinged flap of sclera is made and a deeper flap excised, exposing the Schlemm's canal. An ultrasound imaging system is used to identify the canal and to visualise the surgical instruments when they are in the 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. When catheterisation of the entire canal is complete a suture is tied to the tip of the microcatheter and it is withdrawn, pulling the suture into the canal. The suture is cut, tied in a loop encircling the inner wall of the canal and tightened. This widens the canal. The superficial flap is sutured.

4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#) *[add URL]*.

- 4.1 In a systematic review and meta-analysis of 215 eyes, comparing 100 eyes treated by canaloplasty against 115 eyes treated by trabeculectomy, there was no statistically significant difference between groups for complete success rates (maximum postoperative intraocular pressure [IOP] of 18 mmHg without medications) and qualified success rates at 1-year follow-up (maximum IOP of 18 mmHg with or without medications). In a case series of 224 patients who had canaloplasty the complete success rates at 1-, 2- and 3-year follow-up were 44% (64/144), 38% (30/80) and 31% (9/29) and the qualified success rates were 75% (108/44), 74% (59/80) and 59% (17/29).
- 4.2 In the systematic review and meta-analysis of 215 eyes, the mean IOP reduction was statistically significantly lower in the canaloplasty group at 1-year follow-up (weighted mean difference -2.33, 95% CI -4.00 to -0.66). In a review of 914 eyes treated by canaloplasty alone (n=777 eyes) or canaloplasty combined with phacoemulsification (n=137 eyes), the mean IOP reduction (after a maximum of 36 months follow-up) ranged from 29% to 66% in patients who had canaloplasty only and from 42% to 46% in patients who had canaloplasty with phacoemulsification. In the case series of 224 patients there was a statistically significant decrease in mean IOP (\pm standard deviation [SD]) at 1-year, 2-year and 42-month follow-up, from 29.4(\pm 7.9) mmHg before surgery to

16.8(±4.2) mmHg, 17.1(±4.7) mmHg and 16.9(±3.1) mmHg respectively ($p < 0.0001$).

4.3 In the systematic review and meta-analysis of 215 eyes there was no statistically significant difference between groups for reduction in anti-glaucoma medications at 1 year (weighted mean difference -0.54, 95% CI -1.18 to 0.09). In the review of 914 eyes, mean medications reduction (after a maximum of 36 months follow-up) ranged from 25% to 100% in patients who had canaloplasty only and from 66% to 86% in patients who had canaloplasty with phacoemulsification. In a randomised controlled trial (RCT) of 59 patients comparing phaco-canaloplasty ($n=29$) with phaco-non-penetrating deep sclerectomy ($n=30$), there was a statistically significant decrease in the mean (\pm SD) number of medications used in both groups, from 2.64(\pm 0.68) before surgery to 0.27(\pm 0.67) at 1 year in the phaco-canaloplasty group and from 2.89(\pm 0.94) to 0.55(\pm 0.94) in the phaco-non-penetrating deep sclerectomy group ($p < 0.05$ for the difference within groups, no statistically significant difference between groups).

4.4 In a retrospective comparative study of 327 patients who had canaloplasty ($n=175$) or trabeculectomy ($n=152$), which collected self-reported questionnaire data 2 years after surgery, the mean score (\pm SD) for satisfaction with results of surgery (ranging from 0, totally discontent, to 10 totally content) was statistically significantly higher in the canaloplasty group (8.09 ± 2.71 compared with 7.46 ± 2.61 , $p=0.034$). There were statistically significantly fewer revision surgeries reported in the canaloplasty group (mean number of revision surgeries per patient 0.12 ± 0.43 compared with 0.67 ± 1.14 , $p < 0.001$). Patients were statistically significantly more positive after canaloplasty (2.30 ± 0.83 compared with 1.96 ± 0.87 ,

$p=0.009$), stress caused by surgery and follow-up or treatments was statistically significantly lower in the canaloplasty group (4.18 ± 0.86 compared with 3.59 ± 1.12 , $p<0.001$ and 4.36 ± 0.80 compared with 3.40 ± 1.20 , $p<0.001$ respectively), and nonvisual and visual ocular symptoms were statistically significantly lower in the canaloplasty group ($p<0.05$).

- 4.5 The specialist advisers listed the following key efficacy outcomes: intraocular pressure reduction and glaucoma medication use reduction.

5 Safety

This section describes 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 [interventional procedure overview](#) *[add URL]*.

- 5.1 Intraocular pressure (IOP) of more than 30 mmHg after the procedure was reported in 2% to 9% of eyes in a review of 914 eyes treated by canaloplasty alone ($n=777$ eyes) or by canaloplasty combined with phacoemulsification ($n=137$ eyes) at a maximum of 36 months follow-up.
- 5.2 Hyphaema was reported statistically significantly more frequently in the canaloplasty group ($n=100$) than in the trabeculectomy group ($n=115$) at 1-year follow-up, in a systematic review and meta-analysis of 215 eyes (odds ratio [OR] 8.80, 95% confidence interval [CI] 2.25 to 34.51). Hyphaema (greater than 1 mm layered blood) was reported in 23% (7/30) of patients treated by canaloplasty and in 1 patient treated by trabeculectomy within 90 days of the procedure in a randomised controlled trial (RCT) of 62 patients.

- 5.3 Descemet's membrane detachment reporting was not statistically significantly different between groups in the systematic review and meta-analysis of 215 eyes (OR 4.49, 95% CI 0.72 to 27.82). Descemet's membrane detachment was reported in 2% to 6% of eyes in the review of 914 eyes at a maximum of 36 months follow-up. Microperforation of Descemet's membrane during the procedure was reported in 7% (2/30) of patients treated by canaloplasty in the RCT of 62 patients comparing canaloplasty (n=30) with trabeculectomy (n=32). Trabeculo Descemet's membrane rupture was reported in 1 patient in each group during the procedure in an RCT of 59 patients treated by phaco-canaloplasty (n=29) or phaco-non-penetrating deep sclerectomy (n=30).
- 5.4 Hypotony was reported statistically significantly less frequently in the canaloplasty group in the systematic review and meta-analysis of 215 eyes (OR 0.36, 95% CI 0.13 to 0.99). Shallow anterior chamber reporting was not statistically significantly different between groups. Flat anterior chamber was reported in 0% to 2% of eyes in the review of 914 eyes, and persistent hypotony was reported in 0% to 1% of eyes.
- 5.5 Central retinal artery occlusion was reported in 1 out of 36 patients in the phaco-canaloplasty group and in none of the patients in the trabeculectomy group in a retrospective comparative study of 77 patients.
- 5.6 Ocular decompression retinopathy was reported in a single case report 1 day after canaloplasty. It was treated with tobramycin and dexamethasone. Three months after canaloplasty, IOP remained in

control at 16 mmHg and all retinal haemorrhages had completely resolved.

- 5.7 Choroidal effusion was reported statistically significantly less frequently in the canaloplasty group than in the trabeculectomy group, in the systematic review and meta-analysis of 215 eyes (OR 0.12, 95% CI 0.03 to 0.48). Choroidal detachment was reported in 7% (2/29) of patients who had phaco-canaloplasty and in none of the patients who had phaco-non-penetrating deep sclerectomy, in the RCT of 59 patients.
- 5.8 Cataract formation was reported in 0% to 8% of eyes in the review of 914 eyes at a maximum of 36 months follow-up.
- 5.9 Anterior synechiae during the procedure was reported in 1 patient treated by canaloplasty in the RCT of 62 patients. It was treated by surgical peripheral iridotomy.
- 5.10 Conjunctival leak was reported in 10% (3/30) of patients treated by canaloplasty and in 9% (3/32) of patients treated by trabeculectomy within 90 days of the procedure in the RCT of 62 patients. Aqueous leakage from the conjunctival flap was reported in less than 1% (2/214) of eyes in the case series of 224 patients, within 90 days of the procedure.
- 5.11 Corneal erosion was reported in 1 patient treated by canaloplasty and in 44% (14/32) of patients treated by trabeculectomy within 90 days of the procedure in the RCT of 62 patients.
- 5.12 Bleb formation was reported in 0% to 4% of eyes in the review of 914 eyes.

- 5.13 Cells in the anterior chamber after the procedure were reported in 2 patients who had phaco-canaloplasty and in 1 patient who had phaco-non-penetrating deep sclerectomy, in the RCT of 59 patients.
- 5.14 Iris incarceration was reported in 1 patient in each group in the RCT of 59 patients who had phaco-canaloplasty or phaco-non-penetrating deep sclerectomy.
- 5.15 Suture cheese wiring was reported in 0% to 2% of eyes in the review of 914 eyes.
- 5.16 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not list any anecdotal adverse events or theoretical adverse events.

6 Committee comments

- 6.1 A newer and less invasive ab interno canaloplasty procedure is being developed, but there was very little evidence on this.
- 6.2 The chance of success of a later trabeculectomy procedure, should one be needed, is reduced after this procedure.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).
- 7.2 This guidance is a review of NICE's interventional procedure guidance on [canaloplasty for primary open-angle glaucoma](#).

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