NICE guidance

Ab externo canaloplasty for primary open-angle glaucoma

Interventional procedures guidance
Published: 13 September 2017

www.nice.org.uk/guidance/ipg591

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.

This guidance replaces IPG260.

1 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 overview.

4.1 In a systematic review and meta-analysis of 1,498 eyes, comparing canaloplasty with trabeculectomy, there was no statistically significant difference between groups for complete success rates (maximum postoperative intraocular pressure [IOP] of 18 mmHg without medication) and qualified success rates (maximum IOP of 18 mmHg with or without medication) after the procedure. 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 out of 144), 38% (30 out of 80) and 31% (9 out of 29) respectively, and the qualified success rates were 75% (108 out of 144), 74% (59 out of 80) and 59% (17 out of 29) respectively.

4.2 In the systematic review and meta-analysis of 1,498 eyes, the mean IOP reduction was 9.94 mmHg (95% confidence interval [CI] 8.42 to 11.45) and was statistically significantly lower in the canaloplasty group (mean difference between groups -3.61, 95% CI -5.53 to -1.69 mmHg) at 1-year follow-up. In a

review of 914 eyes treated by canaloplasty alone (n=777 eyes) or with phacoemulsification (n=137 eyes), the mean IOP reduction (after a maximum of 36 months' follow-up) ranged from 29% to 66% with canaloplasty alone and from 42% to 46% with canaloplasty plus phacoemulsification. In the case series of 224 patients, there was a statistically significant decrease in mean IOP (±standard deviation [SD]) from 29.4±7.9 mmHg before surgery to 16.8±4.2 mmHg at 1 year, 17.1±4.7 mmHg at 2 years and 16.9±3.1 mmHg at 42 months ($p<0.0001$).

4.3 In the systematic review and meta-analysis of 1,498 eyes, the mean reduction in antiglaucoma medication use was 2.11 (95% CI 1.80 to 2.42) 1 year after canaloplasty, and there was no statistically significant difference in medication reduction between groups (mean difference -0.37, 95% CI -0.83 to 0.08). In the review of 914 eyes, mean medication use reduction (after a maximum of 36 months' follow-up) ranged from 25% to 100% with canaloplasty alone and from 66% to 86% with canaloplasty plus phacoemulsification. In a randomised controlled trial 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 (±SD) number of medications used in both groups, from 2.64±0.68 before surgery to 0.27±0.67 at 1 year in the phaco-canaloplasty group and from 2.89±0.94 to 0.55±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 (±SD) for satisfaction with results of surgery (ranging from 0, totally discontented, to 10, totally contented) was statistically significantly higher in the canaloplasty group (8.09±2.71) compared with the trabeculectomy group (7.46±2.61, $p=0.034$). In the same study, 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 the trabeculectomy group (0.67±1.14, $p<0.001$). Also, patients were statistically significantly more likely to have a positive mood after canaloplasty (2.30±0.83) compared with trabeculectomy (1.96±0.87, $p=0.009$), stress caused by surgery or follow-ups and treatments was statistically significantly lower with canaloplasty (4.18±0.86 and 4.36±0.80 respectively)

compared with trabeculectomy (3.59±1.12 and 3.40±1.20 respectively; p<0.001), 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 reduced use of glaucoma medication.

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 overview.

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 with phacoemulsification (n=137 eyes) at a maximum of 36 months' follow-up.

5.2 Hyphaema (greater than 1 mm layered blood) was statistically significantly more frequent in the canaloplasty group than in the trabeculectomy group at 1-year follow-up, in a systematic review and meta-analysis of 1,498 eyes (odds ratio [OR] 9.24, 95% confidence interval [CI] 3.09 to 27.60). The incidence of hyphaema in the canaloplasty group was 25% (304 out of 1,221). Hyphaema was reported in 23% (7 out of 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 was only seen in the canaloplasty group, with an incidence of 3% (37 out of 1,185) at 1-year follow-up in the systematic review and meta-analysis of 1,498 eyes. 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 out of 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 statistically significantly less frequent after canaloplasty than after trabeculectomy at 1-year follow-up, in the systematic review and meta-analysis of 1,498 eyes (OR 0.32, 95% CI 0.13 to 0.80). The incidence of hypotony in the canaloplasty group was 9% (94 out of 1,091). 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 or detachment was statistically significantly less frequent in the canaloplasty group than in the trabeculectomy group, in the systematic review and meta-analysis of 1,498 eyes within 1 year of the procedure (OR 0.25, 95% CI 0.06 to 0.97). Choroidal detachment was reported in 7% (2 out of 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 incidence was not statistically significantly different between the canaloplasty group and the trabeculectomy group within 1-year follow-up, in the systematic review and meta-analysis of 1,498 eyes (OR 0.72, 95% CI 0.16 to 3.14). Conjunctival leak was reported in 10% (3 out of 30) of patients treated by canaloplasty and in 9% (3 out of 32) of patients treated by trabeculectomy

within 90 days of the procedure in the RCT of 62 patients.

5.11 Corneal erosion was reported in 1 patient treated by canaloplasty and in 44% (14 out of 32) of patients treated by trabeculectomy within 90 days of the procedure in the RCT of 62 patients.

5.12 Detectable conjunctival bleb was reported in 2% (17 out of 899) of patients after canaloplasty, in the systematic review and meta-analysis of 1,498 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 The committee was told that 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 Patient commentary was sought but none was received.

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.

ISBN: 978-1-4731-2677-0

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.