The efficacy and safety of canaloplasty for the management of primary open angle glaucoma: A systematic review protocol

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Abstract

Background: Glaucoma forms the leading cause of irreversible blindness worldwide, with a disproportionately rising prevalence in Asian and African countries. Primary open angle glaucoma (POAG) accounts for the majority of cases. Medical therapies of POAG are not without side effects, meanwhile surgical treatments carry high complication rates. Ab-interno canaloplasty promises a safer, minimally invasive yet effective treatment option for mild-to-moderate POAG, as well as a cost-effective technique for low-resource countries. Despite this, no systematic review currently exists to verify this procedure's efficacy.

Objective: To develop a protocol for a systematic review aimed at evaluating the efficacy canaloplasty against all other forms of POAG treatment.

Methods: This systematic review and meta-analysis will include randomised controlled trials (RCTs) evaluating the short-term, medium-term and long-term efficacy and safety of ab-interno canaloplasty in treating POAG in comparison to all other treatments with the primary outcome measure of mean change in intraocular pressure (IOP). Secondary outcome measures include proportion of participants medication free after treatment and mean change in health-related quality of life. MEDLINE, Embase, Cochrane Library

and ClinicalTrials.gov databases will be searched for relevant RCTs. All studies will be subject to pre-specified inclusion and exclusion criteria. Quality of eligible RCTs will be assessed using the Cochrane risk of bias tool. Data will be extracted with a focus on raw data where possible and analysis will be performed using Revman 5.4 software to compare the mean changes in IOP (mmHg) between ab-interno canaloplasty and other comparator therapies. A funnel plot will be used to assess risk of publication bias if 10 or more trials are included in the review. I2 statistics will be used to assess heterogeneity. Sensitivity analysis will be conducted to exclude studies with high-risk of bias and, where possible, on the primary outcome. The GRADE approach will be used to summarise the main findings.

Results: The results of this systematic review are not yet available as it is still at the protocol stage. This protocol was registered on the PROSPERO database for systematic reviews (CRD42024558671) on the 27th of June 2024. Data collection for this review began on the 14th of July 2024 with the anticipated completion date being within the following year.

Conclusions: The findings of this systematic review will be important to patients, clinicians and policymakers worldwide in addressing the growing burden and health inequality of glaucoma. Clinical Trial: Trial registration: PROSPERO CRD42024558671

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Conclusions: The findings of this systematic review will be important to patients, clinicians and policymakers worldwide in addressing the growing burden and health inequality of glaucoma.

Trial registration: PROSPERO CRD42024558671

Keywords: Systematic review; ab-interno canaloplasty; glaucoma; minimally invasive surgery; meta-analysis; protocol

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Introduction

"Glaucoma" is an umbrella term used to describe a group of chronic progressive optic neuropathies associated with raised intraocular pressure (IOP) [1]. It forms the leading cause of irreversible blindness worldwide, having caused 11% of all blindness in adults aged 50 and above in 2020 [2]. Glaucoma currently affects 76m adults around the globe, and this is predicted to rise to 111.8m by 2040, with primary open angle glaucoma (POAG) being the commonest subtype [3]. Furthermore, this rising prevalence is disproportionately affecting Asian and African populations, with, for instance, a higher incidence and severity of the disease being found at a younger age amongst adults in Nigeria [4]. This is attributed to poor access to treatment [4]. It is therefore of interest to adopt new, cost-effective yet efficient methods of treatment that may be readily delivered in low-resource countries to ease the rising epidemic of glaucoma. This is not only vital to providing care in low-resource countries most affected by glaucoma, and tackling the health inequality, but would be of use at a time of increasing healthcare costs in the United Kingdom (UK) [5].

Treatment and prevention of glaucoma progression, and thereby preservation of vision, is centred around reducing IOP with regular use of topical eyedrops, laser therapy, and/or surgery [6]. Unfortunately, intolerance of side effects such as dry eye and irritation has made for low adherence amongst patients using eyedrops in comparison to adherence to medication for other chronic conditions [7,8]. Surgical techniques such as the gold-standard trabeculectomy aren't without significant risks, with a 78% increase in cataract formation and upto 21.3% of patients requiring complication-related surgery [9,10]. Surgery is therefore reserved for cases refractory to other therapy [11].

Minimally invasive surgical procedures show the potential to effectively reduce IOP in the long term, removing the need for indefinite daily self-administration of eye drops. This may not only be preferable for patients, but also prevents vision loss related to nonadherence to topical treatment.

Ab-Interno canaloplasty is a new, minimally invasive surgical procedure regarded as highly effective in reducing IOP, with fewer complications and a simpler post-operative care regimen than other surgical interventions [12,13]. It acts to permanently dilate Schlemm’s canal, which facilitates up to 96% of aqueous humour drainage and is found to be of reduced dimensions in glaucomatous eyes [14, 15]. It is currently approved by NICE (National Institute for Health and Care Excellence) for

cases of mild-to-moderate POAG [16]. It promises a safer and more cost-effective alternative to other treatment options in the long term. However, whilst NICE acknowledge the procedure as safe, they have found little evidence on its efficacy [16]. Considering the potential benefits for patients worldwide and the recent uptake of the procedure in the UK, it is important to critically evaluate the evidence for whether canaloplasty is both efficacious and cost-effective. No systematic review currently exists to consolidate and verify this procedure's efficacy.

This systematic review aims to compare:
1. The short term and long-term efficacy of canaloplasty against all other forms of open angle glaucoma treatment.
2. The mean IOP changes in canaloplasty to determine the therapeutic effects.
3. The safety of canaloplasty as a treatment against other treatment options for open angle glaucoma.

Methods

Study Design

We will conduct a systematic review and meta-analysis of randomised controlled trials (RCTs) performing canaloplasty. This protocol will be conducted in accordance with PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-analyses- Protocol statement) [additional file 1] and has been prospectively registered on PROSPERO (registration number CRD42024558671).

All RCTs will be included irrespective of their publication status or language. If articles are not in English, we will use translation assistance (other reviewers who are native to the language or Google PDF translate software).

Types of Participants

Participants included will be those with primary open angle glaucoma. We will also include all participants with ocular hypertension, normal-tension glaucoma, or possible glaucoma (suspects for glaucoma). There will be no restrictions regarding region, nation, sex, duration, setting or demographic factors.

Types of Interventions

We will consider ab-interno canaloplasty performed with the OMNI® Surgical System or the iTRACK microcatheter. However, we will not apply any particular inclusion or exclusion criteria to these or other treatment delivery parameters.

Ab Interno canaloplasty will be compared against any comparator, including the following:
1. Conventional glaucoma surgery (trabeculectomy);
2. Laser Treatment (trabeculoplasty);
3. Other minimally invasive glaucoma techniques;
4. Medical treatment

Types of outcome measures

Our primary outcome will be Mean change in IOP measured using the Goldmann applanation tonometry.

However, the reporting of a particular outcome as criterion is not necessary for eligibility for review. Nor will we exclude studies solely on an outcome of interest not being included.

Secondary outcomes

- Proportion of participants that were medication free (not using eyedrops).
- Mean change in number of IOP-lowering topical eyedrops taken per day.
- Proportion of participants who required further glaucoma surgery, as recorded by the investigators of the included trial.
- Rate of visual field progression (decibels (dB)/time) or proportion of participants whose field loss progressed in the follow-up period.
- Mean change in HRQoL (Health-related quality of life).
- Cost effectiveness reporting for each intervention.

Adverse Effects

- loss of visual acuity (more than 2 Snellen lines or more than 0.3 logMAR, according to the method of recording visual acuity; or loss of light perception);
- bleeding, as recorded by the investigators;
- endophthalmitis, as recorded by the investigators;
- IOP spikes (postoperative rise in IOP, measured using Goldmann applanation tonometry, of more than 10 mmHg compared to the previous assessment, including measurements taken during the first postoperative month).

Search methods for identification of studies

Electronic searches

We will search the following electronic databases for randomised controlled trials, placing no restrictions to language or year of publication:

- Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register) in the Cochrane Library (February 2024; Appendix 1).
- MEDLINE Ovid (1946 to present; Appendix 2)
- Embase Ovid (1980 to present; Appendix 3)
- International Standard Randomised Controlled Trial Number registry (ISRCTN; Appendix 4)
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (Appendix 5)
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP; Appendix 6).

Our search strategy is detailed in Supplementary material 1.

Searching other resources

To identify further studies that may meet the inclusion criteria, we will search the reference lists of all included studies. We will also search conference proceedings from the following meetings from 1980 onwards:

- American Academy of Ophthalmology (AAO);

- Association of Research in Visual Science and Ophthalmology (ARVO); and
- World Ophthalmology Congress (WOC) and the World Glaucoma Congress (WGC).

Data collection and analysis

Selection of studies

We will remove duplicate references and import the search results into the web-based review management software Covidence.

Two review authors (MMA and SI) will independently screen titles and abstracts for all articles identified by the search. If abstracts are not available, a full text screen of the article will be carried out. We will then retrieve full-text reports of any potential studies for inclusion to assess eligibility. In the event of any disagreement regarding eligibility, a third review author (AT) will be the arbitrate. If we reject any full text reports, we plan to record the reasons for this.

If we have doubts about either the study population or the intervention(s), we will contact the study authors (via email) for clarification so that the decision to include or exclude can be properly informed. We will give them a month to reply.

Data extraction and management

In situations where information from the included studies is missing or unclear, our protocol will involve reaching out to the respective individuals or organizations for clarification.

We aim to acquire the most comprehensive numerical data accessible to enhance the analysis of the included studies. Rather than opting for less accurate approaches, such as extracting numeric values from graphs, our plan will be to gather the data directly from individuals or organizations.

In the event that extraction from graphs becomes necessary, two review authors will independently perform the task, with a third review author serving as an arbitrator in case of any discrepancies.

Risk of bias assessment in included studies

Two authors (MMA and SI) will independently assess studies for risk of bias using Cochrane 'Risk of bias' tool [17]. We will evaluate the seven domains reporting bias as 'low', 'high' or 'unclear'.

Measures of treatment effect

Continuous data will be summarised as the mean difference or standardised mean difference, with a 95% confidence interval comparing canaloplasty with the comparator group. We will express dichotomous data as risk ratios, with 95% confidence intervals.

Dealing with missing data

For studies with missing data, we will contact study investigators by email and give them one month to respond. Ideally, the studies we review will have used intention-to-treat (ITT) analyses.

We will document the proportion of missing data within each trial. We will attempt to assess the reasons for missing data to determine whether they are missing at random. If we consider that they are missing at random, we will use the available data.

Reporting bias assessment

A funnel plot will be used to assess risk of publication bias if 10 or more trials are included in the review. Where appropriate, we will perform statistical tests for funnel plot asymmetry, to assess publication bias, as recommended in *Chapter 13 of the Cochrane Handbook for Systematic Reviews of Interventions* [18].

Synthesis methods

Data analysis will be performed using Revman 5.4 software.

Investigation of heterogeneity and subgroup analysis

We plan to assess heterogeneity between trials by assessing forest plots and examining the I^2 value and 95% confidence intervals. We will examine the I^2 value and use the guidance provided by the *Cochrane Handbook for Systematic Review for Interventions* for interpretation of this value [17].

Sensitivity analysis

We will conduct a sensitivity analysis which will exclude studies which are classified as having overall high risk of bias in one or more key domains. Where possible, we will also perform the following sensitivity analyses for our primary outcome:

- Inclusion of only trials with low risk of attrition bias.
- Inclusion of trials with a total sample size of 50 or more randomised participants, to detect potential small-study effects.
- Inclusion of mixed types of glaucoma in study population.

Certainty of the evidence assessment

We will summarise the main findings, including strengths and limitations of evidence for both primary and secondary outcomes, using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach [19].

We plan to provide a summary of the effectiveness of the intervention and general interpretation of the evidence in the context of other evidence and implications for practice and future research. We will also present a 'Summary of findings' table for each comparison listed in the Types of

Interventions, for each outcome.

Results

This review aims to evaluate the short-term, medium-term and long-term efficacy of ab-interno canaloplasty in treating patients with suspected or confirmed POAG in comparison to other glaucoma treatments. The results of this review are not yet available as it is still at the protocol stage. The anticipated completion date of this review is the 30th of December 2024. The findings of this review will help verify this procedure's efficacy which will aid in its adoption worldwide thereby reducing the level of health inequality and the global burden imposed by this condition.

Discussion

Canaloplasty vs Current Glaucoma Treatments

Ab-interno canaloplasty is an exciting new treatment for the field which, despite its minimally invasive nature, offers promising results with fewer complications and a simpler post-operative care regimen than other surgical interventions [12,13]. It acts to permanently dilate Schlemm's canal, which is found to be of reduced dimensions in glaucomatous eyes [14, 15]. It is currently approved by NICE for cases of mild-to-moderate POAG [16], however, they have found little evidence on its efficacy [16]. Considering the potential benefits for patients worldwide, it is important to critically evaluate the evidence for whether canaloplasty is both efficacious and cost-effective. To date no systematic review of the efficacy of canaloplasty has been conducted. Trabeculotomy remains the gold standard in treatment of glaucoma.

Comparison with Prior Work

Previous reviews of glaucoma treatment document large heterogeneity with a variety of descriptions for IOP and safety outcomes [20]. This can lead to research resource wastage and reduce the quality of strength of Glaucoma studies. To keep reporting standardised with previous evidence of glaucoma care [21] we will report outcomes in the short term (6-18 months), medium term (18-36 months) and long term (36 months or longer).

Another systematic review on primary outcomes of glaucoma care suggested visual field acuity, safety, and optic nerve head morphology as the most important outcomes to glaucoma experts and treatment [22]. In an effort to standardise reporting of outcomes and strengthen the research we hope to report mean changes of IOP as our primary outcome as this is the most found in primary studies and most used primary outcome and one of the most important [22].

Conclusions

Randomised control trials involving eyes can be difficult to conduct. To conduct the most comprehensive review we plan to exclude within person studies because of the potential for medical treatment such as one eye treatment affecting the other eye results. For the same reason, we will exclude paired-eye studies which randomised one eye to one intervention and the other to the alternative intervention.

We will however review studies which included one eye per participant. If a study randomised eyes, regardless of whether they were in the same participant, we will contact the study authors for more information. If possible, we will only include eyes which had the first intervention.

Acknowledgements

MMA and SI are both lead first authors of this protocol and helped in the following domains equally: background, study selection, data extraction and synthesis, risk of bias, write-up and review. CA and AT are the supervisors of this protocol, AT originally came up with the conception of this review. Both CA and AT contributed to the following domains: background, study selection, write-up and review. No financial funding or grants were used to support this study publication.

Conflicts of interest

None declared

Abbreviations

AAO - American Academy of Ophthalmology
ARVO - Association of Research in Visual Science and Ophthalmology
CENTRAL - Cochrane Central Register of Controlled Trials
GRADE - Grades of Recommendation, Assessment, Development and EvaluatioF
HRQoL – Health-related quality of life
IOP – Intraocular pressure
ISRCTN - International Clinical Trials Registry Platform
ITT - Intention-to-Treat
NICE – National Institute for Heath and Care Excellence
POAG – Primary open angle glaucoma
RCT - Randomised Controlled Trials
UK – United Kingdom
WGC - World Glaucoma Congress
WHO - International Clinical Trials Registry Platform
WOC - World Ophthalmology Congress

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Supplementary Files

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