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[Intervention Protocol]

Early versus delayed timing of vitrectomy after open-globe injury

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess the effects of early versus delayed timing of vitrectomy after open-globe injury on visual outcomes.

BACKGROUND

Description of the condition

Ocular trauma is a major cause of ocular morbidity worldwide. Estimates suggest that the global incidence of ocular trauma is between 3.5 and 4.5 per 100,000 [1, 2]. Open-globe injuries are defined as 'full thickness defects' of the eye wall due to either a laceration or rupture [3]. A ruptured globe occurs when blunt force applied to the eye causes a rapid and catastrophic increase in intraocular pressure. Lacerating injuries are caused by sharp objects, and the injury can be further subdivided into perforating, penetrating, and intraocular foreign body (IOFB) under the Birmingham Eye Trauma Terminology (BETT), an internationally accepted system for globe injury classification [3]. Zone of injury also affects prognosis and is defined by the international Ocular Trauma Classification Group as: Zone I: involving the cornea and limbus; Zone II: up to 5 mm posterior to the limbus; and Zone III: extending more than 5 mm posterior to the limbus [4]. The main cause of anatomical and functional failure after open-globe injury is scarring, including corneal opacity, and proliferative vitreoretinopathy (PVR).

Description of the intervention and how it might work

The timing of surgical management for open-globe injuries is a matter of debate. It is generally accepted that primary globe repair should be completed as soon as possible (at least within 24 hours) after injury to minimise the risk of complications such as endophthalmitis and expulsive haemorrhage [5, 6]. Primary repair restores the integrity of the globe, allowing the resolution of hypotony whilst repairing the barrier against infection. Pars plana vitrectomy (referred to henceforward as vitrectomy) is performed in eyes with IOFB, retinal detachment, or high risk of PVR. There is a dearth of clear international guidance for timing of vitrectomy after open-globe injuries, and significant variation in practice [6].

Early vitrectomy (e.g. within three days) or vitrectomy at the time of primary repair may reduce the opportunity for inflammation to occur and the risk of postoperative complications, including endophthalmitis, retinal detachment, and PVR [7, 8, 9, 10]. Early vitrectomy can be technically more difficult, with often reduced visibility due to corneal oedema and increased risk of intraoperative haemorrhage. In contrast, a delayed approach (e.g. up to 14 days) may allow time for oedema and haemorrhage to clear so that surgery is more comparable to an elective vitrectomy, with better posterior segment visibility, greater wound stability and allowing posterior vitreous detachment to occur spontaneously, making vitrectomy safer. However, significant PVR and retinal detachment may have already occurred by later time points, and the incidence and severity of postoperative complications may be higher [11, 12, 13, 14, 15].

Why it is important to do this review

Open-globe injuries are a serious form of ocular trauma and an important cause of vision loss worldwide. With a lack of consensus or clear international guidelines on their management, there is wide variation in practice in all areas of management. A recent survey of current practice patterns for the management of open-globe injuries collected from experts at eye trauma centres and emergency departments worldwide highlighted significant variation in timing of vitrectomy, with 21.2% considering the optimal timing within four days, 18.2% within four to seven days, and 45.5% seven days or more after primary repair [6]. Surgery is the mainstay of open-globe injury management, and incorrect timing of surgery will lead to irreversible vision loss as a result of endophthalmitis, PVR, and retinal detachment. The optimal timing for vitrectomy after open-globe injury therefore needs to be systematically evaluated.

OBJECTIVES

To assess the effects of early versus delayed timing of vitrectomy after open-globe injury on visual outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) or quasi-RCTs in this review. As we anticipate few RCTs, we plan to also include quasi-randomised trials, defined as studies that employ a method of allocating patients to a treatment arm that is not strictly random (e.g. allocating by hospital number). We will exclude cluster- and cross-over RCTs and studies that include only a single arm, such as early or late timing of intervention. We will include all studies irrespective of publication status. There will be no restrictions on date or language.

Types of participants

We will include participants of any age who have sustained an open-globe injury. We will define open-globe injury as 'full thickness defects' of the eye wall due to either a laceration or rupture as stated by the Birmingham Eye Trauma Terminology (BETT) [3]. We will also use the BETT to define injury types, and where available we will use the Ocular Trauma Score (OTS) and presenting visual acuity to determine severity [4].

Where studies include only a subset of relevant participants, we will include only the eligible participants. If this information is not provided separately, we will contact the study authors to obtain unpublished data for eligible participants. We will allow the authors a period of two months to respond. If we receive no response, we will conduct the review based on the available information and document the circumstances in a narrative summary.

Types of interventions

We will search for trials of timing of vitrectomy after open-globe injury, aiming to include any study that directly investigates the effect of different timing of vitrectomy after open-globe injury. Following a scoping literature review performed before the writing of the methods of this protocol, several non-randomised studies have reported discrete time frames for timing of vitrectomy. We therefore anticipate that the studies identified in this review will fall into the following groups.

- Early, defined as vitrectomy within four days of open-globe injury
- Delayed, defined as vitrectomy four to seven days after open-globe injury
- Late, defined as vitrectomy seven days or more after open-globe injury

Where studies with continuous reporting do not report a cut-off period for differentiating early versus delayed timing of vitrectomy, we will extract participant data and categorise the results into the predefined time frames for early, delayed, and late as above. If we are unable to extract participant data, we will contact the study authors for this information. We will evaluate the findings of the included studies, and if necessary include additional discrete time periods for timing of vitrectomy for further analysis. Where categorising participant data into time periods is not possible, we will provide a narrative summary of findings.

Outcome measures

Reporting one or more of the outcomes listed here is not an eligibility criterion. Relevant studies that measure our critical and important outcomes but do not report the data in a usable format will be narratively described.

Best-corrected visual acuity (BCVA) measured on logMAR (logarithm of the Minimum Angle of Resolution) chart (or equivalent decimal or Snellen charts) will be a critical outcome. All visual acuity data will be converted to logMAR equivalents for analysis. Where categorical variables are used to record visual acuity (i.e. hand motion (HM), light perception (LP), and counting fingers (CF)), we will use a standardised conversion to covert these measurements into continuous data to ensure the visual acuity data can be analysed appropriately [16]. Where studies give a categorical outcome (e.g. good vision is equal to or better than 6/60), we will extract continuous visual outcome data for analysis.

A minimum one-month follow-up of participants will be required for critical outcomes. We will record BCVA and proportion of participants who developed endophthalmitis; who developed proliferative vitreoretinopathy; who needed repeat retinal detachment surgery; with unsuccessful retinal reattachment without repeat surgery; and who had evisceration or enucleation at any time point postoperatively and reported at up to and including one month, three to six months, more than 12 months, and final follow-up where available.

Critical outcomes

- Best-corrected visual acuity (BCVA)
- Proportion of participants who developed endophthalmitis
- Proportion of participants who developed proliferative vitreoretinopathy (PVR)

Important outcomes

- Proportion of participants who needed repeat retinal detachment surgery
- Proportion of participants with unsuccessful retinal reattachment, defined as retinal re-detachment or persistent retinal detachment within six months of repair that did not result in repeated retinal detachment surgery
- Proportion of participants who had evisceration or enucleation (eye removal)

Search methods for identification of studies

Electronic searches

We will search the following bibliographic databases.

- Cochrane Central Register of Controlled Trials (CENTRAL; latest issue; which contains the Cochrane Eyes and Vision Trials register) in the Cochrane Library
- MEDLINE Ovid (1946 to present)
- Embase Ovid (1980 to present)
- PubMed (1948 to present)
- ISRCTN registry (www.isrctn.com/editAdvancedSearch)
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov/)
- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (www.who.int/ictrp)

We will apply the Cochrane sensitivity-maximising RCT filter to the appropriate databases (e.g. MEDLINE and Embase) and consult a medical librarian before performing the searches. We will not use any language restrictions in the electronic searches for trials. We will restrict the searches to after 1969 (the invention of vitrectomy) [17].

Searching other resources

We will search the reference lists of included trials to identify any other eligible trials or relevant systematic reviews that our search strategy may have missed, and we will perform a Google Scholar search with keywords taken from the preliminary search strategy (Supplementary material 1) to identify further potentially relevant studies. Where we identify potentially relevant studies, we will contact authors for missing data presumed to be relevant to the review objective.

Our review will not extend beyond the focus on effects of healthcare interventions to address additional types of evidence (e.g. economic issues or qualitative research questions), and as such there will be no additional searches for different types of evidence.

Data collection and analysis

Selection of studies

Three review authors (DM, LB, TK) will independently assess titles and abstracts of records identified by the search to determine potential relevance. We will use EndNote to manage the search results [18]. We will identify and exclude duplicates. We will exclude reports that do not meet the inclusion criteria and obtain the full-text reports of trials deemed potentially relevant. Author decisions on study eligiblity will then be compared, with any disagreements between review authors resolved by discussion or by consulting a fourth review author if needed. We will record excluded studies and the reasons for their exclusion in a 'Characteristics of excluded studies' table. We will record the study selection process in sufficient detail to complete a PRISMA flow diagram [19].

Data extraction and management

Three review authors (DM, LB, TK) will independently collect data using standardised Cochrane data collection forms. Any disagreements between review authors will be resolved by discussion or by involving a fourth review author if necessary. One review author will transfer data into RevMan software [20]. Where there are missing data, we will email the primary investigators to request the information. We will allow the authors a period of two

months to respond. If we receive no response, we will conduct the review based on the available information.

We will collect information on study design, participant characteristics, study eligibility criteria, details of the intervention, outcomes assessed, the source of study funding and any conflicts of interest stated by the investigators. We will develop and pilot the data extraction form using a representative sample of the studies to be reviewed and update the extraction form as required. We will summarise the characteristics of included studies and present this information in a 'Characteristics of included studies' table.

Risk of bias assessment in included studies

Three review authors (DM, LB, TK) will independently assess risk of bias in included studies using the Cochrane RoB 2 tool and following the methods specified in Chapter 8 of the *Cochrane Handbook for Systematic Reviews and Interventions* [21]. Any disagreements will be resolved through discussion. It is noted that authors performing risk of bias assessment and GRADE assessment are highly unlikely to be authors on potentially eligible studies, with the authors not having published RCTs on the timing of vitrectomy.

We will assess the risk of bias according to the following domains.

- Bias arising from the randomisation process
- Bias due to deviations from intended interventions
- Bias due to missing outcome data
- Bias in measurement of the outcome
- Bias in selection of the reported result

We will assess the risk of bias for the following outcomes, as reported in the summary of findings table.

- BCVA (measured on logMAR chart) (at three to six months and at final follow-up)
- Proportion of participants who developed endophthalmitis (within 12 months of primary repair)
- Proportion of participants who developed PVR (within 12 months of primary repair)

We are interested in assessing the effects of intervention adherence. To address these types of bias, we will use the signalling questions and algorithms recommended in RoB 2 to assign each domain one of the following levels of bias: 'low risk of bias', 'some concerns', or 'high risk of bias'. We will contact trial investigators for clarification of parameters graded as 'unclear'. We will present an overall risk of bias judgement for each study according to the algorithms in RoB 2 tool [22]; in case of disagreement between review authors regarding either the individual domains of a study or the overall risk of bias, a fourth review author will adjudicate.

We will use the RoB 2 Excel tool to implement RoB 2 and will store and present our detailed RoB 2 assessments as supplementary online material [22]. In addition, we will include figures to illustrate the risk of bias, and where possible we will add this information to figures showing meta-analysis (e.g. forest plots). If there is insufficient information to perform risk of bias assessment, we will contact study authors to obtain the missing information. We will allow the authors a period of two months to respond, after which we will perform the risk of bias assessment with the available information.

The overall risk of bias assessment will inform the GRADE assessment of the certainty of evidence and summary of findings table.

Measures of treatment effect

We will follow the guidance in Chapter 6 of the *Cochrane Handbook for Systematic Reviews of Interventions* and select appropriate effect measurements for the critical outcome measures, which include continuous and dichotomous data [21]. We plan to report risk ratios (RR) with 95% confidence intervals (CI) for dichotomous variables, and to compare normally distributed continuous data using the mean difference (MD) or standardised mean difference (SMD) with 95% CIs.

Unit of analysis issues

The unit of analysis will be the aggregate data of participants with open-globe injuries who underwent vitrectomy according to the group to which they were randomised. We will use participants (rather than eyes) with an open-globe injury as the unit of analysis. If there is uncertainty about the methodology used, we will contact the authors for clarification.

Dealing with missing data

Where possible, we plan to perform a per-protocol analysis using published data, and, if necessary, additional data from primary investigators. We will aim to collect and utilise the most detailed numerical data to facilitate analysis. Where statistical data are missing or unclear, we will contact the primary trial investigators for clarification and further information.

Reporting bias assessment

If more than 10 trials are included in the meta-analysis, we will construct funnel plots and consider tests for asymmetry to assess publication bias. We acknowledge the difficulty of detecting publication bias when there is a small number of included studies.

Synthesis methods

We will assess clinical and methodological heterogeneity amongst studies by careful review. If no substantial heterogeneity is identified, we will combine study data and assess statistical heterogeneity using the I^2 statistic to quantify inconsistency amongst the trials in each analysis and by examining forest plots. We will consider I^2 values greater than 50% as indicating that heterogeneity is of concern. If there is low evidence of heterogeneity between studies, we will meta-analyse the results using a random-effects model, unless the number of studies is three or fewer, in which case we will use a fixed-effect model.

If meta-analysis is precluded due to clinical and methodological heterogeneity, we will combine details of included studies such as population, intervention, and outcome measures in a narrative synthesis with tabulated summary of the data. We may pool the data regardless of statistical heterogeneity if we consider this to be a useful summary of the individual trial results. Narrative synthesis without meta-analysis will follow Synthesis Without Meta-analysis (SWiM) guidelines in methods, presentation of results, and discussion [23]. We will perform meta-analysis (if possible) on all studies that meet our inclusion criteria, regardless of the risk of bias. Given the difficulty in designing a trial with low risk of bias for a surgical intervention such as this, we expect all

studies to be at high risk of bias for blinding; we will discuss the impact of this in narrative review.

Investigation of heterogeneity and subgroup analysis

In the case of sufficient studies, we plan to analyse the effect of the intervention according to specific subgroups, as follows.

- Zone of injury: do different zones of injury predispose participants to worse visual outcomes? As described in the Background, zone of injury affects structures injured and therefore visual outcomes.
- Mechanism of injury: how does mechanism of injury (e.g. blast injury) impact visual outcomes? Different injury mechanisms are associated with differing injury severities caused by different levels of energy transfer, affecting prognosis and visual outcome.
- Injury severity (Ocular Trauma Score (OTS)): what is the significance of the initial OTS on visual outcomes? Similar to zone of injury, OTS assesses injury severity, which will affect visual outcome.
- Regimen of antimicrobial prophylaxis: does varying antimicrobial choice, dose, and duration impact endophthalmitis rates? Endophthalmitis is the other main complication of open-globe injury (after PVR) that prejudices visual outcome in addition to injury severity.

We will use a formal statistical approach in RevMan to analyse differences amongst subgroups [20].

Equity-related assessment

We do not plan to investigate health inequity in this review.

Sensitivity analysis

If sufficient data permit meta-analysis, we will perform sensitivity analyses to explore the impact of excluding studies at an overall high risk of bias on the effect sizes for each critical outcome.

Certainty of the evidence assessment

We will follow the guidance in Chapter 14 of the *Cochrane Handbook for Systematic Reviews and Interventions* when creating the summary of findings table and assessing the certainty of evidence [24]. We will include the following outcomes in the summary of findings table for the comparison of early versus delayed timing of vitrectomy for open-globe injuries.

- BCVA at final follow-up (measured on logMAR chart) (at three to six months and at final follow-up)
- Proportion of participants who developed endophthalmitis (within 12 months of primary repair)
- Proportion of participants who developed PVR (within 12 months of primary repair)

Two review authors (DM, LB) will independently use the GRADE approach to assess the certainty of evidence for each outcome based on the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness, and publication bias), employing GRADEpro GDT software [25]. Any disagreements between authors will be resolved through discussion. We will justify all decisions to downgrade the certainty of the evidence using footnotes.

Consumer involvement

Review authors did not involve consumers.

SUPPLEMENTARY MATERIALS

Supplementary materials are available with the online version of this article: 10.1002/14651858.CD016086.

Supplementary material 1 Search strategies

ADDITIONAL INFORMATION

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Editorial and peer-reviewer contributions

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- Sign-off Editor (final editorial decision): Gianni Virgili, Department NEUROFARBA, University of Florence, Italy and IRCCS - Fondazione Bietti, Rome, Italy;
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Anupa Shah, Cochrane Central Editorial Service;
- Editorial Assistant (conducted editorial policy checks, collated peer-reviewer comments, and supported the editorial team): Lisa Wydrzynski, Cochrane Central Editorial Service;
- Copy Editor (copy editing and production): Lisa Winer, Cochrane Central Production Service;
- Peer reviewers (provided comments and recommended an editorial decision): Mohammad Soleimani, University of Illinois at Chicago, Chicago, IL (clinical/content review); David Fleischman, University of North Carolina (clinical/content review); Clare Miles, Cochrane Evidence Production and Methods Directorate (methods review); Jo Platt, Central Editorial Information Specialist (search review).

Contributions of authors

RB conceived the review idea. DM, SH, SFH, TK, LB, and RB were involved in methodology design and data acquisition. All authors were involved in the research design and writing and/or reviewing of the protocol manuscript.

Declarations of interest

DM: no commercial or non-commercial conflicts of interest relevant to this review.

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Registration and protocol

Cochrane approved the proposal for this review in August 2023.

Data, code and other materials

Data sharing not applicable to this article as it is a protocol, so no datasets were generated or analysed.

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