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Efficacy of PreserFlo MicroShunt Versus Trabeculectomy in Glaucoma Treatment: A Systematic Review, Meta-Analysis, and Meta-Regression

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 November 2024 and was last updated on 16 November 2024.

INTRODUCTION

Review question / Objective Is there a difference in the efficacy of PreserFlo MicroShunt compared to Trabeculectomy in the surgical management of patients with glaucoma?

Rationale Glaucoma is the second leading cause of preventable blindness worldwide. Trabeculectomy remains the gold standard surgical treatment for glaucoma when less invasive therapies (medical therapies) have failed, a position it has held since the 1960s. However, alternative options, such as MicroShunt implants, have been increasingly studied. These newer approaches have been associated with lower complication rates in certain patient populations. Despite the presence of several well-designed, prospective studies with high internal and external validity, the lack of statistical power in some trials limits definitive conclusions regarding the potential integration of these new surgical techniques into clinical practice. The objective of this systematic review and meta-analysis is to evaluate the efficacy of the MicroShunt as a treatment option using a large sample size, providing the statistical power necessary to draw more robust conclusions. Additionally, this study will compare the MicroShunt to trabeculectomy, the current gold standard, to assess the relative effectiveness of these two surgical approaches.

Condition being studied Glaucoma that is refractory to medical therapies and requires surgical intervention.

METHODS

Search strategy We will use a boolean string system composed of: "Glaucoma" AND "trabeculectomy" AND "MicroShunt", "Glaucoma" AND "trabeculectomy" AND "PreserFlo", "Glaucoma" AND "trabeculectomy" AND "PreserFlo MicroShunt", "Glaucoma" AND " PreserFlo", "trabeculectomy" AND "MicroShunt", "trabeculectomy" AND "PreserFlo MicroShunt", "trabeculectomy" AND "PreserFlo". The databases

designated for performing the search, will be PubMed, CENTRAL Cochrane and ClinicalTrials.gov.

Participant or population We will include patients with glaucoma refractory to medical therapies who require surgical management and are enrolled in randomized controlled trials or observational studies comparing PreserFlo MicroShunt directly with trabeculectomy.

Intervention PreserFlo MicroShunt.

Comparator Trabeculectomy.

Study designs to be included Will be included studies with Experimental Design (Randomized controlled trial) and Observational design with a sample size of >10 patients.

Eligibility criteria For the purposes of this systematic review, we will include peer-reviewed journal articles published in English between January 2013 and November 2024. Eligible studies must have an experimental (randomized controlled trial) or observational (retrospective or prospective) design that directly compares PreserFlo MicroShunt and trabeculectomy for the treatment of glaucoma, with a minimum sample size of 10 patients. We will exclude studies such as brief comments, letters to the editor, literature reviews, systematic reviews (with or without meta-analysis), and studies that compare PreserFlo MicroShunt and trabeculectomy in contexts unrelated to glaucoma, or when combined with other therapies that alter the direct comparison between these two procedures.

Information sources PubMed, Central Cochrane and clinicalTrials.gov registry.

Main outcome(s) The primary outcomes to be assessed include the complete surgical outcome (success rate, failure rate, and pre- vs. post-treatment measures), all reported intra- and post-operative complications, and the procedure characteristics, such as surgical time and other relevant factors. These outcomes will be measured using appropriate statistical methods according to the systematic review findings, that could include mean differences, binary outcomes (e.g., relative risk or odds ratio), and/or time-to-event outcomes (e.g., hazard ratio), depending on the nature of the data.

Additional outcome(s) Additional outcomes will include medium- and long-term effects, adverse effects, complications, treatment failures, and any other relevant findings related to the treatment outcome. These outcomes will be assessed through the systematic review, with appropriate statistical methods applied to the collected data. Depending on the nature of the data, statistical analyses may involve the use of mean differences, binary outcomes (such as relative risk or odds ratio), and/or time-to-event analyses (such as hazard ratios). Furthermore, the following study-level information will be extracted: author(s), year of publication, country of study origin, baseline demographic data (including sample size, patient age, and pre-existing conditions), as well as any other relevant patient characteristics at the time of study enrollment.

Data management Three researchers will be involved in extracting, collecting, and analyzing the data from the systematic review. Two researchers will be responsible for data extraction and collection, while the third will oversee the process, inspecting the data and conducting the statistical analysis. Any discrepancies in the data will be resolved through consensus. The softwares that will be used to collect and manage the data, will be Excel, and Rstudio for statistical analysis.
In cases where data is missing or could not be collected, a three-step approach will be followed: First, the original study authors will be contacted to request the missing data. If this is not possible, a validated mathematical method will be applied to estimate the missing data. Finally, if neither of the previous steps is successful, the variable in question will be excluded from the analysis.

Quality assessment / Risk of bias analysis The Quality assessment/ Risk of bias analysis will be performed during the data extraction process by 2 researchers, the designated tools for that purpose will be the "Cochrane Collaboration tool for assessing the risk of bias for clinical trials" for assessing the Randomized controlled trials, and the "Methodological Index for Nonrandomized Studies (MINORS)" for non randomized observational studies. Any discrepancy will be approached by a general consensus.

Strategy of data synthesis The statistical analysis will be guided by the findings of the systematic review. If the effect size in each study is measured as a Mean Difference, a meta-analysis will be conducted using the Standardized Mean Difference (SMD) with the inverse variance method to weight the studies. A Random Effects or Fixed Effects model will be selected based on the degree of heterogeneity identified during the review process. The REML method will be applied to estimate heterogeneity.

If the effect size is reported as a binary outcome (e.g., Relative Risk, Odds Ratio, or Hazard Ratio), a logarithmic transformation will first be applied. Meta-analysis will then be conducted using the inverse variance method for study weights. The analysis will use either the REML method or the Mantel-Haenszel method, depending on the author's criteria and the specific characteristics of the data, with a Fixed Effects or Random Effects model selected based on the observed heterogeneity. Heterogeneity will be assessed using the Higgins I^2 statistic and the Cochrane Q test. An amount of heterogeneity of >50% will be considered to be high; a Pvalue of <0.05 will be used to define a statistical significant result.
If the necessary criteria are met, a Meta-Regression will be performed to assess both heterogeneity and the potential influence of various study-level variables on the overall effect size. A Funnel plot could be performed to complement the data exploration, looking for publication bias assessment including an Egger's test.

Subgroup analysis A subgroup analysis could be performed if the criteria for a meta-regression is not accomplished, and, there are evidence of high amount of heterogeneity, the variables used to this analysis will be defined according to the findings of the systematic review.

Sensitivity analysis A sensitivity analysis will not be conducted.

Language restriction English.

Country(ies) involved Mexico.

Keywords Glaucoma, Trabeculectomy, Ocular Hypertension, Filtering Surgery, Minimally Invasive Surgeries.

Dissemination plans The dissemination plan aims to present the research through a congress abstract and potentially publish a peer-reviewed journal article.

Contributions of each author

Author 1 - Maria Isabel Arias Gallardo - Author 1 will contribute with the study design, data extraction, statistical analysis, drafting of the manuscript and final review process.
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