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INPLASY

Efficacy of Paul drainage device in the treatment of glaucoma : A single-arm Meta analysis

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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 04 May 2024 and was last updated on 04 May 2024.

INTRODUCTION

Review question / Objective (1) the population treated with the PAUL drainage device for glaucoma, regardless of gender, age, and race. (2) the intervention was PAUL drainage device with no restrictions on the valve style. (3) the outcomes studied included any of the following: postoperative intraocular pressure, postoperative mean visual acuity, postoperative reduction in IOP-lowering medication types, Failure Rate During Follow-up, Complete Success Rate at 12 Months, Qualified Success Rate at 12 Months, Incidence of Complications During Follow-up.

Condition being studied Glaucoma is a common multi-factorial eye disease in ophthalmology, caused by degeneration of retinal ganglion cells, leading to progressive optic neuropathy, the exact mechanisms of which remain unclear. Reports suggest that by 2040, the global population of glaucoma patients will exceed 100 million, imposing a significant burden on global health. The most common signs and symptoms of glaucoma are elevated intraocular pressure and eye pain.Clinical researchers primarily focus on reducing aqueous humor production and promoting aqueous humor outflow to lower intraocular pressure, thereby slowing the disease's progression. The PAUL glaucoma implant (PGI), developed by Singapore's Advanced Ophthalmic Innovations Pte Ltd, is a new type of non-valve glaucoma drainage device, measuring 16.1 mm in length and 21.9 mm in width, with an inner diameter of 0.127 mm and an outer diameter of 0.467 mm. The goal of PGI is to reduce postoperative complications, and it has been successfully used in glaucoma treatment.

METHODS

Participant or population The population treated with the PAUL drainage device for glaucoma, regardless of gender, age, and race.

Intervention The intervention was PAUL drainage device with no restrictions on the valve style.

Comparator None.

Study designs to be included The study types included single-arm studies or cohort studies in Chinese or English.

Eligibility criteria Studies were excluded if one of the following conditions is met: 1. Repeatedly published literature; 2. Conference abstracts, conference records, reviews, meta-analyses, errata, letters, and case reports; 3. Lack of relevant data or inability to extract complete information; 4. Studies with fewer than 10 cases; 5. Follow-up time less than 3 months.

Information sources A systematic search of online databases including PubMed, EMBASE, MEDLINE, the Cochrane library and the Clinical Trials Registry (www. clinicaltrials. gov) was performed until the end of March 2024.

Main outcome(s) The outcomes studied included any of the following: postoperative intraocular pressure, postoperative mean visual acuity, postoperative reduction in IOP-lowering medication types, Failure Rate During Follow-up, Complete Success Rate at 12 Months, Qualified Success Rate at 12 Months, Incidence of Complications During Follow-up.

Quality assessment / Risk of bias analysis The Cochrane Collaboration's tool for assessing the risk of bias was utilized to assess the risk of bias in RCTs, including: (1) sequence generation; (2) allocation concealment; (3) blinding of participants and personnel; (4) blinding of outcome assessment; (5) incomplete outcome data; (6) selective outcome reporting; and (7) other bias. Besides, the Newcastle-Ottawa Scale (NOS) was used to assess the quality of cohort studies consisting of three factors: patient selection, comparability of the study groups, and the assessment of outcomes. We assigned a score of 0–9 to each study following the evaluation; higher scores represent higher study quality. A total score of ≥ 7 was considered good quality.

Strategy of data synthesis Heterogeneity analysis was performed first, and the extent of heterogeneity was determined. If the heterogeneity among study results was low ($P > 0.10$ and $I2 \leq 50\%$), a fixed-effect model was used to combine the effect sizes; if the heterogeneity was high ($P \leq 0.10$ and $I2 > 50\%$), a random-effects model was used.

Subgroup analysis The outcomes was performed subgroup analysis by different follow-time.

Sensitivity analysis Sensitivity analyses were performed to examine the robustness of the results and the effect of potential effect modifiers by excluding one study in each turn.

Country(ies) involved China.

Keywords Glaucoma; Paul drainage device; single-arm Meta analysis.

Contributions of each author
Author 1 - Xin Li.

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