iStent Inject Implantation for Pseudoexfoliative Glaucoma. A Scoping Review

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SUMMARY

Purpose: To evaluate the effect of standalone iStent inject implantation on intraocular pressure and the medication burden in patients with pseudoexfoliative (PEX) glaucoma, and to compare these findings with results reported for open-angle glaucoma without subtype stratification.
Materials and Methods: A search was conducted in PubMed Central, the Cochrane Library, and the ClinicalTrials.gov registry using keywords; *"iStent", "standalone",* and *"pseudoexfoliative"*. A total of 182 articles were identified, of which only one study met the inclusion criteria (see PRISMA Flow 2020 diagram). For comparison, the only available meta-analysis from Healey et al. [4] was used. (keywords: *"iStent", "standalone", "meta-analysis"*)
Results: Due to the limited number of eligible studies, a scoping review approach was adopted. The vast majority of screened studies did not provide data for individual subtypes of open-angle glaucoma or include outcomes from combined cataract surgery. The single included study comprised 15 eyes of 15 patients with PEX glaucoma. The followup period was 6 months. Intraocular pressure was reduced from 23.75 ±3.28 mmHg to 15.33 ±1.07 mmHg, representing a 35% reduction ($p < 0.001$), and antiglaucoma medication was reduced from an average of 2.33 to 1.04 ($p < 0.001$).
Conclusion: This scoping review provides an initial overview of current research on the standalone use of MIGS iStent inject in patients with PEX glaucoma. A major limitation is the identification of only a single relevant study, which precludes a deeper synthesis and metaanalysis. Overall, the available evidence remains limited and represents only a preliminary step toward further research that may yield more comprehensive insights and stronger foundations for clinical decisionmaking.
Key words: glaucoma, pseudoexfoliative, iStent Inject, standalone surgery

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INTRODUCTION

Glaucoma refers to a group of pathologies distinguished by chronic progressive neuropathy of the optic nerve, leading to characteristic morphological changes on the optic nerve papilla, as well as in the retinal nerve fiber layer. These changes are associated with progressive loss of the ganglion cells, leading to visual field impairment . The only factor that can be influenced by treatment is intraocular pressure. Pseudoexfoliation syndrome is an ocular manifestation of a systemic disorder, characterized in the eye by the presence of deposits of abnormal fibrillar material on a variety of intraocular structures of the anterior segment. This material may accumulate in the trabecular meshwork and impair the drainage of intraocular fluid. It may be present both bilaterally and asymmetrically. Pseudoexfoliation material can also be found in other parts of the body, including the skin, lungs, heart, liver, and kidneys. Pseudoexfoliation syndrome is associated with myocardial infarction, stroke, and arterial hypertension. The etiology is unknown, and is associated with the formation of an abnormal extracellular matrix in the cellular basement membrane. Upon a finding of characteristic glaucomatous changes on the optic nerve papilla and the presence of pseudoexfoliation material on any structure of the eye, we refer to this condition as pseudoexfoliative glaucoma. This is secondary open-angle glaucoma. The high rate of complications of classic glaucoma surgery (in which we include trabeculectomy and drainage devices) has led to the introduction of new types of operations using special implants – MIGS – minimally invasive glaucoma surgery. Implants from this group create a low-resistance bypass between the anterior chamber and the Schlemm's canal [1].

iStent Inject W is composed of an injector with two stents, which are progressively inserted into the trabecular meshwork via a corneal incision using an ab in-

terno technique. The base of the implant is visible by means of a gonioscopic examination in the anterior chamber, and lies on the trabecular meshwork. The central cavity of the implant enables the flow of the intraocular fluid into the Schlemm's canal. It is made of titanium coated with heparin and is non-ferromagnetic, thus patients with this implant can undergo magnetic resonance imaging examination. This is the smallest implant used in medicine. The dimensions of the implant are 0.36 mm in length and 0.23 mm in width. The width of the internal lumen is 0.08 mm [2].

This overview aims to map the scope of the current research. With reference to the limited number of studies found, a scoping review has been used instead of a systematic review with a meta-analysis.

MATERIAL AND METHODS

When compiling this overview, the aim was to evaluate the effectiveness of iStent on the most common form of secondary open-angle glaucoma – pseudoexfoliative (PEX) glaucoma. This type of glaucoma has different pathophysiological mechanisms from primary open--angle glaucoma, and as a result it is relevant to assess whether an implant will be similarly effective also in this group of patients. However, the great majority of available studies have only included small numbers of patients with PEX glaucoma, whose data were not analyzed separately but combined with the results of patients with primary open-angle glaucoma. This fact represents a significant limitation for the interpretation of the results.

Another important aspect was the attempt to assess the effectiveness of iStent implantation separately. For this reason, studies in which iStent was implanted simultaneously with cataract surgery were excluded from the cohort. The combination of these two procedures may pronouncedly influence the resulting values of intraocular pressure and thereby distort the actual benefit of the implant itself. Furthermore, a number of the excluded studies did not describe the configuration of the chamber angle before surgery, or also included patients with a narrow chamber angle, in whom a greater reduction of intraocular pressure is primarily to be expected also after cataract surgery alone. The inclusion of such studies would not enable us to obtain quality and unambiguously interpretable results.

For the above reasons, strict inclusion criteria were applied in the selection of the literature, in order to ensure the highest possible validity in evaluating the effect of iStent implantation as a standalone procedure, and at the same time to enable identification of data relating to PEX glaucoma.

RESULTS

Selection of articles

A search of the literature was conducted on December 31, 2025 in the PubMed and Cochrane Library databases, and in the ClinicalTrials.gov register. Predefined key words were used, which combined the name of the implant and its separate use: („istent"[All Fields] OR „istents"[All Fields]) AND „standalone"[All Fields] AND („pseudoexfoliation"[All Fields] OR „pseudoexfoliations"[All Fields] OR „pseudoexfoliative"[All Fields]). This combination was chosen with the aim of identifying studies evaluating the effect of iStent implantation without concurrent cataract surgery, specifically in patients with PEX glaucoma, which is the most common form of secondary open-angle glaucoma.

A total of 182 records were identified, which were subsequently subjected to a screening process. First, duplicate records were removed, after which the titles and abstracts were assessed in terms of their relevance. In the next phase, full texts were evaluated according to the predetermined eligibility criteria: only studies in which iStent implantation was performed as a standalone procedure (without combination with cataract surgery), and where separate data relating to PEX glaucoma was available, were included in the cohort. After the application of these criteria, only one study remained which met the conditions for inclusion in the scoping review. The entire selection process is presented in Figure 1. PRISMA 2020 flow diagram.

Characteristics of the included study

The study conducted by Klamann et al. was a retrospective cohort study from a single center, focusing on patients with open-angle glaucoma (primary open-angle glaucoma, PEX glaucoma, pigment glaucoma) with insufficiently controlled intraocular pressure despite pharmacotherapy. The study included 35 eyes of 35 patients. Of these 35 patients, 17 had primary open-angle glaucoma (POAG), 15 PEX glaucoma and 3 pigment glaucoma (PG). All the patients had moderate glaucoma, and target intraocular pressure was set at below 16 mmHg. Follow- up lasted six months without any loss of patients. The surgical procedure consisted in the implantation of two iStent Inject stents into the Schlemm's canal as a standalone procedure. Values of intraocular pressure, the number of antiglaucoma drugs, and the incidence of complications were evaluated [3].

Results of study

The follow-up period was 6 months. Patients in the group with PEX glaucoma recorded a reduction of intraocular pressure by 35% ($p < 0.001$), and the number of used antiglaucoma drugs was also reduced from an average of 2.33 to 1.04 ($p < 0.001$). Mean intraocular pressure before surgery was 23.75 ±3.28 mmHg, decreasing to 15.33 ±1.07 mmHg six months after surgery [3].

Comparison with studies not stratified by subtype of open-angle glaucoma

In the sole available meta-analysis conducted by the authors Healey et al. [4] investigating iStent as a standalone operation without differentiation of the subtype of

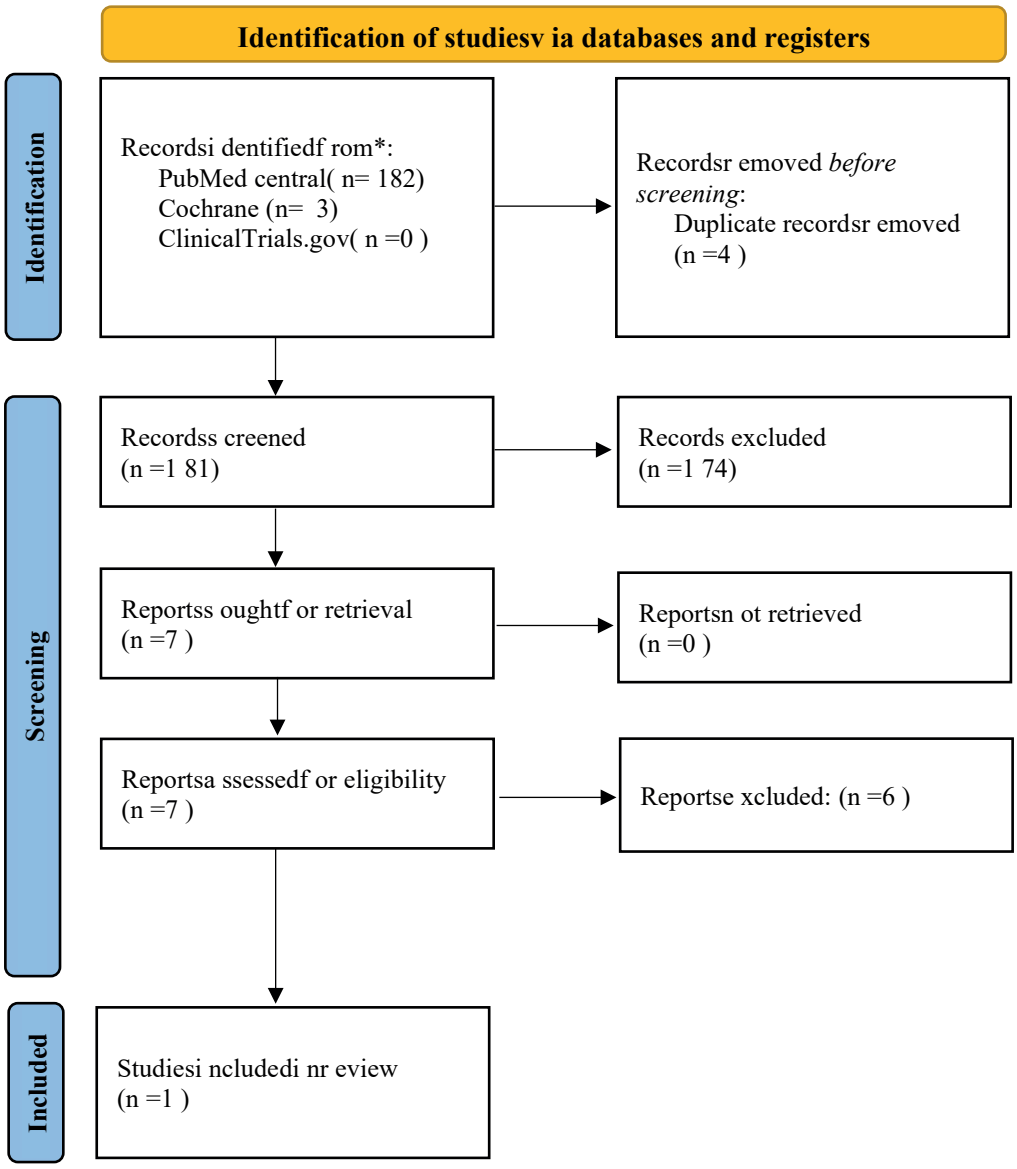

Figure 1. Prizma 2020 flow diagram

open-angle glaucoma, the summary data show an average reduction of intraocular pressure by 7.01 mmHg, thus a reduction by 31.1%, within an interval of 6–12 months after the procedure, and a reduction of the local theraphy burden by approximately 1.0 medication within a follow-up period of 6–18 months. In this comparison, patients with PEX glaucoma therefore show a somewhat more pronounced reduction of intraocular pressure, and a similarly significant reduction of the number of used antiglaucoma medication in comparison with the broader population of patients with open-angle glaucoma without differentiation of the subtype [4]. Table 1.

DISCUSSION

We identified only one study with a separately evaluated cohort of patients with PEX glaucoma. In this group, implantation of iStent Inject as a standalone procedure led to a significant reduction of intraocular pressure, as well as a reduction of the need for medication in patients with PEX glaucoma, and it was therefore confirmed that iStent can be effective also for this subtype of glaucoma. However, this study has a number of major limitations. It was a retrospective study

Table 1. Comparison of the PEX subgroup results from the study by Klamann et al. with the meta-analysis by Healey et al. that did not stratify glaucoma by subtype

Glaucoma type	IOP reduction	Medication reduction
PEX	8.42 mmHg (35%)	-1.29
Unstratified by subtype	7.01 mmHg (31.1%)	-1.0

PEX – pseudoexfoliative, IOP – intraocular pressure

from a single center, which included only 15 patients in the PEX glaucoma branch, and the follow-up period was only six months. In this study, a more pronounced reduction of intraocular pressure, as well as of the need for antiglaucoma medication, was recorded in the group of patients with PEX glaucoma, in comparison with the results of the meta-analysis of cohorts of patients with open-angle glaucoma without differentiation by subtype. Further research with a larger cohort is required to reach more reliable conclusions.

CONCLUSION

This scoping review represents an introductory mapping of the current knowledge relating to the standalone use of MIGS iStent Inject in patients with PEX glaucoma. In conclusion we may state that the knowledge we have in this field so far remains limited, and rather represents an initial step towards further research, which could then facilitate a deeper understanding and provide more reliable source materials for clinical practice.

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