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Role of minimally invasive glaucoma procedures increasing the outflow of aqueous humor through the conventional pathway in advanced treatment of glaucoma

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ABSTRACT

The objective of glaucoma surgery is to prevent the progression of the disease. In practice, surgical treatment of glaucoma is typically undertaken when pharmacotherapy is ineffective, poorly tolerated, contraindicated, or improperly used by the patient. Minimally invasive glaucoma surgery (MIGS) represents one of the latest advancements in surgical approaches for managing glaucoma. MIGS is mainly used in the treatment of primary open-angle glaucoma and some types of secondary open-angle glaucoma, in particular pseudoexfoliation glaucoma. Minimally invasive glaucoma procedures to increase the outflow of aqueous humor via the conventional route, including ab interno goniotomy with the Kahook blade, iStent, Hydrus Microstent, Trabectome, excimer laser trabeculotomy, ab interno canaloplasty, and gonioscopy-assisted transluminal trabeculotomy are considered to be the safest. Another benefit of MIGS is the possibility to perform the surgical procedure concurrently with cataract phacoemulsification, while also preserving the bulbar conjunctiva, thereby enabling potential future procedures, if needed.

An analysis of the outcomes of studies on standalone MIGS procedures improving aqueous humor outflow via the conventional pathway, as well as combined procedures with cataract phacoemulsification, shows their high efficacy in lowering intraocular pressure and reducing the number of active substances used for treatment, which crucially contributes to the success of glaucoma therapy, preservation of functional visual acuity, and improvement in the quality of life for patients. The aim of this study was to review the literature on the topic of minimally invasive glaucoma procedures increasing the outflow of aqueous humor via the conventional pathway.

KEY WORDS: trabectome, Hydrus Microstent, excimer laser trabeculotomy, ab interno canaloplasty, minimally invasive glaucoma surgery, ab interno goniotomy with Kahook dual blade.

INTRODUCTION

Glaucoma is a term describing a group of disorders characterized by optic neuropathy, associated with connective tissue remodeling and loss of nerve tissue, which culminates in the development of a distinct pattern of visual dysfunction [1]. Glaucoma encompasses a diverse spectrum of diseases, all of which involve the death of retinal ganglion cells in the process of apoptosis [2]. Untreated glaucoma leads to irreversible blindness; the condition ranks as the second most prevalent cause of vision loss. It is estimated that 64.3 million people worldwide are affected by glaucoma. Reducing intraocular pressure is recognized as the sole effective treatment for glaucoma, and all therapeutic approaches, including pharmaceutical, laser-based, and surgical interventions, rely on this principle [3].

The main risk factor for the development of glaucomatous neuropathy is elevated intraocular pressure (IOP) [2]. Other risk factors include a thin cornea, positive family history, myopia greater than –3.0 D, diabetes mellitus, hypertension, hypotension, Raynaud's syndrome, and migraine [4].

Glaucoma can progress asymptomatically for many years. In its initial phase, the disease may not cause pain, ocular irritation, or a decline in visual acuity. However, if left untreated, it progresses to a slow, irreversible loss of vision.

The diagnosis of glaucoma can be confirmed or ruled out on the basis of all primary examinations, i.e. tonometry, go-

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nioscopy, stereoscopic assessment of the optic disc, and perimetry [4]. Further diagnostic insights can also be obtained from optic disc evaluation by optical coherence tomography.

HYDRODYNAMICS OF AQUEOUS HUMOR

Aqueous humor is secreted by the ciliary processes and flows into the posterior chamber at an average rate of 2-3 µl/min. Production occurs via active secretion, ultrafiltration, and simple diffusion. Aqueous humor production rate fluctuates throughout the day, decreasing by half during sleep. It is also known to decrease with age. Other potential factors contributing to a decreased production of aqueous humor include trauma, intraocular inflammation, and carotid artery stenosis [1]. From the posterior chamber, aqueous humor flows through the pupillary opening to the anterior chamber, from where it is drained via three routes:

- conventional pathway (pressure-dependent flow through the trabecular mesh into Schlemm's canal and then to the episcleral venous plexuses),
- unconventional pathway (pressure-independent flow through the uveoscleral pathway to the suprachoroidal space),
- via the iris [1, 5].

CLASSIFICATION OF GLAUCOMA

Glaucoma is subdivided into:

- open-angle glaucoma (primary and secondary),
- closed-angle glaucoma (primary and secondary),
- pediatric glaucoma.

Minimally invasive glaucoma treatments are mainly used for managing primary open-angle glaucoma and certain types of secondary open-angle glaucoma, particularly pseudoexfoliation glaucoma [6].

TREATMENT OF GLAUCOMA

The aim of glaucoma treatment is to preserve visual function and the associated quality of life by reaching the target intraocular pressure, preventing progression of optic nerve damage, and maintaining stable visual field test parameters. Target pressure values are individual for each patient and depend, among others, on the extent of glaucomatous damage, pre-treatment intraocular pressure, age and life expectancy of the patient, rate of disease progression, and presence of other risk factors [4].

Currently, there is a broad array of therapeutic options available for treatment, ranging from pharmacotherapy (prostaglandin analogues, β-blockers, carbonic anhydrase inhibitors, and α2 agonists) to laser therapy and surgical interventions [1, 4].

The European Glaucoma Society (EGS) advises considering surgical intervention for glaucoma when there is no possibility to control the progression of neuropathy with conservative treatment with the use of two or more topical medications. At the same time, the Polish Society of Ophthalmology (PTO) emphasizes that surgical treatment should not be regarded solely as a last-line option [6]. In practice, surgical treatment is typically undertaken when pharmacotherapy is ineffective, poorly tolerated, contraindicated, or improperly used by the patient [1].

Surgical methods for treating primary and secondary open-angle glaucoma can be classified based on the severity of glaucomatous damage:

- early to intermediate glaucoma:
  - non-penetrating procedures (deep sclerectomy, viscocanalostomy, canaloplasty),
  - minimally invasive procedures (iStent, Trabectome, XEN Gel Stent [Aquesys], Cy-Pass),
  - trabeculectomy,
  - endoscopic cyclophotocoagulation (ECP);
- intermediate to advanced glaucoma:
  - trabeculectomy,
  - glaucoma drainage implants, including mini drainage devices: Ex Press and Gold Shunt, XEN Gel Stent (AqueSys),
  - transscleral or endoscopic laser cyclophotocoagulation procedures [6].

Conventional antiglaucoma procedures, such as trabeculectomy or drainage implants, while highly effective, carry a relatively elevated risk of postoperative complications [7, 8]. Therefore, in the contemporary world, there is a continual need to search for therapies that offer optimal disease control while minimizing side effects and maintaining a high quality of life for patients.

MIGS methods represent some of the most advanced techniques in the surgical management of glaucoma. They are characterized by a very good safety profile, short duration, minimal disruption to ocular structures, absence of clinically significant complications, lack of postoperative effect on ocular refraction, and improved patient comfort. They are preferred for managing early to moderately advanced stages of glaucoma [6]. An added benefit is that MIGS procedures can be performed concurrently with cataract phacoemulsification surgery. These procedures preserve the bulbar conjunctiva, allowing other procedures to be performed in the future, if necessary [9, 10].

Minimally invasive glaucoma treatments can be categorized based on their mechanism of action into:

- procedures increasing the outflow of aqueous humor:
  - via Schlemm's canal:
    - ab interno goniotomy,
    - iStent,
    - Hydrus Microstent,
    - Trabectome,
    - excimer laser trabeculostomy (ELT),
    - ab interno canaloplasty (ABiC),
    - gonioscopy-assisted transluminal trabeculotomy (GATT),
  - via the suprachoroidal space:
    - Cy-Pass Microstent,
    - iStent Supra,
    - into the subconjunctival space:
    - XEN Gel Stent (AqueSys);

- inhibiting the production of aqueous humor:
    - endoscopic cyclophotocoagulation (ECP) [3].

Because of the benefits mentioned above, the role of minimally invasive procedures enhancing the outflow of aqueous humor through the conventional pathway has been rising. Consequently, there is a need to analyze these methods more closely.

Ab interno goniotomy using Kahook Dual Blade

In 2015, the Food and Drug Administration (FDA) approved the application of Kahook Dual Blade (KDB) for minimally invasive glaucoma surgery. The process facilitates excision of a portion of the trabecular meshwork, which lowers resistance to the outflow of aqueous humor from the anterior chamber into Schlemm's canal, leading to a reduction of intraocular pressure [10].

In the study by Majer *et al*., the KDB procedure was conducted concurrently with cataract phacoemulsification surgery. At the 6-month follow-up, a mean reduction in IOP from 21.90 ±3.9 mmHg to 18.14 ±3.2 mmHg (a 17.53% decrease) was achieved along with a decrease in the number of active substances used from 2.2 ±1.1 to 0.88 ±1.0 (60%). Furthermore, the number of active substances decreased by at least one in 82% of eyes 6 months after the procedure [10].

In their study, Barry *et al*. analyzed the outcomes of studies investigating the standalone ab interno goniotomy procedure performed with the Kahook blade. A decrease in IOP from a mean of 20.30 ±7.3 mmHg before treatment to 18.0 ±3.0 mmHg four to 6 months after treatment was noted. Furthermore, there was a reduction in the number of active substances from 2.4 ±1.26 to 0.2 ±0.63 [11].

In the study by Greenwood *et al*., evaluating the efficacy of combined ab interno goniotomy using the KDB with cataract phacoemulsification, a decrease in IOP was achieved, from 17.4 ±5.2 mmHg preoperatively to 12.8 ±2.6 mmHg 6 months postoperatively. Additionally, the number of active substances was reduced from 1.6 ±1.3 to 0.9 ±1.0 [12].

Similarly, in the 12-month follow-up study conducted by Dorairaj *et al*., patients who underwent cataract phacoemulsification combined with KDB goniotomy experienced a reduction in IOP from a mean of 16.8 ±0.6 mmHg to 12.4 ±0.3 mmHg (a 26.2% decrease). Furthermore, the number of active substances decreased from 1.6 ±0.2 to 0.8 ±0.1 (a 50% reduction) [13].

Another study, conducted by Hirabayashi *et al*., demonstrated a reduction in IOP by a mean of 2.1 ± 4.67 mmHg at the six-month follow-up, along with a reduction in the number of active substances used for treatment by 1.2 ±1.4 [14].

Furthermore, Bardahl *et al*. demonstrated a more significant reduction in IOP and a decrease in the number of active substances in the eyes with higher baseline IOP values [15].

Trabectome

Trabectome is a device used for performing ab interno trabeculotomy. The procedure involves electroablation of the trabecular meshwork and the inner wall of Schlemm's canal, followed by the removal of bands of cauterized tissue by aspiration and irrigation [3]. The method was approved by the FDA in 2004. The procedure has a favorable safety profile.

In the study by Minckler *et al*., who analyzed a group of 25 patients treated with standalone trabeculotomy, a reduction in intraocular pressure from 28.2 ±4.4 mmHg to 17.4 ±3.5 mmHg was achieved six months after the procedure. Furthermore, the authors noted a reduction in the number of active substances used by patients from 1.2 ±0.6 to 0.4 ±0.6 [16].

In another study, conducted by Mizoguchi *et al*. on 82 eyes with primary open-angle glaucoma and pseudoexfoliation glaucoma, a reduction in IOP from the mean value of 22.3 ±6.8 mmHg to 14.0 ±3.9 mmHg was observed 24 months after the procedure [17].

Other studies have also shown that the degree of intraocular pressure reduction post-surgery is contingent upon its baseline values [18].

Shoji *et al*. also assessed the effect of the Trabectome procedure on intraocular pressure in patients with secondary open-angle glaucoma, noting a reduction in IOP from a mean of 33.6 ±11.1 mmHg to 14.7 ±2.9 mmHg at 12 months after the procedure. Furthermore, the authors demonstrated no statistically significant differences in the efficacy of lowering IOP in patients with primary and secondary open-angle glaucoma, as well as no differences between the procedure performed alone and combined with cataract phacoemulsification [19].

iStent

The iStent is an L-shaped, heparin-coated titanium microstent measuring 1 mm by 0.33 mm, with a lumen diameter of 120 µm. It is positioned within the trabecular meshwork to establish a connection between the anterior chamber and Schlemm's canal, which facilitates the drainage of aqueous humor, leading to a reduction in intraocular pressure [3, 20].

One implant reduces intraocular pressure by a mean of 8-17.3%, while two implants can lower it by 20-48% [3, 21, 22]. Likewise, the implantation of one iStent decreases the number of active substances used for treatment by 1.68, while two and three iStents result in a reduction by 1.88 and 2.0, respectively, during the six months following the procedure [23].

iStent implantation is very commonly combined with cataract phacoemulsification. A six-month follow-up of patients after the combined procedure (89 eyes with primary open-angle glaucoma and two eyes with glaucoma associated with pseudoexfoliation syndrome) in the study by Hajduga-Szewczyk revealed a mean reduction in IOP of 3.36 ±3.91 mmHg (18.92%) and a decrease in the number of active substances by 1.61 ±1.20 (77.78%) [20].

Hydrus Microstent

The implant is made of a highly flexible biocompatible material called Nitinol and measures 8 mm in length. The design of the implant is suited to fit Schlemm's canal and enables the cannulation of up to three clock hours of the canal [3].

A study conducted by Fea *et al*., including 67 patients with primary open-angle glaucoma who underwent Hydrus implantation with simultaneous cataract phacoemulsification, showed a reduction in intraocular pressure from 19.4 ±4.4 mmHg to 15.7 ±2.5 mmHg during a two-year follow-up. The mean number of active substances used decreased from 2.1 ±1.0 to 0.7 ±1.0 [24].

In the study conducted by Pfeiffer *et al*. comparing the therapeutic efficacy of standalone cataract removal with the combined procedure involving the implantation of a Hydrus microstent, a considerable superiority of the combined procedure in reducing IOP and the number of active substances was demonstrated two years postoperatively. Importantly, no significant differences in the safety profile were observed [25].

Bicket *et al*. reported that the probability of achieving glaucoma control without the need to use eye drops both at 6-18 months and over 18 months postoperatively was significantly higher in patients who underwent combined surgery [26].

Excimer laser trabeculotomy

The procedure involves photoablation of the trabecular tissue and the inner wall of Schlemm's canal via the ab interno approach using 308 nm excimer laser. It allows for precise excision of the trabecular meshwork and the anterior wall of Schlemm's canal, while sparing the posterior wall. It enhances the outflow of aqueous humor from the anterior chamber into the canal, thereby reducing the impact of thermal damage on adjacent tissues and preventing scarring [3, 27].

In the studies by Babighian *et al*., intraocular pressure decreased from 24.8 ±2.0 mmHg to 16.9 ±2.1 mmHg and from 25.0 ±1.9 mmHg to 17.6 ±2.2 mmHg two years after performing the standalone ELT procedure [28, 29].

Berlin *et al*. also assessed the efficacy of standalone ELT compared to the combined procedure with cataract phacoemulsification over a two-year follow-up period. Patients undergoing ELT alone showed a decrease in IOP from 24.1 ±0.7 mmHg to 16.8 ±1.0 mmHg at the two-year mark. Also, the number of active substances used was reduced from 2.25 ±1.26 before the procedure to 1.46 ±1.38 at one year after the procedure. The combined treatment led to a reduction in intraocular pressure from 22.4 ±0.6 mmHg to 12.6 ±1.5 mmHg at two years of follow-up. The combined procedure was found to be more effective. Similarly to other MIGS methods, the extent of intraocular pressure reduction was found to depend on the baseline IOP values [27].

Ab interno canaloplasty

ABiC is a method that reduces the resistance to aqueous humor outflow in the area of the filtration angle by dilating Schlemm's canal. The procedure involves making a small goniotomy within the trabecular meshwork, followed by the insertion of a catheter through it circumferentially into Schlemm's canal and advancing it either 180° or 360°. After removing the catheter, a viscoelastic agent (such as Healon GV) is injected into the canal to dilate it.

In a 12-month follow-up conducted by Hughes *et al*., involving 64 patients (89 eyes), with 72 eyes treated by ab interno canaloplasty combined with simultaneous cataract removal and 17 eyes treated without phacoemulsification, IOP decreased by a mean of 24.5 ±8.3 mmHg to 16.5 ±3.4 mmHg. Furthermore, there was a reduction in the number of active substances used from 2.5 ±1.3 to 1.8 ±1.4. In the aforementioned study, no statistically significant differences in patient outcomes were found between the two methods. The efficacy of the procedures spanning 180° and 360° of Schlemm's canal was also compared and, again, no statistically significant differences were observed [30].

In contrast, the two-year follow-up by Lewis *et al*. revealed a decrease in IOP from 23.2 ±4.0 mmHg to 16.3 ±3.7 mmHg and a reduction in the number of active substances used from 2.0 ±0.8 to 0.6 ±0.8 in patients undergoing standalone canaloplasty. Meanwhile, in patients treated with the combined procedure, IOP dropped from 23.1 ±5.5 mmHg to 13.4 ±4.0 mmHg, and the number of active substances decreased from 1.7 ±1.0 to 0.2 ±0.4 [31].

Gonioscopy-assisted transluminal trabeculotomy

GATT is a method first proposed in 2014, which involves insertion of a microcatheter with a fiber optic light circumferentially into Schlemm's canal, spanning 360°, via an ab interno approach, and then cutting the trabecular meshwork, which decreases the resistance to aqueous humor outflow.

Grover *et al*. demonstrated a mean decrease in IOP of 7.7 ±6.2 mmHg (30%) and a reduction in the number of active substances by 0.9 ±1.3 in 57 patients with primary open-angle glaucoma at six months after the procedure. Additionally, the authors observed a decrease in IOP by 11.1 ±6.1 mmHg (39.8%) at 12 months. In a cohort of patients with secondary open-angle glaucoma, based on an analysis of outcomes achieved in 28 individuals, a decrease in IOP by 17.2 ±10.8 mmHg (52.7%) and a reduction in the number of active substances by 2.2 after six months of follow-up were observed [32].

In another study by Grover *et al*., conducted among patients with primary open-angle glaucoma, a mean decrease in IOP of 9.2 mmHg (37.3%) and a reduction in the number of active substances used for treatment by 1.43 were observed at the 24-month follow-up. In turn, a mean decrease in intraocular pressure of 14.1 mmHg (49.8%) and a reduction in the number of active substances used by 2.0 was observed in a cohort of patients with secondary open-angle glaucoma [33].

During a 12-month follow-up, Rahmatnejad *et al*. reported a mean IOP reduction of 44% and a decrease in the number of active substances used from a mean of 3.1 ±1.1 to 1.2 ±0.9 in patients with primary open-angle glaucoma at 12 months postoperatively [34].

Because of the advantages associated with simultaneous MIGS treatment and cataract phacoemulsification, the combined effect of these procedures on intraocular pressure and

on the number of active substances used by patients is frequently assessed. As a consequence, studies evaluating the effect of standalone cataract phacoemulsification surgery on intraocular pressure are also documented in the literature. In the study conducted by Majstruck *et al*., a reduction in intraocular pressure of 1.15 ±3.0 mmHg (6.8 ±18.1%) was observed at the 12-month follow-up. However, there was no statistically significant effect on the number of active substances used [35].

Baek *et al*. examined the outcomes of 754 patients (106 diagnosed with glaucoma) who underwent cataract phacoemulsification. One year after surgery, the authors observed mean IOP reductions of 1.03 ±3.72 mmHg and 1.08 ±3.79 mmHg in patients without and with glaucoma, respectively [36].

In their analysis of 461 patients diagnosed with primary open-angle glaucoma, Chen *et al*. reported a mean IOP reduction of 13% 17 months after phacoemulsification. In patients with pseudoexfoliation glaucoma (132 patients), the researchers observed a mean decrease in IOP of 20% [37].

According to the cited studies, cataract phacoemulsification alone has a favorable effect on intraocular pressure in patients with primary open-angle glaucoma and glaucoma associated with pseudoexfoliation syndrome. However, the degree of intraocular pressure reduction is significantly greater in patients undergoing the combined procedure [10, 26].

The objective of glaucoma surgery is to halt the progression of the disease. MIGS procedures are generally regarded as having a good safety profile; however, they are not entirely free of complications. In some cases, during the initial postoperative period, vision may temporarily worsen, and intraocular pressure may initially be higher compared to pre-procedure levels. Hemorrhage into the anterior chamber and hyphema are also observed. These are transient symptoms that usually resolve within a few days after the procedure and do not signify treatment failure, of which the patient should be informed. More serious complications, like postoperative hypotension or cyclodialysis, are very rare. Procedures that increase the outflow of aqueous humor through Schlemm's canal rank among the safest minimally invasive glaucoma interventions, while providing high efficacy in reducing intraocular pressure [38].

DISCLOSURES

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