IJISET - International Journal of Innovative Science, Engineering & Technology, Vol. 12 Issue 01, January 2025
ISSN (Online) 2348 – 7968 | Impact Factor – 6.72
www.ijiset.com

Mathematical Modelling of the Therapeutic Efficacy of Metipranolol in Primary Open Angle Glaucoma Management

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Abstract: Primary Open Angle Glaucoma (POAG), a leading cause of irreversible blindness, arises from elevated intraocular pressure (IOP) due to impaired aqueous humour outflow through the trabecular meshwork and Canal of Schlemm. This study presents a mathematical model analysing aqueous humour dynamics within the compliant, porous Canal of Schlemm, modelled as an elliptical channel. Using the Navier-Stokes equations, the model evaluates the effects of key parameters, including the filtration constant, canal geometry, and IOP, on pressure distribution and volume flux. The results demonstrate the therapeutic efficacy of Metipranolol, a beta-adrenergic blocker, in enhancing the filtration constant, improving aqueous humour drainage, and significantly reducing IOP. Additionally, larger canal dimensions are shown to increase drainage capacity, especially under elevated IOP conditions. These findings highlight the critical role of pharmacological interventions and anatomical factors in glaucoma management, offering a comprehensive framework for mitigating POAG progression.

Keywords: Primary Open Angle Glaucoma (POAG), Intraocular Pressure (IOP), Aqueous Humour Dynamics, Canal of Schlemm, Metipranolol, Beta-Adrenergic Blocker, Mathematical Modeling, Navier-Stokes Equations, Filtration Constant, Fluid Dynamics, Elliptical Channel, Glaucoma Management.

Introduction: Primary Open Angle Glaucoma (POAG) is one of the most prevalent and severe forms of glaucoma, affecting millions of people globally. It is a chronic, progressive optic neuropathy characterized by the slow and insidious loss of retinal ganglion cells, which eventually leads to irreversible blindness if left untreated. POAG is a leading cause of blindness, especially among individuals over the age of 60, and it affects people of all racial and ethnic backgrounds, though it is more common in populations of African, Asian, and Hispanic descent. According to the World Health Organization (WHO), glaucoma is the second leading cause of blindness worldwide, with POAG accounting for the majority of these cases. The pathophysiology of POAG primarily involves the impairment of aqueous humour outflow, which results in an increase in intraocular pressure (IOP). IOP is the pressure exerted by the fluid inside the eye, and its regulation is critical for maintaining normal eye function. Elevated IOP is considered the primary risk factor for POAG, as it can cause damage to the optic nerve head, leading to progressive visual field loss. However, not all individuals with elevated IOP develop POAG, and some people with normal IOP may also develop the disease, indicating that other factors, such as vascular insufficiency and genetic predisposition, may also contribute to the disease's progression. Early detection and effective management of elevated IOP are crucial for preventing vision loss in POAG patients. Currently, the management of POAG primarily focuses on the reduction of IOP, which has been shown to slow or halt the progression of optic nerve damage. There are several classes of medications used to treat

POAG, including prostaglandin analogs, beta-blockers, alpha agonists, carbonic anhydrase inhibitors, and rho kinase inhibitors. Among these, beta-blockers have long been a cornerstone of therapy due to their proven efficacy in lowering IOP. Metipranolol, a non-selective beta-blocker, is one such medication used in the management of POAG. It works by reducing aqueous humour production through its action on beta-adrenergic receptors located in the ciliary body of the eye. By inhibiting these receptors, Metipranolol decreases the production of aqueous humour, thereby reducing IOP. This reduction in IOP is crucial in preventing the progression of optic nerve damage in POAG patients Figure (1). In addition to its use as a monotherapy, Metipranolol is often prescribed in combination with other agents to enhance the therapeutic effect and improve patient outcomes. While effective, the response to Metipranolol can vary depending on individual factors such as age, comorbidities, and genetic predisposition, highlighting the need for personalized treatment regimens. Mathematical modeling has become an essential tool in pharmacology and drug therapy, offering a systematic approach to understanding the complex dynamics of drug distribution, absorption, elimination, and therapeutic efficacy. In the context of POAG management, mathematical models can provide insights into how Metipranolol and other therapeutic agents interact with the ocular system to reduce IOP. These models can predict the time course of drug concentrations in ocular tissues, the resulting changes in IOP, and the optimal dosing strategies for individual patients. Mathematical models can also be used to simulate various scenarios, such as the impact of varying dosages, the influence of patient-specific factors, and the potential effects of combination therapies. By using differential equations and computational simulations, researchers can quantify the effects of Metipranolol on IOP and optimize treatment regimens for maximal efficacy.

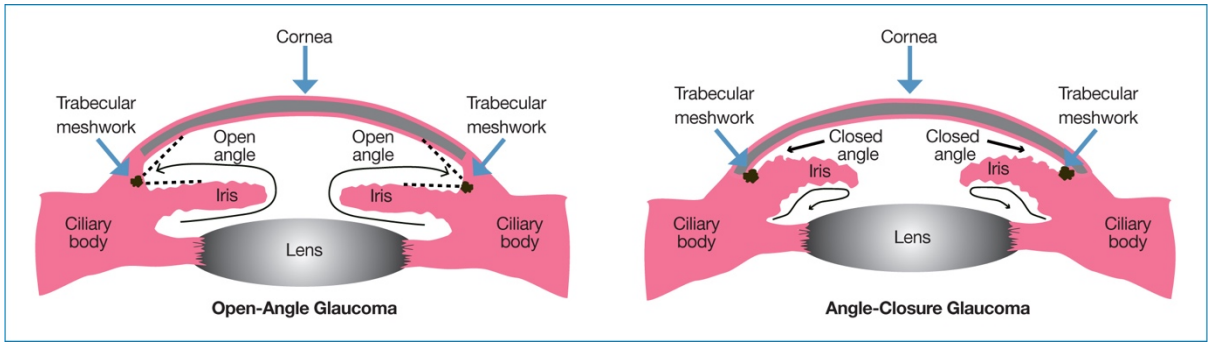

Figure (1): Flow of Aqueous humor in Open-Angle Glaucoma and Angle Closure Glaucoma in human eye

This approach not only helps in understanding the drug's pharmacokinetic and pharmacodynamic properties but also provides a predictive framework for improving clinical decision-making and personalizing treatment strategies. The primary goal of this research is to develop a mathematical model that predicts the therapeutic efficacy of Metipranolol in reducing IOP over time. This model will incorporate key pharmacokinetic parameters, such as drug absorption, distribution, and elimination, as well as pharmacodynamic factors influencing IOP reduction. By providing a more precise understanding of Metipranolol's effects, this model aims to enhance clinical management strategies and contribute to better patient outcomes in POAG treatment. Metipranolol acts by binding to beta-adrenergic receptors in the ciliary body of the eye. As a non-selective beta-blocker, it blocks both β1 and β2 receptors, leading to a reduction in the production of aqueous humour. Studies have shown that Metipranolol reduces IOP by inhibiting the action of these receptors on the ciliary epithelium, thus decreasing the secretion of aqueous humour. This results in a lowered IOP, which helps prevent optic nerve

damage in glaucoma patients. Unlike some other beta-blockers, Metipranolol is also noted for its relatively low systemic absorption, which minimizes the risk of systemic side effects, such as bradycardia or hypotension. However, its efficacy can be influenced by factors such as drug dosage, the patient's baseline IOP, and the presence of other ocular conditions. Several studies have explored Metipranolol's mechanism of action and have demonstrated its efficacy in reducing IOP. For example, clinical trials have shown that Metipranolol significantly lowers IOP when administered topically and is often used in conjunction with other drugs, such as prostaglandin analogs, for enhanced therapeutic effect. Additionally, research has indicated that Metipranolol's effect on aqueous humour production is comparable to other beta-blockers, though its formulation and dosing regimen may influence patient adherence and overall treatment success. Mathematical modeling has been widely used in glaucoma research to understand the complex dynamics of IOP regulation and the effects of different therapeutic agents. Previous models have incorporated both linear and nonlinear approaches to describe IOP dynamics, with a focus on drug interactions, ocular anatomy, and fluid dynamics within the eye. These models are typically based on systems of ordinary differential equations (ODEs) that represent the rate of change of various parameters over time. For example, some models focus on the relationship between aqueous humour production and outflow resistance, while others explore the effects of different drugs on these processes. Previous studies have demonstrated the utility of these models in predicting the effects of both single-agent therapies and combination therapies in glaucoma management.

However, while existing models provide valuable insights, they often lack the necessary detail or precision to account for the full complexity of drug dynamics, especially when considering factors such as varying drug responses in different patient populations. In the context of Metipranolol, prior mathematical models have been used to describe the drug's distribution in the body, its elimination via metabolism and excretion, and its effects on IOP. These models typically include parameters such as the drug's absorption rate, bioavailability, volume of distribution, and clearance rate. By incorporating these pharmacokinetic parameters, the model can simulate the drug's concentration at different time points and predict its effect on IOP. Some models also take into account the ocular pharmacokinetics, specifically how Metipranolol is absorbed into the eye, its interaction with the ciliary body, and its ultimate effect on aqueous humor production. More complex models may incorporate patient-specific factors, such as age, weight, baseline IOP, and response to treatment, to better predict therapeutic outcomes. Although these models have shown promise, there remains a need for more refined approaches to better simulate the clinical variability in drug efficacy and optimize treatment strategies for individual patients.

Mathematical Formulation of the Problem: Most of the aqueous humour entering Schlemm's canal must flow some distance along the canal to reach a collector channel. A segment of the canal between two collectors is modelled as elliptical channel. Half of the amount of the aqueous humour percolating into the canal segment approaches the collector to the right of the midpoint between two collectors, and other half to the left. Thus, the flow at the midpoint, described by $z = 0$, is zero. Due to symmetry, the aqueous flow is considered in half of the segment in the z-direction. Thus, aqueous flow in the segment is considered as fluid flow through a narrow elliptical channel. In this study, It is consider that the inner wall of Schlemm's canal deform in proportional to local pressure drop across it, the inner endothelium wall of the canal which is in contact of the trabecular meshwork is porous and collapsible, aqueous flow is steady, laminar, Newtonian, viscous, and incompressible and all collector channels are equidistant and of the same size, and the same amount of the aqueous humour is drained by each channel.

The Navier-Stokes equation which a partial differential equation expressing the local balance of the momentum in a fluid around any point of space at any time is given by

$$\rho \frac{Dv}{Dt} = -\nabla p + \mu \nabla^2 v + f \quad (1)$$

where

$\frac{Dv}{Dt}$ = Instantaneous acceleration

$-\nabla p$ = Dynamic pressure

$\mu \nabla^2 v$ = Shear viscosity term

f = External force

ρ = Density

μ = Kinematic viscosity

After introducing the assumptions mentioned above, the governing Navier–Stokes equations reduce to:

$$-\frac{\partial p}{\partial x} = 0 \quad (2)$$

$$-\frac{\partial p}{\partial y} = 0 \quad (3)$$

$$-\frac{\partial p}{\partial z} + \mu \Delta^2 v_z = 0 \quad (4)$$

And the equation of continuity is

$$-\frac{\partial v_z}{\partial z} = 0 \quad (5)$$

From steady-state material balance in infinitesimal element of the canal segment.

$$w(z)\, dz = q(z+dz) - q(z) \quad (6)$$

where w(z) represents the filtration flux of the aqueous humor per unit length and q(z) the aqueous volume flux in the canal.

Expanding q(z + dz) in a Taylor series:

$$\frac{dq(z)}{dz} = w(z) \quad (7)$$

Where $q(z) = \iint v_z dx dy,$ (8)

$$w(z) = G[P_I - p(z)] \quad (9)$$

G is the filtration constant of the porous wall and P_I is the intraocular pressure.

The physically realistic and mathematically consistent boundary conditions are prescribed below:

$$v_z(x, y) = 0 \ around \ the \ inner \ perimeter, \quad (10)$$

$$p(z = L) = P_0 \quad (11)$$

$$\frac{dp}{dz}_{z=0} = 0 \quad (12)$$

where P_0 is the pressure at the mouth of a collector channel.

Solution of the Problem: A segment of the canal between two collectors is modelled as elliptical channel. The Equ. (2) and (3) show that the pressure is a function of z at most. The velocity is a function of x and y at most, both the pressure gradient and the viscous term must equal a constant.

Thus the governing differential equation becomes:

$$\frac{1}{\mu}\frac{\partial p}{\partial z}=\frac{\partial^2 v_z}{\partial x^2}+\frac{\partial^2 v_z}{\partial y^2} \tag{13}$$

For the elliptic boundary v_z is

$$v_z = k\left(\frac{x^2}{a^2}+\frac{y^2}{b^2}-1\right) \tag{14}$$

where k is unknown parameter.

Using Equation no. (14) in Equ. (13),

$$k=\frac{1}{2\mu}\left(\frac{a^2b^2}{a^2+b^2}\right)\frac{dp}{dz} \tag{15}$$

Substituting the value of k in equation (14),

$$v_z=\frac{1}{2\mu}\left(\frac{a^2b^2}{a^2+b^2}\right)\left(\frac{x^2}{a^2}+\frac{y^2}{b^2}-1\right)\frac{dp}{dz} \tag{16}$$

Now, the aqueous outflow is given by:

$$q(z)=\iint v_z\,dxdy=\frac{\pi abk}{2} \tag{17}$$

After putting value of k, the aqueous out flux is

$$q(z)=\frac{1}{4\mu}\left(\frac{\pi a^3b^3}{a^2+b^2}\right)\frac{dp}{dz} \tag{18}$$

The inner endothelium surface of elliptical segment in Schlemm's canal is porous and aqueous humor percolate in it, and outer surface is non-porous.

Thus for elliptical boundary, from Eq. (7)

$$\frac{dq}{dz}=\frac{\pi}{2}(a+b)\;w(z) \tag{19}$$

From Equ. (9) and (18), the governing differential equation for evaluating the pressure is obtained by eliminating q(z) and w(z) and given below:

$$\frac{d^2p}{dz^2}-m^2p(z)=m^2P_I\,. \tag{20}$$

where

$$m=\left(\frac{2\mu(a+b)(a^2+b^2)}{a^3b^3}G\right)^{1/2}$$

The solution of Eq. (20) subjecting the boundary conditions (11) and (12), is given below:

$$p=P_I-\frac{P_I-p_0}{\cosh(ml)}\cosh(mz) \tag{21}$$

And also

$$q(z) = \frac{ml}{4\mu}\left(\frac{\pi a^3 b^3}{a^2 + b^2}\right)\left[\frac{(P_I - p_0)}{\cosh(ml)}\sinh(mz)\right] \quad (22)$$

$$w(z) = \frac{m^2}{2\mu(a+b)}\left(\frac{a^3 b^3}{a^2 + b^2}\right)\left[\frac{(P_I - p_0)}{\cosh(ml)}\cosh(mz)\right] \quad (23)$$

Results and discussion: Typical values of various parameters are shown below in the Table (1). Analytical results of the proposed model for the flow of aqueous humor in the canal of Schlemm have been obtained and presented through graphs. The results derived from the plots emphasize the intricate relationship between the filtration constant (G), the dimensions of the Canal of Schlemm (major axis (a) and minor axis (b)), and intraocular pressure (IOP) in controlling the volume flux (q) of aqueous humor. These parameters play a critical role in maintaining normal intraocular pressure, and their modulation is essential for managing glaucoma, particularly Primary Open Angle Glaucoma (POAG).

Table (1): Typical values of the parameters appearing in the model and their approximate corresponding values in the human aqueous outflow network

Parameter	Description	Typical Physiological value
μ	Viscosity of Aqueous humor	0.75cp
A	Semi Major axis of the elliptical canal	132 μm
B	Minor axis of the elliptical canal	15 μm
G	Filtration constant	8.28182e_009 mm2 s/g
2l	Length of canal between two collector channel	1.2mm
R	Radius of the circular canal	0.13mm
P_0	Pressure at the mouth of the collector channel	12mmHg

An increase in intraocular pressure causes an increase in the fluid pressure in the canal. The fluid pressure falls off on either side of the midpoint between two collectors. This means that the inner canal wall will experience more pressure difference (P_1- p) towards the collector channels. The canal, therefore, should have a greater tendency to collapse near and at the collector channel exit. The analysis of the plots reveals the critical role of canal dimensions, filtration constant (G), and intraocular pressure (IOP) in determining the volume flux (q) of aqueous humor within the Canal of Schlemm.

The Figure (2) highlights the direct impact of the filtration constant (G) on the volume flux (q). The relationship is linear, showing that as G increases, the flow of aqueous humor through the canal improves significantly. The filtration constant represents the permeability of the trabecular meshwork and the inner wall of the canal, which are critical for facilitating drainage. Higher G values correspond to a more effective outflow pathway, reducing the pressure build-up in the anterior chamber. Furthermore, the influence of IOP on this relationship is evident, as higher IOP values amplify the volume flux. This is because the increased pressure gradient drives a greater flow of aqueous humor through the compliant canal walls. The ability of Metipranolol to enhance G demonstrates its therapeutic potential in improving drainage efficiency and mitigating the risk of optic nerve damage caused by elevated IOP. This finding aligns with the established pharmacological action of Metipranolol as a beta-adrenergic blocker that reduces aqueous humor production and facilitates outflow, effectively lowering intraocular pressure in glaucoma patients. The Figure (3) explores the role of the major axis (a) of the elliptical canal in influencing q. As a increases, the canal's cross-sectional area expands,

allowing more aqueous humor to flow through it. The relationship is positively correlated, with the volume flux increasing significantly with larger values of a. This observation underscores the importance of canal geometry in maintaining effective drainage. A wider canal provides less resistance to fluid flow, thereby contributing to the regulation of IOP. The impact of this increase is particularly pronounced at higher IOP values, where the pressure gradient is greater, driving a more substantial flow of aqueous humor. This finding highlights the interplay between canal geometry and pressure-driven fluid dynamics, suggesting that anatomical variations in the canal could influence the efficacy of glaucoma treatment. The Figure (4) illustrates the influence of the minor axis (b) on the volume flux (q). Like the major axis, an increase in the minor axis results in a higher q. However, the effect of b on the volume flux is slightly less pronounced than that of a. Nonetheless, the contribution of the minor axis to the overall drainage capacity of the Canal of Schlemm remains significant. Larger canal dimensions, in both the major and minor axes, provide a greater cross-sectional area for fluid flow, facilitating more efficient drainage of aqueous humor. This finding reinforces the idea that the geometric properties of the canal play a crucial role in the management of glaucoma. Maintaining or enhancing the canal's dimensions could improve the outflow of aqueous humor, reducing intraocular pressure and preventing damage to the optic nerve.

The Figure (5) highlights the direct impact of the filtration constant (G) on the volume flux (q). The relationship is linear, showing that as G increases, the flow of aqueous humor through the canal improves significantly. The filtration constant represents the permeability of the trabecular meshwork and the inner wall of the canal, which are critical for facilitating drainage. Higher G values correspond to a more effective outflow pathway, reducing the pressure build-up in the anterior chamber. Furthermore, the influence of IOP on this relationship is evident, as higher IOP values amplify the volume flux. This is because the increased pressure gradient drives a greater flow of aqueous humor through the compliant canal walls. The ability of Metipranolol to enhance G demonstrates its therapeutic potential in improving drainage efficiency and mitigating the risk of optic nerve damage caused by elevated IOP. This finding aligns with the established pharmacological action of Metipranolol as a beta-adrenergic blocker that reduces aqueous humor production and facilitates outflow, effectively lowering intraocular pressure in glaucoma patients. These findings emphasize the importance of canal geometry and filtration properties in managing glaucoma. Metipranolol's effectiveness stems from its ability to enhance the filtration constant (G), which directly influences the volume flux. Additionally, physiological changes that maintain or enlarge canal dimensions could further aid in alleviating the symptoms of Primary Open Angle Glaucoma (POAG). Overall, the results reinforce the significance of both pharmacological interventions and anatomical considerations in glaucoma treatment strategies. These findings emphasize the importance of canal geometry and filtration properties in managing glaucoma. Metipranolol's effectiveness stems from its ability to enhance the filtration constant (G), which directly influences the volume flux. Additionally, physiological changes that maintain or enlarge canal dimensions could further aid in alleviating the symptoms of Primary Open Angle Glaucoma (POAG). Overall, the results reinforce the significance of both pharmacological interventions and anatomical considerations in glaucoma treatment strategies.

Overall, the analysis of these plots provides valuable insights into the dynamics of aqueous humor flow and the factors influencing intraocular pressure. The ability of Metipranolol to increase the filtration constant (G) demonstrates its effectiveness in enhancing the drainage of aqueous humor, which is critical for controlling POAG. Furthermore, the role of canal geometry, as characterized by the major and minor axes, highlights the importance of anatomical and physiological factors in glaucoma management. These findings suggest that a

combination of pharmacological interventions, such as the use of Metipranolol, and strategies to maintain or improve canal dimensions could provide a comprehensive approach to reducing intraocular pressure and slowing the progression of glaucoma. By addressing both the physical and biological aspects of aqueous humor dynamics, these interventions can contribute significantly to preserving vision and improving the quality of life for patients with glaucoma.

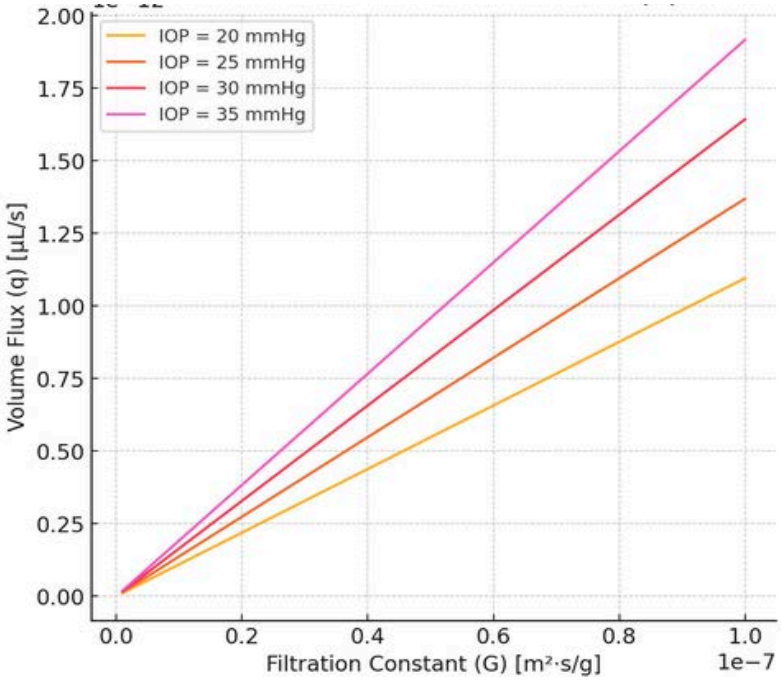

Figure (2): Variation of volume flux (q) with filtration constant (G) for different values of IOP

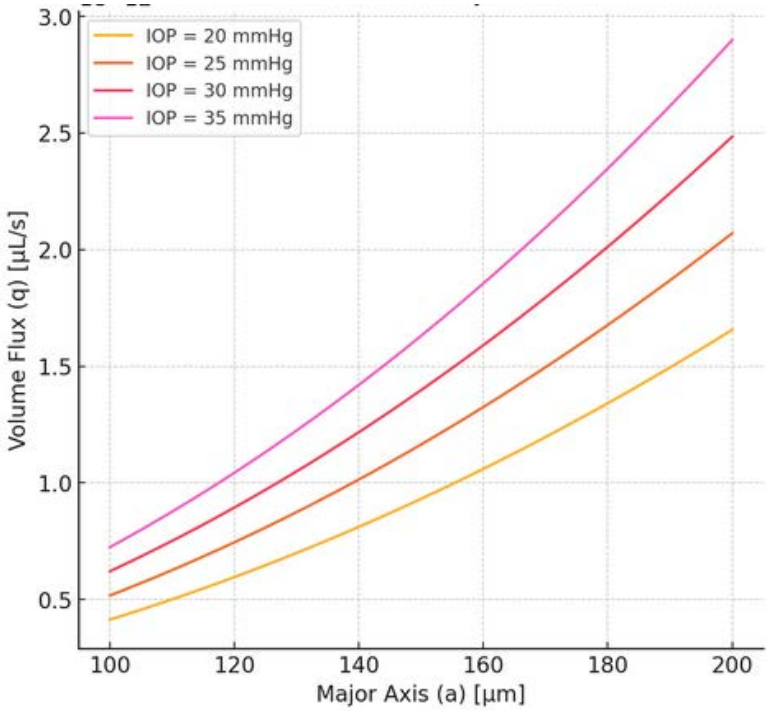

Figure (3): Variation of volume flux (q) with major axis (a) for different values of IOP

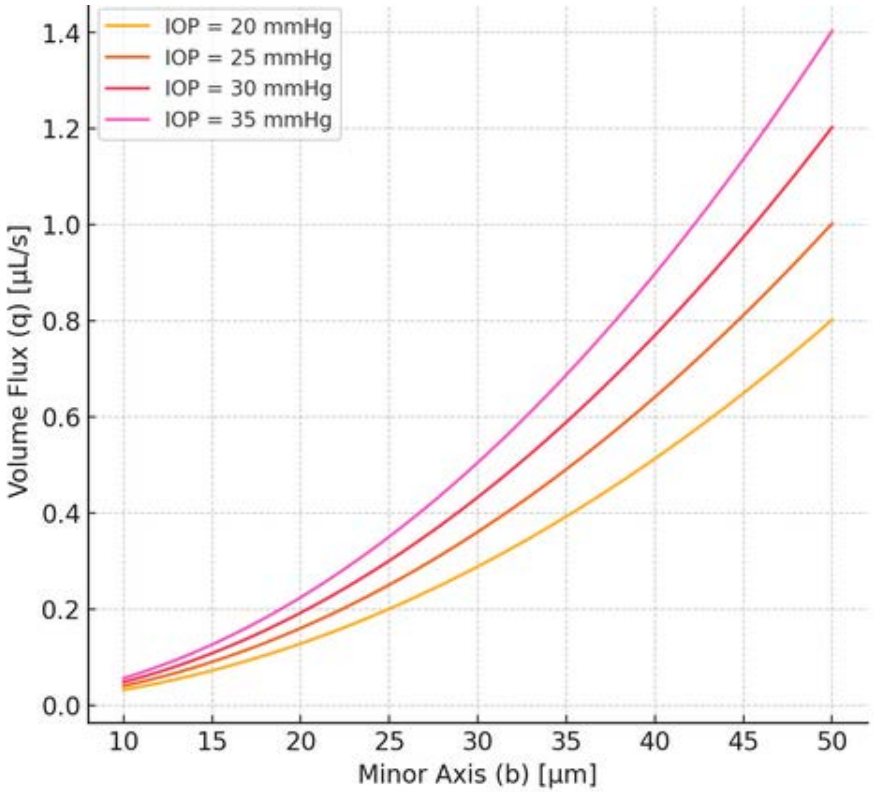

Figure (4): Variation of volume flux (q) with minor axis (b) for different values of IOP

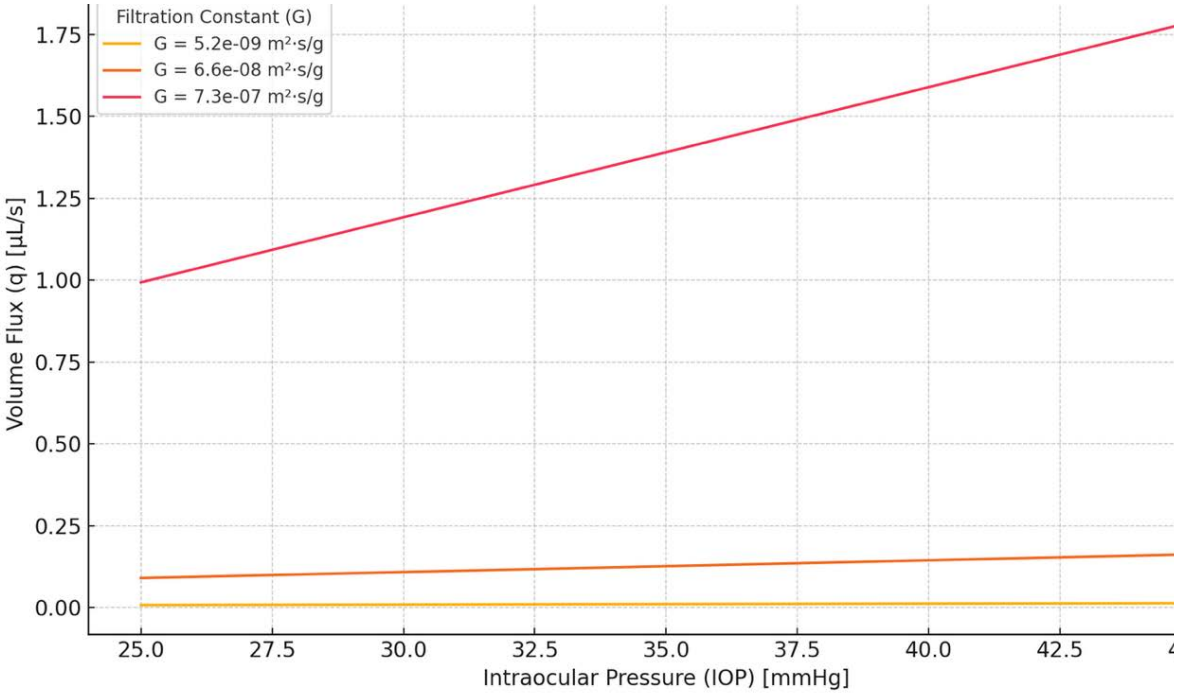

Figure (5): Impact of Metipranolol on volume flux (q) in canal of Schlemm with Intraocular pressure (IOP) and filtration constant (G)

Conclusion: This study provides a detailed mathematical and analytical framework to evaluate the dynamics of aqueous humor flow within the Canal of Schlemm and the therapeutic role of Metipranolol in managing Primary Open Angle Glaucoma (POAG). The findings reveal that Metipranolol significantly enhances the filtration constant (GGG), facilitating increased volume flux and improving aqueous humor drainage, which effectively reduces intraocular pressure (IOP). The results also underscore the importance of canal geometry, where larger dimensions of the major and minor axes of the elliptical canal further enhance drainage capacity, particularly under higher IOP conditions. The interplay between pharmacological interventions and canal anatomy is critical in glaucoma management. Metipranolol's ability to reduce IOP, combined with the role of optimal canal geometry, highlights a multifaceted approach to controlling the progression of glaucoma and preventing irreversible vision loss. These insights provide a foundation for further research into therapeutic strategies that integrate both fluid dynamics and clinical treatments for better outcomes in glaucoma care.

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