

# CHANGES IN THE TREATMENT PLANS OF GLAUCOMA PATIENTS IN A REAL-WORLD SITUATION

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## ABSTRACT

**OBJECTIVE:** To determine the changes in glaucoma prescriptions during a single visit in real-world situation at Al-Shifa Trust Eye Hospital, Rawalpindi, Pakistan.

**METHODS:** This cross-sectional descriptive study was conducted at Glaucoma Department of Al-Shifa Trust Eye Hospital, Rawalpindi, Pakistan from September 1<sup>st</sup>, 2015 to February 29<sup>th</sup>, 2016 after the ethical approval. Of total 876 consecutive participants, 868 were included in the study. Complete ocular examination was carried out for each subject including intraocular pressure (IOP) by Goldmann, visual field and nerve fiber analysis if it was scheduled. Ocular and systemic co-morbidities as well as ocular surgeries were also noted. Number of topical medications including anti-glaucoma and other drugs were recorded before and after their visit. The changes in anti-glaucoma medications were then categorized as unchanged, changed, added or deleted. The results were analyzed via SPSS version-24.

**RESULTS:** A total 1600 eyes of 868 patients were included in this study. Out of 868 patients, 507 (58.41%) were males and 291 (33.52%) were in 61-70 years age group. Majority of patients (n=680/868: 78.34%) had open-angle glaucoma. Out of 1600 eyes studied, 574 (35.87%) had moderate and 556 (34.75%) had severe stage of glaucomatous optic neuropathy. During single visit, glaucoma-related prescriptions were unchanged, changed, added and deleted in 618/868 (71.20%), 84/868 (9.68%), 95/868 (10.94%) & 71/868 (8.18%) patients respectively. In our study, 911/1600 (56.94%) eyes achieved target IOP = 14 mmHg.

**CONCLUSION:** In real-world situation, most of our glaucoma patients were stable and required no changes to their prescriptions in single visit.

**KEYWORDS:** Glaucoma (MeSH); Prescriptions (MeSH); Regimen (MeSH); Intraocular Pressure (MeSH); Optic Nerve Diseases (MeSH); Glaucoma hemifield test (Non-MeSH); Tomography, Optical Coherence (MeSH); Visual Fields (MeSH).

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## INTRODUCTION

Glaucoma is a disease of the optic nerve and the leading cause of irreversible blindness globally.<sup>1</sup> Over the last three decades, the understanding and treatment of glaucoma has evolved significantly, but many modern treatment paradigms have yet to reach the medical practice. These include an increasing awareness that glaucoma is an optic nerve neuropathy rather than an elevated

intraocular pressure (IOP), as well as a declining dependence on a low IOP as the primary treatment target.<sup>2</sup> Once diagnosed, the patient will have to follow-up lifelong with the glaucoma surgeons. Lowering the intraocular pressure (IOP) is the only proven treatment option for glaucoma<sup>3</sup> which can be achieved with medicines, lasers, and surgery. What should be the target IOP is a big debate among glaucoma surgeons.<sup>4</sup> However, all agree that the target IOP is the IOP where glaucoma-

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related nerve damage halts.<sup>5</sup> In the Advanced Glaucoma Intervention Study's (AGIS) post hoc analysis it was found that the group with a mean IOP of 14 mmHg did better than those with a mean of 18mmHg.<sup>6</sup> That is why most glaucoma surgeons try to achieve 14 mmHg IOP in their patients.

In our setup, we have our challenges to deal with; poverty, ignorance, non-compliance, logistics, and social factors are some of them.<sup>7</sup> These challenges compel our glaucoma surgeons to go for aggressive treatment and achieve the target IOP of 14 mmHg or less in their patients. Ideally speaking a treatment plan is a plan that glaucoma patients and treating ophthalmologists agree to manage glaucoma. And the details should be included in the medical record and updated regularly as needed. Patients with glaucoma need a clear understanding of the disease which gradually steals the vision.

But little is known about the real-world situation regarding when, why, and how the changes are done in the glaucoma prescriptions. The purpose of this study was to investigate the changes in glaucoma prescriptions during a single visit. This will increase our understanding of glaucoma care provided to our patients and will identify how many of our patients are controlled or otherwise during that visit.

## METHODS

This cross-sectional study was conducted at the Glaucoma Clinic, Al-Shifa trust eye hospital Rawalpindi, Pakistan from September 1<sup>st</sup>, 2015 to February 29<sup>th</sup>, 2016. Out of 876 consecutive participants aged 18 years and above who presented to the clinic during the study period, 868 were included in the study after taking informed consent.

The ethical approval was obtained from the University of Malakand and Al-Shifa Trust Eye Hospital, Rawalpindi before the study and adhered to the tenets of the declaration of Helsinki. Each participant was examined by one of the three glaucoma specialists. After the written informed consent, complete history was taken from each participant and then recorded the following; gender, age in years, glaucoma diagnoses, intraocular pressure (IOP) in mmHg, and cup to disc ratio (CDR) for each eye. IOP categorization was done as; group-1 = 14 mmHg and group-2 >14 mmHg. Glaucoma hemifield test (GHT) and nerve fiber analysis by optical coherence

tomography were recorded if scheduled. Previous records were checked for glaucoma or other ocular surgeries. Ocular diseases other than glaucoma as well as systemic diseases present were also observed and recorded on that visit. Those participants were excluded from the study whose previous records couldn't be traced. Our objective was to check the change in glaucoma prescriptions during one visit so we recorded the number of topical anti-glaucoma and other topical medications. One of the purposes of the regimen change was to improve cost efficiency to provide real improvements in quality of life.<sup>8</sup> The change in regimen was left to the clinical judgment of the glaucoma specialists and was defined as:

**CHANGED:** if one topical anti-glaucoma medication was replaced with another formula; it might be due to the inability to effectively lower the IOP, drug-related side effects, dosage problems, or affordability issues of the participants.

**UNCHANGED:** if the same treatment was continued forward.

**ADDED:** if there were additions to the existing regimen indicating that the glaucoma was not controlled in these participants.

**DELETED:** deletion of one or more topical anti-glaucoma medications; this was because the disease was controlled and aggressive treatment was not required.

SPSS version 24 was used for the statistical analysis. Frequencies were calculated for the categorical variables and mean & standard deviation were calculated for the continuous variables. A p-value of = 0.05 was taken as significant.

Out of 876 participants examined during the study period, the records of 08 (0.9%) couldn't be found and hence data of 868 participants was finally available for analysis.

## RESULTS

The baseline characteristics of our study participants are shown in Table I. A total of 1600 eyes of 868 patients were studied. Of total 868 patients, 507

**TABLE I: CHARACTERISTICS OF STUDY PARTICIPANTS (N=868)**

Characteristics		Frequency (%)
Gender	Male	507 (58.41)
	Female	361 (41.59)
Age (years)	18 - 40	101 (11.64)
	41 - 50	135 (15.55)
	51 - 60	185 (21.31)
	61 - 70	291 (33.52)
	> 70	156 (17.97)
Type of glaucoma	Open angle Glaucoma	680 (78.34)
	Closed angle Glaucoma	92 (10.60)
	Not mentioned	80 (9.22)
	Suspects	16 (1.84)
Intra Ocular Pressure (IOP) (mmHg)	Right Eye	787 (49.19)
	Left Eye	813 (50.81)
Cup-to-disc ratio (CDR)	≤0.5	310 (21.53)
	0.6 to 0.8	574 (39.86)
	>0.8	556 (38.61)
	Not mentioned	296 (20.56)
Visual field defects (GHT)	Within normal limits	32 (3.69)
	Outside normal limits	286 (32.95)
	Not known	550 (63.36)
Glaucoma related procedures		400 (46.08)
Ocular diseases other than glaucoma		203 (23.39)
Ocular surgeries other than glaucoma		28 (3.22)
Systemic characteristics	Hypertensive	234 (26.97)
	Smoker	212 (24.42)
	Diabetic	163 (18.78)

% = percentage, SD = standard deviation, GHT = glaucoma hemifield test. Open angle glaucoma was the most prevalent in our study group. The results of most of visual fields were not known due to nature of the study. A significant number of our subjects had systemic comorbidities as well.

TABLE II: SUMMARY OF CHANGES IN ANTI-GLAUCOMA MEDICATIONS

Parameters		No. of topical anti-glaucoma medicines						Frequency N=868 (%)
		0 (n=219)	1 (n=308)	2 (n=205)	3 (n=128)	4 (n=6)	5 (n=2)	
Effect on frequency of anti-glaucoma medications	Changed	2 (0.9%)	40 (13.0%)	21 (10.2%)	19 (14.8%)	2 (33.3%)	0	84 (9.68%)
	Unchanged	165 (26.70%)	219 (35.44%)	142 (22.98%)	92 (14.89%)	0	0	618 (71.20%)
	Added	50 (22.8%)	29 (9.4%)	16 (7.8%)	0	0	0	95 (10.94%)
	Deleted	2 (0.9%)	20 (6.5%)	26 (12.7%)	17 (13.3%)	4 (66.7%)	2 (100%)	71 (8.18%)
Mean IOP in mmHg (SD)	Right	14.46 (6.88)	15.40 (5.85)	16.89 (8.10)	18.52 (9.29)	28.0 (12.24)	25.0 (4.24)	-
	Left	14.65 (5.49)	14.65 (5.49)	15.63 (6.14)	15.63 (6.14)	15.33 (10.17)	26.0 (5.65)	-

IOP = Intraocular pressure in mmHg, % = percentage, SD = standard deviation. Almost half of our subjects achieved IOP = 14 mmHg with or without topical antiglaucoma medications. A larger number didn't require any change in the treatment plan.

TABLE III: OCULAR PROBLEMS OTHER THAN GLAUCOMA IN STUDY PARTICIPANTS

Ocular problems	Frequency (%) (N=868)
Lens and refractive problems (n=88)	Cataract
	Pseudoexfoliation
	Pathological myopia
	Dislocation
Retina and vitreous (n=65)	Central retinal vein occlusion
	Retinal detachment
	Age related macular degeneration
	Diabetic retinopathy/maculopathy
	Branch retinal vein occlusion
	Macular scar/hole
	Retinitis pigmentosa
	Epiretinal membrane
	Hypertensive retinopathy
	Retinal vasculitis
	Vitreous hemorrhage
Cornea & Ocular surface disease (n=23)	Opacity/Haze
	Bullous Keratopathy
	Vernal keratoconjunctivitis
	Keratoconus
	Herpetic keratitis
	Dry eyes
	Episcleritis
	Pemphigus
Uveal tract (n=15)	Uveitis
	Rubeosis iridis
	Choroidal detachment
Lids and adnexa (n=6)	Trauma
	Blepharitis
	Trichiasis
Miscellaneous (n=6)	Phthisis bulbi
	Optic atrophy
	Endophthalmitis
	Iridocorneal dysgenesis
Total	

% = percentage. In descending order, cataract, pseudoexfoliation and central retinal vein occlusion were the common ocular comorbidities in our subjects.

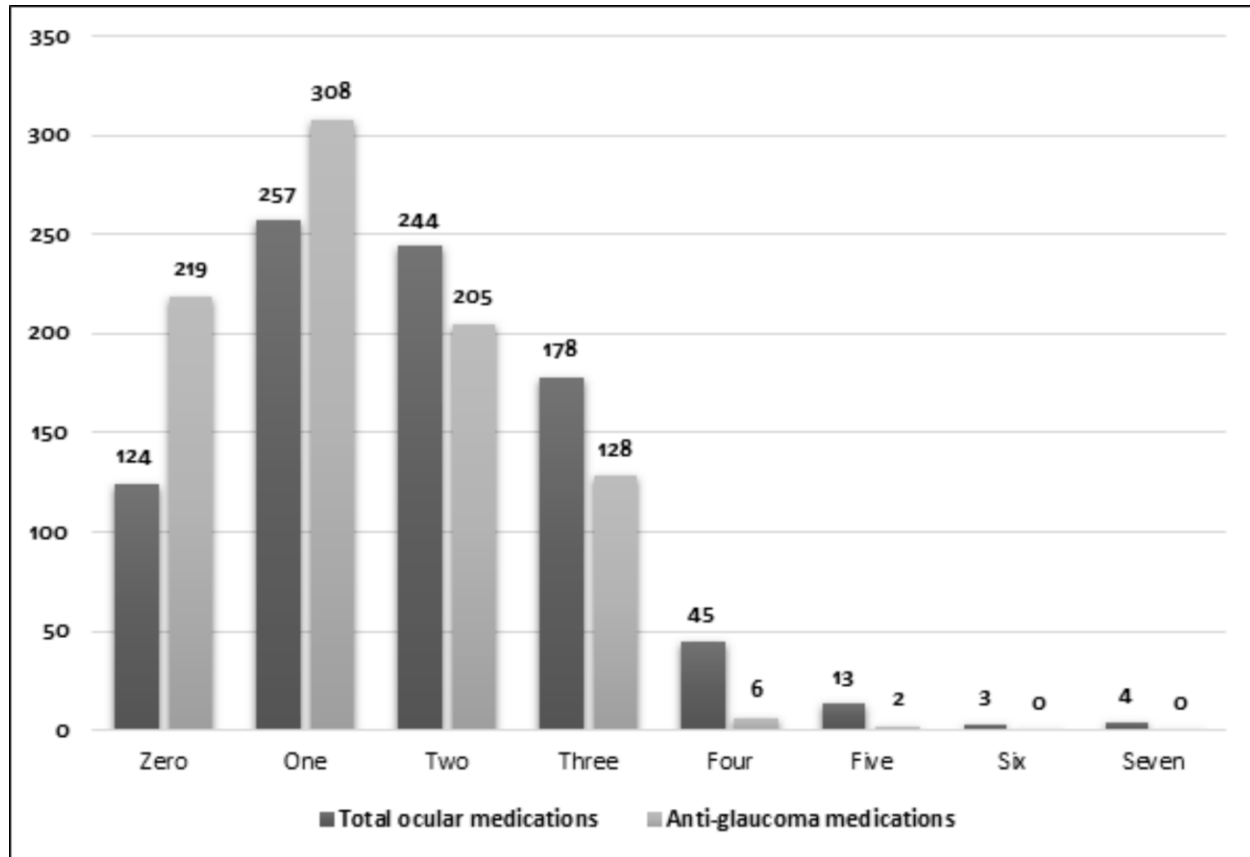


Figure 1: Burden of Ocular medications, Figure shows the burden of anti-glaucoma and the total topical medications in our group. Most of subjects were on two or less medications

(58.41%) were males. About half of the patients ( $n=447$ ; 51.5%) had age of more than 60 years. Open-angle glaucoma was the most common ( $n=680$ ; 78.34%) type of glaucoma and hypertension ( $n=234$ ; 26.97%), was the most common systemic diagnosis.

Out of 1600 eyes evaluated for glaucoma severity, 574 (35.87%) had moderate and 556 (34.75%) had severe stage of glaucomatous optic neuropathy. The mean IOP was  $16.14 \pm 7.51$  mm Hg and  $15.86 \pm 7.1$  mm Hg in right and left eyes respectively.

Figure 1 demonstrates the burden of anti-glaucoma and other ophthalmic medications in our study group.

Out of 868 patients, 219 (25.2%) patients including 128 (58.4%) males & 91 (41.6%) females were not using any anti-glaucoma medications.

Table II shows the utilization of topical anti-glaucoma medications and their effect on other variables. Additional

glaucoma medications were advised to 95 (10.94%), changes in the existing regimen were observed in 84 (9.68%) participants and in 618 (71.20%) cases no change was advised in existing anti-glaucoma medications. In this study, 911 (56.94%) eyes (each eye was taken separately) achieved the target IOP of  $\leq 14$  mm Hg and among them 87.05% of patients were using  $\leq 2$  medicines.

Of 868, 203 (23.39) patients had ocular problems other than glaucoma (Table III). Common ocular problems other than glaucoma observed included lens and refractive problems ( $n=88$ ; 10.13%), retina and vitreous problems ( $n=65$ ; 7.49%), cornea & ocular surface diseases ( $n=23$ ; 2.65%), uveal tract related problems ( $n=15$ ; 1.73%), lids and adnexal problems ( $n=6$ ; 0.69%) and miscellaneous problems ( $n=6$ ; 0.69%).

In this study, 400 (46.1%) patients had history of glaucoma-related surgeries including 306 (35.25) cases of trabeculectomy and 57 (6.57%) cases

of Trans-scleral Cycloablation. Cataract was the most common ( $n=258$ ; 29.72%) surgery other than glaucoma-related surgery (Table IV).

## DISCUSSION

Our objective was to find out the change in prescriptions of glaucoma patients in the real-world situation. To our knowledge, this is the first study on this topic, which has looked into the glaucoma regimen in a real-world situation. In our study, 732 (84.33%) participants were using 2 or fewer antiglaucoma medicines and among them, 219 (25.23%) were free of antiglaucoma medicines. Nayak S et al.<sup>9</sup> reported in their study that 73.4% of their participants were on 2 or fewer antiglaucoma medicines. Our figures are different than theirs because of three reasons; the difference in the sample size, length of the study period, and some of our patients were previously treated surgically (Table IV) which may better explain this

TABLE IV: PREVIOUS RECORD OF OCULAR SURGERIES INCLUDING GLAUCOMA SURGERY

Type of surgery		No. of anti-glaucoma medications						Frequency (%) N=868
		0	1	2	3	4	5	
<b>Glaucoma Surgeries (n=400)</b>	Combined cataract and glaucoma	6	4	3	4	-	-	17 (1.96)
	Trans-scleral Cycloablation	21	16	15	5	-	-	57 (6.57)
	Ahmed Glaucoma Valve	2	1	-	1	-	-	4 (0.46)
	Trabeculectomy	102	77	58	66	3	-	306 (35.25)
	YAG peripheral iridotomy	1	5	9	-	-	-	15 (1.73)
	Fugo Blade	-	1	-	-	-	-	1 (0.12)
<b>Other ocular surgeries (n=284)</b>	Cataract	49	108	62	35	3	1	258 (29.72)
	Corneal repair	1	1	-	-	-	-	2 (0.23)
	Cryotherapy	1	-	-	-	-	-	1 (0.12)
	Intravitreal anti-VEGF	1	1	-	-	-	-	2 (0.23)
	Retinal Detachment	1	4	1	1	-	-	7 (0.81)
	Tarsorrhaphy	1	-	1	-	-	-	2 (0.23)
	Vitrectomy	-	2	3	4	-	-	9 (1.04)
	Keratoplasty	-	1	2	-	-	-	3 (0.35)

%=percentage; VEGF=Vascular endothelial growth factor; Trabeculectomy and cataract surgeries were the most common glaucoma and non-glaucoma procedures previously performed in our subjects.

difference. The utilization of topical antiglaucoma drugs has already been described elsewhere.<sup>10</sup>

When we checked for the changes in the prescriptions, we found no change in drug regimen in 618 (71.2%) of participants on their scheduled visit. This shows that the treating consultants were satisfied with the glaucoma status at that visit. This number became 689 (79.38%) if we considered the group in which one or more medicine was removed because aggressive treatment was not required. It indicates that our glaucoma physicians were satisfied with 4 out of 5 patient's glaucoma status. There has been a lot of research on blindness from treated glaucoma and it has been reported that about 10% of patients will go blind even practicing the evidence-based guidelines.<sup>11</sup> We also found the same in our study group as 95 (10.94%) of our participants required additional IOP lowering agents, either because their IOP was not controlled or they showed progression. However, it should be emphasized that our study reports single visit results and the actual figure may vary with the longer follow-up.<sup>12</sup>

About half of our study group (46.08%) had previous glaucoma-related surgeries and among them, trabeculectomy was the most commonly (76.5%) performed surgery. One-third of the trabeculectomy group were without any topical anti-glaucoma

medication. The strength of this study is that it has given us information about the real-world scenario in the glaucoma regimen. It has quite a large sample to conclude that most of the glaucoma patients are stable on their follow-up visits, however, some may still progress despite all the treatment. The limitations of the study are of the descriptive design, single-center study and some of the missing data i.e. CDR, Visual field status and glaucoma diagnosis were missing in some charts. So, we couldn't determine how the glaucoma physicians decided about the changes in treatment plans. We recommend that in the future comparative design with the drug regimen relation to the tests may give us more insight on this topic.

## CONCLUSION

In our study, most of our glaucoma patients were stable and required no changes to their prescriptions in their single visit.

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### AUTHOR'S CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under:

**MS:** Conception & study design, acquisition, analysis and interpretation of data, drafting the manuscript, approval of the final version to be published

**YJM:** Conception, analysis and interpretation of data, drafting the manuscript, approval of the final version to be published

**WA:** Conception & study design, critical review, approval of the final version to be published

**MAK:** Analysis and interpretation of data, critical review, approval of the final version to be published

**FA:** Conception & study design, analysis and interpretation of data, critical review, approval of the final version to be published

*Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.*

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Authors declared no conflict of interest

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### DATA SHARING STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request



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