Original Research Article

Barriers to compliance to topical anti-glaucoma medication among glaucoma patients

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ABSTRACT

Introduction: Medical management is the primary modality of therapy for primary open angle glaucoma. Due to the nature and complexity of treatment and its chronicity, noncompliance is an important limiting factor for its success. In our study, we attempt to identify the barriers affecting adherence, persistence & compliance to topical anti-glaucoma medications in order to be able to overcome them.

Materials and Methods: A structured validated questionnaire identifying various barriers, like demographic, social, physical, medication related, doctor related and patient related, affecting compliance, adherence and persistence to topical anti-glaucoma medications was administered to 300 consenting patients. Results were analyzed using SPSS 19.0 software.

Result: In our study, 89% of patients were found adherent to the treatment and 62 % were fully compliant. Compliance was found to be better in patients with higher education, good income, positive family history of glaucoma, awareness about the disease consequences; in patients who were given clear instructions by prescriber; and in those who were self-dependent for drug instillation.

Conclusion: Identification of barriers affecting compliance, adherence and persistence to medical treatment can help to develop strategies to overcome them. A simplified regimen should be prescribed to aid in compliance. Efforts must also be made by medical professionals to educate the patients about the nature and severity of disease, its outcome, importance of regular and continued use of topical medications, technique of drug instillation and necessity of follow up visits.

1. Introduction

Glaucoma is the second leading cause of preventable blindness in the world as defined by the World Health Organization (WHO).[1] Both types of glaucoma, open angle (OAG) and angle closure (ACG), affected about 60.5 million people worldwide in 2010. More than 76 million people are now affected with glaucoma worldwide and the number is expected to increase to 111.8 million individuals in 2040.[2] Medical management is the primary modality of therapy in majority cases of glaucoma, surgery being reserved only for medically intractable or advanced glaucomas or patients intolerant to the medications. Glaucoma being a disease for lifetime, adherence to medical therapy is of paramount importance in halting its progression and preventing further vision loss. Noncompliance to medical management has long been recognized as an important limiting factor in the medical management of any chronic disease.[3] It is a major problem in patients of glaucoma as well. Compliance is defined as the extent to which a patient acts in accordance with the prescribed interval and dose of a dosing regimen;[4] adherence is a measure of degree to which patient follows prescribed instruction during a defined period of time and persistence is defined as the criterion

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that evaluates the time until the patient first discontinues use of medication.[5] Generally speaking, all these 3 are referred to as 'compliance'. Poor compliance with treatment results in suboptimal intraocular pressure (IOP) control and is known to influence glaucoma progression over time and increase the risk of visual loss.[6–8] Many studies have attributed compliance to factors like age, gender, level of education and fear of blindness. Other factors include poor communication with the health care provider, cost of treatment, forgetfulness and difficulty in instilling the eye drops. Most of these studies agreed that compliance is a multi-factorial complex behavior.[9,10] Compliance to anti-glaucoma medications is also difficult to measure. This is because of the phenomenon of 'white coat adherence' wherein the patient usually overestimates his / her compliance and sticks to the prescribed regimen 2-3 days prior to his/her scheduled follow-up visit; so even intraocular pressure cannot be considered as a clue to patient compliance.[11,12] In developing countries where socioeconomic standards are poor and the patients are not well-educated, if educated at all, it is even more challenging to measure patient compliance.[13] In our cross-sectional study, done in a tertiary glaucoma referral Centre, at a regional institute, receiving patients with diverse findings, we attempt to identify factors which affect adherence, persistence & compliance to topical anti-glaucoma medications and which can be corrected or improved.

2. Material and Methods

Ethical approval was obtained for our study and ethical measures were adhered through all phases of the research. This cross sectional survey was conducted on patients attending glaucoma clinic of a tertiary eye care center, using at least one topical anti-glaucoma medication for a duration of minimum two months. The study duration was from March 2021 to May 2021. Patients less than 18 years of age and those who had undergone prior surgical management were excluded. A structured validated questionnaire was administered to collect the data. It was translated into Hindi and Gujarati and delivered in the language which the patients could understand after taking an informed consent. In case of illiterate patients, their attendants were asked to write on their behalf with appropriate consent. Simple random sampling was used and the sample size consisted of 300 patients, which was calculated by formula $\{N=z^2pq/e^2$, where N= sample size, z=confidence level at 95%,p=prevalence rate of glaucoma in population of Gujarat, q=1-p,e=allowable error(5%)\}. The questionnaire identified various barriers affecting compliance to topical anti-glaucoma medications like demographic, social, physical, medication related, doctor related and patient related. Presence of systemic comorbidities like hypertension, diabetes, arthritis, psychiatric illness and

thyroid disease were also evaluated because of the influence of the diseases and their treatments (side effects, polypharmacy) on overall drug compliance. Results were analyzed using SPSS 19.0 software. Descriptive analyses were reported as percentages. For comparing categorical data, chi square test was performed. Bivariate and multivariate logistic regression analysis models were used to test for the preferential effect of all the independent variables on compliance, adherence and persistence. A p value less than 0.05 was considered statistically significant.

3. Results

Three hundred patients were enrolled in the study. Demographic characteristics of all the patients are summarized in Table 1:

Table 1: Demographic characteristics of all the patients (n= 300)

		Count	**%**
Age group	<45	41	13.7
	45-55	76	25.3
	>55	183	61.0
Gender	Male	179	59.7
	Female	121	40.3
Education	Illiterate	99	33.0
	Primary	72	24.0
	Secondary	43	14.3
	Higher secondary	45	15.0
	Graduation	32	10.7
	Post graduation	9	3.0
Occupation	Business	13	4.3
	Job	36	12.0
	Retired	111	37
	Labourer	58	19.3
	House manager	82	27.3
Income per month	<=10000	161	77.0
	11000-20000	28	13.4
	>=21000	20	9.6
	Not earning	91	30.33

Out of 300 patients, 267 (89%) always followed the exact frequency & time of drug instillation as advised by doctor, 31 (10.3%) sometimes followed the same and 2 (0.7%) never followed the same. So majority of patients adhered to the treatment. (Figure 1)

Majority of patients, 186 (62%) never forgot to instill medication, 77 (25.7%) rarely forgot, 36 (12%) sometimes forgot and 1 (0.3%) frequently forgot to instill medication. Thus only 62 % of patients were fully compliant. (Figure 2)

Out of 300 patients, 134 (44.7%) bought the new drug before the previous drug finished, 100 (33.3%) bought the new drug after one or two days finishing previous one, 24 (8%) bought the new drug at variable duration, 22 (7.30%) bought the new drug after follow up visit with doctor only and 20 (6.7%) bought the new drug one week after finishing the previous one. (Figure 3)
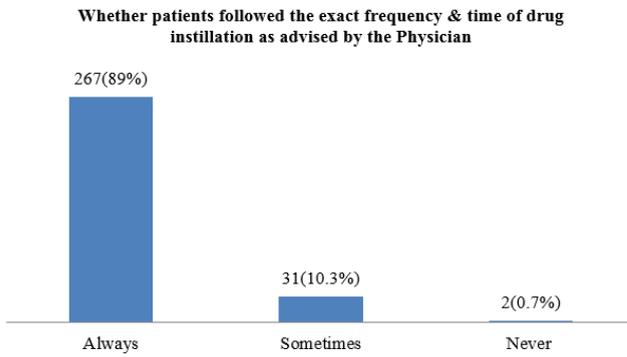
Whether patients followed the exact frequency & time of drug instillation as advised by the Physician

267(89%)

31(10.3%)

2(0.7%)

Always   Sometimes   Never

Fig. 1: Patients adherence to the exact schedule of drug instillation

Whether patients forgot to instill the medication(s)

186(62%)

77(25.7%)

36(12%)

1(0.3%)

Never   Rarely   Sometimes   Frequently
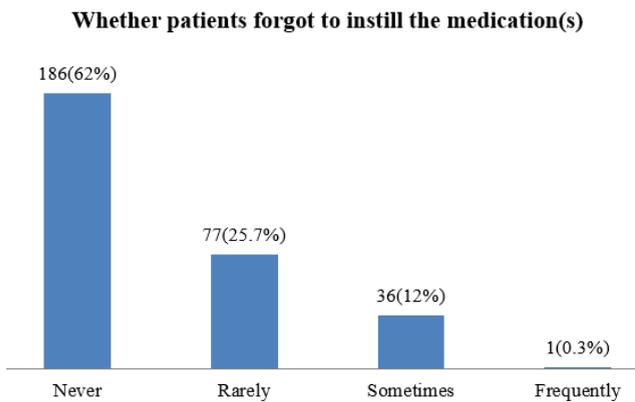
Fig. 2: Omission of drug instillation (compliance to treatment)

When did patients buy the new medications after consuming the existing ones.

134(44.7%)

100(33.3%)

24(8%)   22(7.30%)   20(6.7%)

Before the previous drug finishes   After one or two days   Variable durations   After follow up with doctor only   After one week
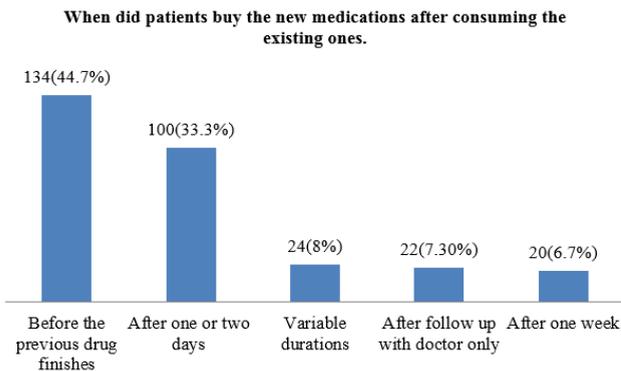
Fig. 3: Persistence to treatment

Only 62 % of patients were fully compliant. There was a statistically significant association between higher level of education and better compliance. (p<0.05) The reasons shared for forgetfulness were age, life style, psychiatric illness, concomitant drug effect and other reasons like holidays. One patient had no apparent reason for his forgetfulness. Patients with lower education level were found to more frequently forget drug instillation (p<0.05).

Forty one (40.2%) patients specifically forgot to instill eye drops on social occasions, 31(30.4%) patients forgot when they were emotionally upset, 10(9.8%) patients forgot to instill on Sundays, While 20 (19.6%) patients forgot for other nonspecific reasons.

Educated and retired patients were found to use the drugs persistently (p<0.05).

Knowledge, awareness and personal factors: (Table 2)

Out of 300 patients, 23 (7.7%) were diagnosed to have glaucoma since 2 months, 39 (13%) since 3 - 11 months, 42 (14%) since 12 months, 40 (13.3%) since 13 - 24 months, 50 (16.7%) since 25 - 48 months, 19 (6.3%) since 49 - 60 months and 87 (29%) had glaucoma since more than 60 months. Twenty one patients (7%) were living alone. Thirty five (11.7%) were living with their partners and 244 (81.3%) were living with their family.

Fifty eight (19.30%) patients had a positive family history of glaucoma while 228 (76%) patients did not. Fourteen (4.70%) patients were not sure about the same. Two hundred and fourteen patients (71.30%) knew about the possibility of irreversible vision loss due to glaucoma while 86 (28.7%) did not.

Multivariate logistic regression analysis of various factors evaluated for association with compliance to antiglaucoma medications is shown in Table 3.

Adherence to treatment was seen in patients with positive family history of glaucoma compared to patients without such a history and was found to be statistically significant (p<0.04). (Table 4) A bivariate analysis of factors evaluated for association with adherence to antiglaucoma medications is shown in this table.

Better persistence was found in patients who knew that glaucoma causes irreversible vision loss compared to those patients who did not know it and this difference was statistically significant (p<0.001). A bivariate analysis of factors was done for association with noncompliance and non persistence to antiglaucoma medications. (Tables 5 and 6)

Statistically significant difference in adherence, compliance and persistence was found between patients who believed that there was a risk of vision loss from not using anti-glaucoma medications properly and those who did not believe that (p<0.00). (Tables 3, 4 and 5)

3.1. Systemic co-morbidity

One hundred and forty eight patients (49.30%) patients had associated medical co-morbidities. Majority patients [91 (61.5%)] had hypertension (HTN), 28 (18.8%) had diabetes mellitus (DM), 18 (12.1%) had both HTN and DM, 4 (2.7%) had thyroid disease, 3 (2.1%) had both HTN and thyroid, 2 (1.4%) had HTN, DM and thyroid, 2 (1.4%) had thyroid and cardiac disease. One hundred and forty four patients (94.10%) were taking regular treatment for their medical co-morbidities, 1(0.70%) was taking irregular

Table 2: Association of knowledge of glaucoma induced irreversible vision loss and demographic factors.

		Patient knows that glaucoma causes irreversible loss of vision						Pearson Chi-Square Tests*		
		Yes		No		Total				
		Count	%	Count	%	Count	%	Chi-square	Df	Significance
Age Group	<45	33	80.5	8	19.5	41	100.0			
	45-55	51	67.1	25	32.9	76	100.0	2.352	2	.308
	>55	130	71.0	53	29.0	183	100.0			
	Total	214	71.3	86	28.7	300	100.0			
Sex	Male	123	68.7	56	31.3	179	100.0			
	Female	91	75.2	30	24.8	121	100.0	1.488	1	.223
	Total	214	71.3	86	28.7	300	100.0			
Education	Illitrate	73	73.8	26	26.2	99	100.0			
	Primary	56	77.8	16	22.2	72	100.0			
	Secondary	22	51.2	21	48.8	43	100.0			
	Higher secondary	31	68.9	14	31.1	45	100.0	12.885	5	.021 *
	Graduation	24	75.0	8	25.0	32	100.0			
	Post graduation	8	88.9	1	11.1	9	100.0			
	Total	214	71.3	86	28.7	300	100.0			
Occupation	Business	11	84.6	2	15.4	13	100.0			
	Job	26	72.2	10	27.8	36	100.0			
	Retired	71	71.0	29	29.0	100	100.0			
	Labour	43	74.1	15	25.9	58	100.0	2.053	5	.842
	Other	7	63.6	4	36.4	11	100.0			
	House wife	56	68.3	26	31.7	82	100.0			
	Total	214	71.3	86	28.7	300	100.0			
Income per month	<=10000	101	62.7	60	37.3	161	100.0			
	11000-20000	23	82.1	5	17.9	28	100.0	3.982	2	.137
	>=21000	13	65.0	7	35.0	20	100.0			
	Total	137	65.6	72	34.4	209	100.0			

* The Chi-square statistic is significant at the .05 level.

Table 3: Multivariate logistic regression analysis of factors evaluated for association with compliance to antiglaucoma medications.

Factor	Chi-square test	Degrees of freedom (df)	P value
Knowledge of irreversible vision loss caused by glaucoma	12.885	5	0.021
Existence of medical co-morbidities	72.941	45	0.005
Treatment for medical co-morbidity	10.076	4	0.039
Problems with drug purchase.	18.770	10	0.043
Dependency for drug purchase	4.205	1	0.040
Preferred time for drop instillation	49.435	25	0.002
Side effects of drops after instillation	11.860	5	0.037
Instructions by prescriber about drug schedule and usage	12.988	5	0.023
Knowledge about importance of punctual occlusion in topical drug use	7.888	2	0.019
Forgetfulness in instilling medications	29.378	15	0.014
Reasons for forgetfulness	69.974	30	0.000
Awareness about risk of vision loss following non compliance	89.699	10	0.000
Persistence with treatment	43.581	20	0.002

Table 4: Bivariate analysis of factors evaluated for association withadherence to antiglaucoma medications.

Factor	Chi-square test	Degrees of freedom (df)	P value
Family history of glaucoma	9.865	4	0.043
Convenience of drug schedule	41.787	4	0.000
Presence of any side effect.	10.281	2	0.006
Side effects of drops after instillation as noticed by patient.	44.352	24	0.007
Instructions by prescriber about drug schedule and usage	7.183	2	0.028
Recall of instructions given by prescriber.	85.663	4	0.000
Reasons for forgetfulness	14.529	6	0.024
Specific days or occasions of non adherence	8.243	3	0.041
Knowledge of the importance of frequency and time of drug instillation.	11.980	2	0.003
Awareness about risk of vision loss following non adherence	18.154	4	0.001

Table 5: Bivariate analysis of factors evaluated for association with non Compliance to antiglaucoma medication.

Factors	Chi-square test	Degrees of freedom (df)	P value
Knowledge of irreversible vision loss caused by glaucoma	16.418	3	0.001
Dependency for drug instillation.	13.334	6	0.038
Preferred time for drop instillation.	26.640	15	0.032
Reasons for forgetfulness	90.968	12	0.000
Specific days or occasions of forgetfulness.	21.472	6	0.002
Awareness about risk of vision loss following non Persistence	33.293	6	0.000

Table 6: Bivariate analysis of factors evaluated for association with nonpersistence to antiglaucoma medication.

Factors	Chi-square test	Degrees of freedom (df)	P value
Drug schedule convenient to patient.	35.859	8	0.000
Reasons for patient's forgetfulness.	75.922	24	0.000
Whether patients believed that the risk of vision loss could be due to not using anti glaucoma medications properly as prescribed.	30.584	8	0.000

treatment and 8 (5.20%) were not taking any treatment at all. We found a statistically significant association between patients with higher education and presence of medical co-morbidity (p<0.005). (Table 3) We also found a statistically significant association between patients having good income and regular treatment of their systemic disease. (p<0.039). (Table 3)

3.2. Factors related to glaucoma medications

One hundred and twelve patients (37.30%) were using anti glaucoma medications since 2 - 12 months, 38 (12.7%) were using since 13 - 24 months, 46 (15.3%) since 25 - 48 months, 20 (6.7%) since 49 - 60 months and 84 (28%) were using since more than 60 months. Majority patients [104 (34.7%)] were using two drugs, 82 (27.3%) were using three drugs, 61 (20.3%) were using single drug, 41 (13.7%) were using four drugs and 12 (4%) were using more than four drugs. About 61% patients faced problems while buying drugs like higher cost of drugs, unavailability of drugs and

lack of nearby availability of drugs, 37.7% did not face any problem and 1.7% patients occasionally faced problems. (Figure 4). Patients with poor education level were found to have more problems while buying drugs and this difference was statistically significant. (p<0.04)
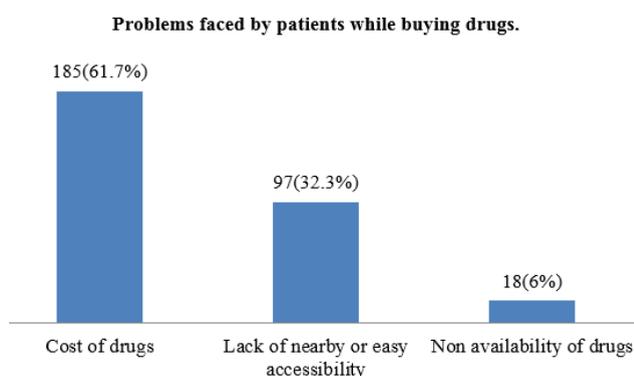
Fig. 4: Problems faced by patients while buying drugs

Majority patients [192 (64%)] were self-dependent for buying the drugs, 107 (35.7%) were dependent on their family members and 1 (0.3%) patient was dependent on others like relatives or neighbors. Patients with lower education, female patients and retired patients were specifically found to be dependent on the family for drug purchase. (p<0.04) (Table 3) Statistically significant difference in compliance and persistence was found between patients who were independent for drug instillation and those who were dependent on family members (p<0.03). (Tables 3 and 5)

Majority patients [233 (77.7%)] did not face any difficulty while instilling drops, 23 (7.7%) noticed some wastage of drops, 18 (6%) faced difficulties in controlling the number of drops instilled into the eye, 10 (3.3%) faced difficulties in squeezing the bottle, 7 (2.3%) faced difficulties while opening or puncturing the drug bottle, 7 (2.3%) experienced involuntary blinking during instillation and 2 (0.7%) faced some physical difficulty while instillation. The drug schedule was convenient for 259 (86.3%) patients but not convenient for 33 (11%) patients. It was only partially convenient for 8 (2.7%) patients. A statistically significant difference in adherence and persistence was found between patients who had a convenient drug schedule and those who did not (p<0.00). (Tables 4 and 5) One hundred and sixteen (38.7%) patients preferred morning and night time for drop instillation, 35 (11.7%) preferred morning and evening, 28 (9.3%) preferred night time only, 5 (1.7%) preferred morning time only, 4 (1.3%) preferred evening time only while 112 (37.3%) were fine with any time. Educated (graduation and above) patients were not preferential for time of drug instillation and this was found to be significant (p<0.002). (Table 3) A statistically significant difference in compliance and persistence was found in non-preferential patients. (p<0.03) (Tables 3 and 5)

Side effects were noticed by 111 (37%) patients after drug instillation whereas 189 (63%) patients did not notice any side effects. The side effects noticed, in decreasing order of incidence, were redness, burning, dryness, eyelash growth, itching, foreign body sensation, headache and periocular skin pigmentation. Younger patients reported more side effects and it was found to be statistically significant (p<0.03). (Table 3) A statistically significant difference in adherence was found between patients experiencing side effects of drop instillation and those who did not. (p<0.00) (Table 4) Two hundred and eighty-five patients (95%) did not stop drugs even after adverse reaction, 6 (2%) stopped the use occasionally whereas 9 (3%) completely omitted the use subsequently.

Majority patients [288 (96%)] were clearly instructed by the prescribing doctor about the drug schedule and usage whereas 12(4%) were not. A statistically significant difference in adherence was found between patients who received clear instructions and those who did not (p<0.02). (Table 4) Out of the 300 patients, 276 (92%) could clearly recall the instructions, 12 (4%) could not remember at all whereas 12 (4%) could do so only partly. A statistically significant difference in adherence was found between patients who could remember the instructions and those who could not (p<0.00). (Table 4)

Thirty six patients (12%) were aware of the importance of punctual occlusion in topical drug use whereas 264 (88%) were not. Young patients (<55 years) were significantly aware of this importance (p<0.05). Out of 300 patients, 249 (83%) did not know the importance of frequency of drug and time of instillation whereas 51 (17%) knew the importance (p<0.00).

Most patients [173 (57.7%)] believed that the prescription of multiple drugs affected their compliance, 10 (3.3%) were not sure about at all while 117 (39%) did not feel so. Nine (3%) patients believed that drug usage interfered with their routine schedule though 291(97%) did not believe that. Majority [192 (64%)] believed that reduced number and frequency of drugs would improve compliance.

From the suggestions received to improve compliance, 144 (48%) patients recommended the use of media and educational videos by prescribers to explain regarding the use of medications, 54 (18%) patients proposed to request their doctors to check their current technique of drop instillation and 36 (12%) patients believed that the prescriber should suggest cues to easily remember the eye drop instillation time matching with their daily activities.

4. Discussion

Despite meaningful advancements in technology, availability of better therapeutic tools and improved knowledge of disease, patients still continue to go blind from glaucoma.[14] Medical management remains the first line of treatment for majority of the patients and the major reason for its failure is non-compliance to the drug therapy. It becomes imperative therefore to acknowledge, understand and overcome the barriers to compliance. In our study, we could identify certain barriers affecting the compliance of patients towards medications like demographic factors (age, gender); social factors (income, education, occupation, malpractices under influence of quacks, religious superstitions); physical factors (systemic disease - hypertension, diabetes, asthma, psychiatric illness, connective tissue disorder); medication related factors (number of antiglaucoma medications, side effects of medication, frequency of medication, cost of medication); physician related factors (professional incompetency, improper documentation of patient data, over prescription of drugs, misdiagnosis of disease); patient related factors (irregular schedule, loss of follow up, drop out from treatment, poor patient doctor relationship, notwithstanding proper orientation of prescribed medications.) In our cross

sectional study, we have attempted to identify various barriers to compliance, adherence and persistence. In our study, we found that poor education and poor knowledge about glaucoma were the most important barriers affecting every aspect of medical management. In contrast to our study, a study conducted in North India by Ketaki Rajurkar et al. and another done in south India by Prasanna Venkatesh Ramesh showed forgetfulness as the main reason for non compliance.[15,16]

Among medication related barriers, higher cost of drugs, complexity of regimen, inconvenience due to polypharmacy, dependency for drug purchase and drug instillation were found to be major barriers in our study. The study conducted by Robin AL and Covert D also showed that adding a second medication and/or increasing the complexity of glaucoma therapy was associated with a statistically significant decrease in adherence.[17] Mackean JM also stated that patients who were on mono-therapy were more likely to better comply than those on dual therapy, because of less complexity of doses.[18] Eldaly et al. also showed that lack of intra ocular pressure control was mostly related to the economic burden of glaucoma medications in Egypt.[13]

A study conducted in South India by Betsy L Sleath et al. showed that difficulty in squeezing (p=0.04) and opening the bottle (p=0.02) significantly contributed to poor compliance.[19] In contrast, in our study, most of the patients (77.7%) had no difficulties in drug instillation as most of them had been using drugs for more than 12 months and had adapted to the technique.

The study conducted by Orit Cohen Castel et al. stated an association between better adherence and understanding of the disease and its medical treatment. They found that clinicians can influence patients' understanding and concerns about the threat of illness and the belief in the effectiveness of treatment which are important determinants of adherence.[20] In our study also, patients who were clearly instructed by their doctors about drug schedule, dosage, technique of instillation and its importance were better adherent to treatment compared to those who were not instructed (p<0.02).

Limitations of our study are that it is based on a self-reported questionnaire, so there is a possibility of patients' under reporting of few factors either due to recall bias and/or a desire to please the physician with inaccurate estimation of compliance rate. There are also several strengths to this study, including the wide range of barriers that were evaluated and the analysis of optimal adherence among both patients who were and were not adherent to their medications. Since this study included many glaucoma patients who had been living with the disease for a long time and had continued to return to clinic for follow-up care, this study sample is likely to be more mindful of their disease than the general glaucoma population. To find that even these patients still had many issues managing their drug treatment underscores the need to provide patients with more comprehensive resources for disease self-management, encouragement and support.

5. Conclusion

Our study helps to identify social, physical, medication related, doctor related and patient barriers which affect compliance, adherence and persistence to medical treatment. Higher education level and a positive family history of glaucoma are associated with better compliance. Poor awareness about glaucoma and its outcome, higher cost of drugs, complexity of regimen, multiple drugs, age related forgetfulness, lack of social support and dependency on others were the major barriers to compliance found in our study. Extra efforts must be made by doctors and hospital staff to educate the patients about the nature of disease, its outcome, its impact on quality of life, importance of topical medications, the technique of drug instillation and necessity of follow up visits. A simplified and convenient treatment regimen should be preferred and prescribed. Memory aids like synchronizing drop instillation time with daily activities, alarm reminders, electronic drug monitors, counseling of family member of patients or written instructions may be used to increase compliance. Maximizing patient compliance to medication can reduce the number of surgical interventions, prevent vision loss and reduce the healthcare burden in the long run.

6. Conflict of Interest

There are no conflicts of interest in this article.

7. Source of Funding

None.

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