FACTORS AFFECTING COMPLIANCE AND CHALLENGES IN USING TOPICAL MEDICATIONS IN PATIENTS ATTENDING THE GLAUCOMA CLINIC AT MENELIK II REFERRAL HOSPITAL, ADDIS ABABA, ETHIOPIA

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DECLARATION

I declare that this thesis is my original work and has never been published or presented for a degree in any other University.

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LIST OF ABBREVIATIONS AND ACRONYMS

EDC	-	Eye drop chart
IOP	-	Intraocular Pressure
OHT	-	Ocular Hypertension
POAG	-	Primary Open Angle Glaucoma

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ABSTRACT

Background: In ophthalmology, non-compliance with eye drop therapy particularly for chronic diseases like glaucoma is a well-recognized problem, with 80% of the patients administering their own eye drops using various techniques and methods. Glaucoma is mostly asymptomatic. Non-compliance and difficulties associated with use of glaucoma eye drops can potentially result in treatment failure. There is limited understanding of the challenges these patients face in Ethiopia.

Objective: To determine factors affecting compliance and the challenges of using topical medications in patients attending the glaucoma clinic at Menelik II Referral Hospital.

Study Design: Hospital based cross-sectional study

Study Population: The study included all patients ≥18 years with open angle glaucoma on medication who had at least 6 months of experience with topical glaucoma medications use and visited the hospital during the study period (March 2017 to 3rd July /2018).

Data collection: Participants were interviewed about their knowledge, frequency and pattern of eye drop use to determine their level of compliance, they were interviewed to describe the difficulties experienced when using drops; and finally, they were observed while applying eye drops using artificial tears to determine the appropriateness of their technique. Data on any co-morbidities which may affect eye drop application was also collected. Eye drop practice was further explored in focus group discussion with patients and care givers (pharmacist, residents, ophthalmic nurse and glaucoma specialist) separately.

Non-compliance was defined as missing at least one drop application in the past week.

Results: 198 participants were analyzed. Most (81.3%) patients reported using medications as prescribed but by definition only 69.7% were compliant. The main reasons for non-compliance were forgetfulness (59.5%), unavailability of drops in the pharmacy (10.8%) and financial problem (8.1%). Inappropriate drop application technique was observed often.

Conclusion: The compliance to medication was low mainly due to dose forgetfulness. The socio-demographic characteristics did not affect compliance. Patients using eye drops as instructed were found compliant to treatment.

1.0 BACKGROUND AND LITERATURE REVIEW

1.1 Introduction

Glaucoma represents a group of diseases defined by a characteristic optic neuropathy that is consistent with remodeling of the connective tissue elements of the optic nerve head (also called the optic disc) and with loss of neural tissue associated with the eventual development of distinctive patterns of visual dysfunction [1]. A major risk factor for glaucoma is high intraocular pressure (IOP), with clinicians aiming to reduce it by using various IOP-lowering agents such as miotics, β-blockers, prostaglandin analogs, α-agonists, carbonic anhydrase inhibitors, and epinephrine derivatives or surgical alternatives such as trabeculoplasty, trabeculectomy with or without insertion of drainage tubes [2] [3].

Proper instillation of eye drops essentially includes compliance and performance. Performance, the ability of correctly instilling the eye drop, is affected by number of factors such as age, visual acuity and presence of co-morbid conditions [4]. Several studies have shown that patients experience difficulties in self-instillation of their eye drops [5]. For example, poor techniques can include missing the fornix completely, delivery of an excessive dose, or ocular trauma or bottle contamination due to contact between the tip of the bottle and the globe or lid. Moreover, if the patient has a poor technique they are often unaware of the problem. The difficulties associated with self-instillation of eye drops from commercial bottles have been acknowledged and novel techniques, designs and aids have been proposed [6] [7]. These aids are helpful in facilitating self-instillation, but are limited by requirement of correct technique, physical force, dispensing, cost, availability and comprehension [8].

Topical medications have an important role in the treatment of glaucoma. The current therapeutic approaches are centered on reducing IOP [9], the only known modifiable risk

factor. Topical medications are usually the first line therapy offered for reducing IOP [10] and in many glaucoma patients' medications alone can control the disease. The IOP control with topical medications is influenced by several physiological and non-physiological factors [11] [12]. Thus, this study is designed to determine factors affecting compliance and the challenges of using topical medications among glaucoma patients seen at Menelik II Referral Hospital.

1.2 Literature Review

1.2.1 Global Overview Of Glaucoma

The WHO undertook an analysis of the literature to estimate the prevalence, incidence, and severity of the different types of glaucoma on a worldwide basis. Blindness prevalence for all types of glaucoma was estimated at more than 8 million persons, with 4 million cases caused by POAG. Glaucoma was theoretically calculated to account for 12.3% of cases of blindness; it is therefore the second leading cause of blindness worldwide, following cataract [13].

Data from population-based surveys (PBS) indicate that glaucoma is the second leading cause of blindness, accounting for 8% of blindness among the 39 million people who are blind worldwide. In Africa, glaucoma accounts for 15% of blindness and it is the region with the highest prevalence of blindness relative to other regions world-wide [14]. It is estimated that 60.5 million people world-wide would have glaucoma by 2010, increasing by 20 million by 2020 [15].

Few studies have been conducted to evaluate use of topical medications among glaucoma patients. Study by Tsai *et al*. [16] evaluated the method of eye drop administration, including the handling, storing, and actual administering of eye drops. These aspects of patients' eye drop administration, which may be strongly related to the success of prescribed therapies, were evaluated. In the UK, McVeigh and Vakros [17] in order to improve patient education,

compliance, and administration of eye drops prescribed for patients suffering with glaucoma within a UK Ophthalmology department, an eye drop chart (EDC) was designed, developed, and piloted with patients attending the glaucoma clinic over 1 month. Virani *et al.* 2015 [18] designed a study to evaluate difficulties associated with self-instillation of eye drops in glaucoma patients and to quantitatively assess their impact on intraocular pressure (IOP).

Different methods have been employed by different studies. Tsai *et al.* [16] used a 2-page questionnaire, distributed to 253 sequential glaucoma patients at the time of their regular clinical visit. In addition to providing demographic data, the patients were asked to complete a questionnaire about their current use of eye drops. McVeigh and Vakros [17] utilized a cross-sectional prospective pilot study of 25 patients using an administration aid and a self-reported questionnaire. Virani *et al.* 2015 [18] used a prospective interventional study at primary eye care center. A total of 69 persons diagnosed with glaucoma or ocular hypertension (OHT), who were self-instilling their eye drops, were included in this study.

On results, literature has revealed varied results. Tsai *et al.* [16] found out that 17% of the patients relied on others for the administration of drops and most commonly cited inadequate vision and trouble with manual dexterity leading to this dependency. Of those who self-administered drops, only 16.3% used a mirror. McVeigh and Vakros [17] demonstrated an impressive improvement in nine of eleven categories assessed regarding drop administration and compliance. Sixty-four percent reported finding EDC helpful or useful, and 52% had positive responses when asked if they would continue using EDC. Virani, *et al.* [18] found out that 53% of patients reported subjective difficulties while self-instilling their eye drops. Non-compliance was self-reported in 18% of the patients.

The reviewed studies made important conclusions. Tsai *et al*. [16] concluded that there is need for better instruction in eye drop administration and illuminates some of the methodological

problems that could be overcome to reduce patients' frustration, improve compliance, and increase medication efficacy. McVeigh and Vakros [17] explain that the EDC appears to be a cost-effective way at improving patients' use of topical ocular medications. Virani *et al.* [18] Concluded that assisted eye drop instillation may be beneficial to achieve better IOP control.

1.2.2 Glaucoma in Africa

Studies describing the epidemiology of glaucoma have not addressed the use of topical medication in Africa [19] [20] [21]. There have been many anecdotal reports of high rates of open angle glaucoma (OAG) in Africans, and this seems to begin in a younger age group than among white people [20] [21]. Efforts to understand more about how glaucoma patients use topical medications in Africa have usually been limited by reliance on clinic populations.

A recent study conducted in Ethiopia by Tamrat *et al.* [22] determined the adherence to anti-glaucoma medications and factors associated with non-adherence among patients with ocular hypertension (OHT) or glaucoma at Jimma University Specialized Hospital. It was a hospital based cross sectional study conducted on 200 consecutive patients. Patients with OHT or glaucoma who were taking topical anti-glaucoma medications for more than six months were included. The study subjects were interviewed, and their medical records were reviewed. They established that 135 (67.5%) patients were non-adherent to glaucoma therapy. Non-adherence was associated with older age ($P = 0.04$), advanced stage of glaucoma ($P = 0.01$), longer frequency of follow up ($P = 0.00$) and financial problem ($P = 0.000$).

Yet another study was conducted in Ethiopia by Tadesse and Mulugeta [23] to determine the extent of non-compliance to treatment among glaucoma patients at Menelik II Hospital. It was a hospital based cross sectional study that targeted patients who were on topical anti glaucoma treatment and follow-up at glaucoma clinic, Menelik Hospital during May 1 to July 30, 2014.

Four hundred one eligible patients were interviewed with a pretested structured questionnaire by the principal investigator. Medical charts of each patient were reviewed for specific information like type of previous procedures and visual acuity. The study established that among the 401 patients interviewed, 230 patients (57.4%) were found to be noncompliant. Younger ages, higher educational level, previous history of procedures for glaucoma were associated with better compliance. Factors associated with non-compliance included poor vision, more than one drug therapy, fair or poor understanding of the disease, use of other systemic medications, unavailability of drugs in the market, dependency on others for instilling the drops. Tadesse and Mulugeta concluded that the presence of substantial non-compliance of glaucoma patients at a tertiary center.

A study in Egypt by Abu Hussein *et al.* [24] studied factors affecting patients' compliance to antiglaucoma medication. It was a cross-sectional descriptive study on 440 patients with open angle glaucoma (OAG) recruited for over two years. They found that 36 (53.6%) were noncompliant compared to 204 (46.4%) who were compliant. Patient age above 50 years and low level of education and negative family history of glaucoma were factors significantly associated with poor compliance. It was concluded that Egyptian patients have a high rate of non-compliance compared to the average in literature.

1.2.3 Comorbidities Associated with Glaucoma

Glaucoma and various retinal diseases are leading causes of vision loss worldwide. Numerous retinal diseases are associated with and lead to various types of glaucoma. Ischemic conditions such as central retinal vein occlusion (CRVO) or branch retinal vein occlusion (BRVO), central or branch retinal artery occlusion, malignancy, and proliferative diabetic retinopathy are associated with neovascular glaucoma. Various types of uveitis, including Behçet's disease, sarcoidosis, syphilis, Fuchs iridocyclitis, and juvenile rheumatoid arthritis are causes of

secondary glaucoma. Retinitis pigmentosa is associated with primary open-angle and primary-angle closure glaucoma. Patients with retinal detachments have higher rates of both ocular hypertension and glaucoma than people in the general public [25].

Patients with rheumatoid arthritis, osteoarthritis, carpal tunnel disease and stroke have all been reported as having lower finger strengths. In addition to neurological disease causing lower strengths these can also cause deficits in control and direction of force application, which are also required to coordinate functional tasks such as squeezing a bottle. Other limiting factors in the instillation of an eye drop is the ability to lift a hand to the face, maintain aim, coordination and fine motor control as the bottle is directed close to the eye. These factors in themselves are barriers to compliance [8].

1.2.4 Non-Compliance

In ophthalmology, non-compliance with eye drop therapy is a well-recognized problem, with 80% of the patients administering their own eye drops, [26] using various techniques and methods [27] [28] [29]. This can potentially result in treatment failure if the method used is not appropriate, [27] and due to the asymptomatic nature of glaucoma, good eye drop administration technique and long-term compliance are crucial in order to limit disease progression.

Non-compliance with prescribed treatments has proven to be a significant obstacle to effective glaucoma management. Most patients overestimate their compliance and physicians are unable to determine which patients adhere to prescribed therapy [5] [30]. However, one factor that is often overlooked is the method of each patient's eye drop administration [2] [31]. Some patients instill their drops when sitting, others stand or lie down, and others use a mirror to aid the process. If eye drop instillation is done improperly, it can lead to treatment failure,

unnecessary use of additional medications, and potentially to the spread of infection. In addition, eye care providers often neglect the importance of instruction on how to handle, store, and administer eye drops.

Studies revealed that non-adherent participants are less likely to; believe their eye doctors, spent sufficient time with them, ask their eye doctor if they had any questions, and know of benefits to taking their glaucoma medication regularly, and they have someone to help them to take their glaucoma medications or drive them to eye appointments [32]. In addition, patients with severe glaucoma have been found to be more likely to adhere to topical IOP-lowering medication regimen than those with milder glaucomatous disease [33]. Further, studies have shown that glaucoma treatment adherence improves with increasing age, and older patients require more prescriptions and may be experiencing drop wastage [32] [34].

In other studies, higher non-compliance was found in elderly patients above 50 years old. Older patients may have a lower compliance rate probably due to the lack of support, reduced vision, problems with manual dexterity, coordination, comprehension, or memory loss. And noncompliant patients have hypertension, diabetes with hypertension and ischemic heart disease [24]. Non-adherent glaucoma patients are more likely to have impaired visual acuity or partial vision loss. Physical challenges in self-administering eye drops are commonly cited barriers to glaucoma adherence [32].

2.0 JUSTIFICATION

Previous studies in glaucoma patients in Ethiopia on extent of non-compliance to glaucoma treatment have showed non-compliance rate of 67.5% Tamrat *et al.* [22] and 57.4% Tadesse and Mulugeta [23]. Thus, further exploring of the factors affecting compliance and the challenges of using topical medications in glaucoma patients may be the first step toward improving patient education, compliance, the settings and circumstances. Also, will enable us to assess methods of eye drop administration adopted by patients using topical glaucoma medications. This study attempts to address these issues and would be used to create awareness for health workers to counsel their patients how to comply with prescribed topical medication and proper method of eye drop administration. In addition, there are few studies that have examined the practical aspects around the daily experience of patients' eye drop administration and to identify potential problems that may adversely affect compliance to glaucoma treatment.

3.0 OBJECTIVES

3.1 Broad Objective

To determine factors affecting compliance, and the challenges of using topical medications in patients attending the glaucoma clinic at Menelik II Referral Hospital.

3.2 Specific Objectives

1. To determine the level of compliance to glaucoma medications.
2. To determine factors affecting patient compliance to glaucoma treatment.
3. To determine the method of Eye drop administration adopted by patients.
4. To determine the challenges of using topical glaucoma medications.

4.0 MATERIAL AND METHODS

4.1 Study Design

A hospital based cross-sectional study conducted at glaucoma clinic at Menelik II Referral Hospital, Addis Ababa, Ethiopia.

4.2 Study Area

The factors affecting compliance and the challenges of using topical medications in patients attending the glaucoma clinic done at Menelik II Referral Hospital located in Addis Ababa, Ethiopia, serving as a national referral hospital for eye services. The population being served by the hospital exceeds 15 million. Total number of patients seen annually at glaucoma clinic reach to 5000 to 6000 in five clinic days per week.

Figure 1: Map of Ethiopia showing Addis Ababa

Based on the 2007 census conducted by the Ethiopian national statistics authorities the population of Addis Ababa is 3.6 million; all of the population are urban inhabitants [35]. It is the capital and largest city of Ethiopia.

4.3 Study Period

The study was conducted from March 2017 to 3rd July /2018

4.4 Study Population

Consecutive patients with open angle glaucoma on medication aged 18 years or above, who had been on topical glaucoma medication for at least six months and were attending the glaucoma clinic during the study period were included.

4.5 Inclusion Criteria

All patients with open angle glaucoma on medication aged 18 years or above, who had at least 6 months of experience with topical glaucoma medications use.

4.6 Exclusion Criteria

Subjects suffering with a cognitive impairment /psychiatric disorders

4.7 Case Definition

4.7.1 Compliance

Compliance and adherence: Throughout the literature, compliance and adherence were used interchangeably. Traditionally, compliance has been defined as the extent to which patients' behaviors correspond with physician's recommendations. Compliance means patient's

adherence to regimen and not missing any medication (eye drop). For this study, a patient who missed at least one drop of medication in the last week was defined as non-compliant.

4.7.2 Proper method of eye drop administration

Based on the McVeigh and Vakros [17] and most studies done on proper eye drop administration including Tsai et al [16] the following are the advised steps of proper eye drop administration.

1. Wash your hands with soap and clean water before handling the eye drop
2. Shake the eye drop bottle
3. Open the eye and pull down the lower lid
4. Put one drop in the lower fornix
5. Close the eyelids and apply pressure on the tear duct for 3-5 minutes
6. Allow a gap of minimum 5 minutes between two different eye drops

4.8 Sample Size

The following Cochrans sample size determination formula for finite population correction [36] was used to estimate the proportion of population study size. $n^1 = \frac{NZ^2P(1-P)}{d^2(N-1)+Z^2P\ (1-P)}$

Where

- *n*= sample size with finite population correction,
- *N* = size of the target population = 220 (10*22 days) (estimated minimal number of patients on chronic topical glaucoma medications aged 18 years or above seen in in

Menelik II Referral Hospital is approximately 10 patients per day according to the registry book).

- Z = the value that specifies the level of confidence you want in your confidence interval when you analyze your data. Typical levels of confidence for surveys are 95%, in which case z is set to 1.96.
- P = estimated proportion of patients noncompliant for glaucoma medical treatment is 57% (Tadess and Mulugeta et al 2015).
- d = margin of error = 2.1%

$$n = \frac{220 * 1.96^2 * 0.57(1 - 0.57)}{0.021^2(220 - 1) + 1.96^2 * 0.57\ (1 - 0.57)}$$

n=198

4.9 Tools

4.9.1 Questionnaire

The trained interviewers and primary investigator have asked both demographic information, multiple-choice and open-ended questions about patients' use of eye drops and compliance to treatment. Demographic data collected included age, sex, literacy level, social circumstances, and other comorbidities, as well as method of eye drop administration. Sterile artificial-tear drop was used for each patient for direct observation on eye drop administration technique. Only those who administered their own eye drops and those patients who were accompanied by the person administering their eye drops to the clinic were included in the direct observation part of the study.

4.9.2 Data Collection Procedure

Two nurses from the hospital were selected and trained to assist data collection. An open ended and structured questionnaire was filled by the primary investigator and trained assistances. The questionnaire was written in English to collect necessary information from the patients. Data was collected at the time of their regularly scheduled glaucoma clinic visit. Institutional review board approval was obtained, and an informed consent was given to all participants. This study has followed the tenets of the Declaration of Helsinki; ethical principles for medical research involving human subjects.

4.9.3 Focus Group Discussion (FGD)

Selected informants participated in the FGD; two groups of eight females and eight male patients separately and a group consisting of four ophthalmology senior residents (three third

years and one fourth year) and one ophthalmic nurse (responsible in giving health education to glaucoma patients) were interviewed separately using health care provider interview guide.

A key informant interview was also held with a pharmacist and a glaucoma Specialist using an interview guide.

The FGD was conducted in a selected room within the hospital

An audio recorder was used supplemented by written notes.

The FGD took around 30-45 minutes

A professional transcriber was sought to transcribe the audio recording

The transcription was qualitatively analyzed to supplement quantitative analysis

4.10 Data Management and Analysis

All filled questionnaires were checked by the principal investigator for completeness. Collected data was coded and entered into a Microsoft excel spreadsheet. Statistical analysis was done using Statistical program for social sciences (SPSS) program version 23. Categorical variables were analyzed using frequencies and percentage. Continuous variables were summarized using mean, percentile, range, and standard deviation, where appropriate. Significant differences and associations were determined by p-values of less than 0.05. Multivariable logistic regression analysis was used to estimate odds ratios (ORs) and 95% confidence intervals (CIs).

4.11 Ethical Considerations

4.11.1 Confidentiality

The identity of the patients was kept anonymous during data collection. No record of the identity of the patient was made. No photocopy of the medical records was done. The questionnaires were only available to the statistician and investigator for analysis.

4.11.2 Approval by Ethics Committees

Written ethical approval to conduct the study was obtained from the Ethics and Research Committee of University of Nairobi and Kenyatta National Hospital. Approval was also sought from Menelik II Referral Hospital, Addis Ababa University.

5.0 RESULTS

Flow chart showing 198 studied participants.

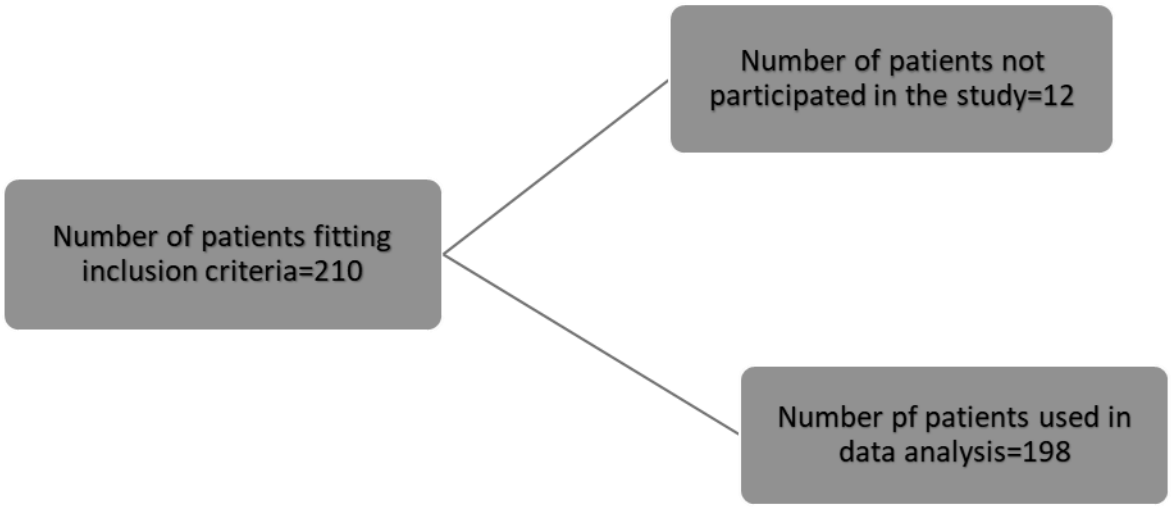

Figure 2: Flow Chart showing data collection (n=198)

Figure below showing among 198 eligible patients, majority (n = 63, 31.8 %) were in the age group of 61-70 years old (mean: 61.8, range: 27 to 93 years).

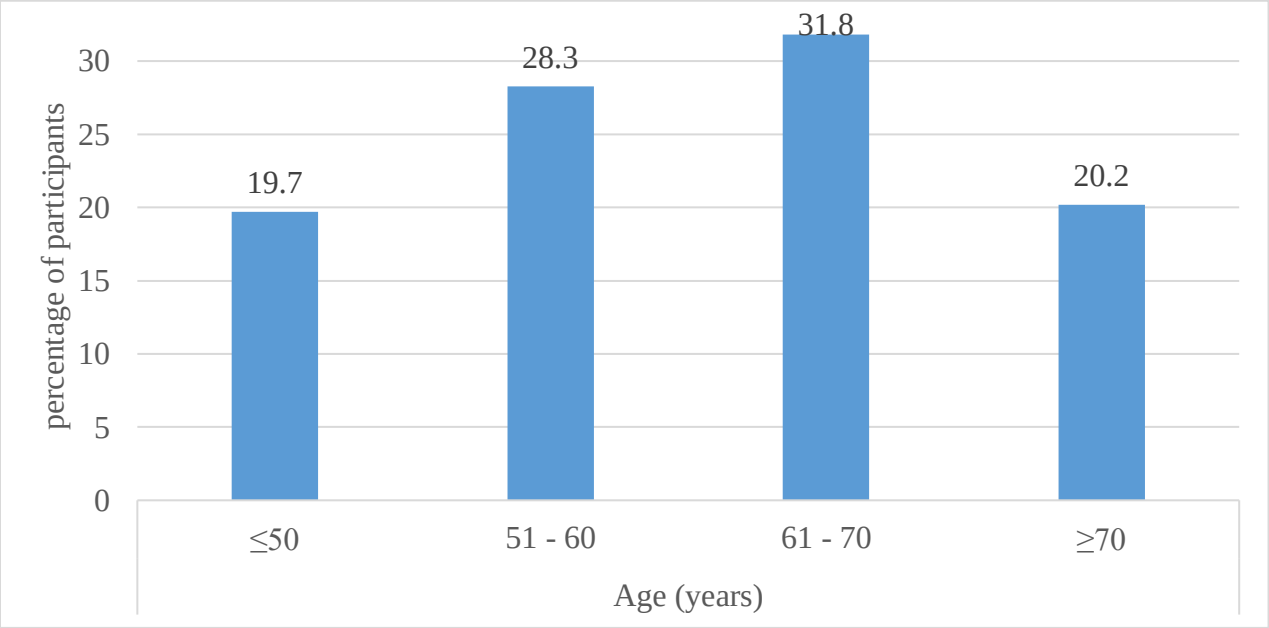

Figure 3: Distribution of study population by Age (n=198)

Most of the studied participants were males (n = 135, 68.2 %) as shown in the figure below.

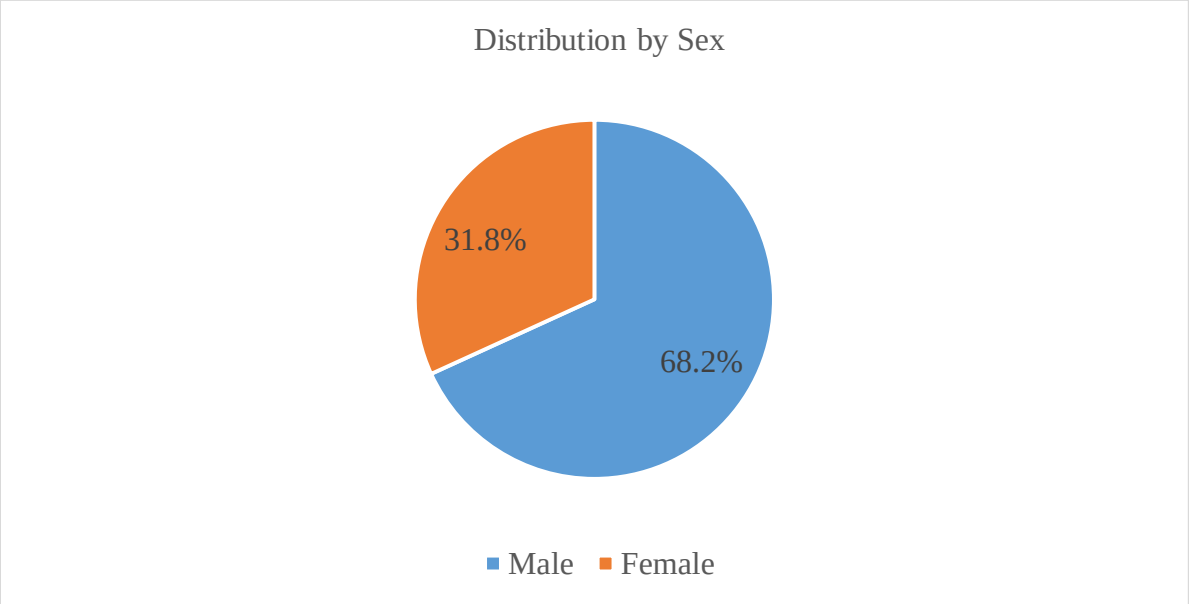

Figure 4: Distribution of study population by Sex (n=198)

Table 1: Socio-demographic characteristics of study patients (n=198)

Variables	Number of patients	%
Marital Status		
Married	142	71.7
Widowed	30	15.2
Divorced	17	8.6
Single	9	4.5
Residence		
Urban	184	92.9
Rural	14	7.1
Highest Education Level attained		
No formal education	48	24.2
Primary	62	31.3
Secondary	54	27.3
Tertiary/College	34	17.2

Data are frequencies (percentages)

The socio-demographic characteristics of the study participants; Majority of the study subjects (n = 184, 92.9 %) were residing in urban areas and most of them are married (n=142,71.7%). Concerning the educational level, 110 (55.5 %) patients had a lower educational level (primary school or none).

Figure below showing monthly income of study participants; about 152 (76.7%) study patients have a monthly income less than 80 USD.

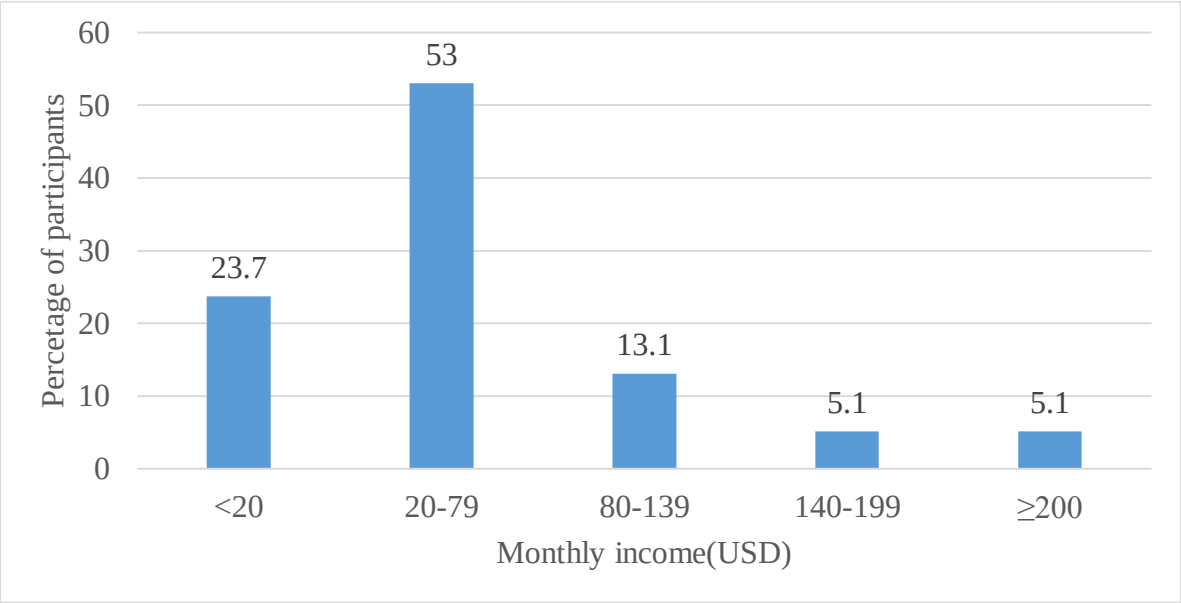

Figure 5: Monthly income of study participants (n=198)

Table 2: Practice (self-reported) of eye drop use (n=198)

Variables	Number of Patients	%
Duration of Treatment (in years)		
½ –2	69	34.8
3 – 5	59	29.8
6 – 9	45	22.7
>10	25	12.6
Who Administers Eye Drops		
Self-administered	165	83.3
Other person[1]	33	16.7
How Respondent Gets Eye Drops		
Buy them myself	106	53.5

Donation[2]	84	42.4
Someone else buys	8	4.1
Out of pocket Expenditure on Medication (USD)		
< 5	118	59.6
5 – 9	28	14.1
10 – 14	25	12.6
≥15	27	13.6
Number of Medications		
One	106	53.5
>1	92	46.5
Time Elapsed to Administer the Second/Consecutive Drop(n=92)		
<5 min	30	32.6
5-10 min	33	35.9
>10 min	29	31.5
Wash Hands Before using Eye Drops		
Yes	98	49.5
No	45	22.7
Sometimes	55	27.8
Are you keeping Latanoprost in Refrigerator (n=34)		
Yes	21	61.8
No[3]	13	38.2
Uses the Eye Drops as Instructed?		
Yes	161	81.3
No	37	18.7
No. of Doses Missed in the Past Week		
None	138	69.7
≥1	60	30.3

Data are frequencies (percentages)

[1]*Other person include family members and neighbors*

[2]*Drugs in free pharmacy*
[3] *Reasons for not putting medication in refrigeration was patient didn't own a refrigerator*

Data shows that 34.8% of patients had a follow up period of 6month to two years with average duration of treatment 5.8 years and about 30.3% (60) glaucoma patients missed one or more dose in the past week, meaning that the level of compliance was 69.7%. Most of the study patients,118 (59.6%) have a monthly out of pocket expenditure less than 5 USD. Patients on Latanoprost 34 (17.2%); 61.8% were keeping the eye drop in the refrigerator before opening.

Figure below showing majority of patients 59.5% were not using their eye drops as instructed because of forgetfulness and 10.8% of patients due to drops unavailable in the market.

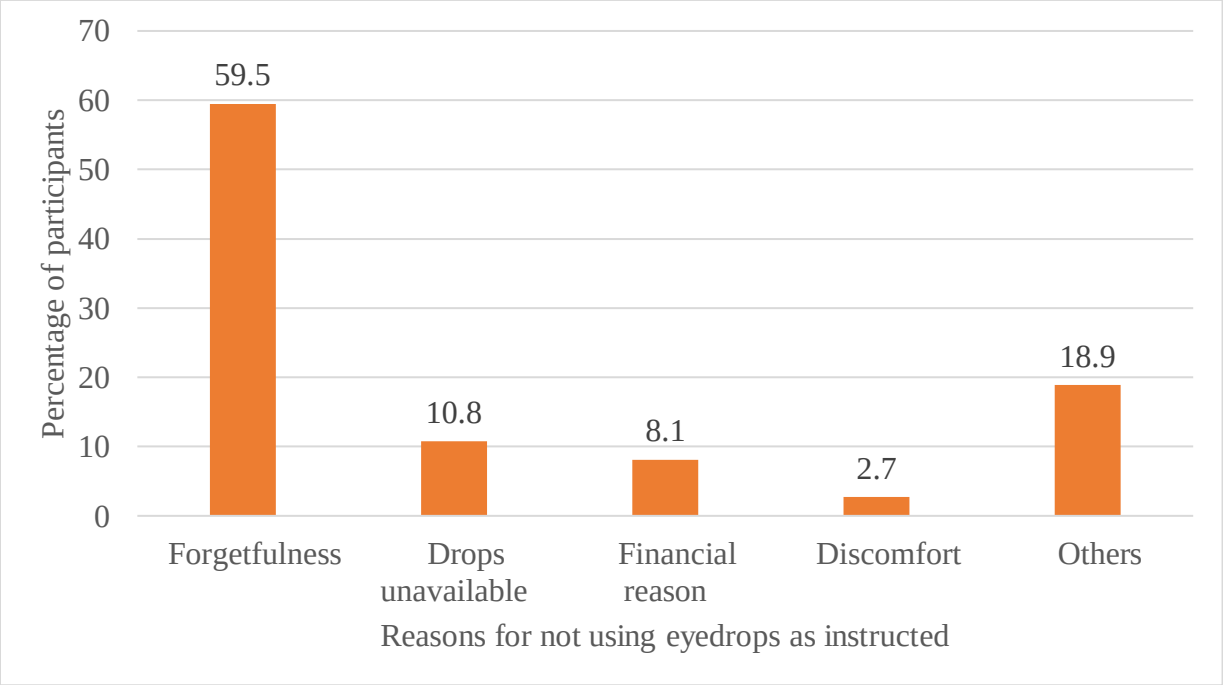

Figure 6: Reasons for not using eye drops as instructed (n=60)

Table 3: Knowledge (instructions received) on eye drop use (n=198)

Variables	Number of Patients	%
Taught about Eye Drops Use		
Yes	182	91.9
No	16	8.1
Person responsible for Teaching Eye Drops Use(n>198;multiple response)		
Nurses in eye clinic	120	42.1
Ophthalmologist	95	33.3
Pharmacist	66	23.2
Others[1]	4	1.4
What was Taught on Use of Eye Drops(n>198;multiple response)		
Frequency of use	111	51.6
Proper storage/handling	40	18.6
Keeping time for applying	39	18.1
Methods of drop administration	22	10.2
Can't remember what was taught	3	1.4

Data are frequencies (percentages)
[1] *Others responsible for teaching eye drops use includes: relatives (2) and reading leaflets (1)*

Data shows that majority (91.9%) of the patients were taught about eye drop use with majority being taught by nurses in the eye clinic (42.1%) followed by ophthalmologist (33.3%).

Table 4: Practice (observed) of eye drop use (n=183)

Variables	Number of Patients	%
Patient shake the eye drop bottle before use		
Yes	57	31.1
No	126	68.9
Dropper tip touches eyes or hands		
Yes	83	45.4

No	100	54.6
Lid held open when patient/relative puts eye drop		
Lower lid	113	61.7
Both upper and lower lid	34	18.6
Upper lid	19	10.4
None	17	9.3
Number of drops put in the eye		
One drop	125	68.3
Two or more drops	58	31.7
Drop miss the patients' eye		
Yes	39	21.3
No	144	78.7
Closes eyelids		
Yes	145	79.2
No	38	20.8

Data are frequencies (percentages)

Table above showing majority of patients (68.9%) were not shaking their eye drop bottle and 45.4% of them have contaminated the dropper tip with eye/hand. About 79.2% of patients observed closing eyelids after instilling eye drops, but none of the patients had pressed on nasolacrimal duct.

Table 5: Difficulties experienced (self-reported) with eye drop use (n=198)

Variables	Number of Patients	%
Difficulties in Applying Eye Drops		
Yes	87	43.9
No	111	56.1
Reported Difficulty in Applying Eye Drops(n=87)		
Poor aiming	39	44.8
Repeated attempts	21	24.1
Contact of the tip of the eye dropper to the eye/skin	16	18.4
Trauma	11	12.6
Medical Comorbidities Making it Difficult to use Eye Drops(n=87)		
Yes[1]	7	8.0

No	80	92

Data are frequencies (percentages)

[1] *Medical comorbidities making it difficult to use eye drops include: arthritis (1), hand tremor (2), Parkinsonism (4)*

Data shows that approximately 44% respondents reported to have difficulties in applying eye drops and it was due to poor aiming of eye drops (44.8%).

Table 6: Univariate analysis of factors that may be associated with compliance to topical medications use

Factors	Compliance N = 138 n(%)	Non-Compliance N = 60 n(%)	OR (95% CI)	P-value
Age (in years)				
≤50	26 (66.7)	13 (33.3)	REF	
51-60	40 (71.4)	16 (28.6)	2.67(0.43-16.37)	0.29
61-70	42 (66.7)	21 (33.3)	1.19 (0.25-5.68)	0.83
≥70	29(74.4)	10(25.6)	1.07(0.25-4.54)	0.93
Sex				
Male	97 (70.3)	38 (63.3)	REF	
Female	41 (29.7)	22 (36.7)	0.73 (0.39-1.38)	0.34
Marital Status				
Single	7 (5.1)	2 (3.3)	1.55 (0.31-7.69)	0.59
Married	100 (72.5)	42 (70.0)	REF	
Divorced	11 (8.0)	6 (10.0)	0.78 (0.27-2.22)	0.64
Widowed	20 (14.5)	10 (16.7)	0.85 (0.37-1.94)	0.70
Residence				
Urban	130 (94.2)	54 (90.0)	REF	
Rural	8 (5.8)	6 (10.0)	0.55 (0.18-1.67)	0.30
Highest Education Level attained				
No formal education	34 (24.8)	13 (21.7)	REF	
Primary	40 (29.2)	22 (36.7)	0.70 (0.37-1.34)	0. 29
Secondary	37 (27.0)	17 (28.3)	0.93 (0.47-1.82)	0.83
Tertiary/College	26 (19.0)	8 (13.3)	1.51 (0.64-3.56)	0.35
Number of Medications				
One	75 (54.3)	31 (51.7)	REF	
>1	63 (45.7)	29 (48.3)	0.90 (0.49-1.65)	0.73
Taught about Eye Drops use				

Yes	127 (92.0)	55 (91.7)	1.05(0.35-3.16)	0.93
No	11 (8.0)	5 (8.3)	REF	
Who Administers Eye Drops				
Self-administered	112 (81.2)	53 (88.3)	REF	
Other person	26 (18.8)	7 (11.7)	1.76 (0.72-4.31)	0.22
Monthly Income (USD)				
< 20	37 (26.8)	10 (16.7)	REF	
20 – 79	69 (50.0)	36 (60.0)	0.68 (0.36-1.23)	0.20
80 – 139	17 (12.3)	9 (15.0)	0.80 (0.33-1.90)	0.61
140 – 199	6 (4.3)	4 (6.7)	0.64 (0.18-2.34)	0.50
≥200	9 (6.5)	1 (1.7)	4.12 (0.51-33.24)	0.19
Out of pocket Expenditure on Medication				
< 5	82 (59.4)	36 (60.0)	REF	
5 – 9	19 (13.8)	9 (15.0)	0.91 (0.38-2.13)	0.82
10 – 14	16 (11.6)	9 (15.0)	0.74 (0.31-1.79)	0.51
≥ 15	21 (15.2)	6 (10.0)	1.62 (0.62-4.23)	0.33

The univariate analysis showed that none of the socio-demographic and clinical factors of the study participants were significantly associated with the medication compliance.

Table 7: Focused Group Discussion with Health care providers

Challenges for compliance	Don't keep time of drops application Drugs not available in the market Financial problem to buy drugs Inadequate knowledge about glaucoma Patient lost to follow up Drugs expensive Finish drops before appointment date Dependent of free drugs

Table 8: Focused Group Discussion with patients

Challenges for compliance	Forgetfulness Drugs get finished before appointment Drug adverse effects Vision not improving despite eye drop use Drugs expensive No eye care Center nearby Need assistance in putting drops Need written instructions Pharmacists don't give instructions Loss of vision despite eye drop use

Table 7 and 8 above shows the focused group discussion with the health workers and patients. The heath workers agree on the need of health education and proper drug use demonstration to improve compliance. Patients report that despite the health education, they still need more reminders as forgetfulness is the most reason for missing doses. Drug adverse effects, finishing eye drops before clinic appointment date and financial problems also are the main contributors to poor compliance.

6.0 DISCUSSION

Glaucoma is the leading cause of irreversible blindness in Ethiopia. Poor glaucoma awareness and under-utilization of ophthalmic services in the country adds to the existing glaucoma burden. In such circumstances, the need for increasing compliance of anti-glaucoma medications becomes imperative to manage this condition. This article reports using a sample of 198 patients through interviews and direct observation of eye drop use to explore the factors affecting compliance, and the challenges of using topical medications in glaucoma patients seen at Menelik II Referral Hospital.

One hundred thirty-eight (69.7 %) patients were found to be compliant which was similar to other studies that reported 56.0% – 72.7% in Greece, Canada, and Dutch [37] [38] [39]. This similarity might be evident owing to the use of a questionnaire for interviewing the patients. On the other hand, the level of compliance to treatment was found to be higher than 45.0% in a previous study conducted in Ethiopia [40] and other studies conducted in USA [32] [41] [42]. This better adherence may be attributable due to health education given on how to use topical medications to glaucoma patients in Menelik II referral hospital since 2014.The wide variation might be partly attributable to inconsistency in the definition of non-adherence, subjectivity and heterogeneity in the assessment methods as well as differences in patient groups [43].

Although a greater number of patients belonged to lower socioeconomic status, our study established that there were almost an equal number of patients under paying and donation category pharmacy (42.4% of patients). Thus, the patients with lower socioeconomic status sometimes opted for paid eye drops in our study due to drug out of stock in free pharmacy in the hospital, which may contribute to non-compliance to treatment.

Among previous studies from developing nations [44], including this present study, the major factor for influencing compliance was dose forgetfulness. Being a developing nation with most of the patients without insurance coverage, we expected cost to be the major cause of non-compliance. However, we noted forgetfulness to be the leading cause contributing for non-compliance. Hence, proper counseling of patients regarding the need for compliance with the treatment should be emphasized by eye care providers. Studies [45] [46] [47] have shown that electronic reminders could improve adherence to chronic conditions, such as glaucoma. Thus, some of the measures that could probably improve compliance are: making patients and relatives aware about the disease and its sequelae, development of support system to remind patient about drops, and use of electronic reminders such as short message service (SMS) and social media applications to increase awareness about the disease.

In our study, a large number of the patients 87(43.9%) had difficulty in applying the eye drops. Poor aim (44.8% of patients) was the main reason for difficulties in applying eye drops, poor aim can result in under-treatment and disease progression. Repeated attempts was also found to be reason for difficulty, repeated attempts can lead to excess medication administration and over-treatment, with higher medication costs and increased risk of side effects. These findings are supported by previous studies across the globe [37] [44]. In addition, about 18.4% patients contaminate the tip of the eye drop container to the eye or skin which made it difficult to use medication. Other studies [48] share similar findings stipulating that contact of the tip of the eye drop container to the eye has consequences that range from contamination to trauma. Therefore, it is recommended that eye drop administration aids should be utilized to minimize improper drop administration technique. Only 10.2% of patients were taught about method of eye drop administration which could be the main reason for the above mentioned difficulties.

In this study, almost all of the socio-demographic and clinical factors of the participants were not significantly associated with the medication compliance during the univariate analysis.

The absence of a relationship between compliance and most of the socio-demographic factors was supported by the previous studies [33] [40] [41] [43] [49]. The absence of this association might be related to the characteristics of patients and qualitative nature of the study. The patients in the present study had a long duration of taking medication (mean duration of treatment was 5.8 years). Therefore, demographic factors might have less influence on the compliance behavior of the study participants.

The self-reported compliance among the patients was 81.3% but the compliance according to the study definition was 69.7%. This could be due to the fact that some of the patients do not understand the instructions given by the medical care giver. It is worrying to note that non-compliance among patients with glaucoma remains high in Ethiopia. This point to the fact that the knowledge of the ill-effects of medication non-compliance among glaucoma patients and awareness about the disease remains low, and there is need to ensure that patient education and community awareness on glaucoma needs to be focused in the country.

About 18.7% of patients were not using their eye drops as instructed by their eye care providers. Most of the reasons reported during focus group discussion with patients and eye care providers were; forgetfulness, side effects most commonly burning eye sensation, drug unavailability, finishing their eye drops before clinic appointment dates and unable to afford buying eye drops. Only 10.2% of study participants responded taught about method of eye drop use, which could contribute to poor technique observed in many patients and likely to non-compliance.

As a follow-up measure in the hospital, to take care of the problem of non-compliance, experts recommend incorporating counselors to explain glaucoma and the need for compliance to anti-glaucoma medications to patients. Thus, novel strategies in patient education for example intensive counseling, audiovisual aids, and patient support groups will need to be adopted. Several reviews have also demonstrated that most successful compliance interventions are complex and include combinations of educational, behavioral and affective components.

7.0 STUDY LIMITATIONS

This study design did not allow in-depth observation of behavior around eye drop use and the challenges experienced at home which is the usual place they are used. An embedded study would do better to identify the factors associated with non-compliance, but this was not feasible in this context.

The method of using self-report through use of questionnaires could result in an overestimation of the results on compliance.

8.0 CONCLUSION

- Compliance was found in majority of the studied participants.
- Large number of patients with lower socioeconomic status were dependent on free drugs, but sometimes opted for paid eye drops due to drug out of stock, which may contribute to non-compliance to treatment.
- Improper technique for drug instillation was frequently observed possibly related to deficient demonstration of technique.

- The main challenges of using topical glaucoma medication were forgetfulness, drug adverse effects, finishing eye drops before clinic appointment date, and inadequate knowledge about the disease.

9.0 RECOMMENDATIONS

- Repeated sensitization on importance of consistent health education and demonstration of eye drops use to eye care providers is crucial to increase compliance to glaucoma treatment.
- The hospital authorities and government officials has to insure the availability of eye drops in all free and paid pharmacy.
- Awareness to the community about Glaucoma and its sequelae through different media communications.

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11.0 APPENDICES

11.1 Informed consent

English Version

Title of Study: Factors affecting compliance and Challenges in using topical medications in glaucoma patients seen at Menelik II referral hospital, Addis Ababa, Ethiopia

Sponsor: Self

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   Addis Ababa University,Ethiopia

Introduction

My name is Dr. Belay Mulugeta. I am doing my postgraduate masters in Ophthalmology at the University of Nairobi. My postgraduate thesis is on challenges in using topical medications among glaucoma patients seen at Menelik II referral hospital, Addis Ababa, Ethiopia.

It is a cross sectional study will be done in January/ 2018.

The purpose of this consent form is to give you information that might help you to decide whether to participate in the study or not. You are allowed to ask questions related to the study and implications on your part. The consenting process will take place in a private place that is comfortable to you.

Purpose of study

The results of this study will enable us to know the challenges in using topical medications among glaucoma patients seen at Menelik II referral hospital, Addis Ababa, Ethiopia

Study design and site

The study will be a cross sectional study done at Menelik Hospital

Procedures to be followed

The principal investigator together with the trained interviewers will evaluate the challenges of glaucoma patients in using topical medications.

Benefits

The results of the study will bring out the challenges in using topical medications among glaucoma patients so us to improve health education, compliance and settings and services of glaucoma treatment.

Risks of accessing records

There is no risk if we access the records in this study. We will maintain privacy and confidentiality of all information obtained.

Assurance of confidentiality

The information given and records will remain confidential and will not appear when we present this study or publish its results. You will receive a copy of the consent form.

Storage of data

The data will be stored in secure cabinets and computers with password/s and will only be accessible to the investigators.

Range of information desired

Patient demographic data, compliance related, method of eye drop use by interviewing and direct observation of eye drop application technique and focus group discussion with patients and care givers.

Right to refuse or withdraw

It is important that you understand the following general principles that will apply to all participants in the study:

1. Participation is entirely voluntary.
2. You may withdraw from this study at any time without penalty or loss of benefits.

Please feel free to ask any questions that you may have. Do you agree to participate?

I acknowledge that this consent form has been fully explained to me in a language that I understand and had the opportunity to ask questions which have been answered to my satisfaction. I agree voluntarily to participate in this study and understand that I have the right to withdraw at any time without penalty.

Participant's name (optional): _____

Participant's signature or thumb print: _____

Date: _____

Study No.: _____

Name of witness: _____

Signature of witness: _____ Date: _____

Investigator's signature: _____ Date: _____

Contact: If you have questions in future, please contact The Secretary, University of Nairobi, College of Health Sciences Ethical Review Committee, P. O. Box 19676-00202, Nairobi, and Telephone: 020-2726300-9 ext. 44355, email uonknherc@uonbi.ac.ke

TRANSLATED CONSENT: AMHARIC LANGUAGE

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11.2 Questionnaire

Instruction for interviewer

Fill the response in the space after the question. For example, in Q3. If the participant is female, write 2. DO NOT circle, tick or cross the answer.

BIODATA

1. File No.: _____
2. Age: _____
3. Sex:

   1=Male

   2=Female

4. Marital status

   1=Single

   2=Married

   3=Divorced

   4=Widowed

5. Residence:

   1=Urban

   2=Rural

6. Highest educational level:

   0=No schooling

   1=Primary

   2=Secondary

   3=Tertiary

7. What is your estimated monthly income (Ethiopian Birr)?

   _____

8. How much do you spend on medication per month (Ethiopian Birr)?

   _____

Compliance related

9. For how long have you been on treatment?

   _____

10. Who pays for your eye drops?

    1=Donation

    2=Buying them myself

    3=Someone else buys for me

11. How many glaucoma medications have you been using for the last 6 months?

    1=One

2=Two

3=≥ three

12. How long do you wait before you put the next drop?

_____

13. How frequently are you putting your eye drops?

Eye drop	Frequency of use

14. Are you using eye drops as instructed?

1=Yes [Go to Q16]

0=No [Go to Q15]

15. If no, why you are not using as instructed?

1=Forgetfulness

2=Drops unavailable/ out of market

3=Discomfort

4=Financial reason/ Problem buying

5=Others

16. How many doses in total have you missed in the past week?

0=None

1=≥ 1

Difficulties with Eye Drop Administration and Methods of administration

17. Who administers your eye drops?

1=Self-administered [Go to Q18]

2=Other person, Specify_____ [Go to Q26]

18. Do you have any difficulties applying eye drops?

1=Yes

0=No

19. What difficulties do you have in applying eye drops?

_____

_____

_____

20. Do you have any medical condition that makes it difficult for you to use your eye drop/s?

1=Yes [Go to Q21]

0=No [Go to Q22]

21. If yes, which medical condition do you have?

_____

_____

_____

22. Have you been taught how to use drops?

1=Yes [Go to Q23]

0=No [Continue to Q25]

23. If yes, who taught you?

1=Ophthalmologist

2=Nurses in eye clinic

3=Pharmacist

4=Others, specify _____

24. What were you taught about how to use drops?

_____

_____

25. Do you wash your hands before using your eye drops?

1=Yes

0=No

2=Sometimes

26. Do you have any medications that you were instructed to put in refrigerator?

1=Yes [Go to Q27]

0=No [Go to Q28]

27. Do you put them in the refrigerator?

1=Yes

0=No

28. If not, why? _____

Direct Observation of Eye Drop Administration

Instruction:

i. *Include only patients who administer their own eye drops and those patients who are accompanied by the person administering their eye drops.*

ii. *Provide sterile artificial tear drops for each patient and observe the following.*

29. Does the patient shake the eye drop bottle before use?

1=Yes

0=No

30. Does the dropper tip touch his/her eyes or hands?

1=Yes

0=No

31. Which lid was held open when the patient puts eye drop?

1=Upper lid

2=Lower lid

3=Both upper and lower lids

4=None

32. How many drops do they put in their eyes?

1=One drop

2=Two or more drops

33. Do the drops miss the patients' eye?

1=Yes

0=No

34. Do they close the eyelids or press on the tear ducts after putting the drops?

1=Yes

0=No

11.2.1 Interview Guide

A) For health care providers

1. What is your view on patient compliance to glaucoma treatment?
2. What is your view on demonstrating or counseling patients on how to use eye drops?

   Frequency of use

   Hand washing

   Skin touch [see criteria for demonstration]

   Adverse effects (is it general or specific to the medication prescribed?)

3. What is your view on the methods of administration, handling and storing eye drops?

   Storage (where, fridge, cupboard; how long?)

4. What are the main challenges you have noticed in glaucoma patients using topical medications?

B) Focus Group Discussion guide – with patients

1) What do think is your challenge in using eye drops?
2) Do you get adequate instruction from care providers how to use eye drops?
3) What is your opinion on missing eye drops?

QUESTIONNAIRE IN AMHARIC LANGUAGE

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11.3 Study time frame

Activities	**MAY 2017**	**JUN 2017**	**JUL 2017**	**AUG 2017**	**SEP 2017**	**OCT 2017**	**NOV 2017**	**DEC 2017**	**JAN 2018**	**FEB 2018**	**MAR 2018**	**APR 2017**

Proposal Development												
ERC Approval												
Data Collection												
Data Analysis												
Report Writing												
Dissemination of Findings												

11.4 Budget

Item	Quantity	Unit cost (KES)	Total KES
Proposal			

Printing and Packing	55 pages	10	550
Photocopy of Proposal	110 pages	3	330
Binding Proposal	3 copies	120	360
Proposal Printing 2nd draft	55 pages	10	550
Photocopy of proposal 2nd draft	55 pages	3	165
Binding of proposal 2nd draft	2 copies	120	240
Ethics			2,000
Sub-total			**4195**
Contracted services			
Statistician Research assistants	1 2	40,000 7,500	40,000 15,000
Sub-totals			**55,000**
Data Collection			
Printing of questionnaire	5 pages	10	50
Photocopy of questionnaire	* 990	3	2970
Siccaprotect eye drop	*198	285	56,430
Subtotal			**59,450**
Transport / Communications			
Tickets(Nairobi–Addis Ababa-Nairobi)			30,000
Telephones calls			5,000
Transport to the hospital			3,000
Accommodation and food	30	5,000	150,000
Subtotal			**188,000**
Results			
Printing of results (colored)	3*70 pages	20	4,200
Printing of results (black and white)	3*70 pages	10	2,100

White and black	70*8 copies	3	1680
Colored copies	70*8 copies	20	11,200
Binding of final paper	8 copies	200	1,600
Subtotal			**20,780**
Grand total			**327,425**

11.5 Ethics approval certificate

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KENYATTA NATIONAL HOSPITAL
APPROVED
10 JAN 2018
KNH/UoN-ERC
P.O. Box 20723-00202 NRB.

KNH-UON ERC
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Website: http://www.erc.uonbi.ac.ke
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Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/15

10th January 2018

Dr. Belay Mulugeta Yizengaw
Reg. No.58/82454/2015
Dept.of Ophthalmology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Belay

RESEARCH PROPOSAL: "FACTORS AFFECTING COMPLIANCE AND CHALLENGES IN USING TOPICAL MEDICATIONS IN GLAUCOMA PATIENTS SEEN AT MENELIK II REFERRAL HOSPITAL, ADDIS ABABA, ETHIOPIA (P655/11/2017)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 10th January 2018 – 9th January 2019.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

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