ASSESSMENT OF THE INSTILLATION TECHNIQUE AND THE HANDLING OF EYE DROP MEDICATIONS IN GLAUCOMA PATIENTS ATTENDING JUDO FROM THE MONTH OF MARCH TO MAY 2019



A RESEARCH REPORT SUBMITTED TO DEPARTMENT OF OPHTHALMOLOGY, MEDICAL SCIENCES FACULTY, INSTITUTE OF HEALTH, JIMMA UNIVERSITY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE SPECIALIZATION DEGREE IN OPHTHALMOLOGY

August, 2019

Jimma, Ethiopia

JIMMA UNIVERSITY, INSTITUTE OF HEALTH, FACULTY OF MEDICAL SCIENCES, DEPARTMENT OF OPHTHALMOLOGY

ASSESSMENT OF THE INSTILLATION TECHNIQUE AND THE HANDLING OF EYE DROP MEDICATIONS IN GLAUCOMA PATIENTS ATTENDING JUDO FROM THE MONTH OF MARCH TO MAY 2019

BY: DR. SAGNI JELKEBA (MD)

ADVISORS

- 1. Dr. Aemero Abateneh (MD)
- 2. Dr. Kumale Tolesa (MD)
- 3. Dr. Dagmawit Kifle (MD)

August, 2019

Jimma, Ethiopia

ABSTRACT

Aim: The purpose of this study was to assess the instillation technique and handling of antiglaucoma eye drops in glaucoma patients attending Jimma Medical Center, Department of ophthalmology, southwest of Ethiopia.

Method: A hospital based cross sectional study was done on 100 consecutive patients who had been on ocular hypotensive drugs for ≥ 6 months. Study subjects were classified under two study groups, based on who actually administered the eye drop; a self-instilling group comprised of 80 respondents and assisted instillation group comprised of 20 respondents. Respondents of the former and attendants of the latter group were asked to demonstrate how they normally instill the eye drops using a bottle of a sterile artificial tear solution. The procedure was observed and video recorded.

The parameters studied for the self-instilling group were: age, gender, occupation, place of residence, educational level, duration of eye drop use, provision of previous education on how to use the eye drops, head position of instillation, hand of instillation, time elapsed to instill the first drop, and the mean visual acuity. Parameters used to grade the eye drops instillation technique were the different values of the number of drops instilled, locations where drop(s) landed, any touch to the bottle tip, and eyelid closure or pressure on the lacrimal sac area.

Univariate logistic analysis was performed to relate each variable to the eye drop instillation technique, and variables with p \leq 0.05 were included in a multivariate regression model. Finally, the two groups were compared to study the effect of assistance on the performance of the eye drops instillation technique. The eye drops instillation technique and the storage way of the eye drops were, each, studied for association against the level of IOP.

Results: The mean age of the 80 self-instilling patients was 58.93 ± 13.12 years. Sixty-four of them had a poor instillation technique. Of these, 16 (25%) had missed the target (globe) and contaminated the bottle tip; 3 (4.7%) had missed the target without bottle contamination; 16 (25%) had instilled the drop(s) on the globe and touched the globe with a bottle tip; 25 (39.0%) had instilled the drop(s) on the globe without touching the globe and contaminated the bottle tip by touching the fingers, eyelids or face; 4 (6.2%) had instilled the drops on the globe without bottle tip contamination and without eyelid closure.

The mean score assigned for the eye drops instillation technique was 1.58 ± 1.7 . This shows that most respondents had practiced a technique that delivered a drop(s) on the globe and contaminated the tip of bottle by touching the eyelids, face, fingers, cloth, and the globe. The mean number of drops squeezed was 1.31. Two or more drops were squeezed by 32.5% of the patients. Nine patients did not squeeze any drop from the bottle. The problem with most respondents was touching of the bottle tip to the fingers, ocular surface, eyelids or face, which occurred in 57 of the 80 (71.2%) self-instilling patients.

In the multivariate regression analysis, significantly associated factors with a poor technique were increasing age (adjusted OR=9.239, 95% CI 2.356–36.233, p=0.001), and rural dwelling (adjusted OR=6.962, 95% CI 1.229–39.452, p=0.028). Assistance instillation was significantly associated with a good instillation technique (OR=7.429, 95% CI=2.549–21.652, p=0.000). Regarding the parameters of the instillation technique, touching of the bottle tip to the eyelids or face was significantly associated with uncontrolled IOP (adjusted OR=7.24, 95% CI 2.18–23.9, p=0.001). Slight lid closure for more than 1 minute was significantly associated with controlled IOP (adjusted OR=3.16, 95% CI 1.1–9.42, p=0.039).

Conclusion: The majority of glaucoma patients had a poor performance regarding selfinstillation of their eye drop medications. The age and the place of residence were an independent factor associated with the performance of eye drop instillation. Assistance instillation and slight eyelid closure were both significantly associated with good instillation technique.

Key words: eye drop instillation; ophthalmic drops; glaucoma; eye drops handling; antiglaucoma drugs

TABLE OF CONTENT

Contents

ABSTRACT	3
ACKNOWLEDGMENT	7
LIST OF TABLES AND FIGURES	8
LIST OF ABBREVIATIONS AND ACRONIUMS	9
CHAPTER 1: INTRODUCTION	10
1.1 Background	10
1.2 Statement of the problem	11
CHAPTER 2: SIGNIFICANCE OF THE STUDY	13
CHAPTER 3: OBJECTIVES OF THE STUDY	14
3.1. General objective	14
3.2. Specific objective	14
CHAPTER 4: METHOD AND POPULATION	15
4.1. Study area and period	15
4.2. Study design	15
4.3 Populations	16
4.3.1 Source population	16
4.3.2 Study population	16
4.3.3 Study unit	16
4.4 Inclusion and exclusion criteria	16
4.4.1 Inclusion criteria	16
4.4.2 Exclusion criteria	16
4.5. Sample size and sampling technique	16
4.5.1. Sample size and sampling procedure	16
4.6 Variables of the study	17
4.7 Data collection procedure	17
4.8 Data analysis	20
4.8.1. Conceptual framework for data analysis	21
4.9 Data quality control	22
4.10. Ethical consideration	22

4.11 Operational definitions	. 23
4.12 Dissemination of findings	. 24
CHAPTER 5: RESULTS	. 25
CHAPTER 6: DISCUSSION	. 35
CHAPTER 7: STRENGTH AND LIMITATIONS	. 38
CHAPTER 8: CONCLUSIONS AND RECOMMENDATIONS	. 39
8.1 Conclusions	. 39
8.2 Recommendations	. 39
REFERENCES	. 40
ANNEX: QUESTIONNAIRE FOR DATA COLLECTION	. 43

ACKNOWLEDGMENT

First of all, thanks to my God! Secondly, I would like to thank Jimma University for giving me the chance to undertake this post graduate research proposal as future career to my final research. I want to express my deepest gratitude to my advisors for your unlimited support, guidance and sharing your knowledge. Special thanks goes to my love Miimmanii koo for your love, support and dedication for being beside me all the time I had been working on this research.

LISTS OF TABLES AND FIGURES

Lists of Tables:

Table 1: The 'target' IOP for OHT, NTG and different stages of glaucoma
Table 2: Scores assigned to the eye drops instillation technique
Table 3: Demographic and clinical characteristics of the total respondents
Table 4: Descriptive statistics of the parameters of eye drops instillation
technique for the self-instilling respondents
Table 5: Univariable logistic regression for predicting poor eye drops
instillation technique in self-instilling respondents
Table 6: Multivariable regression model for predicting poor eye drops
instillation technique among self-instilling respondents
Table 7: Ways of storage of eye drops bottle by the total respondents 32
Table 8: Univariate analysis of the parameters of eye drops instillation
technique for predicting uncontrolled IOP level
Table 9: Multivariate logistic analysis of the parameters of eye drops
instillation technique for predicting uncontrolled IOP level
Table 10: Univariate analysis of the way of drug storage for predicting
uncontrolled IOP level

Lists of Figures:

Figure 1:	Conceptual frame work for the flow of data analysis	21
Figure 2:	Histogram of age distribution of the respondents	25

LIST OF ABBREVIATIONS AND ACRONIUMS

EDM: eye drop medications JMC: Jimma Medical Center JUDO: Jimma university department of ophthalmology GSC: Glaucoma specialty clinic OHT: ocular hypertension NCT: Non-contact tonometer RGCs: retinal ganglion cells IOP: intraocular pressure OD: optic disc ONH: optic nerve head

CHAPTER 1: INTRODUCTION

1.1 Background

Glaucoma is an acquired optic neuropathy characterized by a loss of retinal ganglion cells, progressive cupping of the optic nerve head, and a characteristic visual field loss. It is a multifactorial disease and its precise pathogenesis, despite extensive research, remains unknown. Intraocular pressure is considered the main risk factor for the development and progression of glaucoma (1).

Patient diagnosed to have glaucoma has to be started on anti-glaucoma medications. The goal of treating glaucoma is to lower the IOP below which it is less likely to cause the progression of the disease. Furthermore, some drugs act also as a neuroprotector, having an effect of increasing blood flow to the optic nerve head (1).

There are several drug formulations to treat glaucoma prepared suitably to deliver them in different routes. Topical ocular medications, both prescription and over the counter, are the mainstay of therapy for treating ocular disorders such as glaucoma. Eye drops are the preferred method of treatment because they are effective, non-invasive, and, in theory, easy to use (**2**).

Eye drops can be administered on the patients' eye by physicians, attendants of the patients or can be self-administered by patient themselves.

1.2 Statement of the problem

The efficacy of topical ocular medications depends on the ability to self-administer correctly, patient adherence and compliance with the treatment regimen (**3**). Approximately 80% of patients instill their own eye drops (**4**) and there are many techniques used (**5**,**6**). Some patients instill their drops when sitting, others stand or lie down, others use a mirror to aid the process (**7**).

Although instillation of eye drops may be perceived as a simple task, studies have shown that patients frequently have difficulty instilling eye drops. Over the past decade, several studies have reported that 25% to 90% of subjects fail to administer their eye drops correctly (8-12). Poor techniques include missing the eye completely, delivering an excessive dose, bottle contamination or ocular trauma 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 (13).

Factors associated with an increased risk of poor eye drop instillation technique were poor manual dexterity, poor vision, limited schooling, and older age (9,14,15). Lack of education is likely to be a large problem, as when clinicians prescribe eye drops, proper explanation and demonstration of how the eye drops should be used is often neglected (7). In chronic ocular diseases, such as glaucoma, wherein the elderly population constitutes a major share of those affected, this issue is of great importance (2,9).

Eye care practitioners may prescribe eye drops without properly explaining or showing the technique for correct instillation of eye drops because of the lack of time in busy practice or lack of awareness of the fact that the patient does not know how to correctly instil drops (**16,17**). Additionally, attendants of elderly or illiterate patients who might be informed the way the drug has to be instilled my get bored of administering the drop or may not be around at the time of dosing.

Poor drug instillation technique can constitute poor compliance to the drugs (**2**,**8**) which can lead to treatment failure with a consequent progression of the disease and a higher rate of visual loss (**18**). This may lead to a need for a more frequent follow ups, additional drugs, diagnostic tests, and earlier surgery. These affect patient's economy, and other psychosocial aspects (**19**,**20**).

Furthermore, if eye drop instillation is done improperly it can lead to wastage of drugs, overmedication with systemic absorption and adverse effects, predisposition to infection from contaminated bottle tips, corneal abrasions, and ulcerations (**11,12**).

According to a study done at Gondar University Department of Ophthalmology on the contamination rates of ocular drop medications, dropper tip was more contaminated than the drug content. This was due to the contact of the dropper tips with patients' hand, ocular tissues, and other environmental factors (**21**).

Currently, data is sparse about the technique of eye drop administration in a public practice of a developing country (**12**) where the issue of noncompliance is considered to be very significant (**12**). In Ethiopia, there is no data so far regarding the drug instillation technique being practiced by patients or attendants.

This study is the first of its kind in the country that investigated the eye drops instillation technique and drug handling in patients with glaucoma and assessed the factors associated with poor eye drops instillation technique.

CHAPTER 2: SIGNIFICANCE OF THE STUDY

The results obtained from this study will be used to add up on better care and follow-up of glaucoma patients. It will also be used as input to effort the health professionals involving in care provision for glaucoma patients to focus on providing a professional explanation for patients on how to use the eye drops. It will also be used to enforce the administrative body to provide a necessary equipment which will be used to enhance patient education on how to use their medications properly. Furthermore, as this is the first study done at this specific institution, the results will be used as a stand point for further related studies to be done in this institution or other.

CHAPTER 3: OBJECTIVES OF THE STUDY

3.1 General objective

To assess the eye drops instillation technique and the handling of eye drop medications in glaucoma patients attending JUDO from the month of March to May 2019.

3.2. Specific objectives

To assess the eye drops installation technique by glaucoma patients.

To assess factors affecting the eye drops installation technique by glaucoma patients.

To assess of the eye drops handling by glaucoma patients.

To assess the health education service is being delivered to glaucoma patients on how to handle and instill their drugs.

To assess the effect of the instillation technique on the IOP level.

To assess the effect of the way of eye drops storage on the level of IOP.

CHAPTER 4: METHOD AND MATERIALS

4.1. Study area and period

4.1.1 Study area

Jimma is located in Oromia region of Ethiopia, 352 km south west to the capital Addis Ababa. Jimma town is the administrative center of Jimma Zone.

Based on the 2007 Ethiopian Census (no census recent of this), Jimma town has a total population of 120,960 of whom 60,824 are male and 60,136 are female.

JU was established as higher institution in December 1997 from the already functional Jimma Institute of Health Sciences (Public Health, and Medical Sciences faculty) and two new faculties (Faculty of Business and Economics, and Faculty of Technology).

Jimma Medical Center (JMC) is the only specialized center in the southwestern Ethiopia providing service for a catchment area of 15 million people. It has 800 beds, and provides service with a total of 1600 staff members. It serves about 15,000 inpatients and 160,000 out patients in a year.

4.1.2 Study period

The study was conducted from March to May, 2019.

4.2. Study design

Hospital based cross-sectional study was employed on candidate patients attending JMC department of Ophthalmology, Glaucoma specialty clinic.

4.3 Populations

4.3.1 Source population

All Glaucoma patients attending JMC department of Ophthalmology.

4.3.2 Study population

All Glaucoma patients using eye drop medications on follow up at JMC Glaucoma clinic.

4.3.3 Study unit

Selected glaucoma patients using eye drop medications on follow up at JMC Glaucoma clinic

4.4 Inclusion and exclusion criteria

4.4.1 Inclusion criteria

Patients on follow-up at Glaucoma clinic and using eye drops for glaucoma or ocular hypertension for <u>></u> 6 months.

4.4.2 Exclusion criteria

- > Patients with motility disorders (tremor, arthritis, motor paralysis, deformity).
- > Visual acuity in the better eye of hand movement or worse.
- > Those patients who's the last visit fell in the period from March 1 to May 31, 2019.
- Patients < 16 years of age.</p>
- Post-trabeculectomy patients.

4.5. Sample size and sampling technique

4.5.1. Sample size and sampling procedure

The study was done on 100 consecutive non repeat patients visiting Glaucoma specialty clinic within the stated study period.

4.6. Variables of the study

Dependent variables

- > The eye drops instillation technique.
- Eye drops handling and storage.
- > The level of IOP

Independent variables

Age, gender, place of residence, level of education, occupation, duration of eye drops use, provision of professional explanation on how to use the eye drops, head position during instillation, hand used for instillation, time elapsed to instil the first drop, visual acuity in the better eye, and assistance instillation.

4.7 Data collection procedure

Pretested, structured questionnaire was used to collect data. The age, gender, place of residence, level of education, occupation, duration of eye drops use, history of receiving a professional explanation on eye drops use (classified as never provided, provided but didn't understand, provided and understood), number of different eye drops currently in use, time interval between instillation of subsequent drops (only for patients using more than one eye drops), and the actual way of storage of the eye drops were asked for and recorded.

Also, the diagnosis (whether it was glaucoma or ocular hypertension [OHT]), the stage of the glaucoma, and visual acuity in the better eye were examined and recorded. The IOP was measured and recorded as normal for the disease stage (controlled) or high for the disease stage (uncontrolled).

From the different staging systems of glaucoma (**22–24**), the system used in this study was based on the optic disc examination and was adopted from Indian journal of Ophthalmology (**25**). This system employed a cup-to-disc ratio (CDR) as a means of staging the damage into mild with a CDR of \leq 0.65, moderate 0.7–0.85, and severe \geq 0.9 (**Table 1**). The ONH was assessed by a 90 D fundus lens.

As depicted in **Table 1**, the 'target' IOP was set for a specific glaucoma stage and type and for OHT (**25–27**). In this study, the setting of the 'target' IOP for OHT has considered all cases of OHT as the high risk.

Disease stage	Cup-to-disc ratio	Level of the IOP	
	(CDR)	Considered normal	Considered high for
		for the stage	the stage
Ocular hypertension	*	< 18 mmHg	<u>></u> 18 mmHg
Mild glaucoma	<u><</u> 0.65	< 18 mmHg	<u>></u> 18 mmHg
Moderate glaucoma	0.7 – 0.85	< 15 mmHg	<u>></u> 15 mmHg
Advanced glaucoma	<u>></u> 0.9	< 14 mmHg	<u>></u> 14 mmHg
Normal tension glaucoma	*	IOP fall by 30% from	IOP fall by < 30% from
		baseline	baseline

Table 1: The 'target' IOP for OHT, NTG and different stages of glaucoma.

* CDR was not mentioned as a criterion to set the 'target' IOP.

Finally, Observation was performed in a room provided with a portable sink, soap, chair and bed. Participants were included under one of the two groups, based on who was actually instilled the eye drops into the patient's eye. Patients who have self instilled the eye drops were included under self-instilling group. Patients for whom instillation was performed by their attendants were included under assisted-instillation group.

Patients or attendants were provided with and instructed to instill an artificial tear as they would instill the medication at home. The eye with worse visual acuity was selected for the study. For equal visual acuity, one eye was randomly assigned as the study eye. An observer at a comfortable viewing angle had been observing the technique of instillation assisted by video camera. Parameters recorded for each patient were: whether the patient had washed his/her hands, whether the patient had shaken the eye drops bottle, how did the patient uncapped the bottle, position of the head during instillation (measured from vertical), hand used for instillation, time required to instill the first drop after uncapping the bottle, number of drops squeezed out, where the drops landed, presence of any touch to the tip of the bottle, whether the patient had closed the eyelids slightly or occluded the punctum for ≥ 1 minute after instillation of eye drop. For patients with several attempts of instillation, the one which made them happy was recorded for the study.

The instillation technique was scored from -1 to 4 (**Table 2**). The patients were classified to have a good technique if the score was 4, and poor technique if the score was -1 to 3.

Good instillation technique was defined by instillation of only 1 drop which landed on the globe without any touch to the bottle tip, and with a slight eyelid closure or pressure on the lacrimal sac area for \geq 1 minute after instillation. Good instillation technique was considered a proper instillation technique.

Poor instillation technique (Scored from -1 to 3) was considered in case there was one or more drops landed away from the globe, or an instillation resulted in contamination of the bottle, or that resulted in touching of the globe surface, or presence of awkward technique. Awkward technique was defined as any number of drops landed on the globe without any touch to the tip of bottle and without slight eyelid closure or pressure on the lacrimal sac area. This technique was considered to have neither a benefit to the patient nor a risk of bottle contamination or ocular injury, but considered to have resulted in drug misuse from a lots of drops squeezed out. For this reason, it was included and analyzed under the poor instillation technique.

Table 2: Scores assigned to the performance of eye drops instillation technique.

Description of technique	Score
Only 1 drop landed on the globe, did not contaminate the bottle, slight eyelid	4
closure or pressure on lacrimal sac area for <u>></u> 1 minute.	
Any number of drops landed on the globe, did not contaminate the bottle, and	3
with or without lid closure or pressure on the lacrimal sac area	
Any number of drops landed on the globe, but with bottle tip contamination	2
Any number of drops landed on the globe, but the bottle tip touched the globe	1
surface (for the additional risk of ocular trauma)	
Drop(s) missed the eye, but the bottle tip was not contaminated	0
Drop(s) missed the eye, and still the bottle tip was contaminated	-1

4.8 Data analysis

Statistical analysis was performed by using a commercially available statistical software package IBM SPSS Statistics 25. Normality assumption was assessed by inspection of histograms and by using Kolmogorov-Smirnov and Shapiro-Wilk tests. Categorical variables were expressed as percentages, and continuous variables were expressed using means and standard deviations.

The independent samples t-test was used to compare the normally distributed continuous variables, whereas Mann-Whitney U and Kolmogorov-Smirnov Z test was used for continuous non-normal variables. Chi-square test and Fishers exact test was used to compare categorical data.

The total 100 respondents were categorized into 2 groups depending on who actually administered the eye drops to the patient's eye. Self-administering respondents were categorized under self-instilling group, and respondents for whom the eye drop was administered by attendants were categorized under assisted instillation group.

First, analysis was done to relate different variables to the instillation technique only among the 80 self-instilling respondents. Univariate logistic regression was used to calculate the crude odds ratio (COR) to relate each variable to the eye drops instillation technique. Variables studied were age, gender, place of residence, level of education, occupation, head position of instillation, hand of instillation, duration of use of the eye drops, provision of previous professional explanation, the mean visual acuity, and time elapsed to instill the first drop after uncapping.

A multivariable logistic regression analysis was used to determine the predictors of poor eye drops instillation technique. Variables that were fed to the multivariable regression model were those with univariable significance of \leq 0.05.

Finally, the two groups of participants, the self-instilling group and the assisted instillation group, were compared to assess the performance of eye drops instillation technique, and the effect of assistance on the final eye drops instillation technique was studied.

The eye drops instillation technique and the way of storage of the eye drops were studied, each, for association against the level of the IOP. Statistical significance was accepted if p<0.05 and if the 95% confidence interval (CI) of the OR didn't touch 1.0.

4.8.1 Conceptual framework for analysis

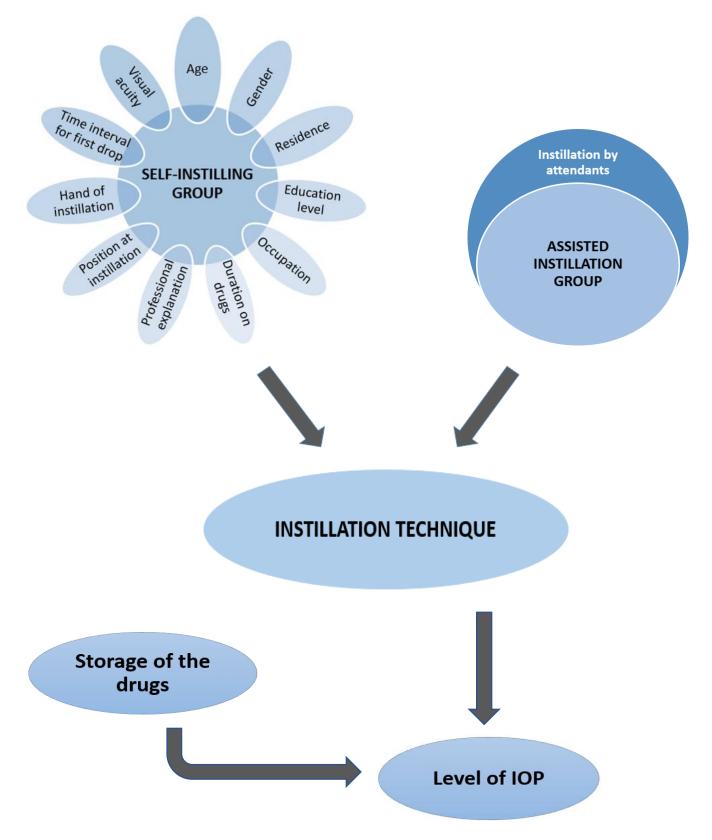


Figure 1: a conceptual frame work for the flow of data analysis in this study.

4.9 Data quality control

Trained nurses were made to involve in the collection of socio-demographic data. Physical examination and direct observation were performed by a final year ophthalmology resident. Adequate training was given for data collectors regarding study objective, interview techniques, measurements and ethical issues during data collection. Pretest was done on 5 patients two weeks before the actual data collection time, and the clarity, length, completeness and consistency, language barriers and contextual gaps on the structured questionnaires were assessed and corrected beforehand. The questionnaires were translated in to Afaan Oromoo and Amharic to facilitate understanding of the respondents. Questionnaires had been checked daily for accuracy, consistency, and completeness. The functionality of the non-contact tonometer (NCT) had been checked every day.

4.10 Ethical consideration

As per the basic principles of World Medical Association Declaration of Helsinki, the ethical clearance was approved by the ethical review committee of Jimma University, College of Health Sciences. The study participants were informed about the purpose of the research and were reassured that confidentiality of information will be maintained during data collection, analysis, interpretation and publication of results. Health education was provided for those patients who had practiced the poor instillation technique.

4.11. Operational definitions

Instillation: adding a drop of eye drop medications to the eye.

Professional explanation on eye drops use: a receipt of an oral or written presentation by the physician or other staff involved in the care process.

Eye drops: refers to hypotensive eye drop medications.

Self-instillation: when patients instil their own eye drops into their eyes.

Assisted instillation: when patient's care giver instil the eye drops to the eye of the patient.

Glaucoma patients: glaucoma patients who are on hypotensive eye drops.

Glaucoma staging: staging the damage caused by the glaucoma, here, based on the optic disc damage which employed a cup-to-disc ratio (CDR). It was staged as mild (early) glaucoma (CDR \leq 0.65), moderate (CDR 0.7–0.85), and severe (CDR \geq 0.9) (**25**).

Target IOP: the level of IOP below which glaucoma progression is less likely.

Controlled (normal for the disease stage) IOP: the level of IOP below the target IOP; defined as per the type and the stage of the glaucoma (**25–27**) (**Table 1**).

- For ocular hypertension and mild (early) glaucoma, IOP < 18 mmHg.
- ➢ For moderate glaucoma, IOP < 15 mmHg</p>
- ➢ For advanced glaucoma, IOP < 14 mmHg</p>
- > For normal tension glaucoma, IOP fall by 30% from baseline

Uncontrolled (high for the disease stage) IOP: any level of IOP above the target IOP as per the type and the stage of the glaucoma.

Good instillation technique:

On target, delivers a single drop to the eye, and does not contaminate the bottle, lid closure for <u>></u>1 minute.

Poor instillation technique: any technique inconsistent with a good technique.

Handling of eye drop drugs: the manipulation of eye drops medication during their administration and storage.

Good eye drops handling: hand washing prior to bottle manipulation, avoiding bottle tip contamination at any time, maintaining caps on prior to or after instillation of eye drops, ensuring good storage (**28**).

Good storage of eye drops: storage of capped eye drops bottle in a cool, dry place and out of reach and out of sight of children (**29**). This includes storage in refrigerator, drawer, storage box, closet, or on the shelf.

Poor storage of eye drops: the way of storage of medications which breaches any of the parameters required for goo storage.

Bottle tip contamination: clinical contamination characterized by any touch to the bottle tip by anything starting from uncapping of the bottle till recapping of the bottle.

4.12 Dissemination of Findings

Findings of this research will be distributed to Jimma University postgraduate and research study office. It will be presented on a national and international scientific conferences. It will also be made available for publication on reputed journals. Further, it will be uploaded and made available on the website of Jimma University.

CHAPTER 5: RESULTS

There were a total of 100 patients recruited. Four patients had an ocular hypertension, and 96 patients had a glaucoma. Patients with a normotensive glaucoma were not encountered during the study period. Sixty-three were male and 37 were females. The mean age of the total respondents was 59.73 \pm 12.46 years, with a range of 24–90 years. The age of the respondents has a normal distribution curve (**Figure 2**).

Sixty-one percent (61/100) of the respondents were urban dwellers, whereas 39 were from rural areas. Illiterate respondents comprised of 47% (47/100). The remained 53 respondents had attended an elementary school or more. Most of the respondents (54%) comprised of farmers (27/100) and housewives (27/100). Respondents on anti-glaucoma eye drops for a duration of 1–5 years comprised the majority, constituting 71% (71/100) of the total.

Ninety-two percent (92/100) of the respondents gave the history that they had received an oral explanation on how to use the eye drops from the care provider. Of these 81 of them reported that they understood the explanation.

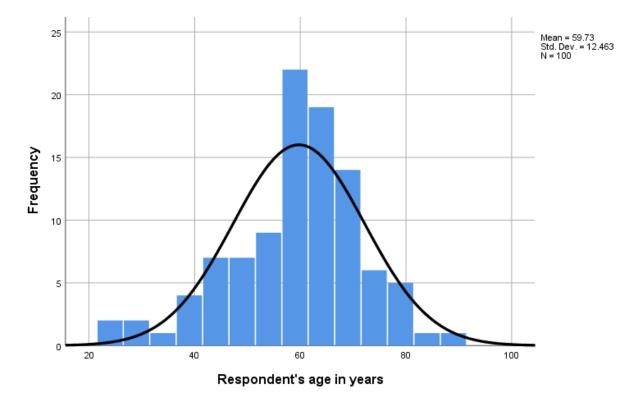


Figure 2: A histogram with a normality curve that shows the age distribution of the patients included in this study.

Of the total respondents, self-instilling respondents were 80. Patients for whom attendants had instilled the eye drops were 20. The mean age of the self-instilling patients was 58.93 ± 13.12 years, and that of assisted instillation patients was 62.95 ± 8.94 .

The demographic and clinical characteristics of the respondents was detailed in Table 3.

Table 3 : Demographic and clinical characteristics of the total respondents.

Variable		Self-instilling (80	Assisted (20
		patients) N (%)	patients) N (%)
Age (years)	< 50	16 (20.0%)	1 (5.0%)
	50-69	46 (57.5%)	14 (70.0%)
	70-89	18 (22.5%)	5 (25.0%)
	Mean (<u>+</u> SD)	58.93 ± 13.12	62.95 ± 8.94
Gender	Male	51 (63.8%)	12 (60.0%)
	Female	29 (36.3%)	8 (40.0%)
Place of residence	Rural	28 (35.0%)	11 (55.0%)
	Urban	52 (65.0%)	9 (45.0%)
Level of education	Never been to school	33 (41.3%)	14 (70.0%)
	Elementary school	25 (31.3%)	3 (15.0%)
	High school	4 (5.0%)	1 (5.0%)
	College and University	18 (22.5%)	2 (10.0%)
Occupation	Farmer	19 (23.8%)	8 (40.0%)
	Merchant	9 (11.3%)	0 (0.0%)
	Government employee	13 (16.3%)	2 (10.0%)
	Private owner	5 (6.3%)	0 (0.0%)
	Daily Laborer	5 (6.3%)	2 (10.0%)
	House wife	20 (25.0%)	7 (35.0%)
	Pensioner	9 (11.3%)	1 (5.0%)
Duration on eye	<1 year	9 (11.3%)	7 (35.0%)
drop medications	1—5 years	60 (75.0%)	11 (55.0%)
	>5—10 years	9 (11.3%)	2 (10.0%)
	>10 years	2 (2.5%)	0 (0.0%)
	Mean (<u>+</u> SD)	3.05 <u>+</u> 3.0	1.78 <u>+</u> 2.35
Explanation for eye	Never provided	7 (8.8%)	1 (5.0%)
drops use	Provided, but didn't understood	8 (10.0%)	3 (15.0%)
	Provided and understood	65 (81.3%)	16 (80.0%)
Mean visual acuity (i	n decimals)	0.41 <u>+</u> 0.29	0.4 <u>+</u> 0.37
Intra-ocular	Normal for the disease stage	33 (41.2%)	11 (55.0%)
pressure	High for the disease stage	47 (58.8%)	9 (45.0%)

Of the 80 self-instilling respondents, 64 (80.0%) had a poor instillation technique, while only 16 (20.0%) respondents had a good instillation technique. Of the poor performers, 16 (25%) had missed the target (globe) and contaminated the tip of bottle; 3 (4.7%) had missed the target without bottle contamination; 16 (25%) had instilled the drop(s) on the globe and touched the globe (cornea or bulbar conjunctiva) with a bottle tip; 25 (39.0%) had instilled the drop(s) on the globe without touching the globe and contaminated the bottle tip by touching the fingers, eyelids or face; 4 (6.2%) had instilled the drops on the globe without bottle tip contamination and without eyelid closure.

The mean score assigned for the eye drops instillation technique was 1.58 ± 1.7 . This shows that most respondents had practiced a technique that delivered a drop(s) on the globe and contaminated the tip of bottle by touching the eyelids, face, fingers, cloth, and the globe. The mean number of drops squeezed was 1.31. Two or more drops were squeezed by 32.5% of the patients. Nine patients did not squeeze any drop from the bottle (**Table 4**).

Variable		Self-instilling	Assisted
		N (%)	N (%)
Numbers of drops	No drops squeezed out	9 (11.3%)	0 (0.0%)
squeezed out	1 drop	45 (56.3%)	17 (85.0%)
	2 drops	20 (25.0%)	3 (15.0%)
	3 drops	4 (5.0%)	0 (0.0%)
	4 drops	2 (2.5%)	0 (0.0%)
	Mean (<u>+</u> SD)	1.31 <u>+</u> 0.836	1.15 <u>+</u> 0.366
Where drop(s) landed	No drops squeezed out	9 (11.3%)	0 (0.0%)
	On the globe	61 (76.3%)	20 (100.0%)
	On eyelids	9 (11.3%)	0 (0.0%)
	Other sites	1 (1.3%)	0 (0.0%)
Touch to the tip of the	Not touched	23 (28.8%)	18 (90.0%)
bottle	Touched to fingers	4 (5.0%)	0 (0.0%)
	Rubbed by cloth	1 (1.3%)	0 (0.0%)
	Touched to the globe	26 (32.5%)	0 (0.0%)
	Touched eyelids or face	26 (32.5%)	2 (10.0%)
Lid closure for >1 minute	Didn't close	21 (26.3%)	4 (20.0%)
after instillation	Closed slightly	53 (66.3%)	15 (75.0%)
	Closed forcefully	6 (7.5%)	1 (5.0%)
Pressure on lacrimal sac	Didn't pressed	79 (98.8%)	20 (100.0%)
area	Pressed the area	1 (1.3%)	0 (0.0%)

Table 4: Descriptive statistics of the parameters of eye drops instillation technique for theself-instilling respondents.

The data listed in **Table 5** are the descriptive statistics of the instillation technique of the 80 self-instilling respondents along with the results of the univariable logistic regression for predicting a poor eye drops instillation technique.

Mean age of the 16 patients with a good technique was 55.75 \pm 9.55, while those of the 64 patients with a poor technique was 59.72 \pm 13.82. Of the 51 male respondents, 16 (31.4%) had a good eye drops instillation technique, while none of the female respondents practiced a good instillation technique.

None of all the 19 farmers nor all the 20 house wives had a good instillation technique. Only 2 of the 9 merchants (22.2%), 8 of the 13 government employee (61.5%), 2 of the 5 private owners (40.0%), 2 of the 5 daily labourers (40.0%), and 2 of the 9 pensioners (22.2%) had a good instillation technique.

Fourteen of the 52 (26.9%) urban residents had a good instillation technique, while only 2 of the 28 (7.1%) rural residents practiced good technique.

Considering the level of education, none of the 33 participants that were never been to school had good technique, while only 3 of 25 participants attended elementary school (12.0%), 2 of 4 participants attended high school (50.0%), and 11 of 18 participants attended college (61.1%) had a good technique. There was a trend that as a level of education gets higher, there was a tendency towards practicing a good instillation technique.

Two of the 9 respondents who were using ocular drop medications for <1 year (22.2%), 12 of the 60 who were on ocular drop medications for 1—5 year (20.0%), 2 of the 9 who were on ocular drop medications for 5—10 year (22.2%), and none of the 9 who were on eye drop medications for >10 years (0.0%) had a good eye drops instillation technique. Respondents were using anti-glaucoma eye drops for a mean of 3.05 ± 3.0 years (0.5—17 years). Those respondents with good eye drops instillation technique had been using the eye drops for mean of 2.58 ± 2.39 years, compared with those with a poor technique who had been using drops for a mean of 3.17 ± 3.16 years.

Three of the 7 respondents (42.9%) who reported that they were never provided health education on how to use the eye drops, and 20% (13/65) of those who reported that they understood the explanation provided had a good eye drops instillation technique. But, none of the 8 respondents who reported that they didn't understood the explanation provided to them had a good instillation technique.

Variable		Good technique	Poor technique	P value
		(n=16) N (%)	(n=64) N (%)	
Age (years)	< 50	3 (18.8%)	13 (81.3%)	0.895
	50-69	10 (21.7%)	36 (78.3%)	
	70-89	3 (17.6%)	14 (82.4%)	
	<u>></u> 90	0	1 (100%)	
	Mean (<u>+</u> SD)	55.75 <u>+</u> 9.55	59.72 <u>+</u> 13.82	0.001
Gender	Male	16 (31.4%)	35 (68.6%)	0.998
	Female	0	29 (100%)	
Place of residence	Rural	2 (7.1%)	26 (92.9%)	0.05
	Urban	14 (26.9%)	38 (73.1%)	
Level of education	Never been to school	0	33 (100%)	0.998
	Elementary school	3 (12.0%)	22 (88.0%)	
	High school	2 (50.0%)	2 (50.0%)	
	College and University	11 (61.1%)	7 (38.9%)	
Occupation	Farmer	0	19 (100%)	0.597
	Merchant	2 (22.2%)	7 (77.8%)	
	Government employee	8 (61.5%)	5 (38.5%)	-
	Private owner	2 (40.0%)	3 (60.0%)	-
	Daily laborer	2 (40.0%)	3 (60.0%)	
	House wife	0	20 (100%)	
	Pensioner	2 (22.2%)	7 (77.8%)	
Duration on eye	<1 year	2 (22.2%)	7 (77.8%)	0.492
drop drugs	1—5 years	12 (20.0%)	48 (80.0%)	
	>5—10 years	2 (22.2%)	7 (77.8%)	
	>10 years	0	2 (100%)	
	Mean (<u>+</u> SD)	2.58 ± 2.39	3.17 ± 3.16	
Explanation for drop	Never provided	3 (42.9%)	4 (57.1%)	0.411
use	Provided, didn't understood	0	8 (100%)	
	Provided and understood	13 (20.0%)	52 (80.0%)	
Head position at	< 45 degrees (n=69)	11 (15.9%)	58 (84.1%)	0.032
instillation	> 45 degrees (n=11)	5 (45.5%)	6 (54.5%)	
Hand used for	Ipsilateral (n=32)	3 (9.4%)	29 (90.6%)	0.063
instillation	Contralateral (n=48)	13 (27.1%)	35 (72.9%)	1
Time elapsed to	< 5 seconds (n=10)	3 (30.0%)	7 (70.0%)	0.215
squeeze the first	5—10 seconds (n=45)	11 (24.4%)	34 (75.6%)	
drop	> 10 seconds (n=25)	2 (8.0%)	23 (92.0%)	1
Mean visual acuity (in	decimals)	0.48 + 0.32	0.38 + 0.28	0.251

Table 5: Univariable logistic regression for predicting poor eye drops instillation techniquein self-instilling respondents.

There were 69 respondents who attempted to instill the eye drops with their head being at 45 degrees or less from the vertical. Only 11 of them (15.94%) performed a good eye drops instillation technique. Five of the 11 respondents (45.5%) who attempted to instil their eye drops with their head being at more than 45 degrees from the vertical had a good eye drops instillation technique.

Thirty-two respondents (40.0%) preferred ipsilateral hand to instill their drops, whereas the remaining 48 (60.0%) attempted to instil the eye drops using the contralateral hand. Only 3 of the former and 13 of the latter had practiced a good instillation technique.

Out of the 10 patients who squeezed out the first drop within 5 seconds of uncapping the bottle, only 3 (30.0%) had a good technique. Forty-five had squeezed the first drop within 5—10 seconds, and 25 respondents attempted to squeeze the first drop after 10 seconds of uncapping the bottle (the 9 respondents who hadn't squeezed any drop were included in this category). Only 11 of the former (24.4%) and 2 of the latter (8.0%) had a good eye drops instillation technique. A higher proportion (81.4%) of those respondents who had a difficulty of squeezing out the drop (all those respondents who attempted to squeeze the first drop after 5 minutes of uncapping the bottle) performed a poor instillation technique.

On the univariable analysis, the only factors significantly associated with a poor instillation technique were advanced age (age > 60 years) (p=0.001, OR=7.667, 95% CI=2.184—26.919), head position at instillation of 45 degrees or less from the vertical (p=0.032, OR=4.394, 95% CI=1.138—16.959) and rural resident (p=0.05, OR=4.789, 95% CI=1.003—22.868).

In the multivariate analysis, the only variables remained significantly associated with a poor eye drop instillation technique were advanced age (adj. OR=9.24, 95% CI 2.4–36.2, p=0.001) and rural residence (adj. OR=6.96, 95% CI 1.23–39.45, p=0.028) (**Table 6**).

Variable	Poor instillation technique (n=64)		
	Adjusted OR	95%CI	P-value
Age <u>></u> 60 years (mean value)	9.24	2.4 - 36.2	0.001
Place of residence (Rural)	6.96	1.23 - 39.45	0.028
Head position of instillation (< 45 degrees)	3.9	0.82 - 19.4	0.087

Table 6: Results of multivariable logistic regression that shows factors associated with pooreye drops instillation technique among self-instilling respondents.

Older age was associated with a 9.24–fold increment in odds of having a poor eye drops instillation technique (adj. OR=9.24, 95% CI 2.4–36.2, p=0.001), when rural dwelling was accounted for. Controlling for age, rural residence was associated with a 6.96–fold increased odds of having a poor eye drops instillation technique (adj. OR=6.962, 95% CI 1.23–39.45, p=0.028).

Regarding the 20 respondents within the assisted instillation group, 13 (65%) respondents had a good instillation technique. Self-instilling respondents were compared with patients within the assisted instillation group to assess the effect of assistance instillation on the eye drops instillation technique. Assistance instillation was significantly associated with a good eye drops instillation technique (OR=7.43, 95% CI=2.55—21.65, p=0.000).

The bottle tip was not touched by 90% (18/20) assisted instillation respondents, whereas in only 28.8% (23/80) of self instilling respondents. Non-touching of bottle tip was significantly associated with assisted instillation technique (OR=10.2, 95% CI 2.13–48.7, p=0.004).

The drops were landed on the globe in all respondents within the assisted instillation group, but in only 76.3% (61/80) of self-instilling respondents. Less number of drops per instillation were squeezed in assisted instillation group than by the self-instilling respondents, with a mean difference of 0.16 (**Table 4**).

Of the total 100 respondents, only 2 respondents (2.0%) had washed their hands before they have attempted the instillation. Only 1 respondent (1.0%) had shaken the bottles before instillation. All of the respondents uncapped the bottle by quenching the cap between the thumb and fingers.

Following the attempted eye drops instillation, 86 (86.0%) respondents recapped the bottle soon of the instillation, 7 (7.0%) recapped after they have opened their eyelids, and another 7 (7.0%) haven't recapped the bottle at all.

Ten of the total respondents (10.0%) were using two or more different eye drops. Of this, 6 participants (60.0%) reported that they instil the second eye drop immediately after the first without any interval. Only 4 of them (40.0%) reported that they instil the second eye drop after 5 minutes of the first.

Thirteen of the total respondents reported that they ever faced a new bottle without a tip hole. Five of them (38.5%) reported that they had opened the bottle by tightening back the cap, while 8 respondents (61.5%) reported that they had opened the bottle with any sharp material available nearby.

Regarding the way of storage of the eye drops, 10 (10.0%) stored their medication in the pocket, 25 (25.0%) stored in the closet, 46 (46.0%) stored on the shelf, 1 (1.0%) stored in the refrigerator, 4 (4.0%) stored on the ground, 2 (2.0%) stored under pillow, 12 (12.0%) stored by covering the bottle with a plastic container and suspended it on the wall. All respondents reported that they store their medications with bottle caps always on.

Eighty-four (84%) respondents had a good way of storage, whereas 16% (16/100) of the respondents had a poor way of storage of their eye drops (**Table 7**).

Grading of storage	Place of storage	Number (%)
	Shelf	46 (46.0%)
Good storage	Closet	25 (25.0%)
	Suspend on the wall	12 (12.0%)
	Refrigerator	1 (1.0%)
	Pocket	10 (10.0%)
Poor storage	On the ground	4 (4.0%)
	Under pillow	2 (2.0%)

Table 7: Ways of storage of eye drops bottle by the total respondents.

The effect of instillation technique on the IOP level for a given stage or type of glaucoma was assesses. Poor eye drops instillation technique was significantly associated with uncontrolled IOP (p=0.000, OR=7.0, 95% CI=2.6 – 18.8).

On univariable analysis, there was a significant association between the IOP level and two of the parameters of the eye drops instillation technique; whether the bottle tip was touched or not, and the status of eyelid closure after instillation of the drop (**Table 8**).

Variable	Intra-ocular pressure (n=100)		P-value	
		Controlled IOP	Uncontrolled	
		[N (%)]	IOP [N (%)]	
Number of drops	No drops at all (n=9)	4 (44.4%)	5 (55.6%)	0.504
	Only 1 drop (n=62)	31 (50.0%)	31 (50.0%)	-
	2 or more drops (n=29)	9 (31.0%)	20 (69.0%)	-
Place where the drop(s)	No drop at all (n=9)	4 (44.4%)	5 (55.6%)	
landed	On the globe (n=81)	36 (44.4%)	45 (55.6%)	0.761
	On eyelids (n=9)	4 (44.4%)	5 (55.6%)	
	On other site (n=1)	0	1 (100%)	
Any touch to the bottle tip	Not touched (n=41)	26 (63.4%)	15 (36.6%)	0.003
	Touched by fingers (n=4)	2 (50.0%)	2 (50.0%)	
	Rubbed by the cloth (n=1)	0	1 (100%)	
	Touched the globe (n=26)	11 (42.3%)	15 (57.7%)	
	Touched eyelids/face (n=28)	5 (17.9%)	(82.1%)	
Lid closure for \geq 1 minutes	No closure (n=25)	7 (28.0%)	18 (72.0%)	
after instillation	Slight closure (n=68)	37 (54.4%)	31 (45.6%)	0.001
	Forceful closure (n=7)	0	7 (100%)	
Lacrimal sac compression	Compressed (n=1)	0	1 (100%)	1.00
	Not compressed (n=99)	44 (44.4%)	55 (55.6%)	

Table 8: Univariate analysis of the parameters of eye drops instillation technique forpredicting uncontrolled IOP level.

The results of multivariate analysis for the association between the parameters of the eye drops instillation technique and the level of IOP were listed in **Table 9**. The parameters of eye drop instillation technique remained significantly associated with the level of IOP were contamination of the bottle tip to eyelids or face (adj. OR=7.24, 95% CI 2.2–23.9, p=0.001), and slight eyelid closure (adj. OR=0.32, 95% CI 0.1–0.95, p=0.039).

When held for the other parameters, bottle tip contamination to the eyelids or face was associated with a 7.24–fold increment of having an uncontrolled IOP (adj. OR=7.24, 95% CI 2.2–23.9, p=0.001), and slight eyelid closure for \geq 1 minute was associated with a 0.32–fold decrement of having an uncontrolled IOP (adj. OR=0.32, 95% CI 0.1–0.95, p=0.039).

Variable		Uncontrolled IOP level		
		Adjusted OR	95% CI	P-value
Any touch to the bottle tip	Not touched	0.14	0.45 - 1.4	0.032
	Touched by fingers	2.31	0.29 - 18.5	0.43
	Rubbed by the cloth	2.54	0.00	1.00
	Touched the globe	1.64	0.54 - 4.91	0.38
	Touched eyelids or face	7.24	2.2 - 23.9	0.001
Lid closure for > 1 minutes	No closure	3.15	1.0 - 9.4	0.12
after instillation	Slight closure	0.32	0.1 - 0.95	0.039
	Forceful closure	0.000	0.0	0.99

Table 9: Multivariate logistic analysis of the parameters of eye drops instillation techniquefor predicting uncontrolled IOP level.

Eleven of the 20 (55.0%) respondents in the assisted instillation group had a controlled IOP, while only 41.3% (33/80) of self-instilling respondents had a controlled IOP. There was no significant association between assisted instillation and the level of IOP (OR=1.74, 95% CI 0.65–4.67, p=0.27).

Regarding to the effect of the way of storage of the eye drops on the level of IOP, there was no significant association between them (**Table 10**).

Place of drug	Number (%) (n=100)	Intraocular pressure		P-value
storage		Controlled IOP [N (%)]	Uncontrolled IOP [N (%)]	
Good storage	84 (84%)	40 (47.6%)	44 (52.4%)	0.163
Poor storage	16 (16%)	4 (25.0%)	12 (75.0%)	

CHAPTER 6: DISCUSSION

This study revealed that there is a difficulty of eye drop instillation with self-instilling glaucoma patients. Of the 80 self-instilling respondents, only 16 patients (20.0%) performed good instillation technique. This result is comparable to the results of the study done in China, which revealed that only 19.7% of patients practiced a correct way of eye drop instillation (**30**).

However, a study done in Brazil showed that 28% of the patients were able to correctly instill the eye drops (**31**), and a study done in London revealed that 39 patients (45.9%) had a good eye drops instillation technique (**32**). The possible factor which might have contributed for these differences was the level of education. In this study, 33 of the 80 participants (41.3%) had never been to school, while all respondents included in the study done in London and Brazil attended a basic (elementary) school and more.

The additional factor which might have contributed for the great discrepancy with that of the result revealed in a study done in London was primarily due to the difference in the grading of the instillation technique. The parameter used in the present study included the status of the eyelid closure after instillation of the eye drop. Slight eyelid closure for 1 minute or more was included as one parameter to grade the instillation as a good technique. This might have added to the reduced percentage of performers of good instillation technique in this study.

The mean score assigned for the eye drops instillation technique was 1.58 ± 1.7 . This shows that most respondents had practiced a technique that delivered a drop(s) on the globe and contaminated the tip of bottle by touching the eyelids, face, fingers, cloth, and the globe. This score value was less than the value (2.4 ± 1.4) reported from the study done in London (**32**). The discrepancy was for the reason that, in this study, there were 16 respondents with the score of -1, whereas no respondents were reported to have a score value of -1 from the study done in London (**32**).

The problem with most of the poor performing patients was touch of the bottle tip with the fingers, ocular surface, eyelids or face. In the present study, this occurred in 57 of the 80 self-instilling patients (71.2%). This result was comparable to the report of the study done in India (75.7%) (**10**).

Such situations pose a problem because bottle contamination is possible (**12, 33**). Lemlem Tamrat et al. reported that the prevalence of bottle contamination among eye drop users was 72.9% (51 of 70). The tip of the dropper bottle was more often contaminated (60.8% (31/51)) than the drop (**34**). According to the report of Tsegaw A. *et al.* there was 11% prevalence of bacterial contamination of eye drop medications. All of the contaminations of the eye medications were found from the dropper tips (**21**).

The mean number of drops squeezed was 1.31 ± 0.836 . This is in line with the report from the study done in Brazil (1.4 ± 0.8) (**31**). Twenty-six of the 80 (32.5%) self-instilling respondents squeezed two or more drops. There was no significant difference between this result and that of the figure reported from the study done in Brazil (which was 27%) (**31**). Ten of the 80 (12.5%) self-instilling respondents were unable to place the squeezed drops in their eyes. This was comparable to the report (13%) of Brown MM, et al. (1984) (**13**).

Seven of the 80 (8.75%) self-instilling respondents reported that professional explanation on how to use their medication was never provided to them. Though seeming low percentage, this is significant as it shows the gap within the health care provision system. On the other hand, 65 of the 80 respondents (81.25%) reported that they understood the explanation provided to them on how to use their eye drops. Still, 52 (80.0%) of them performed poor instillation technique. This showed a significant level of unawareness gap that most patients with a poor instillation technique are unaware they have a problem.

If performed most of the time, poor eye drop instillation technique would lead to wastage of medication with its economic impacts, treatment failure which would lead to disease progression with a higher rate of visual loss (**18**). This would lead to the use of multiple drugs with all their side effects, discontinuation of their medication, or to an early indication for surgical treatment (**19,20**).

Older age was associated with increased odds of having a poor drop instillation technique, when rural dwelling was accounted for, with a 9.2—fold increment in odds (adjusted OR=9.2, 95% CI 2.4—36.2, p=0.001). Similarly, advanced age was revealed as a risk factor for performing poor technique in a study done in China (**30**), Brazil (**31**) and London (**32**).

Controlling for age, rural residence was associated with a 6.96—fold increased odds of a poor eye drop instillation technique (adjusted OR=6.96, 95% CI 1.2—39.4, p=0.028). The possible reason, in this study, for this was the high rate of illiteracy found (p=0.003, 95% CI 1.67–11.8) in rural dwellers. Also, all the 19 farmers of the 80 (100%) self-instilling respondents were rural dwellers, and all had practiced a poor instillation technique.

Assisted instillation was significantly associated with good instillation technique (OR=7.429, 95% CI=2.549—21.652, p=0.000). To the author's knowledge, there was no study done so far to compare with this result.

The bottle tip was not touched to the periocular tissues in 90% (18 of the 20) of assisted instillation respondents while in only 28.8% (23/80) of self instilling respondents. Non-touching of the bottle tip was significantly associated with assisted instillation technique (OR=10.2, 95% CI 2.13–48.7, p=0.004). This might have been due to the reason that the instilling attendants could directly visualize the eye of the patients when instilling the eye drop and, thus, could have avoided touching the bottle tip to periocular structures.

Eighty percent (64/80) of the self-instilling respondents had a poor eye drops instillation technique while only 35% (7/20) of those in the assisted instillation group were poor

performers. The mean age of the respondents under self-instilling group was 58.93 ± 13.12 , while those of assisted instillation group was 62.95 ± 8.94 . This explained that assistance instillation had maximized the performance of the elderly patients who, otherwise, would have a risk of performing poor instillation technique if they had been left self-instilling.

Poor instillation technique was significantly associated with a higher IOP level for the disease stage (p=0.000, OR=7.00, 95% CI=2.606—18.803). Bottle tip touch to the eyelids or face was significantly associated with a high IOP for the disease stage (adjusted OR=7.24, 95% CI 2.18–23.9, p=0.001). This was because touching the bottle tip was one of the criteria to classify the practice as a poor instillation technique.

Slight eyelid closure had a significant association with a controlled IOP (adjusted OR=3.16, 95% CI 1.1–9.42, p=0.039). A randomized controlled trial done in USA (**35**) revealed that eyelid closure did not provide significant additional IOP reduction compared with no eyelid closure in patients using chronic prostaglandin monotherapy. This contradictory result might be due to the difference in the methodology.

Regarding the drug handling, 98% (98 of the total 100) of respondents did not wash their hands before uncapping of the bottle and drop instillation. This was comparable to the report (97%) of Brown MM, et al. (1984) (**13**). The overall risk for possible eye drops bottle contamination was 68%. This was a cumulative risks of contamination during eye drops instillation, storage, and while opening new bottles without a tip hole.

Self-reported way of eye drops storage was analysed and 84% of the total 100 respondents had a good way of storage, whereas 16% of them had a poor way of storage of their eye drops. This shows that a significant percentage of respondents had stored their medications in an environment that could lead to increased degradation of the drug (**36**) with a subsequent reduced potency.

The statistical significance was calculated to assess the association between place of storage of medications and the level of the IOP. Although there was no significant association between them, there was a tendency to have controlled IOP in patients who have stored their medication in a plastic sheets and suspended it on the wall.

CHAPTER 7: STRENGTH AND LIMITATIONS

This study was the first of its kind in the country to look for eye drop instillation technique, eye drops storage and associated factors that could contribute for poor eye drop instillation technique. The limitations were: other factors that could possibly affect the control of IOP were not studied, there was no study done so far on same population to compare the results, and some results of this study were not compared with other study owing to the scarcity of studies on the specific matter.

CHAPTER 8: CONCLUSIONS AND RECOMMENDATIONS

8.1 Conclusions:

The majority of glaucoma patients had a poor performance regarding self-instillation of their eye drop medications. Most of the poor performers had an uncontrolled IOP. Age and place of residence were an independent factors associated with the performance of eye drop instillation.

There was a significant unawareness gap regarding the self performance of the instillation technique. As well, there was a gap in the health provision system in providing all the necessary information regarding the use of the eye drops.

Further, there was a significant risk for clinical contamination of the bottles.

Assistance instillation and slight eyelid closure were both significantly associated with good instillation technique of the eye drop medications.

8.2 Recommendations:

Great attention should be given for glaucoma patients by eye health care providers regarding eye drop instillation technique. Providing professional explanation on how to use the eye drops is mandatory.

A trained health professional should specifically be assigned to teach the patients on how to use and store their eye drop medications.

Screen displays showing good instillation technique should be made available at glaucoma clinic waiting areas for educating patients.

For the elderly patients, special attention should be given and family members should be shown on how to apply the eye drops.

For patients who have uncontrolled IOP despite the adequate treatment and follow up, faulty instillation technique should be considered as a possible factor for causing the uncontrolled IOP.

REFERENCES

- Leske MC, Heijl A, Hussein M et al. ; Early Manifest Glaucoma Trial Group (2003): Factors for glaucoma progression and the effect of treatment: the early manifest glaucoma trial. Arch Ophthalmol 121: 48–56.
- 2. Broadway DC, Cate H. Pharmacotherapy and adherence issues in treating elderly patients with glaucoma. drugs aging. 2015;32(7):569-81.
- 3. Tsai JC. A comprehensive perspective on patient adherence to topical glaucoma therapy. Ophthalmology. 2009;116(11 Suppl):S30-6.
- 4. Kass MA, Hodapp E, Gordon M, Kolker AE, Goldberg I. Part I. Patient administration of eyedrops: interview. Ann Ophthalmol 1982; 14: 775–779.
- 5. Fraunfelder FT. Extraocular fluid dynamics: how best to apply topical ocular medication. Trans Am Ophthalmol Soc 1976; 74: 457–487.
- 6. Zimmerman TJ, Kooner KS, Kandarakis AS, Ziegler LP. Improving the therapeutic index of topically applied ocular drugs. Arch Ophthalmol 1984; 102: 551–553.
- 7. Tsai T, Robin AL, Smith III, JP. An evaluation of how glaucoma patients use topical medications: a pilot study. Trans Am Ophthalmol Soc 2007; 105: 29–35.
- 8. Sleath B, Blalock S, Covert D, Stone JL, Skinner AC, Muir K, et al. The relationship between glaucoma medication adherence, eye drop technique, and visual field defect severity. Ophthalmology. 2011;118(12):2398-402.
- 9. Dietlein TS, Jordan JF, Lüke C, Schild A, Dinslage S, Krieglstein GK. Self-application of single-use eyedrop containers in an elderly population: comparisons with standard eyedrop bottle and with younger patients. Acta Ophthalmol. 2008;86(8):856-9.
- 10. Gupta R, Patil B, Shah BM, Bali SJ, Mishra SK, Dada T. Evaluating eye drop instillation technique in glaucoma patients. J Glaucoma. 2012;21(3):189-92.
- 11. Moore DB, Walton C, Moeller KL, Slabaugh MA, Mudumbai RC, Chen PP. Prevalence of self-reported early glaucoma eye drop bottle exhaustion and associated risk factors: a patient survey. BMC Ophthalmol. 2014;14:79.
- 12. Geyer O, Bottone EJ, Podos SM, Schumer RA, Asbell PA. Microbial contamination of medications used to treat glaucoma. Br J Ophthalmol. 1995;79(4):376-9.
- 13. Brown MM, Brown GC, Spaeth GL. Improper topical self-administration of ocular medication among patients with glaucoma. Can J Ophthalmol 1984; 19: 2–5.
- 14. Kass MA, Meltzer DW, Gordon M, Cooper D, Goldberg J. Compliance with topical pilocarpine treatment. Am J Ophthalmol 1986; 101: 515–523.
- 15. Kholdebarin R, Campbell RJ, Jin YP, Buys YM. Multicenter study of compliance and drop administration in glaucoma. Can J Ophthalmol 2008; 43: 454–461.
- 16. Sayner R, Carpenter DM, Robin AL, Blalock SJ, Muir KW, Vitko M, et al. How glaucoma patient characteristics, self-efficacy and patient-provider communication are associated with eye drop technique. Int J Pharm Pract. 2016;24(2):78-85.

- 17. Djafari F, Lesk MR, Giguère CÉ, Siam G, Freeman EE. Impact of a brief educational intervention on glaucoma persistence: a randomized controlled clinical trial. Ophthalmic Epidemiol. 2015;22(6):380-6.
- 18. Stewart WC, Chorak RP, Hunt HH, et al. Factors associated with visual loss in patients with advanced glaucomatous changes in the optic nerve head. Am J Ophthalmology 1993; 116:176-81.
- 19. Haynes RB, McDonald HP, Garg AX. Helping patients follow prescribed treatment: Clinical applications. JAMA 2002; 288:2880-3.
- 20. Steven L.Mansberger. Are you compliant with addressing Glaucoma adherence? Am J Ophthalmology 2010; 149:1-3.
- 21. Tsegaw A, Tsegaw A, Abula T, Assefa Y. Bacterial contamination of multidose eye drops at ophthalmology department, University of Gondar, Northwest Ethiopia. Middle East Afr J Ophthalmol 2017;24:81-6.
- 22. Brusini P, Johnson CA. Staging functional damage in glaucoma: Review of different classification methods. Surv Ophthalmol. 2007;52(2):156-179.
- 23. Canadian Ophthalmological Society Glaucoma Clinical Practice Guideline Expert Committee. Canadian ophthalmological society evidence-based clinical practice guidelines for the management of glaucoma in the adult eye. Canadian Journal of Ophthalmology/Journal Canadien d'Ophtalmologie. 2009;44:S7-S54.
- 24. Litwak AB. Glaucoma management and treatment. In: Anthony Litwak, ed. The glaucoma handbook. 1st ed. Philadelphia: Pennsylvania College of Optometry; 2001:219-238.
- 25. Sihota R, Angmo D, Ramaswamy D, Dada T. Simplifying "target" intraocular pressure for different stages of primary open-angle glaucoma and primary angle-closure glaucoma. Indian J Ophthalmol 2018;66:495-505.
- 26. Sihota R, Rao A, Srinivasan G, Gupta V, Sharma A, Dada T, et al. Long term scanning laser ophthalmoscopy and perimetry in different severities of primary open and chronic angle closure glaucoma eyes. Indian J Ophthalmol 2017;65:963 8.
- 27. Artes PH, Chauhan BC, Keltner JL, Cello KE, Johnson CA, Anderson DR, et al. Longitudinal and cross- sectional analyses of visual field progression in participants of the ocular hypertension treatment study. Arch Ophthalmol 2010;128:1528-32.
- 28. drug handling Medical Dictionary, © 2009 Farlex and Partners.
- 29. www.cdc.gov/Features/MedicationStorage.
- 30. Xinbo Gao, Qiongman Yang, Wenmin Huang, Tingting Chen, Chenguo Zuo, Xinyan Li, Wuyou Gao, Huiming Xiao. Evaluating Eye Drop Instillation Technique and Its Determinants in Glaucoma Patients. J Ophthalmol, 2018, 1–7.
- 31. Gomes BF, Paredes AF, Madeira N, Moraes HV Jr, Santhiago MR. Assessment of eye drop instillation technique in glaucoma patients. Arq Bras Oftalmol. 2017 Jul–Aug;80(4):238–241.

- 32. Tatham AJ, Sarodia U, Gatrad F, Awan A. Eye drop instillation technique in patients with glaucoma. Eye (Lond). 2013 Nov; 27(11): 1293–1298.
- 33. Kim MS, Choi CY, Kim JM, Woo HY. Microbial contamination of multiply used preservative-free artificial tears packed in reclosable containers. Br J Ophthalmol 2008; 92: 1518–1521.
- 34. Lemlem Tamirat, Yeshigeta Gelaw, Getenet Beyene, Addisu Gize. Microbial Contamination and Antimicrobial Resistance in Use of Ophthalmic Solutions at the Department of Ophthalmology, Jimma University Specialized Hospital, Southwest Ethiopia. Canadian Journal of Infectious Diseases and Medical Microbiology, vol. 2019, 1–8.
- 35. Maul EA, Friedman DS, Quigley HA, Jampel HD. Impact of eyelid closure on the intraocular pressure lowering effect of prostaglandins: a randomised controlled trial. Br J Ophthalmol. 2012 Feb;96(2):250–3.
- 36. Thomas V. Johnson, Preeya K. Gupta, Daljit K. Vudathala, Ian A. Blair, Angelo P. Tanna. Thermal Stability of Bimatoprost, Latanoprost, and Travoprost Under Simulated Daily Use. J Ocul Pharmacol Ther. 2011 Feb; 27(1): 51–59.

ANNEX: QUESTIONNAIRE FOR DATA COLLECTION

JIMMA UNIVERSITY

INISTITUTE OF HEALTH, FACULTY OF MEDICAL SCIENCES DEPARTMENT OF OPHTHALMOLOGY

SPECALITY IN OPHTHALMOLOGY

Information sheet for study participants.

I am ______, a resident physician working in judo. I am assessing the instillation technique and the handling of eye drop medications in glaucoma patients. If you are willing, I want you to participate in the study. So, I am going to ask you some questions concerning the way of your medication usage at home, with a direct observation too. Physical examination will be done on your eyes.

The study will not affect your medical care you need to get, nor there is obligation in participating in the study. The information obtained from you will be kept confidential and will be used for the research purpose only. You don't need to state your name. If you agree to participate in the study, please answer these questions.

If you have any questions concerning the study you can contact the principal investigators by the address found below.

Name of the principal investigator: ____ DR. SAGNI JELKEBA

Address:____0915928714 (cell phone number)

Signature ______

Data Collection Format

Section 1: Sociodemographic and Background data

Date o	f the last visit at GSC			
Identif	ication No:	-		
1.	Age:			
2.	Sex Male	Female 🗌		
3.	Occupation			
	Farmer 🗌	Merchant \Box	Gov	vernment employee 🛛
	Private owner 🛛 Others (explain)	-		use wife \Box
4.	Place of residence		 Urban	
	Level of education			
	Never been to sch	ol 🗌 🛛 A	ttended elementa	ry school \Box
	Attended high scho	bol 🗌 🔰 1	2+ 🗌	
6.	Date of enrollment for dru			
	How many types of anti-g			
	One type 🛛	Two or more	types 🗆	
8.	After instilling one, how m	uch do you sta	y before instilling	the second drug? (only for
	patients who are currently	on more than	one eye drop drug	ns)
	a. Immediately or	ne after the oth	ner	
	b. Less than 5 mir			
	c. 5 minutes or m	ore after the fi	rst	
9.	Did you ever face new bot	tles without op	pening on the tip?	Yes 🗌 🛛 No 🗌
	If yes, how did you try to o	open?		
	1. By tightening t	he bottle cap		
	2. By sharp object	ts		
	3. By manipulatio	n with finger n	ails	
	4. Others (specify)		
10.	Where do you store your	medications?		
	Pocket 🗌		Clothe set 🛛	Shelf 🗌
	Refrigerator \Box		On the ground $\ \square$	Under pillow \Box
	In a reach of childr	en 🗆	Others (explain) _	
11.	How do you store?? Ca	pped 🗌	Uncapped 🗌	Occasionally capped \Box

- 12. Did you receive an explanation by the health care provider about the storage and instillation technique?
 - a. Never provided
 - b. I was told but I didn't understand
 - c. I was told and I understood

Section 2: Physical Examination

Visual acui	ty OD		OS	
IOP	ODmmH	lg	OS	_mmHg
Diagnosis	Ocular	hypertensio	on 🗆	Glaucoma 🗌
Cup to disc	ratio (CDR)			
	Starting CDR:	OD		OS
	Current CDR:	OD		OS

Section 3: Direct Observation

The following observation need to be done in a room with facilities including water, sink, soap, towels and mirror.

1.	Does the patient (attendant) wash hands before instillation? Yes \Box No					
2.	Does the patient (attendant) shake the bottle before instilling? Yes \Box No					
3.	How did the patient (attendant) uncapped the bottle?					
	Quenched between thumb and fingers \Box Quenched by little finger \Box					
	Quenched in the palm \Box The cap fell down \Box					
	Others (specify)					
4.	Estimated head position assumed from the vertical while instillation					
	45 degrees or less More than 45 degrees					
5.	Which hand is used for instillation?					
	Ipsilateral hand Contralateral hand Assisted					
6.	Time required to instill the drop after uncapping the bottle					
	Less than 5 seconds \Box 5–10 seconds \Box > 10 seconds \Box					
7.	Number of drops squeezed out from the bottle					
	One drop More than 1 drop Squeezed out none					
8.	Where does the drop landed? On globe \Box On eyelids \Box Other site \Box					
9.	Any touch to the tip of the bottle?					
	Not touched \Box Touched by fingers \Box Rubbed by cloth \Box					
	Touched the globe \Box Touched eyelids and/or face \Box					
10	. Does the patient close eyelids for \geq 1 minute after instillation? Yes \Box No \Box					
	If yes, how does the lid is closed? Slight closure \Box Forceful closure \Box					
11	. Does the patient press on lacrimal sac area after instillation? Yes \Box No \Box					
12	. Time elapsed to recap the bottle					
	Soon of instillation After eyelid opening Didn't recap					