A Randomized Controlled Clinical Trial to Compare Conventional Drug Instillation to A Device Dropper method in Medical treatment of Glaucoma

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Abstract:

Purpose: To compare and analyze the performance of a device dropper over conventional drop instillation method on ease of administration, compliance, patient satisfaction & intraocular pressure control in persons with glaucoma on ocular hypotensive médications.

Methods: We enrolled 72 individuals with primary open angle glaucoma or ocular hypertension, on treatment with fixed combination (a agonist+ β blocker) drugs for at least 6 months .These were randomized into two groups (36 in each arm). Group 1 administered the drug with a device dropper (DD) and Group 2 used conventional drop instillation(CDI) method. Recruited individuals were interviewed for subjective difficulties using a formatted questionnaire at first month follow up and intraocular pressure (IOP) change from baseline was evaluated.

Results: Baseline demographic & ocular characteristics were similar in both groups. 57.1% in the conventional instillation and none in the device dropper had reported difficulty in using the eye drops on follow up visit. Device dropper group had significantly less spillage and contamination of eye surface or dropper tips, required minimal assistance, accurately targeted on first drop placement directly into the eye compared to conventional drop instillation group(p-value<0.001). Mean intraocular pressure was comparable between the two groups.

Conclusion: Device dropper instillation method was observed to be easier to administer, more accurate in targeting the conjunctival cul-de-sac, reduced wastage with lesser contamination compared to the conventional drop instillation technique. Device droppers may be expected to have better compliance and effectiveness in medical management of glaucoma.

Key-words: glaucoma, device dropper, conventional instillation, compliance, adherence

Key Message: The device dropper was more user friendly, technically easier to instill drops with better accuracy, less spillage and contamination compared with the conventional method of drug instillation, and thus likely to improve compliance in the management of glaucoma.

Introduction:

In India 11.2 million people aged 40 years and older are estimated to have glaucoma.1 Elevated intraocular pressure (IOP) is a major risk factor in progression of glaucoma and lowering of intraocular pressure is associated with delay in progression of disease.23 Medical treatment is the initial treatment modality in management of glaucoma and strict adherence and compliance to recommended therapy is the cornerstone of successful glaucoma therapy. Suboptimal adherence to glaucoma therapy significantly contributes to progressive glaucoma.4

Compliance to any medication refers to the degree or extent of conformity to the recommendations of day to day treatment by the provider with respect to timing, dosage, and frequency. Factors leading to noncompliance have been described in many studies like social/environmental factors (lack of support, major life events, and travel), regimen factors (complexity, costs, and change in medication), individual patient factors (knowledge, memory, motivation), and medical provider factors (dissatisfaction, communication).5

In a study in South India, 42% of patients reported one or more problems in using their glaucoma medications, and around 6% reported less than 100% adherence or compliance to their medications. A patient's inability to successfully instill an eye drop can have multiple consequences like inadequate IOP control that may have a major impact on vision. 4 Improper drug instillation techniques may lead to drug spillage increased drug reactions, dropper tip contamination and significantly enhances cost of therapy.7 A device that could simplify drug instillation and address these difficulties can

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improve adherence to topical medical therapy while eliminating drug wastage, spillage and contamination of dropper tips.8,9

Many studies^{7,8,10,11} previously have attempted to analyze the performance of the various commercially available device droppers and have found them to have better efficacy & patient satisfaction. However these were performed on a small sample, and the devices were not widely used due to high cost, poor accessibility and not being suitable to fit to all eye drop bottles.

We conducted a randomized control study to compare the efficacy, ease of administration, patient compliance and level of satisfaction of a low cost device dropper assisted instillation as compared to conventional drop instillation method in medical management of glaucoma.

Material and Methods:

Our study was a prospective, randomized controlled trial conducted between April 2019-September 2019. A total of 72 eligible participants of glaucoma or ocular hypertension with 144 eyes were included to assess the efficacy of device droppers with 95 % power and 5 % level of significance.10 Enrollment of eligible persons was done after obtaining consent for participation in the study and to use the information for publication in scientific literature. Patients were randomized into two groups by a computer generated randomisation method. The study was approved by the Ethics committee and the Institutional Review Board for conduct of human ocular research (IEC201900314) and adhered to the tenets of the Declaration of Helsinki.

Glaucoma was defined as presence of glaucomatous optic nerve head (ONH) changes with or without high intraocular pressure (IOP) and corresponding visual field defects. We graded the disease severity based on the visual fields using Hodapp Parish Anderson criteria and enrolled only those subjects who presented with moderate glaucoma.12 Ocular hypertension was defined as IOP>21mmHg and corneal thickness <550 microns without evidence of optic nerve damage and visual field defects. We included subjects with Primary open angle glaucoma (POAG) and /or ocular hypertension, aged above 40 years, with baseline IOP not higher than 25 mmHg and those selfadministering the fixed combination [\beta blocker+ a agonist] of medications for 6 months or longer. We excluded patients with best corrected visual acuity (BCVA) less than 6/60 in both eyes, severely constricted visual fields (Mean Deviation greater than -12 dB) ,12persons older than 70, those who were physically weak and infirm, and those unable to use eye drops on their own, those unable to report for follow up and patients presenting with tremors and arthritis.

Detailed ophthalmic examination was done which included BCVA & IOP, slit lamp biomicroscopy, gonioscopy, fundus and visual field for all the patients. Visual field defects were defined by the presence of localized Bjerrum scotoma, nasal step arcuate scotomas and biarcuate scotomas. All the consecutive subjects with defined inclusion criteria were enrolled and recruited by the principal investigator and were randomized into two groups (36 in each arm) based on a computergenerated number Group 1-device dropper group (DD) and Group 2- conventional drop instillation group(CDI). The investigators and paramedical staffs performing ocular examination and distributing questionnaire to the patients were masked to the study groups. Primary outcome was measured as IOP control at follow up visit, Secondary outcomes was comparison of ease of administration using a validated questionnaire10 between the two groups.

In the device dropper group, α short video clip demonstrating how to use the device was shared with every patient. The device was manufactured by Aurolab, Madurai, Tamilnadu, India for the purpose of study and provided free of cost to all the patients. The dropper device was fitted with a lubricating eye drop and live demonstration of its use was given by a trained paramedical staff to the patients randomized to the Dropper Device Group1. Patients randomized to Group2 (conventional drop instillation) were advised to continue using the eye drops as per their routine administration. The paramedical staff assigned for counselling patients provided instructions to reassure the correct technique of eye drop instillation using audio-visual aids. Counseling included instructions on the method of instillation, restricting instillation to α single drop, avoiding tip contamination and strict adherence to the medical treatment regimen advised by the examining ophthalmologist.

All patients were advised to review after 4 weeks and a complete ophthalmologic evaluation including measurement of IOP, visual acuity, slit lamp examination and posterior segment evaluation was completed by ophthalmologists masked to details of the Groups assigned to the patients. IOP was measured by Goldman Applanation tonometry by a single observer and the median of three readings was considered for analysis. A validated questionnaire 10was administered to all the patients by paramedical staff seeking details such as difficulties encountered on using the eye drops.

In order to determine the correct instillation technique and to ensure compliance, the patients were asked to instill eye drops in the presence of an observer at the initial visit (Figure 1). The observer assessed the performance of device dropper over CDI by marking the experiences of the patient with a yes or no response in the given questionnaire. The questions addressed the ease of administration, spillage, single drop into the eye, better aim, bottle tip contact to eye with responses as always, often, sometimes, rarely or never.10

Statistical analysis- Descriptive variables are given with Frequency (Percentage) or Mean (Standard deviation). The data were analyzed with frequency of distribution descriptive statistics. Snellen's equivalent visual acuity was converted to the logarithm of the minimum angle of resolution (logMAR) units for the statistical analysis. Mean \pm SD, Median and inter-quartile range (IQR) were obtained for continuous variables and data were expressed as Numbers or as Percentage for Categorical variables Chi-square test was used to compare the categorical variables of demographic characteristics and Fisher's exact test was used to find out the association of ease of administration with either technique of instillation. Paired ttest or Wilcoxon sign rank test was used to find out the significant difference between the baseline and the follow-up visits,. Student's t-test was used to find out the significant difference between study group and the control group. The intergroup differences for continuous variables were tested with independent t-test. P-value less than 0.05 were considered statistically significant. All statistical analysis was performed using STATA software version 14.0 (Texas, USA).

Results:

The baseline demographic factors between the two groups were similar with no statistically significant difference (Table1)

Table1: Demographic and Diagnostic Characteristics of the Study Participants

	Device dropper (n=36)	Conventio nal drop instillation (n=36)	P-value ^b
$Age(y), Mean \pm SD$	61.6 ±10.2	62.3 ±9.4	0.763°
Male gender, n (%)	18(50.0)	21(58.3)	0.478
Type of glaucoma* Primary open angle Ocular hypertension	62(86.1) 10(13.9)	66(91.7) 6(8.3)	0.289
logMAR VA*, Median(IQR)	0.18(0 to 0.30)	0(0 to 0.18)	0.075 °
RNFLD*, n (%)	39(54.2)	47(65.3)	0.174
Cup disc ratio*, Mean ±SD	0.671 ±0.09	0.679 ±0.10	0.605 °
Visual field defects*, n (%)	30(41.7)	34(47.2)	0.502
Lens status*, n (%) Clear Cataractous Pseudophakic	21(29.2) 35(48.6) 16(22.2)	15(20.8) 32(44.4) 25(34.7)	0.211

^{*}variables were presented in eye-wise (n=72 eyes), IQR –

inter-quartile range

VA- Visual acuity, RNFLD-retina nerve fiber layer defect a independent t-test, b Chi-square test, c Wilcoxon rank sum test

The Mean age of the device dropper group was 61.6 ± 10.2 and that of conventional instillation group was 62.3 ±9.4 years. There were equal number of males and females in Device dropper (DD) group and a slightly higher male preponderance of 21 males (58.3%), 15 females (41.7%) seen in the conventional drop instillation (CDI) group. In the device dropper group, a diagnosis of POAG was present in 86.1 % and OHTN in 13.9%. In the CDI group 91.7% had POAG while 8.3% had OHTN. Median (interquartile range) best corrected visual ocuity measured by log MAR was 0.18 (o to 0.30) in the DD group and o (o to 0.18) in the CDI group, with no statistically significant difference in between the two groups (pvalue=0.07) at baseline.

70 /72 patients were eligible for total analysis-35 in each group with one potient (2.8%) lost to follow up from each group. Boseline Mean ±SD IOP was 16.6 ±3.2 mmHg in the device dropper group and 16.4 ±3.8 in the CDI group with no difference between the two groups (p-value=0.758) (Table 2).

Table2: Comparison of IOP between the Device Dropper and Conventional Drop Instillation Groups

	Device dropper	Conventional drop instillation	P-value ^a
Baseline Mean ±SD (95% CI)	16.6 ±3.2 (15.9 to 17.3)	16.4 ±3.8 (15.5 to 17.3)	0.758
Follow up visit Mean ±SD (95% CI)	16.5 ±3.0 (15.7 to 17.2)	16.4 ±3.0 (15.6 to 17.1)	0.860
P-value d	0.528	0.894	_

^a independent t-test, ^d Paired t-test

At 1 month follow up, the mean IOP was 16.5 ± 3.0 in the DD group and 16.4 ±3.0 in the CDI group with no difference from baseline in both the groups and also no statistically significant difference between the two groups (p-value=0.860).

In the device dropper group, 97.1 % of patients had no difficulty using the eye drops compared to 42.9% in the CDI group (pvalue<0.001) and none of the patients in the DD group needed assistance to instill eye drops on any of the days during the study period as compared to 54.3% of patients in the second group (p-value < 0.001) (Table 3). All patients in the DD group never reported to have touched the eye with the bottle tip,

compared to 2.9% of patients in the CDI group (pvalue<0.001). However in the CDI group there were 57.1% who reported of the bottle tip sometimes touching the eye, 5.7% often reported tip touching the eye, 34.3% reported of the bottle tip rarely touching the eye (Table 3)

Table3: Comparison of Ease of Administration between Device Dropper and Conventional Drop Instillation groups

	Device dropper (n=35)	Conventional drop instillation (n=35)	P-value ^e
Had difficulty using eye drops Yes No	1(2.9) 34(97.1)	20(57.1) 15(42.9)	<0.001
Needed help to instill eye drops in any of the day Yes No	- 35(100.0)	19(54.3) 16(45.7)	<0.001
Touched eye with bottle tip Often Sometimes Rarely Never	- - - - 35(100.0)	2(5.7) 20(57.1) 12(34.3) 1(2.9)	<0.001
Spilled drops outside eye Often Sometimes Rarely Never	- 6(17.1) 25(71.4) 4(11.4)	5(14.3) 16(45.7) 13(37.1) 1(2.9)	0.001
Applied a single drop Always Often Sometimes Rarely	4(11.4) 26(74.3) 5(14.3)	1(2.9) 18(51.4) 15(42.9) 1(2.9)	0.012
Placed drop directly into eye Always Often Sometimes Rarely	11(31.4) 23(65.7) 1(2.9)	1(2.9) 23(65.7) 9(25.7) 2(5.7)	<0.001

^e Fisher's exact test

71.4% of patients in the DD group and 37.1% in the CDI group, rarely reported of drug spillage outside the eye. In the CDI group there was a greater spillage compared to the DD group (p-value=0.001) with 45.7% patients sometimes reporting of spillage and 14.3% often reported of spillage of eye drops outside the eye (Table 3). In the DD group 74.3% of the patients often applied a single drop into the eye compared to 51.4% of potients in the CDI group (p-value= 0.012). Also in the DD group 31.4% of patients could always place the eye drops directly into the eye compared to only 2.9 % in the CDI group (p-value<0.001).

Discussion:

The current study evaluated the comparative effectiveness and ease of administration of ocular hypotensive medications in a cohort of individuals with POAG or Ocular hypertension using a low cost device dropper or the conventional drug instillation method. Our study results report the superior performance of device droppers over CDI with 97% reporting no difficulty and none requiring assistance in instilling the drug accurately into the eve.

Nordmann et al 10 study had reported that the Xal-Ease device dropper performed better than the dropper bottle in their cohort, requiring no help in drop instillation, and also reduced the risk of the bottle tip touching the eye. Similarly, the device dropper used in our study had performed well with no patient needing assistance to instill drops nor touching the eye with the bottle tip.

Interestingly, the subjects in the DD group had a better target on the eye, with less spillage and contamination compared to CDI group .The device dropper had facilitated easier view of the tip of the bottle that helped in targeting the eye drop directly into the eye avoiding contact with the ocular surface and eyeloshes. All patients in the DD group never reported touching the eye with the tip of the bottle, compared to 2.9% in the CDI group. 5.7 % of patients in the CDI group often, 34.3 % rorely and 57.1 % reported sometimes of the bottle tip touching the eye respectively. Similar observations were reported by Davies et al, 7 where the tip was contaminated in 42% -53% with conventional bottle, while none had shown contamination of the bottle tip when using the upright eye drop bottle (UEB).

On analyzing the efficacy of the device dropper over CDI, in terms of IOP control, it was to have no change in mean IOP at the follow up visit in both the groups .We believe a better technique to deliver the drop may have an indirect impact on better compliance. Virani et al, 13 reported better control of IOP by 10-13 % and lesser consumption of eye drop bottle by 14% in assisted instillation compared to the self instillation. We had recruited and randomized persons already on medical treatment, who had required no change in therapy to reduce

IOP at the time of inclusion in the study. This may partly account for insignificant differences in mean IOP at month 1 follow up between the two groups. A randomized, cross over study of newly diagnosed, treatment naïve patients, with a longer observation on device dropper or conventional technique of drug instillation is likely to provide more reliable answers to issues of compliance as well as any differences in treatment efficacy between the two groups

Brown et al, 14 in their study reported most patients to be unaware of the faulty techniques of drug instillation that may affect the IOP leading to an unintentional part of poor compliance. Use of an instillation device may help address some, if not all, difficulties for glaucoma patients who have to continue taking the medications for life time.

In our study, we found better patient satisfaction in individuals using device droppers in terms of ease of use, better accuracy, less wastage and reduced contamination. In the DD group none reported of spillage compared to 14 .1 % often reporting of spillage in CDI. Likewise in a study by Gupta et al, 15 31.43% had a spillage of the eye drops on the eyelids or cheek and 75.7% touched the eye with tip of the bottle with only 8.57% correctly instilling the eye drops. In the current study the device dropper group had always targeted the eye in 31.4% & 11.4% had always instilled a single drop in the cul de sac compared to 2.9% in the CDI group. Another study 16 had observed that of the 204 visually impaired patients, 71% could apply their drops, but only 29% managed without touching the ocular surface and 1.4 drops were needed to apply the equivalent of one drop successfully. Poor instillation techniques with medications not getting into the eyes have been observed to be a major cause of progressive glaucoma.16,17

Assisted instillation of eye drop may be required by glaucoma patients depending on one's age, visual acuity, and general health, cognition ability and comprehension of individual and perhaps prevailing socio-cultural practices in community. Kass et al,18 in an interview based study found that only 20.6 % of patients relied on others for eye drop instillation, while a majority of patients self-administered their medications. Several difficulties have been noted with self administration like folsely torgeting the eye drop, difficulties in squeezing the bottle, forgetting to instill drop in time, extrα-drops instillation, and difficulty in puncturing the bottle entry. 6,14,15,18,19

Drug delivering aids are helpful in facilitating self instillation, however one should understand the limitations like learning curve,20 physical force,21 dispensing, cost, and availability. Several glaucoma medications are commercially available with device droppers that are suited to fit only that particular eye drop and cannot be interchanged with other eye drops. Additionally its high cost makes it unaffordable to all patients.

It is to be noticed that unlike the XAL-Ease, 10 which was designed only for the application of the fixed combination of latanoprost and its combination with timolol, our device dropper can be fitted with almost all eye drop containers coming in various shapes.

The major strength of our study was that in addition to assessing the self reported outcomes of the performance of the device droppers, we also studied the ease of administration as graded by an observer who was masked to the study groups. Secondly the study was a randomized controlled trial, with the ophthalmic personnel performing the study procedures blinded to the study groups. All patients enrolled had previous experience with self administration of eye drops thereby eliminating the learning effects. Lastly the study had recruited individuals using only a particular fixed combination of glaucoma medications to compare the efficacy in both the groups.

Our study had a few limitations like the small sample size, short follow up and also the results of the study are largely based on self reported responses which may not actually reflect practical difficulties in ensuring compliance in glaucoma potients requiring indefinite therapy. Secondly a crossover study where a single cohort of patients report sequentially on the use of both techniques could have provided a better comparison and understanding about the benefits of the device dropper being studied. Moreover compliance was measured by self-reporting responses from patients, rather than weighing the bottles used and counting the drops remaining in it, which could also result in potential bias in interpreting levels of compliance to medical therapy. In conclusion, the device dropper had similar IOP reduction as the CDI, but it was more user friendly, technically easier to instill drops with better accuracy, less spillage and contamination compared with the conventional method of drug instillation, and thus likely to improve compliance.

Additionally, the low cost, easy accessibility and universal compatibility to most commercially available eye drop containers, makes the device dropper a promising option to improve compliance in the management of chronic glaucoma .Future research focusing on randomized, controlled and cross over studies of newly diagnosed persons with glaucoma are required to evaluate long term efficacy and compliance of device droppers as compared to conventional drug instillation techniques.

Legend to figure -

Figure 1 (α ,b) showing device dropper mentioned in our study, (c) showing the potient using device dropper to instill drop inside eye.

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JOURNAL UPDATE

Pseudostrabismus is a relatively frequent diagnosis in the first year of life

A new retrospective study reports the birth prevalence of pseudostrabismus during a single decade. During the first year of life, 1 in 113 children in Olmsted, Minnesota, were diagnosed with pseudostrabismus. Strabismus was subsequently diagnosed in 4.9% of pseudostrabismus infants—a rate that is lower than what has been previously reported but similar to prior observations in the same pediatric population. These findings suggest that the apparent elevated strabismus risk among patients with pseudostrabismus may not be causal, but instead, due to confounding factors.

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