An Objective Evaluation of Eyedrop Instillation in Patients With Glaucoma

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Objectives: To evaluate the performance of patients with ocular hypertension and glaucoma who are experienced in the instillation of topical ocular hypotensive medications.

Methods: We conducted a prospective, open-label study at a single private practice site. We enrolled 139 patients with a diagnosis of glaucoma or ocular hypertension who used 1 or more topical ocular hypotensive medications for at least 6 months and who instilled their own medications. Patients were questioned regarding their use of topical ocular hypotensive medications, and we used a video recording to evaluate patient performance of eyedrop instillation with 2 bottle designs.

Results: Patients reported relatively good performance on eyedrop instillation. One hundred twenty-nine of 139 patients (92.8%) reported no problem putting in their eyedrops, and 86 of 139 (61.9%) believed that they never missed their eye when administering the drops. The proportions of patients who were able to instill a single drop into the eye without touching the bottle to the eye were 14 of 64 (21.9%) with a 15-mL bottle and 36 of 117 (30.8%) with a 2.5-mL bottle.

Conclusions: Under a single direct observation, patients experienced in the use of topical ocular hypotensive agents performed relatively poorly when instilling a single eyedrop into the eye without touching the bottle tip to the eye or the ocular adnexae.

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THE CONSISTENT LOWERING of intraocular pressure has been reported to both minimize the risk of developing optic nerve damage and prevent its progression.[1-4] Topical ocular pharmacotherapy, one of the key therapies and usually the first therapy used to treat elevated intraocular pressure, depends on patient adherence with the prescribed treatment regimen and patient performance, which is the ability to correctly instill the eyedrop. Patient adherence is a complex issue, requiring the patient to admit having an illness, fill and continue to refill the prescription, instill the correct number of drops, and instill them at the correct time of day. These issues have been evaluated in the now classic studies from 2 decades ago using electronic monitors, as well as in more recent studies using novel monitoring techniques and pharmacy records.[5-12] With respect to solid oral dosage forms in adults (eg, capsules), health care providers may usually correctly assume that oral ingestion is properly executed (with the possible exception of dysphagia).[13] However, the proper delivery of an eyedrop to the eye may pose significant problems for many individuals. The challenges in instilling eyedrops from commercial bottles have been noted by others, and novel designs have been proposed for bottles and tips.[14,15] In this study, we desired to evaluate more fully patient performance in the instillation of topical ocular hypotensive medications in experienced patients with ocular hypertension and glaucoma.

METHODS

DESIGN

We conducted a prospective, open-label study at a single private practice site. All patients provided written informed consent. This research protocol followed the tenets of the Declaration of Helsinki; was approved by the Southwest Independent Institutional Review Board, Fort Worth, Texas; and adhered to the Health Insurance Portability and Accountability Act.

PROCEDURES

Patients completed a questionnaire regarding their use of topical ocular hypotensive medications (**Table 1**). They were then escorted to a separate, dedicated ophthalmic examination room with a reclining examination chair, a sink, hand soap, towels, a makeup mirror, a wall mirror, and a digital movie camera (Xacti C5 VPC-C5; Sanyo Electric Co, Ltd, Osaka, Japan). We

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Table 1. Patient Questionnaire

Do you put in your own eyedrops?
Do you have trouble putting in your own eyedrops?
Did someone teach you how to put eyedrops in?
Do you wash your hands every time before putting eyedrops in?
Do you use a mirror to put in your eyedrops?
Do you ever miss your eye when putting in eyedrops?
Do you touch the eye with the bottle tip?
Do you use ≥1 type of eyedrop?
If yes, do you pause ≥1 minute between different types of eyedrops?

used the following 2 different bottle types: a syndiotactic polypropylene bottle (similar to that marketed for travoprost [Travatan; Alcon Laboratories, Inc, Fort Worth], filled with 2.5 mL of a travoprost vehicle), and a low-density polyethylene bottle (similar to that marketed for lubricated eyedrops [Systane; Alcon Laboratories, Inc], filled with 15 mL). Patients using travoprost or latanoprost were assigned to use the 2.5-mL bottle, and those using bimatoprost, α-adrenoceptor agonists, β-adrenoceptor antagonists, brinzolamide, or muscarinic agonists were assigned to use the 15-mL bottle.

An examiner read the following script to each patient: "This (These) bottle(s) is (are) similar to the bottle(s) you use to instill your eyedrops. It (They) contains only artificial tears or a sterile solution and does not contain any pharmaceutically active agents. I would like you to please put 1 drop into your eye just as you would at home. I will be 'videoing' exactly how you take your eyedrops." Patients were videotaped for 1 eye only per bottle.

STUDY POPULATION

We included patients with a diagnosis of glaucoma or ocular hypertension in 1 or both eyes who used 1 or more topical ocular hypotensive medications for at least 6 months and who instilled their own medications. We excluded from the study patients with known hypersensitivity to over-the-counter artificial tears. Because we could not obtain Ocumeter-style bottles (Merck & Co, Whitehouse Station, New Jersey), patients using dorzolamide hydrochloride (Trusopt; Merck & Co,) or the fixed combination of dorzolamide and timolol maleate (Cosopt; Merck & Co) as their sole ocular hypotensive medication were excluded from the study. Patients were required to have had a complete eye examination within the preceding 6 months.

STATISTICAL ANALYSIS

One reader (J.L.S.) scored all of the video recordings for a number of performance measures, including the location of drop application, whether the bottle tip touched the eye or the ocular adnexae, and the number of drops instilled. We collected information about the nature, duration, and pharmacological treatment of glaucomatous disease from the patient's medical record.

No sample size estimate was performed. All data from the surveys, video scoring, and medical record review were analyzed using commercially available software (PC-SAS, version 9.1.3; SAS Institute Inc, Cary, North Carolina).

RESULTS

We enrolled 173 patients (222 video observations) from April 25 through August 15, 2007. The data from 34 patients (41 videos) were lost because of a technical error; thus, data from 139 patients were available for analyses (181 videos; 117 with the 2.5-mL bottle and 64 with the 15-mL bottle). Prestudy characteristics for these 139 patients are given in **Table 2**. The population was in the latter part of the seventh decade of life and approximately 70% were white. Patients used a mean of 1.9 ocular hypotensive medications and had moderately advanced glaucoma (perimetric mean defect, −7.5 dB).

Table 2. Prestudy Characteristics

Characteristic	Findings
No. of patients	139
Age, y	
Mean (SD)	67.4 (13.5)
Range	21-94
No. of ocular hypotensive medications	
Mean (SD)	1.9 (0.9)
Range	1 to 4
Perimetric mean defect, dB	
Mean (SD)	−7.5 (8.3)
Range	−33.6 to 0.7
Race, No. (%) (n=138)[a]	
African American	36 (26.1)
Asian	2 (1.4)
White	96 (69.6)
Hispanic	2 (1.4)
Indian	2 (1.4)
Sex, No. (%) (n=138)[b]	
Female	75 (54.3)
Male	63 (45.7)

[a] Because of rounding, the percentages do not total 100.
[b] The sex of 1 patient was inadvertently not recorded.

Table 3. Number of Drops Instilled[a]

	15-mL Low-Density Polyethylene Bottle[b] (n=64)	2.5-mL Polypropylene Bottle[c] (n=116)
Drops instilled	45	90
No. of drops		
Mean (SD)[d]	1.8 (1.2)	1.8 (1.4)
0	1	2
1	25	55
2	11	14
3	3	6
≥4	5	13
Stream of fluid instilled	19	26

[a] Unless otherwise indicated, data are expressed as number of patients.
[b] Similar to that marketed for lubricated eyedrops (Systane; Alcon Laboratories, Inc, Fort Worth, Texas).
[c] Similar to that marketed for travoprost (Travatan; Alcon Laboratories, Inc).
[d] Excludes the patients with the stream of fluid.

As observed on the videos, the patients used a mean (SD) of 1.8 (1.2) drops with the 15-mL bottle and 1.8 (1.4) drops with the 2.5-mL bottle per instillation, with a wide range (**Table 3**). Some observations noted a stream of fluid instilled from the bottle, including observations 19 of 64 patients (29.7%) for the 15-mL bottle and 26 of 116 (22.4%) for the 2.5-mL bottle.

The 3 key performance criteria selected for observation were instillation into the eye, instillation of a single drop, and no touching of the bottle to the eye or the ocu-

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Table 4. Tabulation of Video Observations Criterion Performance[a]

Single Drop Instilled	In the Eye	Touching		Total
		No[b]	Yes	
15-mL low-density polyethylene bottle[c]				
No	No	1	9	**10**
	Yes	14	15	**29**
Yes	No	5	1	**6**
	Yes	*14*	5	**19**
Total		34	30	**64**
2.5-mL polypropylene bottle[d]				
No	No	3	6	**9**
	Yes	18	34	**52**
Yes	No	4	7	**11**
	Yes	*36*	8	**44**
Total		61	55	**116**

[a] One video of a patient using the 2.5-mL polypropylene bottle could not be scored. Unless otherwise indicated, data are expressed as number of patients.
[b] Refers to touching of the tip of the bottle to the eye or the ocular adnexae. Italics are used for the numbers of patients who met all 3 criteria.
[c] Similar to that marketed for lubricated eyedrops (Systane; Alcon Laboratories, Inc, Fort Worth, Texas).
[d] Similar to that marketed for travoprost (Travatan; Alcon Laboratories, Inc).

Table 5. Tabulation of Video Observations of Triple Success Stratified by Prestudy Characteristics[a]

Characteristic	15-mL Low-Density Polyethylene Bottle (n=64)[b]	2.5-mL Polypropylene Bottle (n=117)[c]
All	14/64 (21.9)	36/117 (30.8)
Age category, y		
≤65	7/29 (24.1)	20/51 (39.2)
>65	7/35 (20.0)	16/66 (24.2)
Sex		
Female	5/36 (13.9)	16/61 (26.2)
Male	9/27 (33.3)	19/54 (35.2)
Race		
White	11/37 (29.7)	27/83 (32.5)
Nonwhite	3/27 (11.1)	9/34 (26.5)
Glaucoma duration, y		
≤5	4/19 (21.1)	11/31 (35.5)
>5	10/45 (22.2)	25/86 (29.1)
Glaucoma severity[d]		
Mild	9/23 (39.1)	25/64 (39.1)
Moderate	2/15 (13.3)	5/23 (21.7)
Severe	3/26 (11.5)	6/30 (20.0)
Previous glaucoma surgery		
No	3/13 (23.1)	11/29 (37.9)
Yes	11/51 (21.6)	25/88 (28.4)
Drop technique taught by		
Self	7/32 (21.9)	22/54 (40.7)
Others	7/31 (22.6%)	13/61 (21.3)
Visual acuity		
20/60 or better	14/54 (25.9%)	34/103 (33.0)
>20/60 to 20/200	0	2/12 (16.7)

[a] Sample sizes differ because of missing data for prestudy characteristics. Data are expressed as number/total number (percentage) of patients.
[b] Similar to that marketed for lubricated eyedrops (Systane; Alcon Laboratories, Inc, Fort Worth, Texas).
[c] Similar to that marketed for travoprost (Travatan; Alcon Laboratories, Inc).
[d] Based on categories by Hodapp et al.[16]

lar adnexae. These triple criteria were achieved by 14 of 64 patients (21.9%) with the 15-mL bottle and 36 of 116 (31.0%) with the 2.5-mL bottle (**Table 4**). The triple criteria were stratified by demographic and glaucoma disease measures (**Table 5**). There was a trend toward better performance by men than by women and in patients with milder glaucomatous disease according to the perimetric mean defect as categorized by Hodapp et al.[16]

Patients reported relatively good performance on eyedrop instillation. Specifically, of the 139 patients, 129 (92.8%) reported no problem instilling their eyedrops, 86 (61.9%) believed that they never missed their eye when administering the eyedrops, and 110 (79.2%) believed that they never touched their eye with the bottle tip. Most patients (86 of 139 [61.9%]) also reported that they washed their hands before instilling the eyedrops. On observation, patients washed their hands in only 3 of 180 video-recorded instillations (1.7%).

Before participation in the study, 40 patients used medications found in both bottle groups and therefore underwent testing using the 2.5- and 15-mL bottles. By definition, patients using more than 1 ocular hypotensive agent had worse glaucomatous disease. This subset provided a potential direct comparison between the 2 bottle types. As observed on the video recordings, the patients used a mean (SD) of 1.6 (1.0) drops with the 15-mL bottle and 1.4 (0.8) drops with the 2.5-mL bottle. The proportions of patients meeting the triple criteria were 9 of 40 patients (22.5%) with the 15-mL bottle and 11 of 40 (27.5%) with the 2.5-mL bottle.

COMMENT

Our study, which we believe is the first to assess eyedrop administration objectively by using video recordings, showed that objective performance of eyedrop administration on a single visit was relatively poor. Using the triple criteria of successful instillation of a single drop—and only a single drop—without touching the bottle tip to the eye, we found that less than one-third of the observed instillations were performed successfully. A portion of patients was unable to get a drop in their eye (20 of 116 [17.2%] and 16 of 64 [25.0%]) with the 15-mL and 2.5-mL bottles, respectively). Electronic monitoring studies of topical ocular hypotensive agents report that patient adherence in taking the prescribed medications at the correct time is less than perfect, ranging from approximately 70% to 95%.[5-9] Optimal pharmacotherapy requires that patients adhere to the treatment regimen and instill the eyedrops correctly.

Our results are generally consistent with those of previous objective studies of patient performance. In a study of 150 patients, Brown et al[17] found that 83% of patients were able to get the drop into the eye and that 47% did not touch the eye or the ocular adnexa with the bottle tip. The authors did not mention how the observations were made or whether the patients used artificial tear bottles. In a 2-part study, Kass et al[18,19] interviewed 141 patients regarding their adherence to an eyedrop instillation regimen, and then 2 observers subjectively observed administrations for success. They reported a mean

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of 2.6 drops administered and observed touching of the bottle tip to the eye or the ocular adnexae on approximately 50% of the instillations. The authors did not provide the relationship between the first part of the study (the questionnaire) and the second parts of the study (the observation). Norell et al[20] used an electronic compliance monitor and fluorescein staining to study self-administration of medication by 82 patients with primary open-angle glaucoma. Of the 10 patients who administered the medication themselves, 8 (80%) were able to get 1 or more drops in the eye. In a more recent, multicenter study using direct observation, Kholdebarin et al[21] reported that 33.8% of their 500 patients demonstrated an improper administration technique, 6.8% missed their eye, and 28.8% contaminated the bottle tip. That study also evaluated patients' perspectives on their adherence to the prescribed dosing regimen. The study relied on live observation by multiple observers to assess performance. In our experience, review of the video recordings by a single investigator was required to determine whether a single drop actually hit the eye or multiple eyedrops were administered. Also, given our observation that bottle size and shape may affect performance, the generalizability of the unspecified artificial tear bottle used by the previous study is not clear.

In addition to confirming the observation of the relatively poor performance of patients in instillation technique, our study provides 2 additional clinically important findings. First, patient perceptions about their performance do not seem to concur with instillation performance on objective observation. Second, the use of a video recording allows for better documentation and evaluation of eyedrop administration. Even with multiple observers, it may be difficult to detect where an eyedrop lands, how many drops are actually administered, or whether the eyedrop bottle actually touched the eyelid.

Our observations suggest that eyedrop instillation performance may be better in male than in female patients and better in patients with better visual function (as defined by perimetric mean defect and central visual acuity). In the subset of patients using both bottle types, performance may be better with the smaller 2.5-mL bottle than with the larger 15-mL bottle. However, our study was not designed to determine whether there was a difference in bottle types. This was a pilot, nonrandomized study with a single in-office visit and with a small sample size in some of the subgroups. Our study is also limited by the exclusion of users of Ocumeter bottles. As a single-observation study, we have no information as to whether advising patients about their performance and educating them on correct instillation technique would have any effect on future short- or long-term performance.

In our study, most patients (86 of 139 [61.9%]) reported that they routinely washed their hands before instilling eyedrops. This was consistent with a report from Tsai et al[22] of 65%. However, as observed, only 3 of 180 patients (1.7%) used the materials provided to wash their hands.

The apparently poor and variable performance seen in this study, combined with the previous reports of relatively poor treatment adherence, gives concern to those diagnosing and treating patients with glaucomatous disease. Patients' perspectives on their ability to adhere to a prescribed dosing regimen and to properly instill eyedrops are inconsistent with results of electronic compliance monitoring and direct observation of performance, respectively. These discrepancies suggest that caution is needed when accepting patient reports in assessment of patient adherence and performance. Our study underscores the need for eye care providers to observe eyedrop instillation as an integral part of the evaluation of patients with glaucoma being treated with eyedrops.

Underdosing, because of either poor adherence or poor performance, means that patients are not receiving the prescribed medication. Overdosing, as seen in the present study by the instillation of multiple drops at a given time, and in previous electronic monitoring studies as instillation at additional times,[7] has the potential for several problems, including systemic adverse events (eg, systemic β-adrenoceptor blockade with a β-adrenoceptor antagonist), ocular adverse events (eg, increased lid pigmentation with a prostaglandin analogue), and a more rapid use of the bottle, which is dispensed according to the fill volume, not the number of days of use.

Several caveats apply to our observations. The use of a single session for only 1 eye, selected for resource issues, may have resulted in an observation of relatively poorer performance than the patient routinely used. Our study was conducted at a single private glaucoma subspecialty practice with a single session per patient. The generalizability of our findings to other clinical settings, expanded observations, and a more diverse patient population is not known and may be the subject of additional research. Another issue that is not possible to evaluate fully is the potential influence of the presence of the camera and an observer (ie, it may have improved or worsened performance). We also were unable to retrieve video observations for 34 of 173 patients (19.7%). Although the demographic data of these patients were similar to those analyzed, it is not possible to know those results.

In summary, we found that, under a single direct observation, patients experienced in the use of topical ocular hypotensive agents have relatively poor performance when instilling a single eyedrop into the eye without touching the bottle tip to the eye or the ocular adnexae.

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In the extraction of senile cataract by the flap operation downward, it occasionally happens that an unintentional innervation of the ocular muscles, immediately after the section is completed, forces the lens, with its capsule unruptured, out of the eye. The lens then ordinarily preserves its senile, flattened form, but at times I have observed that with liquefaction of the cortex the extruded lens in its intact capsule exhibits the round form which is found post mortem in the eyes of the young. Since the liquefied cortex can have no particular elasticity, this fact can be explained only as being due to the elasticity of the lens capsule, and it is also conceivable that an elastic membrane filled with soft contents should naturally take on a spherical shape when this is not prevented by a counter-traction. The greater thickness of the anterior capsule thus explains also its greater curvature in accommodation. The evident change in the form of the lens in accommodation is usually explained as being due to the effort of the lens substance to assume a spherical shape. This view, doubtless, proceeds from the idea of the "musculus crystallinus," held by the older anatomists (Loewenhoek, Pemberton, and also Thomas Young), yet I believe, on the ground of the preceding observation, that the elasticity of the lens capsule alone is sufficient to produce the change in shape, while the lens proper plays a more passive role.

So long as the lens is young and soft, and offers only a slight resistance to a change in shape, the elasticity of the capsule predominates, but when the lens becomes gradually harder, it offers a constantly increasing resistance. If then the cortex becomes liquefied in senile cataract, the elasticity of the capsule again predominates, and it approaches the spherical shape as soon as it ceases to be held tense by the zonula.

Reference: Schweigger C. On the mechanism of accommodation. *Arch Ophthalmol*. 1897;26:584-585.

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